

**16.2.7 Laboratory Results**

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Basophils (10 <sup>9</sup> /L)	Screening	05JAN2016/11:00	0.02	0 - 0.1	Yes
		Day 1	26JAN2016/10:00	0.00	0 - 0.1	No
		Week 1	01FEB2016/10:30	0.00	0 - 0.1	No
		Week 2	11FEB2016/12:00	0.02	0 - 0.1	No
		Week 4	24FEB2016/13:00	0.02	0 - 0.1	No
		Week 6	08MAR2016/11:30	0.05	0 - 0.1	No
		Week 8	24MAR2016/10:52	0.03	0 - 0.1	No
		Early Term	21APR2016/08:00	0.05	0 - 0.1	Yes
		Week 28	19MAY2016/12:20	0.01	0 - 0.1	No
		Week 32	16JUN2016/10:25	0.02	0 - 0.1	No
		Week 40	11AUG2016/12:00	0.00	0 - 0.1	No
		Week 44	08SEP2016/12:10	0.03	0 - 0.1	No
		Week 48	06OCT2016/12:30	0.01	0 - 0.1	No
	Blood film	Screening	05JAN2016/11:00			Yes
		Day 1	26JAN2016/10:00			No
		Week 1	01FEB2016/10:30			No
		Week 2	11FEB2016/12:00			No
		Week 4	24FEB2016/13:00			No
		Week 6	08MAR2016/11:30			No
		Week 8	24MAR2016/10:52			No
		Early Term	21APR2016/08:00			Yes
		Week 28	19MAY2016/12:20			No
		Week 32	16JUN2016/10:25			No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Blood film	Week 40	11AUG2016/12:00			No
		Week 44	08SEP2016/12:10			No
		Week 48	06OCT2016/12:30			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	05JAN2016/11:00	0.12	0 - 0.4	Yes
		Day 1	26JAN2016/10:00	0.11	0 - 0.4	No
		Week 1	01FEB2016/10:30	0.10	0 - 0.4	No
		Week 2	11FEB2016/12:00	0.05	0 - 0.4	No
		Week 4	24FEB2016/13:00	0.02	0 - 0.4	No
		Week 6	08MAR2016/11:30	0.12	0 - 0.4	No
		Week 8	24MAR2016/10:52	0.14	0 - 0.4	No
		Early Term	21APR2016/08:00	0.15	0 - 0.4	Yes
		Week 28	19MAY2016/12:20	0.13	0 - 0.4	No
		Week 32	16JUN2016/10:25	0.14	0 - 0.4	No
		Week 40	11AUG2016/12:00	0.18	0 - 0.4	No
		Week 44	08SEP2016/12:10	0.10	0 - 0.4	No
		Week 48	06OCT2016/12:30	0.14	0 - 0.4	No
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	05JAN2016/11:00	336	300 - 350	Yes
		Day 1	26JAN2016/10:00	335	300 - 350	No
		Week 1	01FEB2016/10:30	323	300 - 350	No
		Week 2	11FEB2016/12:00	331	300 - 350	No
		Week 4	24FEB2016/13:00	335	300 - 350	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Ery. Mean Corpuscular HGB Concentration (g/L)	Week 6	08MAR2016/11:30	324	300 - 350	No
		Week 8	24MAR2016/10:52	298 L	300 - 350	No
		Early Term	21APR2016/08:00	321	300 - 350	Yes
		Week 28	19MAY2016/12:20	323	300 - 350	No
		Week 32	16JUN2016/10:25	325	300 - 350	No
		Week 40	11AUG2016/12:00	327	300 - 350	No
		Week 44	08SEP2016/12:10	314	300 - 350	No
		Week 48	06OCT2016/12:30	332	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	05JAN2016/11:00	28.2	26 - 33.5	Yes
		Day 1	26JAN2016/10:00	28.5	26 - 33.5	No
		Week 1	01FEB2016/10:30	28.0	26 - 33.5	No
		Week 2	11FEB2016/12:00	27.9	26 - 33.5	No
		Week 4	24FEB2016/13:00	28.2	26 - 33.5	No
		Week 6	08MAR2016/11:30	28.5	26 - 33.5	No
		Week 8	24MAR2016/10:52	28.5	26 - 33.5	No
		Early Term	21APR2016/08:00	28.1	26 - 33.5	Yes
		Week 28	19MAY2016/12:20	27.8	26 - 33.5	No
		Week 32	16JUN2016/10:25	27.6	26 - 33.5	No
		Week 40	11AUG2016/12:00	27.7	26 - 33.5	No
		Week 44	08SEP2016/12:10	27.8	26 - 33.5	No
		Week 48	06OCT2016/12:30	28.8	26 - 33.5	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Ery. Mean Corpuscular Volume (fL)	Screening	05JAN2016/11:00	84.1	80 - 99	Yes
		Day 1	26JAN2016/10:00	85.0	80 - 99	No
		Week 1	01FEB2016/10:30	86.8	80 - 99	No
		Week 2	11FEB2016/12:00	84.1	80 - 99	No
		Week 4	24FEB2016/13:00	84.2	80 - 99	No
		Week 6	08MAR2016/11:30	87.7	80 - 99	No
		Week 8	24MAR2016/10:52	95.7	80 - 99	No
		Early Term	21APR2016/08:00	87.7	80 - 99	Yes
		Week 28	19MAY2016/12:20	86.2	80 - 99	No
		Week 32	16JUN2016/10:25	85.0	80 - 99	No
		Week 40	11AUG2016/12:00	84.9	80 - 99	No
		Week 44	08SEP2016/12:10	88.5	80 - 99	No
		Week 48	06OCT2016/12:30	86.5	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	05JAN2016/11:00	4.39	3.95 - 5.15	Yes
		Day 1	26JAN2016/10:00	4.28	3.95 - 5.15	No
		Week 1	01FEB2016/10:30	4.39	3.95 - 5.15	No
		Week 2	11FEB2016/12:00	4.27	3.95 - 5.15	No
		Week 4	24FEB2016/13:00	3.86 L	3.95 - 5.15	No
		Week 6	08MAR2016/11:30	3.83 L	3.95 - 5.15	No
		Week 8	24MAR2016/10:52	4.18	3.95 - 5.15	No
		Early Term	21APR2016/08:00	4.05	3.95 - 5.15	Yes
		Week 28	19MAY2016/12:20	4.35	3.95 - 5.15	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Erythrocytes (10 <sup>12</sup> /L)	Week 32	16JUN2016/10:25	4.67	3.95 - 5.15	No	
		Week 40	11AUG2016/12:00	4.65	3.95 - 5.15	No	
		Week 44	08SEP2016/12:10	4.68	3.95 - 5.15	No	
		Week 48	06OCT2016/12:30	4.52	3.95 - 5.15	No	
	Hematocrit (%)	Screening	05JAN2016/11:00	36.9	33 - 45	Yes	
		Day 1	26JAN2016/10:00	36.4	33 - 45	No	
		Week 1	01FEB2016/10:30	38.1	33 - 45	No	
		Week 2	11FEB2016/12:00	35.9	33 - 45	No	
		Week 4	24FEB2016/13:00	32.5 L	33 - 45	No	
		Week 6	08MAR2016/11:30	33.6	33 - 45	No	
		Week 8	24MAR2016/10:52	40.0	33 - 45	No	
		Early Term	21APR2016/08:00	35.5	33 - 45	Yes	
		Week 28	19MAY2016/12:20	37.5	33 - 45	No	
		Week 32	16JUN2016/10:25	39.7	33 - 45	No	
		Week 40	11AUG2016/12:00	39.5	33 - 45	No	
		Week 44	08SEP2016/12:10	41.4	33 - 45	No	
		Week 48	06OCT2016/12:30	39.1	33 - 45	No	
	Hemoglobin (g/L)	Screening	05JAN2016/11:00	124	115 - 155	Yes	0
		Day 1	26JAN2016/10:00	122	115 - 155	No	0
		Week 1	01FEB2016/10:30	123	115 - 155	No	0
		Week 2	11FEB2016/12:00	119	115 - 155	No	0
		Week 4	24FEB2016/13:00	109 L	115 - 155	No	1

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007 Hemoglobin (g/L)	Week 6	08MAR2016/11:30	109 L	115 - 155	No	1
	Week 8	24MAR2016/10:52	119	115 - 155	No	0
	Early Term	21APR2016/08:00	114 L	115 - 155	Yes	1
	Week 28	19MAY2016/12:20	121	115 - 155	No	0
	Week 32	16JUN2016/10:25	129	115 - 155	No	0
	Week 40	11AUG2016/12:00	129	115 - 155	No	0
	Week 44	08SEP2016/12:10	130	115 - 155	No	0
	Week 48	06OCT2016/12:30	130	115 - 155	No	0
	Leukocytes (10 <sup>9</sup> /L)					
	Screening	05JAN2016/11:00	6.49	3 - 10	Yes	0
	Day 1	26JAN2016/10:00	5.41	3 - 10	No	0
	Week 1	01FEB2016/10:30	4.98	3 - 10	No	0
	Week 2	11FEB2016/12:00	5.38	3 - 10	No	0
	Week 4	24FEB2016/13:00	7.80	3 - 10	No	0
	Week 6	08MAR2016/11:30	5.01	3 - 10	No	0
	Week 8	24MAR2016/10:52	5.68	3 - 10	No	0
	Early Term	21APR2016/08:00	5.14	3 - 10	Yes	0
	Week 28	19MAY2016/12:20	5.58	3 - 10	No	0
	Week 32	16JUN2016/10:25	5.53	3 - 10	No	0
	Week 40	11AUG2016/12:00	5.96	3 - 10	No	0
	Week 44	08SEP2016/12:10	5.75	3 - 10	No	0
	Week 48	06OCT2016/12:30	5.34	3 - 10	No	0
Lymphocytes (10 <sup>9</sup> /L)	Screening	05JAN2016/11:00	2.55	1.2 - 3.65	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Lymphocytes (10 <sup>9</sup> /L)	Day 1	26JAN2016/10:00	2.81	1.2 - 3.65	No	0
		Week 1	01FEB2016/10:30	1.69	1.2 - 3.65	No	0
		Week 2	11FEB2016/12:00	2.06	1.2 - 3.65	No	0
		Week 4	24FEB2016/13:00	1.99	1.2 - 3.65	No	0
		Week 6	08MAR2016/11:30	1.47	1.2 - 3.65	No	0
		Week 8	24MAR2016/10:52	1.86	1.2 - 3.65	No	0
		Early Term	21APR2016/08:00	1.90	1.2 - 3.65	Yes	0
		Week 28	19MAY2016/12:20	2.15	1.2 - 3.65	No	0
		Week 32	16JUN2016/10:25	1.98	1.2 - 3.65	No	0
		Week 40	11AUG2016/12:00	2.15	1.2 - 3.65	No	0
		Week 44	08SEP2016/12:10	2.06	1.2 - 3.65	No	0
		Week 48	06OCT2016/12:30	2.43	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	05JAN2016/11:00	0.46	0.2 - 1	Yes	
		Day 1	26JAN2016/10:00	0.22	0.2 - 1	No	
		Week 1	01FEB2016/10:30	0.35	0.2 - 1	No	
		Week 2	11FEB2016/12:00	0.31	0.2 - 1	No	
		Week 4	24FEB2016/13:00	0.35	0.2 - 1	No	
		Week 6	08MAR2016/11:30	0.34	0.2 - 1	No	
		Week 8	24MAR2016/10:52	0.41	0.2 - 1	No	
		Early Term	21APR2016/08:00	0.36	0.2 - 1	Yes	
		Week 28	19MAY2016/12:20	0.42	0.2 - 1	No	
		Week 32	16JUN2016/10:25	0.44	0.2 - 1	No	
		Week 40	11AUG2016/12:00	0.48	0.2 - 1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Monocytes (10 <sup>9</sup> /L)	Week 44	08SEP2016/12:10	0.55	0.2 - 1	No	
		Week 48	06OCT2016/12:30	0.43	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	05JAN2016/11:00	0.32	0 - 0.38	Yes	4
		Day 1	26JAN2016/10:00	0.27	0 - 0.38	No	4
		Week 1	01FEB2016/10:30	0.00	0 - 0.38	No	4
		Week 2	11FEB2016/12:00	0.00	0 - 0.38	No	4
		Week 4	24FEB2016/13:00	0.00	0 - 0.38	No	4
		Week 6	08MAR2016/11:30	0.00	0 - 0.38	No	4
		Week 8	24MAR2016/10:52	0.00	0 - 0.38	No	4
		Early Term	21APR2016/08:00	0.00	0 - 0.38	Yes	4
		Week 28	19MAY2016/12:20	0.00	0 - 0.38	No	4
		Week 32	16JUN2016/10:25	0.00	0 - 0.38	No	4
		Week 40	11AUG2016/12:00	0.24	0 - 0.38	No	4
		Week 44	08SEP2016/12:10	0.00	0 - 0.38	No	4
		Week 48	06OCT2016/12:30	2.22 H	0 - 0.38	No	0
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	05JAN2016/11:00	2.99	2 - 7.5	Yes	0
		Day 1	26JAN2016/10:00	2.00	2 - 7.5	No	0
		Week 1	01FEB2016/10:30	2.84	2 - 7.5	No	0
		Week 2	11FEB2016/12:00	2.94	2 - 7.5	No	0
		Week 4	24FEB2016/13:00	5.41	2 - 7.5	No	0
		Week 6	08MAR2016/11:30	3.03	2 - 7.5	No	0

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Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Neutrophils, Segmented (10 <sup>9</sup> /L)	Week 8	24MAR2016/10:52	3.24	2 - 7.5	No	0
		Early Term	21APR2016/08:00	2.68	2 - 7.5	Yes	0
		Week 28	19MAY2016/12:20	2.87	2 - 7.5	No	0
		Week 32	16JUN2016/10:25	2.95	2 - 7.5	No	0
		Week 40	11AUG2016/12:00	2.92	2 - 7.5	No	0
		Week 44	08SEP2016/12:10	3.01	2 - 7.5	No	0
		Week 48	06OCT2016/12:30	0.11 L	2 - 7.5	No	4
	Platelets (10 <sup>9</sup> /L)	Screening	05JAN2016/11:00	227	150 - 400	Yes	0
		Day 1	26JAN2016/10:00	263	150 - 400	No	0
		Week 1	01FEB2016/10:30	224	150 - 400	No	0
		Week 2	11FEB2016/12:00	208	150 - 400	No	0
		Week 4	24FEB2016/13:00	221	150 - 400	No	0
		Week 6	08MAR2016/11:30	292	150 - 400	No	0
		Week 8	24MAR2016/10:52	261	150 - 400	No	0
		Early Term	21APR2016/08:00	244	150 - 400	Yes	0
		Week 28	19MAY2016/12:20	252	150 - 400	No	0
		Week 32	16JUN2016/10:25	243	150 - 400	No	0
		Week 40	11AUG2016/12:00	284	150 - 400	No	0
		Week 44	08SEP2016/12:10	288	150 - 400	No	0
		Week 48	06OCT2016/12:30	248	150 - 400	No	0
301-011	Basophils (10 <sup>9</sup> /L)	Screening	07JAN2016/12:00	0.00	0 - 0.1	Yes	

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(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011 Basophils (10 <sup>9</sup> /L)	Day 1	27JAN2016/08:30	0.00	0 - 0.1	Yes
	Week 1	03FEB2016/11:00	0.01	0 - 0.1	Yes
	Week 2	11FEB2016/11:30	0.01	0 - 0.1	Yes
	Week 4	26FEB2016/10:20	0.02	0 - 0.1	No
	Week 6	10MAR2016/10:45	0.02	0 - 0.1	No
	Week 8	24MAR2016/09:31	0.02	0 - 0.1	No
	Week 12	19APR2016/09:20	0.01	0 - 0.1	Yes
	Week 16	18MAY2016/10:10	0.02	0 - 0.1	No
	Week 20	21JUN2016/10:35	0.00	0 - 0.1	No
	Week 24	12JUL2016/10:00	0.05	0 - 0.1	Yes
	Week 28	09AUG2016/09:50	0.01	0 - 0.1	No
	Week 32	06SEP2016/09:00	0.02	0 - 0.1	No
	Week 36	06OCT2016/09:50	0.01	0 - 0.1	No
	Week 40	03NOV2016/11:00	0.01	0 - 0.1	No
	Week 44	06DEC2016/10:30	0.02	0 - 0.1	No
	Week 48	03JAN2017/10:45	0.02	0 - 0.1	No
Blood film	Screening	07JAN2016/12:00			Yes
	Week 1	03FEB2016/11:00			Yes
	Week 2	11FEB2016/11:30			Yes
	Week 4	26FEB2016/10:20			No
	Week 6	10MAR2016/10:45			No
	Week 8	24MAR2016/09:31			No
	Week 12	19APR2016/09:20			Yes

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(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011 Blood film	Week 16	18MAY2016/10:10			No
	Week 20	21JUN2016/10:35			No
	Week 24	12JUL2016/10:00			Yes
	Week 28	09AUG2016/09:50			No
	Week 32	06SEP2016/09:00			No
	Week 36	06OCT2016/09:50			No
	Week 40	03NOV2016/11:00			No
	Week 44	06DEC2016/10:30			No
	Week 48	03JAN2017/10:45			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	0.30	0 - 0.4	Yes
		Day 1	0.29	0 - 0.4	Yes
		Week 1	0.10	0 - 0.4	Yes
		Week 2	0.09	0 - 0.4	Yes
		Week 4	0.04	0 - 0.4	No
		Week 6	0.02	0 - 0.4	No
		Week 8	0.11	0 - 0.4	No
		Week 12	0.05	0 - 0.4	Yes
		Week 16	0.03	0 - 0.4	No
		Week 20	0.15	0 - 0.4	No
		Week 24	0.14	0 - 0.4	Yes
		Week 28	0.29	0 - 0.4	No
		Week 32	0.34	0 - 0.4	No
		Week 36	0.38	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Eosinophils (10 <sup>9</sup> /L)	Week 40	03NOV2016/11:00	0.31	0 - 0.4	No
		Week 44	06DEC2016/10:30	0.18	0 - 0.4	No
		Week 48	03JAN2017/10:45	0.31	0 - 0.4	No
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	07JAN2016/12:00	344	300 - 350	Yes
		Day 1	27JAN2016/08:30	325	300 - 350	Yes
		Week 1	03FEB2016/11:00	340	300 - 350	Yes
		Week 2	11FEB2016/11:30	345	300 - 350	Yes
		Week 4	26FEB2016/10:20	347	300 - 350	No
		Week 6	10MAR2016/10:45	354 H	300 - 350	No
		Week 8	24MAR2016/09:31	298 L	300 - 350	No
		Week 12	19APR2016/09:20	335	300 - 350	Yes
		Week 16	18MAY2016/10:10	331	300 - 350	No
		Week 20	21JUN2016/10:35	325	300 - 350	No
		Week 24	12JUL2016/10:00	318	300 - 350	Yes
		Week 28	09AUG2016/09:50	326	300 - 350	No
		Week 32	06SEP2016/09:00	331	300 - 350	No
		Week 36	06OCT2016/09:50	335	300 - 350	No
		Week 40	03NOV2016/11:00	319	300 - 350	No
		Week 44	06DEC2016/10:30	332	300 - 350	No
		Week 48	03JAN2017/10:45	323	300 - 350	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	07JAN2016/12:00	30.4	26 - 33.5	Yes
		Day 1	27JAN2016/08:30	28.8	26 - 33.5	Yes
		Week 1	03FEB2016/11:00	29.6	26 - 33.5	Yes
		Week 2	11FEB2016/11:30	29.3	26 - 33.5	Yes
		Week 4	26FEB2016/10:20	29.1	26 - 33.5	No
		Week 6	10MAR2016/10:45	29.8	26 - 33.5	No
		Week 8	24MAR2016/09:31	29.6	26 - 33.5	No
		Week 12	19APR2016/09:20	29.9	26 - 33.5	Yes
		Week 16	18MAY2016/10:10	30.5	26 - 33.5	No
		Week 20	21JUN2016/10:35	30.8	26 - 33.5	No
		Week 24	12JUL2016/10:00	29.5	26 - 33.5	Yes
		Week 28	09AUG2016/09:50	29.6	26 - 33.5	No
		Week 32	06SEP2016/09:00	29.8	26 - 33.5	No
		Week 36	06OCT2016/09:50	29.6	26 - 33.5	No
		Week 40	03NOV2016/11:00	29.3	26 - 33.5	No
		Week 44	06DEC2016/10:30	29.9	26 - 33.5	No
		Week 48	03JAN2017/10:45	29.7	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	07JAN2016/12:00	88.2	80 - 99	Yes
		Day 1	27JAN2016/08:30	88.5	80 - 99	Yes
		Week 1	03FEB2016/11:00	87.1	80 - 99	Yes
		Week 2	11FEB2016/11:30	85.1	80 - 99	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Ery. Mean Corpuscular Volume (fL)	Week 4	26FEB2016/10:20	83.8	80 - 99	No
		Week 6	10MAR2016/10:45	84.2	80 - 99	No
		Week 8	24MAR2016/09:31	99.3 H	80 - 99	No
		Week 12	19APR2016/09:20	89.1	80 - 99	Yes
		Week 16	18MAY2016/10:10	92.3	80 - 99	No
		Week 20	21JUN2016/10:35	94.7	80 - 99	No
		Week 24	12JUL2016/10:00	92.7	80 - 99	Yes
		Week 28	09AUG2016/09:50	90.8	80 - 99	No
		Week 32	06SEP2016/09:00	90.0	80 - 99	No
		Week 36	06OCT2016/09:50	88.4	80 - 99	No
		Week 40	03NOV2016/11:00	91.9	80 - 99	No
		Week 44	06DEC2016/10:30	90.1	80 - 99	No
		Week 48	03JAN2017/10:45	91.8	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	07JAN2016/12:00	4.41	3.95 - 5.15	Yes
		Day 1	27JAN2016/08:30	4.45	3.95 - 5.15	Yes
		Week 1	03FEB2016/11:00	4.59	3.95 - 5.15	Yes
		Week 2	11FEB2016/11:30	4.50	3.95 - 5.15	Yes
		Week 4	26FEB2016/10:20	4.44	3.95 - 5.15	No
		Week 6	10MAR2016/10:45	4.30	3.95 - 5.15	No
		Week 8	24MAR2016/09:31	4.19	3.95 - 5.15	No
		Week 12	19APR2016/09:20	4.22	3.95 - 5.15	Yes
		Week 16	18MAY2016/10:10	4.26	3.95 - 5.15	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011 Erythrocytes (10 <sup>12</sup> /L)	Week 20	21JUN2016/10:35	4.19	3.95 - 5.15	No
	Week 24	12JUL2016/10:00	4.24	3.95 - 5.15	Yes
	Week 28	09AUG2016/09:50	4.33	3.95 - 5.15	No
	Week 32	06SEP2016/09:00	4.50	3.95 - 5.15	No
	Week 36	06OCT2016/09:50	4.49	3.95 - 5.15	No
	Week 40	03NOV2016/11:00	4.43	3.95 - 5.15	No
	Week 44	06DEC2016/10:30	4.45	3.95 - 5.15	No
	Week 48	03JAN2017/10:45	4.38	3.95 - 5.15	No
Hematocrit (%)	Screening	07JAN2016/12:00	38.9	33 - 45	Yes
	Day 1	27JAN2016/08:30	39.4	33 - 45	Yes
	Week 1	03FEB2016/11:00	40.0	33 - 45	Yes
	Week 2	11FEB2016/11:30	38.3	33 - 45	Yes
	Week 4	26FEB2016/10:20	37.2	33 - 45	No
	Week 6	10MAR2016/10:45	36.2	33 - 45	No
	Week 8	24MAR2016/09:31	41.6	33 - 45	No
	Week 12	19APR2016/09:20	37.6	33 - 45	Yes
	Week 16	18MAY2016/10:10	39.3	33 - 45	No
	Week 20	21JUN2016/10:35	39.7	33 - 45	No
	Week 24	12JUL2016/10:00	39.3	33 - 45	Yes
	Week 28	09AUG2016/09:50	39.3	33 - 45	No
	Week 32	06SEP2016/09:00	40.5	33 - 45	No
	Week 36	06OCT2016/09:50	39.7	33 - 45	No
	Week 40	03NOV2016/11:00	40.7	33 - 45	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Hematocrit (%)	Week 44	06DEC2016/10:30	40.1	33 - 45	No	
		Week 48	03JAN2017/10:45	40.2	33 - 45	No	
	Hemoglobin (g/L)	Screening	07JAN2016/12:00	134	115 - 155	Yes	0
		Day 1	27JAN2016/08:30	128	115 - 155	Yes	0
		Week 1	03FEB2016/11:00	136	115 - 155	Yes	0
		Week 2	11FEB2016/11:30	132	115 - 155	Yes	0
		Week 4	26FEB2016/10:20	129	115 - 155	No	0
		Week 6	10MAR2016/10:45	128	115 - 155	No	0
		Week 8	24MAR2016/09:31	124	115 - 155	No	0
		Week 12	19APR2016/09:20	126	115 - 155	Yes	0
		Week 16	18MAY2016/10:10	130	115 - 155	No	0
		Week 20	21JUN2016/10:35	129	115 - 155	No	0
		Week 24	12JUL2016/10:00	125	115 - 155	Yes	0
		Week 28	09AUG2016/09:50	128	115 - 155	No	0
		Week 32	06SEP2016/09:00	134	115 - 155	No	0
		Week 36	06OCT2016/09:50	133	115 - 155	No	0
		Week 40	03NOV2016/11:00	130	115 - 155	No	0
		Week 44	06DEC2016/10:30	133	115 - 155	No	0
		Week 48	03JAN2017/10:45	130	115 - 155	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	07JAN2016/12:00	4.93	3 - 10	Yes	0
		Day 1	27JAN2016/08:30	5.78	3 - 10	Yes	0
		Week 1	03FEB2016/11:00	5.48	3 - 10	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Leukocytes (10 <sup>9</sup> /L)	Week 2	11FEB2016/11:30	4.73	3 - 10	Yes	0
		Week 4	26FEB2016/10:20	4.72	3 - 10	No	0
		Week 6	10MAR2016/10:45	3.69	3 - 10	No	0
		Week 8	24MAR2016/09:31	4.52	3 - 10	No	0
		Week 12	19APR2016/09:20	4.85	3 - 10	Yes	0
		Week 16	18MAY2016/10:10	4.79	3 - 10	No	0
		Week 20	21JUN2016/10:35	4.95	3 - 10	No	0
		Week 24	12JUL2016/10:00	4.51	3 - 10	Yes	0
		Week 28	09AUG2016/09:50	4.83	3 - 10	No	0
		Week 32	06SEP2016/09:00	4.42	3 - 10	No	0
		Week 36	06OCT2016/09:50	4.76	3 - 10	No	0
		Week 40	03NOV2016/11:00	5.07	3 - 10	No	0
		Week 44	06DEC2016/10:30	4.88	3 - 10	No	0
		Week 48	03JAN2017/10:45	4.97	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	07JAN2016/12:00	1.97	1.2 - 3.65	Yes	0
		Day 1	27JAN2016/08:30	2.20	1.2 - 3.65	Yes	0
		Week 1	03FEB2016/11:00	1.82	1.2 - 3.65	Yes	0
		Week 2	11FEB2016/11:30	1.93	1.2 - 3.65	Yes	0
		Week 4	26FEB2016/10:20	1.88	1.2 - 3.65	No	0
		Week 6	10MAR2016/10:45	1.49	1.2 - 3.65	No	0
		Week 8	24MAR2016/09:31	1.61	1.2 - 3.65	No	0
		Week 12	19APR2016/09:20	1.68	1.2 - 3.65	Yes	0
		Week 16	18MAY2016/10:10	1.52	1.2 - 3.65	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Lymphocytes (10 <sup>9</sup> /L)	Week 20	21JUN2016/10:35	1.73	1.2 - 3.65	No	0
		Week 24	12JUL2016/10:00	1.67	1.2 - 3.65	Yes	0
		Week 28	09AUG2016/09:50	1.93	1.2 - 3.65	No	0
		Week 32	06SEP2016/09:00	1.84	1.2 - 3.65	No	0
		Week 36	06OCT2016/09:50	2.08	1.2 - 3.65	No	0
		Week 40	03NOV2016/11:00	2.39	1.2 - 3.65	No	0
		Week 44	06DEC2016/10:30	2.25	1.2 - 3.65	No	0
		Week 48	03JAN2017/10:45	2.32	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	07JAN2016/12:00	0.30	0.2 - 1	Yes	
		Day 1	27JAN2016/08:30	0.58	0.2 - 1	Yes	
		Week 1	03FEB2016/11:00	0.48	0.2 - 1	Yes	
		Week 2	11FEB2016/11:30	0.48	0.2 - 1	Yes	
		Week 4	26FEB2016/10:20	0.58	0.2 - 1	No	
		Week 6	10MAR2016/10:45	0.34	0.2 - 1	No	
		Week 8	24MAR2016/09:31	0.34	0.2 - 1	No	
		Week 12	19APR2016/09:20	0.48	0.2 - 1	Yes	
		Week 16	18MAY2016/10:10	0.45	0.2 - 1	No	
		Week 20	21JUN2016/10:35	0.59	0.2 - 1	No	
		Week 24	12JUL2016/10:00	0.59	0.2 - 1	Yes	
		Week 28	09AUG2016/09:50	0.57	0.2 - 1	No	
		Week 32	06SEP2016/09:00	0.49	0.2 - 1	No	
		Week 36	06OCT2016/09:50	0.57	0.2 - 1	No	
		Week 40	03NOV2016/11:00	0.58	0.2 - 1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Monocytes (10 <sup>9</sup> /L)	Week 44	06DEC2016/10:30	0.52	0.2 - 1	No	
		Week 48	03JAN2017/10:45	0.54	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	07JAN2016/12:00	0.10	0 - 0.38	Yes	4
		Day 1	27JAN2016/08:30	0.00	0 - 0.38	Yes	4
		Week 1	03FEB2016/11:00	0.00	0 - 0.38	Yes	4
		Week 2	11FEB2016/11:30	0.00	0 - 0.38	Yes	4
		Week 4	26FEB2016/10:20	0.00	0 - 0.38	No	4
		Week 6	10MAR2016/10:45	0.00	0 - 0.38	No	4
		Week 8	24MAR2016/09:31	0.00	0 - 0.38	No	4
		Week 12	19APR2016/09:20	0.00	0 - 0.38	Yes	4
		Week 16	18MAY2016/10:10	0.00	0 - 0.38	No	4
		Week 20	21JUN2016/10:35	0.10	0 - 0.38	No	4
		Week 24	12JUL2016/10:00	0.14	0 - 0.38	Yes	4
		Week 28	09AUG2016/09:50	0.00	0 - 0.38	No	4
		Week 32	06SEP2016/09:00	0.00	0 - 0.38	No	4
		Week 36	06OCT2016/09:50	1.52 H	0 - 0.38	No	0
		Week 40	03NOV2016/11:00	0.00	0 - 0.38	No	4
		Week 44	06DEC2016/10:30	0.05	0 - 0.38	No	4
		Week 48	03JAN2017/10:45	0.54 H	0 - 0.38	No	3
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	07JAN2016/12:00	2.27	2 - 7.5	Yes	0
		Day 1	27JAN2016/08:30	2.72	2 - 7.5	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Neutrophils, Segmented (10 <sup>9</sup> /L)	Week 1	03FEB2016/11:00	3.07	2 - 7.5	Yes	0
		Week 2	11FEB2016/11:30	2.22	2 - 7.5	Yes	0
		Week 4	26FEB2016/10:20	2.25	2 - 7.5	No	0
		Week 6	10MAR2016/10:45	1.82 L	2 - 7.5	No	1
		Week 8	24MAR2016/09:31	2.45	2 - 7.5	No	0
		Week 12	19APR2016/09:20	2.63	2 - 7.5	Yes	0
		Week 16	18MAY2016/10:10	2.77	2 - 7.5	No	0
		Week 20	21JUN2016/10:35	2.33	2 - 7.5	No	0
		Week 24	12JUL2016/10:00	1.94 L	2 - 7.5	Yes	1
		Week 28	09AUG2016/09:50	2.03	2 - 7.5	No	0
		Week 32	06SEP2016/09:00	1.73 L	2 - 7.5	No	1
		Week 36	06OCT2016/09:50	0.19 L	2 - 7.5	No	4
		Week 40	03NOV2016/11:00	1.78 L	2 - 7.5	No	1
		Week 44	06DEC2016/10:30	1.86 L	2 - 7.5	No	1
		Week 48	03JAN2017/10:45	1.24 L	2 - 7.5	No	2
	Platelets (10 <sup>9</sup> /L)	Screening	07JAN2016/12:00	224	150 - 400	Yes	0
		Day 1	27JAN2016/08:30	224	150 - 400	Yes	0
		Week 1	03FEB2016/11:00	181	150 - 400	Yes	0
		Week 2	11FEB2016/11:30	201	150 - 400	Yes	0
		Week 4	26FEB2016/10:20	178	150 - 400	No	0
		Week 6	10MAR2016/10:45	208	150 - 400	No	0
		Week 8	24MAR2016/09:31	255	150 - 400	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Platelets (10 <sup>9</sup> /L)	Week 12	19APR2016/09:20	179	150 - 400	Yes	0
		Week 16	18MAY2016/10:10	229	150 - 400	No	0
		Week 20	21JUN2016/10:35	186	150 - 400	No	0
		Week 24	12JUL2016/10:00	176	150 - 400	Yes	0
		Week 28	09AUG2016/09:50	183	150 - 400	No	0
		Week 32	06SEP2016/09:00	199	150 - 400	No	0
		Week 36	06OCT2016/09:50	179	150 - 400	No	0
		Week 40	03NOV2016/11:00	185	150 - 400	No	0
		Week 44	06DEC2016/10:30	184	150 - 400	No	0
		Week 48	03JAN2017/10:45	174	150 - 400	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Basophils (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	0.02	0 - 0.1	Yes
		Day 1	02FEB2016/11:10	0.02	0 - 0.1	Yes
		Week 1	09FEB2016/10:00	0.04	0 - 0.1	No
		Week 2	16FEB2016/11:00	0.00	0 - 0.1	No
		Week 4	01MAR2016/10:30	0.02	0 - 0.1	No
		Week 6	16MAR2016/11:45	0.02	0 - 0.1	No
		Week 8	31MAR2016/09:52	0.05	0 - 0.1	No
		Week 12	28APR2016/08:15	0.01	0 - 0.1	Yes
		Week 16	26MAY2016/12:10	0.02	0 - 0.1	No
		Week 20	22JUN2016/09:55	0.01	0 - 0.1	No
		Week 24	20JUL2016/09:30	0.02	0 - 0.1	Yes
		Week 28	18AUG2016/10:45	0.06	0 - 0.1	No
		Week 32	15SEP2016/10:00	0.01	0 - 0.1	No
		Week 36	13OCT2016/12:30	0.01	0 - 0.1	No
		Week 40	10NOV2016/10:15	0.01	0 - 0.1	No
		Week 44	06DEC2016/11:00	0.01	0 - 0.1	No
		Week 48	03JAN2017/12:00	0.01	0 - 0.1	No
	Blood film	Screening	06JAN2016/11:00			Yes
		Day 1	02FEB2016/11:10			Yes
		Week 1	09FEB2016/10:00			No
		Week 2	16FEB2016/11:00			No
		Week 4	01MAR2016/10:30			No
		Week 6	16MAR2016/11:45			No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Blood film	Week 8	31MAR2016/09:52			No
		Week 12	28APR2016/08:15			Yes
		Week 16	26MAY2016/12:10			No
		Week 20	22JUN2016/09:55			No
		Week 24	20JUL2016/09:30			Yes
		Week 28	18AUG2016/10:45			No
		Week 32	15SEP2016/10:00			No
		Week 36	13OCT2016/12:30			No
		Week 40	10NOV2016/10:15			No
		Week 44	06DEC2016/11:00			No
		Week 48	03JAN2017/12:00			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	0.07	0 - 0.4	Yes
		Day 1	02FEB2016/11:10	0.12	0 - 0.4	Yes
		Week 1	09FEB2016/10:00	0.13	0 - 0.4	No
		Week 2	16FEB2016/11:00	0.07	0 - 0.4	No
		Week 4	01MAR2016/10:30	0.08	0 - 0.4	No
		Week 6	16MAR2016/11:45	0.08	0 - 0.4	No
		Week 8	31MAR2016/09:52	0.10	0 - 0.4	No
		Week 12	28APR2016/08:15	0.09	0 - 0.4	Yes
		Week 16	26MAY2016/12:10	0.06	0 - 0.4	No
		Week 20	22JUN2016/09:55	0.06	0 - 0.4	No
		Week 24	20JUL2016/09:30	0.10	0 - 0.4	Yes
		Week 28	18AUG2016/10:45	0.19	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Eosinophils (10 <sup>9</sup> /L)	Week 32	15SEP2016/10:00	0.08	0 - 0.4	No
		Week 36	13OCT2016/12:30	0.05	0 - 0.4	No
		Week 40	10NOV2016/10:15	0.09	0 - 0.4	No
		Week 44	06DEC2016/11:00	0.12	0 - 0.4	No
		Week 48	03JAN2017/12:00	0.10	0 - 0.4	No
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	06JAN2016/11:00	351 H	300 - 350	Yes
		Day 1	02FEB2016/11:10	343	300 - 350	Yes
		Week 1	09FEB2016/10:00	343	300 - 350	No
		Week 2	16FEB2016/11:00	337	300 - 350	No
		Week 4	01MAR2016/10:30	339	300 - 350	No
		Week 6	16MAR2016/11:45	346	300 - 350	No
		Week 8	31MAR2016/09:52	332	300 - 350	No
		Week 12	28APR2016/08:15	330	300 - 350	Yes
		Week 16	26MAY2016/12:10	339	300 - 350	No
		Week 20	22JUN2016/09:55	324	300 - 350	No
		Week 24	20JUL2016/09:30	333	300 - 350	Yes
		Week 28	18AUG2016/10:45	332	300 - 350	No
		Week 32	15SEP2016/10:00	321	300 - 350	No
		Week 36	13OCT2016/12:30	337	300 - 350	No
		Week 40	10NOV2016/10:15	330	300 - 350	No
		Week 44	06DEC2016/11:00	333	300 - 350	No
		Week 48	03JAN2017/12:00	320	300 - 350	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	06JAN2016/11:00	30.3	26 - 33.5	Yes
		Day 1	02FEB2016/11:10	29.3	26 - 33.5	Yes
		Week 1	09FEB2016/10:00	29.2	26 - 33.5	No
		Week 2	16FEB2016/11:00	29.0	26 - 33.5	No
		Week 4	01MAR2016/10:30	29.2	26 - 33.5	No
		Week 6	16MAR2016/11:45	29.2	26 - 33.5	No
		Week 8	31MAR2016/09:52	29.2	26 - 33.5	No
		Week 12	28APR2016/08:15	29.4	26 - 33.5	Yes
		Week 16	26MAY2016/12:10	29.8	26 - 33.5	No
		Week 20	22JUN2016/09:55	29.5	26 - 33.5	No
		Week 24	20JUL2016/09:30	29.3	26 - 33.5	Yes
		Week 28	18AUG2016/10:45	28.4	26 - 33.5	No
		Week 32	15SEP2016/10:00	28.4	26 - 33.5	No
		Week 36	13OCT2016/12:30	28.9	26 - 33.5	No
		Week 40	10NOV2016/10:15	28.5	26 - 33.5	No
		Week 44	06DEC2016/11:00	28.6	26 - 33.5	No
		Week 48	03JAN2017/12:00	28.6	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	06JAN2016/11:00	86.3	80 - 99	Yes
		Day 1	02FEB2016/11:10	85.4	80 - 99	Yes
		Week 1	09FEB2016/10:00	85.2	80 - 99	No
		Week 2	16FEB2016/11:00	86.0	80 - 99	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Ery. Mean Corpuscular Volume (fL)	Week 4	01MAR2016/10:30	86.0	80 - 99	No
		Week 6	16MAR2016/11:45	84.4	80 - 99	No
		Week 8	31MAR2016/09:52	88.1	80 - 99	No
		Week 12	28APR2016/08:15	89.2	80 - 99	Yes
		Week 16	26MAY2016/12:10	87.9	80 - 99	No
		Week 20	22JUN2016/09:55	91.1	80 - 99	No
		Week 24	20JUL2016/09:30	88.1	80 - 99	Yes
		Week 28	18AUG2016/10:45	85.4	80 - 99	No
		Week 32	15SEP2016/10:00	88.6	80 - 99	No
		Week 36	13OCT2016/12:30	85.9	80 - 99	No
		Week 40	10NOV2016/10:15	86.3	80 - 99	No
		Week 44	06DEC2016/11:00	86.1	80 - 99	No
		Week 48	03JAN2017/12:00	89.5	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	06JAN2016/11:00	5.11	4.4 - 5.8	Yes
		Day 1	02FEB2016/11:10	4.92	4.4 - 5.8	Yes
		Week 1	09FEB2016/10:00	5.07	4.4 - 5.8	No
		Week 2	16FEB2016/11:00	4.93	4.4 - 5.8	No
		Week 4	01MAR2016/10:30	4.80	4.4 - 5.8	No
		Week 6	16MAR2016/11:45	4.73	4.4 - 5.8	No
		Week 8	31MAR2016/09:52	4.38 L	4.4 - 5.8	No
		Week 12	28APR2016/08:15	4.62	4.4 - 5.8	Yes
		Week 16	26MAY2016/12:10	4.70	4.4 - 5.8	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Erythrocytes (10 <sup>12</sup> /L)	Week 20	22JUN2016/09:55	4.37 L	4.4 - 5.8	No
		Week 24	20JUL2016/09:30	4.64	4.4 - 5.8	Yes
		Week 28	18AUG2016/10:45	4.65	4.4 - 5.8	No
		Week 32	15SEP2016/10:00	4.64	4.4 - 5.8	No
		Week 36	13OCT2016/12:30	4.88	4.4 - 5.8	No
		Week 40	10NOV2016/10:15	4.88	4.4 - 5.8	No
		Week 44	06DEC2016/11:00	4.82	4.4 - 5.8	No
		Week 48	03JAN2017/12:00	4.86	4.4 - 5.8	No
	Hematocrit (%)	Screening	06JAN2016/11:00	44.1	37 - 50	Yes
		Day 1	02FEB2016/11:10	42.0	37 - 50	Yes
		Week 1	09FEB2016/10:00	43.2	37 - 50	No
		Week 2	16FEB2016/11:00	42.4	37 - 50	No
		Week 4	01MAR2016/10:30	41.3	37 - 50	No
		Week 6	16MAR2016/11:45	39.9	37 - 50	No
		Week 8	31MAR2016/09:52	38.6	37 - 50	No
		Week 12	28APR2016/08:15	41.2	37 - 50	Yes
		Week 16	26MAY2016/12:10	41.3	37 - 50	No
		Week 20	22JUN2016/09:55	39.8	37 - 50	No
		Week 24	20JUL2016/09:30	40.9	37 - 50	Yes
		Week 28	18AUG2016/10:45	39.7	37 - 50	No
		Week 32	15SEP2016/10:00	41.1	37 - 50	No
		Week 36	13OCT2016/12:30	41.9	37 - 50	No
		Week 40	10NOV2016/10:15	42.1	37 - 50	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Hematocrit (%)	Week 44	06DEC2016/11:00	41.5	37 - 50	No	
		Week 48	03JAN2017/12:00	43.5	37 - 50	No	
301-001	Hemoglobin (g/L)	Screening	06JAN2016/11:00	155	130 - 170	Yes	0
		Day 1	02FEB2016/11:10	144	130 - 170	Yes	0
		Week 1	09FEB2016/10:00	148	130 - 170	No	0
		Week 2	16FEB2016/11:00	143	130 - 170	No	0
		Week 4	01MAR2016/10:30	140	130 - 170	No	0
		Week 6	16MAR2016/11:45	138	130 - 170	No	0
		Week 8	31MAR2016/09:52	128 L	130 - 170	No	1
		Week 12	28APR2016/08:15	136	130 - 170	Yes	0
		Week 16	26MAY2016/12:10	140	130 - 170	No	0
		Week 20	22JUN2016/09:55	129 L	130 - 170	No	1
		Week 24	20JUL2016/09:30	136	130 - 170	Yes	0
		Week 28	18AUG2016/10:45	132	130 - 170	No	0
		Week 32	15SEP2016/10:00	132	130 - 170	No	0
		Week 36	13OCT2016/12:30	141	130 - 170	No	0
		Week 40	10NOV2016/10:15	139	130 - 170	No	0
		Week 44	06DEC2016/11:00	138	130 - 170	No	0
		Week 48	03JAN2017/12:00	139	130 - 170	No	0
301-001	Leukocytes (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	5.44	3 - 10	Yes	0
		Day 1	02FEB2016/11:10	6.98	3 - 10	Yes	0
		Week 1	09FEB2016/10:00	8.34	3 - 10	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Leukocytes (10 <sup>9</sup> /L)	Week 2	16FEB2016/11:00	6.87	3 - 10	No	0
		Week 4	01MAR2016/10:30	6.93	3 - 10	No	0
		Week 6	16MAR2016/11:45	6.60	3 - 10	No	0
		Week 8	31MAR2016/09:52	5.16	3 - 10	No	0
		Week 12	28APR2016/08:15	6.85	3 - 10	Yes	0
		Week 16	26MAY2016/12:10	6.36	3 - 10	No	0
		Week 20	22JUN2016/09:55	5.26	3 - 10	No	0
		Week 24	20JUL2016/09:30	6.03	3 - 10	Yes	0
		Week 28	18AUG2016/10:45	6.24	3 - 10	No	0
		Week 32	15SEP2016/10:00	6.24	3 - 10	No	0
		Week 36	13OCT2016/12:30	5.60	3 - 10	No	0
		Week 40	10NOV2016/10:15	5.40	3 - 10	No	0
		Week 44	06DEC2016/11:00	6.96	3 - 10	No	0
		Week 48	03JAN2017/12:00	6.98	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	2.19	1.2 - 3.65	Yes	0
		Day 1	02FEB2016/11:10	2.80	1.2 - 3.65	Yes	0
		Week 1	09FEB2016/10:00	3.18	1.2 - 3.65	No	0
		Week 2	16FEB2016/11:00	3.44	1.2 - 3.65	No	0
		Week 4	01MAR2016/10:30	2.70	1.2 - 3.65	No	0
		Week 6	16MAR2016/11:45	2.78	1.2 - 3.65	No	0
		Week 8	31MAR2016/09:52	2.22	1.2 - 3.65	No	0
		Week 12	28APR2016/08:15	2.57	1.2 - 3.65	Yes	0
		Week 16	26MAY2016/12:10	2.43	1.2 - 3.65	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Lymphocytes (10 <sup>9</sup> /L)	Week 20	22JUN2016/09:55	2.29	1.2 - 3.65	No	0
		Week 24	20JUL2016/09:30	2.50	1.2 - 3.65	Yes	0
		Week 28	18AUG2016/10:45	2.50	1.2 - 3.65	No	0
		Week 32	15SEP2016/10:00	2.35	1.2 - 3.65	No	0
		Week 36	13OCT2016/12:30	2.00	1.2 - 3.65	No	0
		Week 40	10NOV2016/10:15	2.12	1.2 - 3.65	No	0
		Week 44	06DEC2016/11:00	2.67	1.2 - 3.65	No	0
		Week 48	03JAN2017/12:00	3.04	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	0.33	0.2 - 1	Yes	
		Day 1	02FEB2016/11:10	0.64	0.2 - 1	Yes	
		Week 1	09FEB2016/10:00	0.71	0.2 - 1	No	
		Week 2	16FEB2016/11:00	0.21	0.2 - 1	No	
		Week 4	01MAR2016/10:30	0.35	0.2 - 1	No	
		Week 6	16MAR2016/11:45	0.44	0.2 - 1	No	
		Week 8	31MAR2016/09:52	0.36	0.2 - 1	No	
		Week 12	28APR2016/08:15	0.51	0.2 - 1	Yes	
		Week 16	26MAY2016/12:10	0.43	0.2 - 1	No	
		Week 20	22JUN2016/09:55	0.26	0.2 - 1	No	
		Week 24	20JUL2016/09:30	0.40	0.2 - 1	Yes	
		Week 28	18AUG2016/10:45	0.50	0.2 - 1	No	
		Week 32	15SEP2016/10:00	0.36	0.2 - 1	No	
		Week 36	13OCT2016/12:30	0.58	0.2 - 1	No	
		Week 40	10NOV2016/10:15	0.54	0.2 - 1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Monocytes (10 <sup>9</sup> /L)	Week 44	06DEC2016/11:00	0.73	0.2 - 1	No	
		Week 48	03JAN2017/12:00	0.38	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	0.00	0 - 0.38	Yes	4
		Day 1	02FEB2016/11:10	0.00	0 - 0.38	Yes	4
		Week 1	09FEB2016/10:00	0.00	0 - 0.38	No	4
		Week 2	16FEB2016/11:00	0.82 H	0 - 0.38	No	3
		Week 4	01MAR2016/10:30	0.00	0 - 0.38	No	4
		Week 6	16MAR2016/11:45	0.00	0 - 0.38	No	4
		Week 8	31MAR2016/09:52	0.05	0 - 0.38	No	4
		Week 12	28APR2016/08:15	0.00	0 - 0.38	Yes	4
		Week 16	26MAY2016/12:10	0.00	0 - 0.38	No	4
		Week 20	22JUN2016/09:55		0 - 0.38	No	
		Week 24	20JUL2016/09:30	0.00	0 - 0.38	Yes	4
		Week 28	18AUG2016/10:45	0.25	0 - 0.38	No	4
		Week 32	15SEP2016/10:00		0 - 0.38	No	
		Week 36	13OCT2016/12:30	0.39 H	0 - 0.38	No	4
		Week 40	10NOV2016/10:15	0.00	0 - 0.38	No	4
		Week 44	06DEC2016/11:00	0.35	0 - 0.38	No	4
		Week 48	03JAN2017/12:00	0.07	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	2.82	2 - 7.5	Yes	0
		Day 1	02FEB2016/11:10	3.40	2 - 7.5	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Neutrophils, Segmented (10 <sup>9</sup> /L)	Week 1	09FEB2016/10:00	4.28	2 - 7.5	No	0
		Week 2	16FEB2016/11:00	2.34	2 - 7.5	No	0
		Week 4	01MAR2016/10:30	3.77	2 - 7.5	No	0
		Week 6	16MAR2016/11:45	3.28	2 - 7.5	No	0
		Week 8	31MAR2016/09:52	2.37	2 - 7.5	No	0
		Week 12	28APR2016/08:15	3.68	2 - 7.5	Yes	0
		Week 16	26MAY2016/12:10	3.42	2 - 7.5	No	0
		Week 20	22JUN2016/09:55		2 - 7.5	No	
		Week 24	20JUL2016/09:30	3.01	2 - 7.5	Yes	0
		Week 28	18AUG2016/10:45	2.75	2 - 7.5	No	0
		Week 32	15SEP2016/10:00		2 - 7.5	No	
		Week 36	13OCT2016/12:30	2.56	2 - 7.5	No	0
		Week 40	10NOV2016/10:15	2.64	2 - 7.5	No	0
		Week 44	06DEC2016/11:00	3.08	2 - 7.5	No	0
		Week 48	03JAN2017/12:00	3.39	2 - 7.5	No	0
	Platelets (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	111 L	150 - 400	Yes	1
		Day 1	02FEB2016/11:10	110 L	150 - 400	Yes	1
		Week 1	09FEB2016/10:00		150 - 400	No	
		Week 2	16FEB2016/11:00	110 L	150 - 400	No	1
		Week 4	01MAR2016/10:30	111 L	150 - 400	No	1
		Week 6	16MAR2016/11:45	112 L	150 - 400	No	1
		Week 8	31MAR2016/09:52	121 L	150 - 400	No	1

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Platelets (10 <sup>9</sup> /L)	Week 12	28APR2016/08:15		150 - 400	Yes	
		Week 16	26MAY2016/12:10	119 L	150 - 400	No	1
		Week 20	22JUN2016/09:55	105 L	150 - 400	No	1
		Week 24	20JUL2016/09:30	112 L	150 - 400	Yes	1
		Week 28	18AUG2016/10:45	117 L	150 - 400	No	1
		Week 32	15SEP2016/10:00	127 L	150 - 400	No	1
		Week 36	13OCT2016/12:30	126 L	150 - 400	No	1
		Week 40	10NOV2016/10:15	140 L	150 - 400	No	1
		Week 44	06DEC2016/11:00	136 L	150 - 400	No	1
		Week 48	03JAN2017/12:00	138 L	150 - 400	No	1
301-002	Basophils (10 <sup>9</sup> /L)	Screening	15DEC2015/09:00	0.04	0 - 0.1	Yes	
		Day 1	05JAN2016/09:00	0.01	0 - 0.1	Yes	
		Week 1	14JAN2016/10:00	0.01	0 - 0.1	No	
		Week 2	20JAN2016/10:00	0.01	0 - 0.1	No	
		Week 4	03FEB2016/09:45	0.02	0 - 0.1	No	
		Week 6	17FEB2016/13:00	0.02	0 - 0.1	No	
		Week 8	01MAR2016/09:00	0.01	0 - 0.1	No	
		Week 12	30MAR2016/09:50	0.02	0 - 0.1	No	
		Week 16	26APR2016/10:25	0.01	0 - 0.1	No	
		Week 20	24MAY2016/11:40	0.01	0 - 0.1	No	
		Week 24	21JUN2016/11:30	0.01	0 - 0.1	No	
		Week 28	20JUL2016/11:45	0.02	0 - 0.1	No	
		Week 32	18AUG2016/10:30	0.04	0 - 0.1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Basophils (10 <sup>9</sup> /L)	Week 36	13SEP2016/11:00	0.01	0 - 0.1	No
		Week 40	11OCT2016/12:05	0.01	0 - 0.1	No
		Week 44	09NOV2016/12:30	0.01	0 - 0.1	No
		Week 48	06DEC2016/13:00	0.00	0 - 0.1	No
	Blood film	Screening	15DEC2015/09:00			Yes
		Day 1	05JAN2016/09:00			Yes
		Week 1	14JAN2016/10:00			No
		Week 2	20JAN2016/10:00			No
		Week 4	03FEB2016/09:45			No
		Week 6	17FEB2016/13:00			No
		Week 8	01MAR2016/09:00			No
		Week 12	30MAR2016/09:50			No
		Week 16	26APR2016/10:25			No
		Week 20	24MAY2016/11:40			No
		Week 24	21JUN2016/11:30			No
		Week 28	20JUL2016/11:45			No
		Week 32	18AUG2016/10:30			No
		Week 36	13SEP2016/11:00			No
		Week 40	11OCT2016/12:05			No
		Week 44	09NOV2016/12:30			No
		Week 48	06DEC2016/13:00			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	15DEC2015/09:00	0.00	0 - 0.4	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002 Eosinophils (10 <sup>9</sup> /L)	Day 1	05JAN2016/09:00	0.02	0 - 0.4	Yes
	Week 1	14JAN2016/10:00	0.02	0 - 0.4	No
	Week 2	20JAN2016/10:00	0.02	0 - 0.4	No
	Week 4	03FEB2016/09:45	0.01	0 - 0.4	No
	Week 6	17FEB2016/13:00	0.01	0 - 0.4	No
	Week 8	01MAR2016/09:00	0.03	0 - 0.4	No
	Week 12	30MAR2016/09:50	0.02	0 - 0.4	No
	Week 16	26APR2016/10:25	0.02	0 - 0.4	No
	Week 20	24MAY2016/11:40	0.01	0 - 0.4	No
	Week 24	21JUN2016/11:30	0.00	0 - 0.4	No
	Week 28	20JUL2016/11:45	0.01	0 - 0.4	No
	Week 32	18AUG2016/10:30	0.04	0 - 0.4	No
	Week 36	13SEP2016/11:00	0.01	0 - 0.4	No
	Week 40	11OCT2016/12:05	0.02	0 - 0.4	No
	Week 44	09NOV2016/12:30	0.01	0 - 0.4	No
	Week 48	06DEC2016/13:00	0.03	0 - 0.4	No
Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	15DEC2015/09:00	345	300 - 350	Yes
	Day 1	05JAN2016/09:00	355 H	300 - 350	Yes
	Week 1	14JAN2016/10:00	350	300 - 350	No
	Week 2	20JAN2016/10:00	360 H	300 - 350	No
	Week 4	03FEB2016/09:45	353 H	300 - 350	No
	Week 6	17FEB2016/13:00	356 H	300 - 350	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Ery. Mean Corpuscular HGB Concentration (g/L)	Week 8	01MAR2016/09:00	356 H	300 - 350	No
		Week 12	30MAR2016/09:50	344	300 - 350	No
		Week 16	26APR2016/10:25	350	300 - 350	No
		Week 20	24MAY2016/11:40	346	300 - 350	No
		Week 24	21JUN2016/11:30	350	300 - 350	No
		Week 28	20JUL2016/11:45	329	300 - 350	No
		Week 32	18AUG2016/10:30	335	300 - 350	No
		Week 36	13SEP2016/11:00	328	300 - 350	No
		Week 40	11OCT2016/12:05	343	300 - 350	No
		Week 44	09NOV2016/12:30	341	300 - 350	No
		Week 48	06DEC2016/13:00	342	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	15DEC2015/09:00	30.1	26 - 33.5	Yes
		Day 1	05JAN2016/09:00	30.8	26 - 33.5	Yes
		Week 1	14JAN2016/10:00	30.2	26 - 33.5	No
		Week 2	20JAN2016/10:00	30.5	26 - 33.5	No
		Week 4	03FEB2016/09:45	30.3	26 - 33.5	No
		Week 6	17FEB2016/13:00	30.2	26 - 33.5	No
		Week 8	01MAR2016/09:00	29.8	26 - 33.5	No
		Week 12	30MAR2016/09:50	30.4	26 - 33.5	No
		Week 16	26APR2016/10:25	30.9	26 - 33.5	No
		Week 20	24MAY2016/11:40	31.0	26 - 33.5	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Ery. Mean Corpuscular Hemoglobin (pg)	Week 24	21JUN2016/11:30	32.2	26 - 33.5	No
		Week 28	20JUL2016/11:45	30.7	26 - 33.5	No
		Week 32	18AUG2016/10:30	30.2	26 - 33.5	No
		Week 36	13SEP2016/11:00	30.1	26 - 33.5	No
		Week 40	11OCT2016/12:05	29.6	26 - 33.5	No
		Week 44	09NOV2016/12:30	29.3	26 - 33.5	No
		Week 48	06DEC2016/13:00	29.8	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	15DEC2015/09:00	87.3	80 - 99	Yes
		Day 1	05JAN2016/09:00	86.6	80 - 99	Yes
		Week 1	14JAN2016/10:00	86.4	80 - 99	No
		Week 2	20JAN2016/10:00	84.8	80 - 99	No
		Week 4	03FEB2016/09:45	85.9	80 - 99	No
		Week 6	17FEB2016/13:00	84.9	80 - 99	No
		Week 8	01MAR2016/09:00	83.8	80 - 99	No
		Week 12	30MAR2016/09:50	88.5	80 - 99	No
		Week 16	26APR2016/10:25	88.1	80 - 99	No
		Week 20	24MAY2016/11:40	89.7	80 - 99	No
		Week 24	21JUN2016/11:30	92.1	80 - 99	No
		Week 28	20JUL2016/11:45	93.3	80 - 99	No
		Week 32	18AUG2016/10:30	90.0	80 - 99	No
		Week 36	13SEP2016/11:00	91.6	80 - 99	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Ery. Mean Corpuscular Volume (fL)	Week 40	11OCT2016/12:05	86.4	80 - 99	No
		Week 44	09NOV2016/12:30	85.9	80 - 99	No
		Week 48	06DEC2016/13:00	87.1	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	15DEC2015/09:00	5.18	4.4 - 5.8	Yes
		Day 1	05JAN2016/09:00	4.91	4.4 - 5.8	Yes
		Week 1	14JAN2016/10:00	5.16	4.4 - 5.8	No
		Week 2	20JAN2016/10:00	5.08	4.4 - 5.8	No
		Week 4	03FEB2016/09:45	4.88	4.4 - 5.8	No
		Week 6	17FEB2016/13:00	5.10	4.4 - 5.8	No
		Week 8	01MAR2016/09:00	4.63	4.4 - 5.8	No
		Week 12	30MAR2016/09:50	4.60	4.4 - 5.8	No
		Week 16	26APR2016/10:25	4.86	4.4 - 5.8	No
		Week 20	24MAY2016/11:40	4.67	4.4 - 5.8	No
		Week 24	21JUN2016/11:30	4.78	4.4 - 5.8	No
		Week 28	20JUL2016/11:45	4.63	4.4 - 5.8	No
		Week 32	18AUG2016/10:30	4.61	4.4 - 5.8	No
		Week 36	13SEP2016/11:00	4.99	4.4 - 5.8	No
		Week 40	11OCT2016/12:05	5.06	4.4 - 5.8	No
		Week 44	09NOV2016/12:30	4.98	4.4 - 5.8	No
		Week 48	06DEC2016/13:00	4.87	4.4 - 5.8	No
	Hematocrit (%)	Screening	15DEC2015/09:00	45.2	37 - 50	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Hematocrit (%)	Day 1	05JAN2016/09:00	42.5	37 - 50	Yes	
		Week 1	14JAN2016/10:00	44.6	37 - 50	No	
		Week 2	20JAN2016/10:00	43.1	37 - 50	No	
		Week 4	03FEB2016/09:45	41.9	37 - 50	No	
		Week 6	17FEB2016/13:00	43.3	37 - 50	No	
		Week 8	01MAR2016/09:00	38.8	37 - 50	No	
		Week 12	30MAR2016/09:50	40.7	37 - 50	No	
		Week 16	26APR2016/10:25	42.8	37 - 50	No	
		Week 20	24MAY2016/11:40	41.9	37 - 50	No	
		Week 24	21JUN2016/11:30	44.0	37 - 50	No	
		Week 28	20JUL2016/11:45	43.2	37 - 50	No	
		Week 32	18AUG2016/10:30	41.5	37 - 50	No	
		Week 36	13SEP2016/11:00	45.7	37 - 50	No	
		Week 40	11OCT2016/12:05	43.7	37 - 50	No	
		Week 44	09NOV2016/12:30	42.8	37 - 50	No	
		Week 48	06DEC2016/13:00	42.4	37 - 50	No	
	Hemoglobin (g/L)	Screening	15DEC2015/09:00	156	130 - 170	Yes	0
		Day 1	05JAN2016/09:00	151	130 - 170	Yes	0
		Week 1	14JAN2016/10:00	156	130 - 170	No	0
		Week 2	20JAN2016/10:00	155	130 - 170	No	0
		Week 4	03FEB2016/09:45	148	130 - 170	No	0
		Week 6	17FEB2016/13:00	154	130 - 170	No	0
		Week 8	01MAR2016/09:00	138	130 - 170	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Hemoglobin (g/L)	Week 12	30MAR2016/09:50	140	130 - 170	No	0
		Week 16	26APR2016/10:25	150	130 - 170	No	0
		Week 20	24MAY2016/11:40	145	130 - 170	No	0
		Week 24	21JUN2016/11:30	154	130 - 170	No	0
		Week 28	20JUL2016/11:45	142	130 - 170	No	0
		Week 32	18AUG2016/10:30	139	130 - 170	No	0
		Week 36	13SEP2016/11:00	150	130 - 170	No	0
		Week 40	11OCT2016/12:05	150	130 - 170	No	0
		Week 44	09NOV2016/12:30	146	130 - 170	No	0
		Week 48	06DEC2016/13:00	145	130 - 170	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	15DEC2015/09:00	3.66	3 - 10	Yes	0
		Day 1	05JAN2016/09:00	4.76	3 - 10	Yes	0
		Week 1	14JAN2016/10:00	4.04	3 - 10	No	0
		Week 2	20JAN2016/10:00	3.76	3 - 10	No	0
		Week 4	03FEB2016/09:45	3.94	3 - 10	No	0
		Week 6	17FEB2016/13:00	3.79	3 - 10	No	0
		Week 8	01MAR2016/09:00	4.35	3 - 10	No	0
		Week 12	30MAR2016/09:50	2.76 L	3 - 10	No	2
		Week 16	26APR2016/10:25	3.48	3 - 10	No	0
		Week 20	24MAY2016/11:40	3.34	3 - 10	No	0
		Week 24	21JUN2016/11:30	3.70	3 - 10	No	0
		Week 28	20JUL2016/11:45	3.76	3 - 10	No	0
		Week 32	18AUG2016/10:30	4.40	3 - 10	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Leukocytes (10 <sup>9</sup> /L)	Week 36	13SEP2016/11:00	3.22	3 - 10	No	0
		Week 40	11OCT2016/12:05	4.10	3 - 10	No	0
		Week 44	09NOV2016/12:30	4.06	3 - 10	No	0
		Week 48	06DEC2016/13:00	3.46	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	15DEC2015/09:00	1.65	1.2 - 3.65	Yes	0
		Day 1	05JAN2016/09:00	2.06	1.2 - 3.65	Yes	0
		Week 1	14JAN2016/10:00	1.58	1.2 - 3.65	No	0
		Week 2	20JAN2016/10:00	1.64	1.2 - 3.65	No	0
		Week 4	03FEB2016/09:45	1.37	1.2 - 3.65	No	0
		Week 6	17FEB2016/13:00	1.30	1.2 - 3.65	No	0
		Week 8	01MAR2016/09:00	1.65	1.2 - 3.65	No	0
		Week 12	30MAR2016/09:50	1.13 L	1.2 - 3.65	No	1
		Week 16	26APR2016/10:25	1.16 L	1.2 - 3.65	No	1
		Week 20	24MAY2016/11:40	1.12 L	1.2 - 3.65	No	1
		Week 24	21JUN2016/11:30	1.17 L	1.2 - 3.65	No	1
		Week 28	20JUL2016/11:45	1.64	1.2 - 3.65	No	0
		Week 32	18AUG2016/10:30	1.58	1.2 - 3.65	No	0
		Week 36	13SEP2016/11:00	1.27	1.2 - 3.65	No	0
		Week 40	11OCT2016/12:05	1.72	1.2 - 3.65	No	0
		Week 44	09NOV2016/12:30	1.41	1.2 - 3.65	No	0
		Week 48	06DEC2016/13:00	1.40	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	15DEC2015/09:00	0.44	0.2 - 1	Yes	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Monocytes (10 <sup>9</sup> /L)	Day 1	05JAN2016/09:00	0.55	0.2 - 1	Yes	
		Week 1	14JAN2016/10:00	0.60	0.2 - 1	No	
		Week 2	20JAN2016/10:00	0.47	0.2 - 1	No	
		Week 4	03FEB2016/09:45	0.49	0.2 - 1	No	
		Week 6	17FEB2016/13:00	0.39	0.2 - 1	No	
		Week 8	01MAR2016/09:00	0.56	0.2 - 1	No	
		Week 12	30MAR2016/09:50	0.33	0.2 - 1	No	
		Week 16	26APR2016/10:25	0.41	0.2 - 1	No	
		Week 20	24MAY2016/11:40	0.59	0.2 - 1	No	
		Week 24	21JUN2016/11:30	0.46	0.2 - 1	No	
		Week 28	20JUL2016/11:45	0.59	0.2 - 1	No	
		Week 32	18AUG2016/10:30	0.53	0.2 - 1	No	
		Week 36	13SEP2016/11:00	0.42	0.2 - 1	No	
		Week 40	11OCT2016/12:05	0.79	0.2 - 1	No	
		Week 44	09NOV2016/12:30	0.59	0.2 - 1	No	
		Week 48	06DEC2016/13:00	0.60	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	15DEC2015/09:00	0.732 H	0 - 0.38	Yes	3
		Day 1	05JAN2016/09:00	0.00	0 - 0.38	Yes	4
		Week 1	14JAN2016/10:00	0.00	0 - 0.38	No	4
		Week 2	20JAN2016/10:00	0.00	0 - 0.38	No	4
		Week 4	03FEB2016/09:45	0.00	0 - 0.38	No	4
		Week 6	17FEB2016/13:00	0.00	0 - 0.38	No	4
		Week 8	01MAR2016/09:00	0.00	0 - 0.38	No	4

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Neutrophils Band Form (10 <sup>9</sup> /L)	Week 12	30MAR2016/09:50	0.00	0 - 0.38	No	4
		Week 16	26APR2016/10:25	0.00	0 - 0.38	No	4
		Week 20	24MAY2016/11:40	0.00	0 - 0.38	No	4
		Week 24	21JUN2016/11:30	0.00	0 - 0.38	No	4
		Week 28	20JUL2016/11:45	0.00	0 - 0.38	No	4
		Week 32	18AUG2016/10:30	1.41 H	0 - 0.38	No	2
		Week 36	13SEP2016/11:00	0.00	0 - 0.38	No	4
		Week 40	11OCT2016/12:05	0.12	0 - 0.38	No	4
		Week 44	09NOV2016/12:30	0.00	0 - 0.38	No	4
		Week 48	06DEC2016/13:00	0.10	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	15DEC2015/09:00	0.81 L	2 - 7.5	Yes	3
		Day 1	05JAN2016/09:00	2.12	2 - 7.5	Yes	0
		Week 1	14JAN2016/10:00	1.82 L	2 - 7.5	No	1
		Week 2	20JAN2016/10:00	1.62 L	2 - 7.5	No	1
		Week 4	03FEB2016/09:45	2.05	2 - 7.5	No	0
		Week 6	17FEB2016/13:00	2.07	2 - 7.5	No	0
		Week 8	01MAR2016/09:00	2.10	2 - 7.5	No	0
		Week 12	30MAR2016/09:50	1.26 L	2 - 7.5	No	2
		Week 16	26APR2016/10:25	1.88 L	2 - 7.5	No	1
		Week 20	24MAY2016/11:40	1.61 L	2 - 7.5	No	1
		Week 24	21JUN2016/11:30	2.06	2 - 7.5	No	0
		Week 28	20JUL2016/11:45	1.50 L	2 - 7.5	No	1

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Neutrophils, Segmented (10 <sup>9</sup> /L)	Week 32	18AUG2016/10:30	0.79 L	2 - 7.5	No	3
		Week 36	13SEP2016/11:00	1.51 L	2 - 7.5	No	1
		Week 40	11OCT2016/12:05	1.44 L	2 - 7.5	No	2
		Week 44	09NOV2016/12:30	2.05	2 - 7.5	No	0
		Week 48	06DEC2016/13:00	1.33 L	2 - 7.5	No	2
	Platelets (10 <sup>9</sup> /L)	Screening	15DEC2015/09:00	157	150 - 400	Yes	0
		Day 1	05JAN2016/09:00	158	150 - 400	Yes	0
		Week 1	14JAN2016/10:00	148 L	150 - 400	No	1
		Week 2	20JAN2016/10:00	170	150 - 400	No	0
		Week 4	03FEB2016/09:45	151	150 - 400	No	0
		Week 6	17FEB2016/13:00	151	150 - 400	No	0
		Week 8	01MAR2016/09:00	122 L	150 - 400	No	1
		Week 12	30MAR2016/09:50	191	150 - 400	No	0
		Week 16	26APR2016/10:25	155	150 - 400	No	0
		Week 20	24MAY2016/11:40	168	150 - 400	No	0
		Week 24	21JUN2016/11:30	147 L	150 - 400	No	1
		Week 28	20JUL2016/11:45	200	150 - 400	No	0
		Week 32	18AUG2016/10:30	177	150 - 400	No	0
		Week 36	13SEP2016/11:00	181	150 - 400	No	0
		Week 40	11OCT2016/12:05	178	150 - 400	No	0
		Week 44	09NOV2016/12:30	155	150 - 400	No	0
		Week 48	06DEC2016/13:00	186	150 - 400	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Basophils (10 <sup>9</sup> /L)	Screening	15DEC2015/12:00	0.00	0 - 0.1	Yes
		Day 1	06JAN2016/11:00	0.02	0 - 0.1	Yes
		Week 1	13JAN2016/11:00	0.11 H	0 - 0.1	No
		Week 2	20JAN2016/11:00	0.03	0 - 0.1	No
		Week 4	03FEB2016/11:00	0.03	0 - 0.1	No
		Week 6	18FEB2016/13:30	0.03	0 - 0.1	No
		Week 8	08MAR2016/08:35	0.02	0 - 0.1	No
		Week 12	29MAR2016/09:15	0.00	0 - 0.1	No
		Week 16	25APR2016/08:50	0.02	0 - 0.1	No
		Week 20	26MAY2016/12:50	0.02	0 - 0.1	No
		Week 24	22JUN2016/12:30	0.02	0 - 0.1	No
		Week 28	19JUL2016/10:10	0.00	0 - 0.1	No
		Week 32	16AUG2016/12:10	0.00	0 - 0.1	No
		Week 36	15SEP2016/12:35	0.02	0 - 0.1	No
		Week 40	12OCT2016/11:20	0.02	0 - 0.1	Yes
		Week 44	09NOV2016/12:00	0.01	0 - 0.1	No
		Week 48	14DEC2016/12:00	0.03	0 - 0.1	No
	Blood film	Screening	15DEC2015/12:00			Yes
		Day 1	06JAN2016/11:00			Yes
		Week 1	13JAN2016/11:00			No
		Week 2	20JAN2016/11:00			No
		Week 4	03FEB2016/11:00			No
		Week 6	18FEB2016/13:30			No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Blood film	Week 8	08MAR2016/08:35			No
		Week 12	29MAR2016/09:15			No
		Week 16	25APR2016/08:50			No
		Week 20	26MAY2016/12:50			No
		Week 24	22JUN2016/12:30			No
		Week 28	19JUL2016/10:10			No
		Week 32	16AUG2016/12:10			No
		Week 36	15SEP2016/12:35			No
		Week 44	09NOV2016/12:00			No
		Week 48	14DEC2016/12:00			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	15DEC2015/12:00	0.00	0 - 0.4	Yes
		Day 1	06JAN2016/11:00	0.13	0 - 0.4	Yes
		Week 1	13JAN2016/11:00	0.11	0 - 0.4	No
		Week 2	20JAN2016/11:00	0.12	0 - 0.4	No
		Week 4	03FEB2016/11:00	0.08	0 - 0.4	No
		Week 6	18FEB2016/13:30	0.13	0 - 0.4	No
		Week 8	08MAR2016/08:35	0.07	0 - 0.4	No
		Week 12	29MAR2016/09:15	0.11	0 - 0.4	No
		Week 16	25APR2016/08:50	0.04	0 - 0.4	No
		Week 20	26MAY2016/12:50	0.09	0 - 0.4	No
		Week 24	22JUN2016/12:30	0.07	0 - 0.4	No
		Week 28	19JUL2016/10:10	0.19	0 - 0.4	No
		Week 32	16AUG2016/12:10	0.07	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Eosinophils (10 <sup>9</sup> /L)	Week 36	15SEP2016/12:35	0.11	0 - 0.4	No
		Week 40	12OCT2016/11:20	0.08	0 - 0.4	Yes
		Week 44	09NOV2016/12:00	0.16	0 - 0.4	No
		Week 48	14DEC2016/12:00	0.11	0 - 0.4	No
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	15DEC2015/12:00	328	300 - 350	Yes
		Day 1	06JAN2016/11:00	342	300 - 350	Yes
		Week 1	13JAN2016/11:00	338	300 - 350	No
		Week 2	20JAN2016/11:00	342	300 - 350	No
		Week 4	03FEB2016/11:00	342	300 - 350	No
		Week 6	18FEB2016/13:30	348	300 - 350	No
		Week 8	08MAR2016/08:35	343	300 - 350	No
		Week 12	29MAR2016/09:15	336	300 - 350	No
		Week 16	25APR2016/08:50	333	300 - 350	No
		Week 20	26MAY2016/12:50	334	300 - 350	No
		Week 24	22JUN2016/12:30	326	300 - 350	No
		Week 28	19JUL2016/10:10	326	300 - 350	No
		Week 32	16AUG2016/12:10	333	300 - 350	No
		Week 36	15SEP2016/12:35	329	300 - 350	No
		Week 40	12OCT2016/11:20	329	300 - 350	Yes
		Week 44	09NOV2016/12:00	335	300 - 350	No
		Week 48	14DEC2016/12:00	338	300 - 350	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	15DEC2015/12:00	31.3	26 - 33.5	Yes
		Day 1	06JAN2016/11:00	32.1	26 - 33.5	Yes
		Week 1	13JAN2016/11:00	31.3	26 - 33.5	No
		Week 2	20JAN2016/11:00	31.6	26 - 33.5	No
		Week 4	03FEB2016/11:00	31.4	26 - 33.5	No
		Week 6	18FEB2016/13:30	31.9	26 - 33.5	No
		Week 8	08MAR2016/08:35	31.1	26 - 33.5	No
		Week 12	29MAR2016/09:15	31.0	26 - 33.5	No
		Week 16	25APR2016/08:50	30.5	26 - 33.5	No
		Week 20	26MAY2016/12:50	30.6	26 - 33.5	No
		Week 24	22JUN2016/12:30	30.3	26 - 33.5	No
		Week 28	19JUL2016/10:10	30.5	26 - 33.5	No
		Week 32	16AUG2016/12:10	31.0	26 - 33.5	No
		Week 36	15SEP2016/12:35	30.8	26 - 33.5	No
		Week 40	12OCT2016/11:20	30.3	26 - 33.5	Yes
		Week 44	09NOV2016/12:00	30.3	26 - 33.5	No
		Week 48	14DEC2016/12:00	30.2	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	15DEC2015/12:00	95.4	80 - 99	Yes
		Day 1	06JAN2016/11:00	93.7	80 - 99	Yes
		Week 1	13JAN2016/11:00	92.5	80 - 99	No
		Week 2	20JAN2016/11:00	92.3	80 - 99	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Ery. Mean Corpuscular Volume (fL)	Week 4	03FEB2016/11:00	92.0	80 - 99	No
		Week 6	18FEB2016/13:30	91.8	80 - 99	No
		Week 8	08MAR2016/08:35	90.5	80 - 99	No
		Week 12	29MAR2016/09:15	92.2	80 - 99	No
		Week 16	25APR2016/08:50	91.6	80 - 99	No
		Week 20	26MAY2016/12:50	91.7	80 - 99	No
		Week 24	22JUN2016/12:30	92.9	80 - 99	No
		Week 28	19JUL2016/10:10	93.6	80 - 99	No
		Week 32	16AUG2016/12:10	93.1	80 - 99	No
		Week 36	15SEP2016/12:35	93.5	80 - 99	No
		Week 40	12OCT2016/11:20	92.2	80 - 99	Yes
		Week 44	09NOV2016/12:00	90.5	80 - 99	No
		Week 48	14DEC2016/12:00	89.1	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	15DEC2015/12:00	4.54	3.95 - 5.15	Yes
		Day 1	06JAN2016/11:00	4.30	3.95 - 5.15	Yes
		Week 1	13JAN2016/11:00	4.28	3.95 - 5.15	No
		Week 2	20JAN2016/11:00	4.43	3.95 - 5.15	No
		Week 4	03FEB2016/11:00	4.36	3.95 - 5.15	No
		Week 6	18FEB2016/13:30	4.29	3.95 - 5.15	No
		Week 8	08MAR2016/08:35	4.02	3.95 - 5.15	No
		Week 12	29MAR2016/09:15	4.10	3.95 - 5.15	No
		Week 16	25APR2016/08:50	4.39	3.95 - 5.15	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Erythrocytes (10 <sup>12</sup> /L)	Week 20	26MAY2016/12:50	4.44	3.95 - 5.15	No
		Week 24	22JUN2016/12:30	4.52	3.95 - 5.15	No
		Week 28	19JUL2016/10:10	4.52	3.95 - 5.15	No
		Week 32	16AUG2016/12:10	4.03	3.95 - 5.15	No
		Week 36	15SEP2016/12:35	4.16	3.95 - 5.15	No
		Week 40	12OCT2016/11:20	4.22	3.95 - 5.15	Yes
		Week 44	09NOV2016/12:00	4.42	3.95 - 5.15	No
		Week 48	14DEC2016/12:00	4.51	3.95 - 5.15	No
	Hematocrit (%)	Screening	15DEC2015/12:00	43.3	33 - 45	Yes
		Day 1	06JAN2016/11:00	40.3	33 - 45	Yes
		Week 1	13JAN2016/11:00	39.6	33 - 45	No
		Week 2	20JAN2016/11:00	40.9	33 - 45	No
		Week 4	03FEB2016/11:00	40.1	33 - 45	No
		Week 6	18FEB2016/13:30	39.4	33 - 45	No
		Week 8	08MAR2016/08:35	36.4	33 - 45	No
		Week 12	29MAR2016/09:15	37.8	33 - 45	No
		Week 16	25APR2016/08:50	40.2	33 - 45	No
		Week 20	26MAY2016/12:50	40.7	33 - 45	No
		Week 24	22JUN2016/12:30	42.0	33 - 45	No
		Week 28	19JUL2016/10:10	42.3	33 - 45	No
		Week 32	16AUG2016/12:10	37.5	33 - 45	No
		Week 36	15SEP2016/12:35	38.9	33 - 45	No
		Week 40	12OCT2016/11:20	38.9	33 - 45	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Hematocrit (%)	Week 44	09NOV2016/12:00	40.0	33 - 45	No	
		Week 48	14DEC2016/12:00	40.2	33 - 45	No	
	Hemoglobin (g/L)	Screening	15DEC2015/12:00	142	115 - 155	Yes	0
		Day 1	06JAN2016/11:00	138	115 - 155	Yes	0
		Week 1	13JAN2016/11:00	134	115 - 155	No	0
		Week 2	20JAN2016/11:00	140	115 - 155	No	0
		Week 4	03FEB2016/11:00	137	115 - 155	No	0
		Week 6	18FEB2016/13:30	137	115 - 155	No	0
		Week 8	08MAR2016/08:35	125	115 - 155	No	0
		Week 12	29MAR2016/09:15	127	115 - 155	No	0
		Week 16	25APR2016/08:50	134	115 - 155	No	0
		Week 20	26MAY2016/12:50	136	115 - 155	No	0
		Week 24	22JUN2016/12:30	137	115 - 155	No	0
		Week 28	19JUL2016/10:10	138	115 - 155	No	0
		Week 32	16AUG2016/12:10	125	115 - 155	No	0
		Week 36	15SEP2016/12:35	128	115 - 155	No	0
		Week 40	12OCT2016/11:20	128	115 - 155	Yes	0
		Week 44	09NOV2016/12:00	134	115 - 155	No	0
		Week 48	14DEC2016/12:00	136	115 - 155	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	15DEC2015/12:00	7.90	3 - 10	Yes	0
		Day 1	06JAN2016/11:00	10.33 H	3 - 10	Yes	0
		Week 1	13JAN2016/11:00	10.51 H	3 - 10	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Leukocytes (10 <sup>9</sup> /L)	Week 2	20JAN2016/11:00	10.04 H	3 - 10	No	0
		Week 4	03FEB2016/11:00	8.78	3 - 10	No	0
		Week 6	18FEB2016/13:30	11.21 H	3 - 10	No	0
		Week 8	08MAR2016/08:35	9.62	3 - 10	No	0
		Week 12	29MAR2016/09:15	11.37 H	3 - 10	No	0
		Week 16	25APR2016/08:50	8.64	3 - 10	No	0
		Week 20	26MAY2016/12:50	9.11	3 - 10	No	0
		Week 24	22JUN2016/12:30	7.76	3 - 10	No	0
		Week 28	19JUL2016/10:10	9.46	3 - 10	No	0
		Week 32	16AUG2016/12:10	7.30	3 - 10	No	0
		Week 36	15SEP2016/12:35	8.30	3 - 10	No	0
		Week 40	12OCT2016/11:20	8.29	3 - 10	Yes	0
		Week 44	09NOV2016/12:00	7.24	3 - 10	No	0
		Week 48	14DEC2016/12:00	7.91	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	15DEC2015/12:00	3.48	1.2 - 3.65	Yes	0
		Day 1	06JAN2016/11:00	3.17	1.2 - 3.65	Yes	0
		Week 1	13JAN2016/11:00	3.57	1.2 - 3.65	No	0
		Week 2	20JAN2016/11:00	2.89	1.2 - 3.65	No	0
		Week 4	03FEB2016/11:00	2.18	1.2 - 3.65	No	0
		Week 6	18FEB2016/13:30	3.19	1.2 - 3.65	No	0
		Week 8	08MAR2016/08:35	2.23	1.2 - 3.65	No	0
		Week 12	29MAR2016/09:15	2.39	1.2 - 3.65	No	0
		Week 16	25APR2016/08:50	1.68	1.2 - 3.65	No	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Lymphocytes (10 <sup>9</sup> /L)	Week 20	26MAY2016/12:50	2.59	1.2 - 3.65	No	0
		Week 24	22JUN2016/12:30	2.40	1.2 - 3.65	No	0
		Week 28	19JUL2016/10:10	2.84	1.2 - 3.65	No	0
		Week 32	16AUG2016/12:10	2.41	1.2 - 3.65	No	0
		Week 36	15SEP2016/12:35	2.32	1.2 - 3.65	No	0
		Week 40	12OCT2016/11:20	1.45	1.2 - 3.65	Yes	0
		Week 44	09NOV2016/12:00	2.30	1.2 - 3.65	No	0
		Week 48	14DEC2016/12:00	2.38	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	15DEC2015/12:00	0.63	0.2 - 1	Yes	
		Day 1	06JAN2016/11:00	0.84	0.2 - 1	Yes	
		Week 1	13JAN2016/11:00	0.53	0.2 - 1	No	
		Week 2	20JAN2016/11:00	0.89	0.2 - 1	No	
		Week 4	03FEB2016/11:00	0.62	0.2 - 1	No	
		Week 6	18FEB2016/13:30	1.01 H	0.2 - 1	No	
		Week 8	08MAR2016/08:35	0.65	0.2 - 1	No	
		Week 12	29MAR2016/09:15	0.57	0.2 - 1	No	
		Week 16	25APR2016/08:50	0.65	0.2 - 1	No	
		Week 20	26MAY2016/12:50	0.73	0.2 - 1	No	
		Week 24	22JUN2016/12:30	0.52	0.2 - 1	No	
		Week 28	19JUL2016/10:10	0.57	0.2 - 1	No	
		Week 32	16AUG2016/12:10	0.58	0.2 - 1	No	
		Week 36	15SEP2016/12:35	0.60	0.2 - 1	No	
		Week 40	12OCT2016/11:20	0.81	0.2 - 1	Yes	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Monocytes (10 <sup>9</sup> /L)	Week 44	09NOV2016/12:00	0.75	0.2 - 1	No	
		Week 48	14DEC2016/12:00	0.64	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	15DEC2015/12:00	0.316	0 - 0.38	Yes	4
		Day 1	06JAN2016/11:00	0.52 H	0 - 0.38	Yes	3
		Week 1	13JAN2016/11:00	0.32	0 - 0.38	No	4
		Week 2	20JAN2016/11:00	0.10	0 - 0.38	No	4
		Week 4	03FEB2016/11:00	0.00	0 - 0.38	No	4
		Week 6	18FEB2016/13:30	0.56 H	0 - 0.38	No	3
		Week 8	08MAR2016/08:35	0.00	0 - 0.38	No	4
		Week 12	29MAR2016/09:15	1.25 H	0 - 0.38	No	2
		Week 16	25APR2016/08:50	0.00	0 - 0.38	No	4
		Week 20	26MAY2016/12:50	0.00	0 - 0.38	No	4
		Week 24	22JUN2016/12:30	0.00	0 - 0.38	No	4
		Week 28	19JUL2016/10:10	0.19	0 - 0.38	No	4
		Week 32	16AUG2016/12:10	0.22	0 - 0.38	No	4
		Week 36	15SEP2016/12:35		0 - 0.38	No	
		Week 40	12OCT2016/11:20	1.24 H	0 - 0.38	Yes	2
		Week 44	09NOV2016/12:00	0.00	0 - 0.38	No	4
		Week 48	14DEC2016/12:00	0.00	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	15DEC2015/12:00	3.48	2 - 7.5	Yes	0
		Day 1	06JAN2016/11:00	5.65	2 - 7.5	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Neutrophils, Segmented (10 <sup>9</sup> /L)	Week 1	13JAN2016/11:00	5.89	2 - 7.5	No	0
		Week 2	20JAN2016/11:00	5.92	2 - 7.5	No	0
		Week 4	03FEB2016/11:00	5.87	2 - 7.5	No	0
		Week 6	18FEB2016/13:30	6.28	2 - 7.5	No	0
		Week 8	08MAR2016/08:35	6.65	2 - 7.5	No	0
		Week 12	29MAR2016/09:15	5.91	2 - 7.5	No	0
		Week 16	25APR2016/08:50	6.26	2 - 7.5	No	0
		Week 20	26MAY2016/12:50	5.68	2 - 7.5	No	0
		Week 24	22JUN2016/12:30	4.75	2 - 7.5	No	0
		Week 28	19JUL2016/10:10	5.68	2 - 7.5	No	0
		Week 32	16AUG2016/12:10	4.02	2 - 7.5	No	0
		Week 36	15SEP2016/12:35		2 - 7.5	No	
		Week 40	12OCT2016/11:20	4.64	2 - 7.5	Yes	0
		Week 44	09NOV2016/12:00	4.02	2 - 7.5	No	0
		Week 48	14DEC2016/12:00	4.75	2 - 7.5	No	0
	Platelets (10 <sup>9</sup> /L)	Screening	15DEC2015/12:00	285	150 - 400	Yes	0
		Day 1	06JAN2016/11:00	310	150 - 400	Yes	0
		Week 1	13JAN2016/11:00	307	150 - 400	No	0
		Week 2	20JAN2016/11:00	334	150 - 400	No	0
		Week 4	03FEB2016/11:00	300	150 - 400	No	0
		Week 6	18FEB2016/13:30	294	150 - 400	No	0
		Week 8	08MAR2016/08:35	279	150 - 400	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Platelets (10 <sup>9</sup> /L)	Week 12	29MAR2016/09:15	306	150 - 400	No	0
		Week 16	25APR2016/08:50	320	150 - 400	No	0
		Week 20	26MAY2016/12:50	276	150 - 400	No	0
		Week 24	22JUN2016/12:30	278	150 - 400	No	0
		Week 28	19JUL2016/10:10	312	150 - 400	No	0
		Week 32	16AUG2016/12:10	259	150 - 400	No	0
		Week 36	15SEP2016/12:35	279	150 - 400	No	0
		Week 40	12OCT2016/11:20	261	150 - 400	Yes	0
		Week 44	09NOV2016/12:00	294	150 - 400	No	0
		Week 48	14DEC2016/12:00	334	150 - 400	No	0
301-005	Basophils (10 <sup>9</sup> /L)	Screening	16DEC2015/08:45	0.00	0 - 0.1	Yes	
		Day 1	07JAN2016/10:00	0.05	0 - 0.1	Yes	
		Week 1	13JAN2016/09:30	0.07	0 - 0.1	No	
		Week 2	21JAN2016/10:00	0.03	0 - 0.1	No	
		Week 4	02FEB2016/09:00	0.02	0 - 0.1	No	
		Week 6	17FEB2016/13:00	0.02	0 - 0.1	No	
		Week 8	02MAR2016/09:15	0.02	0 - 0.1	No	
		Week 12	31MAR2016/10:15	0.02	0 - 0.1	No	
		Week 16	26APR2016/10:00	0.04	0 - 0.1	No	
		Week 20	26MAY2016/12:30	0.04	0 - 0.1	No	
		Week 24	23JUN2016/11:45	0.02	0 - 0.1	No	
		Week 28	26JUL2016/09:15	0.00	0 - 0.1	No	
		Week 32	16AUG2016/10:45	0.05	0 - 0.1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Basophils (10 <sup>9</sup> /L)	Week 36	14SEP2016/12:00	0.03	0 - 0.1	No
		Week 40	12OCT2016/12:10	0.01	0 - 0.1	No
		Week 44	10NOV2016/11:00	0.02	0 - 0.1	No
		Week 48	07DEC2016/12:00	0.02	0 - 0.1	No
	Blood film	Screening	16DEC2015/08:45			Yes
		Day 1	07JAN2016/10:00			Yes
		Week 1	13JAN2016/09:30			No
		Week 2	21JAN2016/10:00			No
		Week 4	02FEB2016/09:00			No
		Week 6	17FEB2016/13:00			No
		Week 8	02MAR2016/09:15			No
		Week 12	31MAR2016/10:15			No
		Week 16	26APR2016/10:00			No
		Week 20	26MAY2016/12:30			No
		Week 24	23JUN2016/11:45			No
		Week 32	16AUG2016/10:45			No
		Week 36	14SEP2016/12:00			No
		Week 40	12OCT2016/12:10			No
		Week 44	10NOV2016/11:00			No
		Week 48	07DEC2016/12:00			No
	Blood film (reflex)	Week 28	26JUL2016/09:15			No
		Week 48	07DEC2016/12:00			No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Eosinophils (10 <sup>9</sup> /L)	Screening	16DEC2015/08:45	0.06	0 - 0.4	Yes
		Day 1	07JAN2016/10:00	0.24	0 - 0.4	Yes
		Week 1	13JAN2016/09:30	0.13	0 - 0.4	No
		Week 2	21JAN2016/10:00	0.27	0 - 0.4	No
		Week 4	02FEB2016/09:00	0.28	0 - 0.4	No
		Week 6	17FEB2016/13:00	0.22	0 - 0.4	No
		Week 8	02MAR2016/09:15	0.23	0 - 0.4	No
		Week 12	31MAR2016/10:15	0.13	0 - 0.4	No
		Week 16	26APR2016/10:00	0.16	0 - 0.4	No
		Week 20	26MAY2016/12:30	0.25	0 - 0.4	No
		Week 24	23JUN2016/11:45	0.24	0 - 0.4	No
		Week 28	26JUL2016/09:15	0.15	0 - 0.4	No
		Week 32	16AUG2016/10:45	0.27	0 - 0.4	No
		Week 36	14SEP2016/12:00	0.36	0 - 0.4	No
		Week 40	12OCT2016/12:10	0.21	0 - 0.4	No
		Week 44	10NOV2016/11:00	0.28	0 - 0.4	No
		Week 48	07DEC2016/12:00	0.33	0 - 0.4	No
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	16DEC2015/08:45	363 H	300 - 350	Yes
		Day 1	07JAN2016/10:00	359 H	300 - 350	Yes
		Week 1	13JAN2016/09:30	361 H	300 - 350	No
		Week 2	21JAN2016/10:00	347	300 - 350	No
		Week 4	02FEB2016/09:00	358 H	300 - 350	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Ery. Mean Corpuscular HGB Concentration (g/L)	Week 6	17FEB2016/13:00	357 H	300 - 350	No
		Week 8	02MAR2016/09:15	364 H	300 - 350	No
		Week 12	31MAR2016/10:15	348	300 - 350	No
		Week 16	26APR2016/10:00	354 H	300 - 350	No
		Week 20	26MAY2016/12:30	353 H	300 - 350	No
		Week 24	23JUN2016/11:45	326	300 - 350	No
		Week 28	26JUL2016/09:15	332	300 - 350	No
		Week 32	16AUG2016/10:45	350	300 - 350	No
		Week 36	14SEP2016/12:00	353 H	300 - 350	No
		Week 40	12OCT2016/12:10	358 H	300 - 350	No
		Week 44	10NOV2016/11:00	358 H	300 - 350	No
		Week 48	07DEC2016/12:00	354 H	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	16DEC2015/08:45	32.8	26 - 33.5	Yes
		Day 1	07JAN2016/10:00	32.8	26 - 33.5	Yes
		Week 1	13JAN2016/09:30	32.4	26 - 33.5	No
		Week 2	21JAN2016/10:00	31.5	26 - 33.5	No
		Week 4	02FEB2016/09:00	31.7	26 - 33.5	No
		Week 6	17FEB2016/13:00	31.6	26 - 33.5	No
		Week 8	02MAR2016/09:15	31.9	26 - 33.5	No
		Week 12	31MAR2016/10:15	31.7	26 - 33.5	No
		Week 16	26APR2016/10:00	31.8	26 - 33.5	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Ery. Mean Corpuscular Hemoglobin (pg)	Week 20	26MAY2016/12:30	31.7	26 - 33.5	No
		Week 24	23JUN2016/11:45	31.0	26 - 33.5	No
		Week 28	26JUL2016/09:15	30.7	26 - 33.5	No
		Week 32	16AUG2016/10:45	30.8	26 - 33.5	No
		Week 36	14SEP2016/12:00	31.4	26 - 33.5	No
		Week 40	12OCT2016/12:10	32.3	26 - 33.5	No
		Week 44	10NOV2016/11:00	32.4	26 - 33.5	No
		Week 48	07DEC2016/12:00	31.5	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	16DEC2015/08:45	90.6	80 - 99	Yes
		Day 1	07JAN2016/10:00	91.3	80 - 99	Yes
		Week 1	13JAN2016/09:30	89.7	80 - 99	No
		Week 2	21JAN2016/10:00	90.8	80 - 99	No
		Week 4	02FEB2016/09:00	88.6	80 - 99	No
		Week 6	17FEB2016/13:00	88.5	80 - 99	No
		Week 8	02MAR2016/09:15	87.6	80 - 99	No
		Week 12	31MAR2016/10:15	91.2	80 - 99	No
		Week 16	26APR2016/10:00	89.8	80 - 99	No
		Week 20	26MAY2016/12:30	89.6	80 - 99	No
		Week 24	23JUN2016/11:45	95.1	80 - 99	No
		Week 28	26JUL2016/09:15	92.5	80 - 99	No
		Week 32	16AUG2016/10:45	88.0	80 - 99	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Ery. Mean Corpuscular Volume (fL)	Week 36	14SEP2016/12:00	88.8	80 - 99	No
		Week 40	12OCT2016/12:10	90.2	80 - 99	No
		Week 44	10NOV2016/11:00	90.5	80 - 99	No
		Week 48	07DEC2016/12:00	88.8	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	16DEC2015/08:45	5.30	4.4 - 5.8	Yes
		Day 1	07JAN2016/10:00	5.18	4.4 - 5.8	Yes
		Week 1	13JAN2016/09:30	5.34	4.4 - 5.8	No
		Week 2	21JAN2016/10:00	5.30	4.4 - 5.8	No
		Week 4	02FEB2016/09:00	5.27	4.4 - 5.8	No
		Week 6	17FEB2016/13:00	5.38	4.4 - 5.8	No
		Week 8	02MAR2016/09:15	5.24	4.4 - 5.8	No
		Week 12	31MAR2016/10:15	5.11	4.4 - 5.8	No
		Week 16	26APR2016/10:00	5.19	4.4 - 5.8	No
		Week 20	26MAY2016/12:30	5.40	4.4 - 5.8	No
		Week 24	23JUN2016/11:45	5.55	4.4 - 5.8	No
		Week 28	26JUL2016/09:15	5.21	4.4 - 5.8	No
		Week 32	16AUG2016/10:45	5.35	4.4 - 5.8	No
		Week 36	14SEP2016/12:00	5.29	4.4 - 5.8	No
		Week 40	12OCT2016/12:10	5.11	4.4 - 5.8	No
		Week 44	10NOV2016/11:00	5.28	4.4 - 5.8	No
		Week 48	07DEC2016/12:00	5.18	4.4 - 5.8	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Hematocrit (%)	Screening	16DEC2015/08:45	48.0	37 - 50	Yes	
		Day 1	07JAN2016/10:00	47.3	37 - 50	Yes	
		Week 1	13JAN2016/09:30	47.9	37 - 50	No	
		Week 2	21JAN2016/10:00	48.1	37 - 50	No	
		Week 4	02FEB2016/09:00	46.7	37 - 50	No	
		Week 6	17FEB2016/13:00	47.6	37 - 50	No	
		Week 8	02MAR2016/09:15	45.9	37 - 50	No	
		Week 12	31MAR2016/10:15	46.6	37 - 50	No	
		Week 16	26APR2016/10:00	46.6	37 - 50	No	
		Week 20	26MAY2016/12:30	48.4	37 - 50	No	
		Week 24	23JUN2016/11:45	52.8 H	37 - 50	No	
		Week 28	26JUL2016/09:15	48.2	37 - 50	No	
		Week 32	16AUG2016/10:45	47.1	37 - 50	No	
		Week 36	14SEP2016/12:00	47.0	37 - 50	No	
		Week 40	12OCT2016/12:10	46.1	37 - 50	No	
		Week 44	10NOV2016/11:00	47.8	37 - 50	No	
		Week 48	07DEC2016/12:00	46.0	37 - 50	No	
	Hemoglobin (g/L)	Screening	16DEC2015/08:45	174 H	130 - 170	Yes	1
		Day 1	07JAN2016/10:00	170	130 - 170	Yes	0
		Week 1	13JAN2016/09:30	173 H	130 - 170	No	1
		Week 2	21JAN2016/10:00	167	130 - 170	No	0
		Week 4	02FEB2016/09:00	167	130 - 170	No	0
		Week 6	17FEB2016/13:00	170	130 - 170	No	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Hemoglobin (g/L)	Week 8	02MAR2016/09:15	167	130 - 170	No	0
		Week 12	31MAR2016/10:15	162	130 - 170	No	0
		Week 16	26APR2016/10:00	165	130 - 170	No	0
		Week 20	26MAY2016/12:30	171 H	130 - 170	No	1
		Week 24	23JUN2016/11:45	172 H	130 - 170	No	1
		Week 28	26JUL2016/09:15	160	130 - 170	No	0
		Week 32	16AUG2016/10:45	165	130 - 170	No	0
		Week 36	14SEP2016/12:00	166	130 - 170	No	0
		Week 40	12OCT2016/12:10	165	130 - 170	No	0
		Week 44	10NOV2016/11:00	171 H	130 - 170	No	1
		Week 48	07DEC2016/12:00	163	130 - 170	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	16DEC2015/08:45	6.27	3 - 10	Yes	0
		Day 1	07JAN2016/10:00	4.89	3 - 10	Yes	0
		Week 1	13JAN2016/09:30	6.51	3 - 10	No	0
		Week 2	21JAN2016/10:00	5.53	3 - 10	No	0
		Week 4	02FEB2016/09:00	5.50	3 - 10	No	0
		Week 6	17FEB2016/13:00	4.97	3 - 10	No	0
		Week 8	02MAR2016/09:15	8.02	3 - 10	No	0
		Week 12	31MAR2016/10:15	4.37	3 - 10	No	0
		Week 16	26APR2016/10:00	4.22	3 - 10	No	0
		Week 20	26MAY2016/12:30	6.00	3 - 10	No	0
		Week 24	23JUN2016/11:45	5.43	3 - 10	No	0
		Week 28	26JUL2016/09:15	4.99	3 - 10	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Leukocytes (10 <sup>9</sup> /L)	Week 32	16AUG2016/10:45	5.49	3 - 10	No	0
		Week 36	14SEP2016/12:00	4.82	3 - 10	No	0
		Week 40	12OCT2016/12:10	5.11	3 - 10	No	0
		Week 44	10NOV2016/11:00	5.28	3 - 10	No	0
		Week 48	07DEC2016/12:00	5.87	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	16DEC2015/08:45	2.45	1.2 - 3.65	Yes	0
		Day 1	07JAN2016/10:00	2.30	1.2 - 3.65	Yes	0
		Week 1	13JAN2016/09:30	3.12	1.2 - 3.65	No	0
		Week 2	21JAN2016/10:00	1.81	1.2 - 3.65	No	0
		Week 4	02FEB2016/09:00	1.88	1.2 - 3.65	No	0
		Week 6	17FEB2016/13:00	1.10 L	1.2 - 3.65	No	1
		Week 8	02MAR2016/09:15	2.26	1.2 - 3.65	No	0
		Week 12	31MAR2016/10:15	1.51	1.2 - 3.65	No	0
		Week 16	26APR2016/10:00	1.52	1.2 - 3.65	No	0
		Week 20	26MAY2016/12:30	1.91	1.2 - 3.65	No	0
		Week 24	23JUN2016/11:45	1.74	1.2 - 3.65	No	0
		Week 28	26JUL2016/09:15	2.40	1.2 - 3.65	No	0
		Week 32	16AUG2016/10:45	2.25	1.2 - 3.65	No	0
		Week 36	14SEP2016/12:00	1.71	1.2 - 3.65	No	0
		Week 40	12OCT2016/12:10	2.33	1.2 - 3.65	No	0
		Week 44	10NOV2016/11:00	1.97	1.2 - 3.65	No	0
		Week 48	07DEC2016/12:00	2.44	1.2 - 3.65	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Monocytes (10 <sup>9</sup> /L)	Screening	16DEC2015/08:45	0.50	0.2 - 1	Yes	
		Day 1	07JAN2016/10:00	0.34	0.2 - 1	Yes	
		Week 1	13JAN2016/09:30	0.39	0.2 - 1	No	
		Week 2	21JAN2016/10:00	0.31	0.2 - 1	No	
		Week 4	02FEB2016/09:00	0.34	0.2 - 1	No	
		Week 6	17FEB2016/13:00	0.39	0.2 - 1	No	
		Week 8	02MAR2016/09:15	0.72	0.2 - 1	No	
		Week 12	31MAR2016/10:15	0.42	0.2 - 1	No	
		Week 16	26APR2016/10:00	0.45	0.2 - 1	No	
		Week 20	26MAY2016/12:30	0.40	0.2 - 1	No	
		Week 24	23JUN2016/11:45	0.35	0.2 - 1	No	
		Week 28	26JUL2016/09:15	0.55	0.2 - 1	No	
		Week 32	16AUG2016/10:45	0.38	0.2 - 1	No	
		Week 36	14SEP2016/12:00	0.41	0.2 - 1	No	
		Week 40	12OCT2016/12:10	0.50	0.2 - 1	No	
		Week 44	10NOV2016/11:00	0.49	0.2 - 1	No	
		Week 48	07DEC2016/12:00	0.46	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	16DEC2015/08:45	0.69 H	0 - 0.38	Yes	3
		Day 1	07JAN2016/10:00	0.68 H	0 - 0.38	Yes	3
		Week 1	13JAN2016/09:30	0.07	0 - 0.38	No	4
		Week 2	21JAN2016/10:00	0.00	0 - 0.38	No	4
		Week 4	02FEB2016/09:00	0.00	0 - 0.38	No	4
		Week 6	17FEB2016/13:00	0.00	0 - 0.38	No	4

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Neutrophils Band Form (10 <sup>9</sup> /L)	Week 8	02MAR2016/09:15	0.00	0 - 0.38	No	4
		Week 12	31MAR2016/10:15	0.00	0 - 0.38	No	4
		Week 16	26APR2016/10:00	0.00	0 - 0.38	No	4
		Week 20	26MAY2016/12:30	0.06	0 - 0.38	No	4
		Week 24	23JUN2016/11:45	0.00	0 - 0.38	No	4
		Week 28	26JUL2016/09:15	0.50 H	0 - 0.38	No	3
		Week 32	16AUG2016/10:45	0.55 H	0 - 0.38	No	3
		Week 36	14SEP2016/12:00	0.29	0 - 0.38	No	4
		Week 40	12OCT2016/12:10	0.10	0 - 0.38	No	4
		Week 44	10NOV2016/11:00	0.00	0 - 0.38	No	4
		Week 48	07DEC2016/12:00	0.00	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	16DEC2015/08:45	2.32	2 - 7.5	Yes	0
		Day 1	07JAN2016/10:00	1.27 L	2 - 7.5	Yes	2
		Week 1	13JAN2016/09:30	2.73	2 - 7.5	No	0
		Week 2	21JAN2016/10:00	3.11	2 - 7.5	No	0
		Week 4	02FEB2016/09:00	2.98	2 - 7.5	No	0
		Week 6	17FEB2016/13:00	3.25	2 - 7.5	No	0
		Week 8	02MAR2016/09:15	4.79	2 - 7.5	No	0
		Week 12	31MAR2016/10:15	2.29	2 - 7.5	No	0
		Week 16	26APR2016/10:00	2.05	2 - 7.5	No	0
		Week 20	26MAY2016/12:30	3.40	2 - 7.5	No	0
		Week 24	23JUN2016/11:45	3.08	2 - 7.5	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Neutrophils, Segmented (10 <sup>9</sup> /L)	Week 28	26JUL2016/09:15	1.40 L	2 - 7.5	No	2
		Week 32	16AUG2016/10:45	1.98 L	2 - 7.5	No	1
		Week 36	14SEP2016/12:00	2.02	2 - 7.5	No	0
		Week 40	12OCT2016/12:10	1.96 L	2 - 7.5	No	1
		Week 44	10NOV2016/11:00	2.52	2 - 7.5	No	0
		Week 48	07DEC2016/12:00	2.62	2 - 7.5	No	0
	Platelets (10 <sup>9</sup> /L)	Screening	16DEC2015/08:45	157	150 - 400	Yes	0
		Day 1	07JAN2016/10:00	111 L	150 - 400	Yes	1
		Week 1	13JAN2016/09:30	132 L	150 - 400	No	1
		Week 2	21JAN2016/10:00	168	150 - 400	No	0
		Week 4	02FEB2016/09:00	158	150 - 400	No	0
		Week 6	17FEB2016/13:00	158	150 - 400	No	0
		Week 8	02MAR2016/09:15	230	150 - 400	No	0
		Week 12	31MAR2016/10:15	161	150 - 400	No	0
		Week 16	26APR2016/10:00		150 - 400	No	
		Week 20	26MAY2016/12:30	146 L	150 - 400	No	1
		Week 24	23JUN2016/11:45	153	150 - 400	No	0
		Week 28	26JUL2016/09:15	133 L	150 - 400	No	1
		Week 32	16AUG2016/10:45	125 L	150 - 400	No	1
		Week 36	14SEP2016/12:00	124 L	150 - 400	No	1
		Week 40	12OCT2016/12:10	133 L	150 - 400	No	1
		Week 44	10NOV2016/11:00	150	150 - 400	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Platelets (10 <sup>9</sup> /L)	Week 48	07DEC2016/12:00	138 L	150 - 400	No	1
301-008	Basophils (10 <sup>9</sup> /L)	Screening	19JAN2016/12:00	0.03	0 - 0.1	Yes	
		Day 1	11FEB2016/09:00	0.04	0 - 0.1	No	
		Week 1	17FEB2016/11:00	0.02	0 - 0.1	No	
		Week 2	24FEB2016/08:35	0.05	0 - 0.1	No	
		Week 4	10MAR2016/08:00	0.03	0 - 0.1	No	
		Week 6	24MAR2016/08:02	0.02	0 - 0.1	No	
		Week 8	07APR2016/08:30	0.01	0 - 0.1	Yes	
		Early Term	13APR2016/12:20	0.01	0 - 0.1	Yes	
		Week 28	17MAY2016/08:30	0.04	0 - 0.1	No	
		Week 32	09JUN2016/08:30	0.03	0 - 0.1	No	
		Week 36	06JUL2016/08:25	0.00	0 - 0.1	No	
		Week 40	03AUG2016/08:45	0.03	0 - 0.1	No	
		Week 44	07SEP2016/07:55	0.02	0 - 0.1	No	
		Week 48	19OCT2016/07:20	0.03	0 - 0.1	No	
	Blood film	Screening	19JAN2016/12:00			Yes	
		Day 1	11FEB2016/09:00			No	
		Week 1	17FEB2016/11:00			No	
		Week 2	24FEB2016/08:35			No	
		Week 4	10MAR2016/08:00			No	
		Week 6	24MAR2016/08:02			No	
		Week 8	07APR2016/08:30			Yes	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Blood film	Early Term	13APR2016/12:20			Yes
		Week 28	17MAY2016/08:30			No
		Week 32	09JUN2016/08:30			No
		Week 36	06JUL2016/08:25			No
		Week 40	03AUG2016/08:45			No
		Week 44	07SEP2016/07:55			No
		Week 48	19OCT2016/07:20			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	19JAN2016/12:00	0.49 H	0 - 0.4	Yes
		Day 1	11FEB2016/09:00	0.55 H	0 - 0.4	No
		Week 1	17FEB2016/11:00	0.46 H	0 - 0.4	No
		Week 2	24FEB2016/08:35	0.58 H	0 - 0.4	No
		Week 4	10MAR2016/08:00	0.34	0 - 0.4	No
		Week 6	24MAR2016/08:02	0.21	0 - 0.4	No
		Week 8	07APR2016/08:30	0.04	0 - 0.4	Yes
		Early Term	13APR2016/12:20	0.11	0 - 0.4	Yes
		Week 28	17MAY2016/08:30	0.46 H	0 - 0.4	No
		Week 32	09JUN2016/08:30	0.44 H	0 - 0.4	No
		Week 36	06JUL2016/08:25	0.13	0 - 0.4	No
		Week 40	03AUG2016/08:45	0.36	0 - 0.4	No
		Week 44	07SEP2016/07:55	0.42 H	0 - 0.4	No
		Week 48	19OCT2016/07:20	0.45 H	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	19JAN2016/12:00	342	300 - 350	Yes
		Day 1	11FEB2016/09:00	343	300 - 350	No
		Week 1	17FEB2016/11:00	342	300 - 350	No
		Week 2	24FEB2016/08:35	342	300 - 350	No
		Week 4	10MAR2016/08:00	337	300 - 350	No
		Week 6	24MAR2016/08:02	311	300 - 350	No
		Week 8	07APR2016/08:30	344	300 - 350	Yes
		Early Term	13APR2016/12:20	345	300 - 350	Yes
		Week 28	17MAY2016/08:30	334	300 - 350	No
		Week 32	09JUN2016/08:30	329	300 - 350	No
		Week 36	06JUL2016/08:25	339	300 - 350	No
		Week 40	03AUG2016/08:45	337	300 - 350	No
		Week 44	07SEP2016/07:55	333	300 - 350	No
		Week 48	19OCT2016/07:20	334	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	19JAN2016/12:00	29.9	26 - 33.5	Yes
		Day 1	11FEB2016/09:00	29.5	26 - 33.5	No
		Week 1	17FEB2016/11:00	29.6	26 - 33.5	No
		Week 2	24FEB2016/08:35	29.6	26 - 33.5	No
		Week 4	10MAR2016/08:00	29.3	26 - 33.5	No
		Week 6	24MAR2016/08:02	29.2	26 - 33.5	No
		Week 8	07APR2016/08:30	29.3	26 - 33.5	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Ery. Mean Corpuscular Hemoglobin (pg)	Early Term	13APR2016/12:20	28.8	26 - 33.5	Yes
		Week 28	17MAY2016/08:30	29.8	26 - 33.5	No
		Week 32	09JUN2016/08:30	30.2	26 - 33.5	No
		Week 36	06JUL2016/08:25	29.8	26 - 33.5	No
		Week 40	03AUG2016/08:45	29.7	26 - 33.5	No
		Week 44	07SEP2016/07:55	29.4	26 - 33.5	No
		Week 48	19OCT2016/07:20	29.4	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	19JAN2016/12:00	87.2	80 - 99	Yes
		Day 1	11FEB2016/09:00	86.1	80 - 99	No
		Week 1	17FEB2016/11:00	86.7	80 - 99	No
		Week 2	24FEB2016/08:35	86.3	80 - 99	No
		Week 4	10MAR2016/08:00	86.9	80 - 99	No
		Week 6	24MAR2016/08:02	93.7	80 - 99	No
		Week 8	07APR2016/08:30	85.2	80 - 99	Yes
		Early Term	13APR2016/12:20	83.5	80 - 99	Yes
		Week 28	17MAY2016/08:30	89.2	80 - 99	No
		Week 32	09JUN2016/08:30	91.7	80 - 99	No
		Week 36	06JUL2016/08:25	87.7	80 - 99	No
		Week 40	03AUG2016/08:45	88.2	80 - 99	No
		Week 44	07SEP2016/07:55	88.3	80 - 99	No
		Week 48	19OCT2016/07:20	88.1	80 - 99	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008 Erythrocytes (10 <sup>12</sup> /L)	Screening	19JAN2016/12:00	5.49	4.4 - 5.8	Yes
	Day 1	11FEB2016/09:00	5.52	4.4 - 5.8	No
	Week 1	17FEB2016/11:00	5.50	4.4 - 5.8	No
	Week 2	24FEB2016/08:35	5.48	4.4 - 5.8	No
	Week 4	10MAR2016/08:00	5.43	4.4 - 5.8	No
	Week 6	24MAR2016/08:02	5.11	4.4 - 5.8	No
	Week 8	07APR2016/08:30	5.15	4.4 - 5.8	Yes
	Early Term	13APR2016/12:20	4.55	4.4 - 5.8	Yes
	Week 28	17MAY2016/08:30	5.37	4.4 - 5.8	No
	Week 32	09JUN2016/08:30	5.30	4.4 - 5.8	No
	Week 36	06JUL2016/08:25	5.61	4.4 - 5.8	No
	Week 40	03AUG2016/08:45	5.59	4.4 - 5.8	No
	Week 44	07SEP2016/07:55	5.47	4.4 - 5.8	No
	Week 48	19OCT2016/07:20	5.30	4.4 - 5.8	No
Hematocrit (%)	Screening	19JAN2016/12:00	47.9	37 - 50	Yes
	Day 1	11FEB2016/09:00	47.5	37 - 50	No
	Week 1	17FEB2016/11:00	47.7	37 - 50	No
	Week 2	24FEB2016/08:35	47.3	37 - 50	No
	Week 4	10MAR2016/08:00	47.2	37 - 50	No
	Week 6	24MAR2016/08:02	47.9	37 - 50	No
	Week 8	07APR2016/08:30	43.9	37 - 50	Yes
	Early Term	13APR2016/12:20	38.0	37 - 50	Yes
	Week 28	17MAY2016/08:30	47.9	37 - 50	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Hematocrit (%)	Week 32	09JUN2016/08:30	48.6	37 - 50	No	
		Week 36	06JUL2016/08:25	49.2	37 - 50	No	
		Week 40	03AUG2016/08:45	49.3	37 - 50	No	
		Week 44	07SEP2016/07:55	48.3	37 - 50	No	
		Week 48	19OCT2016/07:20	46.7	37 - 50	No	
	Hemoglobin (g/L)	Screening	19JAN2016/12:00	164	130 - 170	Yes	0
		Day 1	11FEB2016/09:00	163	130 - 170	No	0
		Week 1	17FEB2016/11:00	163	130 - 170	No	0
		Week 2	24FEB2016/08:35	162	130 - 170	No	0
		Week 4	10MAR2016/08:00	159	130 - 170	No	0
		Week 6	24MAR2016/08:02	149	130 - 170	No	0
		Week 8	07APR2016/08:30	151	130 - 170	Yes	0
		Early Term	13APR2016/12:20	131	130 - 170	Yes	0
		Week 28	17MAY2016/08:30	160	130 - 170	No	0
		Week 32	09JUN2016/08:30	160	130 - 170	No	0
		Week 36	06JUL2016/08:25	167	130 - 170	No	0
		Week 40	03AUG2016/08:45	166	130 - 170	No	0
		Week 44	07SEP2016/07:55	161	130 - 170	No	0
		Week 48	19OCT2016/07:20	156	130 - 170	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	19JAN2016/12:00	8.06	3 - 10	Yes	0
		Day 1	11FEB2016/09:00	7.60	3 - 10	No	0
		Week 1	17FEB2016/11:00	7.31	3 - 10	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Leukocytes (10 <sup>9</sup> /L)	Week 2	24FEB2016/08:35	8.04	3 - 10	No	0
		Week 4	10MAR2016/08:00	7.53	3 - 10	No	0
		Week 6	24MAR2016/08:02	7.55	3 - 10	No	0
		Week 8	07APR2016/08:30	6.64	3 - 10	Yes	0
		Early Term	13APR2016/12:20	7.27	3 - 10	Yes	0
		Week 28	17MAY2016/08:30	7.64	3 - 10	No	0
		Week 32	09JUN2016/08:30	6.87	3 - 10	No	0
		Week 36	06JUL2016/08:25	6.59	3 - 10	No	0
		Week 40	03AUG2016/08:45	7.00	3 - 10	No	0
		Week 44	07SEP2016/07:55	7.01	3 - 10	No	0
		Week 48	19OCT2016/07:20	7.28	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	19JAN2016/12:00	2.43	1.2 - 3.65	Yes	0
		Day 1	11FEB2016/09:00	2.25	1.2 - 3.65	No	0
		Week 1	17FEB2016/11:00	2.04	1.2 - 3.65	No	0
		Week 2	24FEB2016/08:35	2.23	1.2 - 3.65	No	0
		Week 4	10MAR2016/08:00	2.27	1.2 - 3.65	No	0
		Week 6	24MAR2016/08:02	2.03	1.2 - 3.65	No	0
		Week 8	07APR2016/08:30	1.39	1.2 - 3.65	Yes	0
		Early Term	13APR2016/12:20	2.31	1.2 - 3.65	Yes	0
		Week 28	17MAY2016/08:30	2.05	1.2 - 3.65	No	0
		Week 32	09JUN2016/08:30	2.26	1.2 - 3.65	No	0
		Week 36	06JUL2016/08:25	2.70	1.2 - 3.65	No	0
		Week 40	03AUG2016/08:45	1.82	1.2 - 3.65	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Lymphocytes (10 <sup>9</sup> /L)	Week 44	07SEP2016/07:55	2.07	1.2 - 3.65	No	0
		Week 48	19OCT2016/07:20	2.24	1.2 - 3.65	No	0
301-008	Monocytes (10 <sup>9</sup> /L)	Screening	19JAN2016/12:00	0.83	0.2 - 1	Yes	
		Day 1	11FEB2016/09:00	0.77	0.2 - 1	No	
		Week 1	17FEB2016/11:00	0.70	0.2 - 1	No	
		Week 2	24FEB2016/08:35	0.69	0.2 - 1	No	
		Week 4	10MAR2016/08:00	0.67	0.2 - 1	No	
		Week 6	24MAR2016/08:02	0.72	0.2 - 1	No	
		Week 8	07APR2016/08:30	0.72	0.2 - 1	Yes	
		Early Term	13APR2016/12:20	0.58	0.2 - 1	Yes	
		Week 28	17MAY2016/08:30	0.82	0.2 - 1	No	
		Week 32	09JUN2016/08:30	0.86	0.2 - 1	No	
		Week 36	06JUL2016/08:25	0.53	0.2 - 1	No	
		Week 40	03AUG2016/08:45	0.69	0.2 - 1	No	
		Week 44	07SEP2016/07:55	0.73	0.2 - 1	No	
		Week 48	19OCT2016/07:20	0.84	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	19JAN2016/12:00	0.00	0 - 0.38	Yes	4
		Day 1	11FEB2016/09:00	0.00	0 - 0.38	No	4
		Week 1	17FEB2016/11:00	0.00	0 - 0.38	No	4
		Week 2	24FEB2016/08:35	0.00	0 - 0.38	No	4
		Week 4	10MAR2016/08:00	0.00	0 - 0.38	No	4
		Week 6	24MAR2016/08:02	0.00	0 - 0.38	No	4

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Neutrophils Band Form (10 <sup>9</sup> /L)	Week 8	07APR2016/08:30	0.00	0 - 0.38	Yes	4
		Early Term	13APR2016/12:20	0.00	0 - 0.38	Yes	4
		Week 28	17MAY2016/08:30	0.00	0 - 0.38	No	4
		Week 32	09JUN2016/08:30	0.00	0 - 0.38	No	4
		Week 36	06JUL2016/08:25	0.13	0 - 0.38	No	4
		Week 40	03AUG2016/08:45	0.11	0 - 0.38	No	4
		Week 44	07SEP2016/07:55	0.00	0 - 0.38	No	4
		Week 48	19OCT2016/07:20	0.22	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	19JAN2016/12:00	4.28	2 - 7.5	Yes	0
		Day 1	11FEB2016/09:00	4.00	2 - 7.5	No	0
		Week 1	17FEB2016/11:00	4.09	2 - 7.5	No	0
		Week 2	24FEB2016/08:35	4.49	2 - 7.5	No	0
		Week 4	10MAR2016/08:00	4.22	2 - 7.5	No	0
		Week 6	24MAR2016/08:02	4.57	2 - 7.5	No	0
		Week 8	07APR2016/08:30	4.48	2 - 7.5	Yes	0
		Early Term	13APR2016/12:20	4.26	2 - 7.5	Yes	0
		Week 28	17MAY2016/08:30	4.28	2 - 7.5	No	0
		Week 32	09JUN2016/08:30	3.28	2 - 7.5	No	0
		Week 36	06JUL2016/08:25	3.10	2 - 7.5	No	0
		Week 40	03AUG2016/08:45	3.99	2 - 7.5	No	0
		Week 44	07SEP2016/07:55	3.77	2 - 7.5	No	0
		Week 48	19OCT2016/07:20	3.50	2 - 7.5	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008 Platelets (10 <sup>9</sup> /L)	Screening	19JAN2016/12:00	206	150 - 400	Yes	0
	Day 1	11FEB2016/09:00	205	150 - 400	No	0
	Week 1	17FEB2016/11:00	187	150 - 400	No	0
	Week 2	24FEB2016/08:35	189	150 - 400	No	0
	Week 4	10MAR2016/08:00	188	150 - 400	No	0
	Week 6	24MAR2016/08:02	166	150 - 400	No	0
	Week 8	07APR2016/08:30		150 - 400	Yes	
	Early Term	13APR2016/12:20	167	150 - 400	Yes	0
	Week 28	17MAY2016/08:30	211	150 - 400	No	0
	Week 32	09JUN2016/08:30	204	150 - 400	No	0
	Week 36	06JUL2016/08:25	186	150 - 400	No	0
	Week 40	03AUG2016/08:45	192	150 - 400	No	0
	Week 44	07SEP2016/07:55	208	150 - 400	No	0
	Week 48	19OCT2016/07:20	201	150 - 400	No	0
301-009 Basophils (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	0.02	0 - 0.1	Yes	
	Day 1	27JAN2016/11:00	0.06	0 - 0.1	No	
	Week 1	02FEB2016/12:00	0.02	0 - 0.1	No	
	Week 2	10FEB2016/12:45	0.04	0 - 0.1	No	
	Week 4	25FEB2016/11:30	0.04	0 - 0.1	No	
	Week 6	09MAR2016/12:00	0.00	0 - 0.1	Yes	
	Week 8	22MAR2016/08:20	0.02	0 - 0.1	No	
	Week 12	19APR2016/11:20	0.03	0 - 0.1	No	
	Week 16	18MAY2016/12:20	0.02	0 - 0.1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Basophils (10 <sup>9</sup> /L)	Week 20	15JUN2016/12:15	0.05	0 - 0.1	No
		Week 24	20JUL2016/13:50	0.00	0 - 0.1	Yes
		Week 28	09AUG2016/12:10	0.00	0 - 0.1	No
		Week 32	06SEP2016/13:10	0.01	0 - 0.1	No
		Week 36	04OCT2016/12:30	0.02	0 - 0.1	No
		Week 40	01NOV2016/12:30	0.00	0 - 0.1	No
		Week 44	29NOV2016/13:15	0.02	0 - 0.1	No
		Week 48	02JAN2017/12:00	0.02	0 - 0.1	No
	Blood film	Screening	06JAN2016/11:00			Yes
		Day 1	27JAN2016/11:00			No
		Week 1	02FEB2016/12:00			No
		Week 2	10FEB2016/12:45			No
		Week 4	25FEB2016/11:30			No
		Week 6	09MAR2016/12:00			Yes
		Week 8	22MAR2016/08:20			No
		Week 12	19APR2016/11:20			No
		Week 16	18MAY2016/12:20			No
		Week 20	15JUN2016/12:15			No
		Week 24	20JUL2016/13:50			Yes
		Week 28	09AUG2016/12:10			No
		Week 32	06SEP2016/13:10			No
		Week 36	04OCT2016/12:30			No
		Week 44	29NOV2016/13:15			No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Blood film	Week 48	02JAN2017/12:00			No
	Blood film (reflex)	Week 40	01NOV2016/12:30			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	0.18	0 - 0.4	Yes
		Day 1	27JAN2016/11:00	0.28	0 - 0.4	No
		Week 1	02FEB2016/12:00	0.26	0 - 0.4	No
		Week 2	10FEB2016/12:45	0.34	0 - 0.4	No
		Week 4	25FEB2016/11:30	0.22	0 - 0.4	No
		Week 6	09MAR2016/12:00	0.00	0 - 0.4	Yes
		Week 8	22MAR2016/08:20	0.21	0 - 0.4	No
		Week 12	19APR2016/11:20	0.27	0 - 0.4	No
		Week 16	18MAY2016/12:20	0.26	0 - 0.4	No
		Week 20	15JUN2016/12:15	0.31	0 - 0.4	No
		Week 24	20JUL2016/13:50	0.40	0 - 0.4	Yes
		Week 28	09AUG2016/12:10	0.04	0 - 0.4	No
		Week 32	06SEP2016/13:10	0.15	0 - 0.4	No
		Week 36	04OCT2016/12:30	0.24	0 - 0.4	No
		Week 40	01NOV2016/12:30	0.28	0 - 0.4	No
		Week 44	29NOV2016/13:15	0.26	0 - 0.4	No
		Week 48	02JAN2017/12:00	0.24	0 - 0.4	No
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	06JAN2016/11:00	356 H	300 - 350	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Ery. Mean Corpuscular HGB Concentration (g/L)	Day 1	27JAN2016/11:00	354 H	300 - 350	No
		Week 1	02FEB2016/12:00	358 H	300 - 350	No
		Week 2	10FEB2016/12:45	357 H	300 - 350	No
		Week 4	25FEB2016/11:30	361 H	300 - 350	No
		Week 6	09MAR2016/12:00	348	300 - 350	Yes
		Week 8	22MAR2016/08:20	355 H	300 - 350	No
		Week 12	19APR2016/11:20	347	300 - 350	No
		Week 16	18MAY2016/12:20	326	300 - 350	No
		Week 20	15JUN2016/12:15	339	300 - 350	No
		Week 24	20JUL2016/13:50	330	300 - 350	Yes
		Week 28	09AUG2016/12:10	344	300 - 350	No
		Week 32	06SEP2016/13:10	335	300 - 350	No
		Week 36	04OCT2016/12:30	330	300 - 350	No
		Week 40	01NOV2016/12:30	352 H	300 - 350	No
		Week 44	29NOV2016/13:15	355 H	300 - 350	No
		Week 48	02JAN2017/12:00	358 H	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	06JAN2016/11:00	31.9	26 - 33.5	Yes
		Day 1	27JAN2016/11:00	31.8	26 - 33.5	No
		Week 1	02FEB2016/12:00	31.7	26 - 33.5	No
		Week 2	10FEB2016/12:45	32.0	26 - 33.5	No
		Week 4	25FEB2016/11:30	32.1	26 - 33.5	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Ery. Mean Corpuscular Hemoglobin (pg)	Week 6	09MAR2016/12:00	31.1	26 - 33.5	Yes
		Week 8	22MAR2016/08:20	31.4	26 - 33.5	No
		Week 12	19APR2016/11:20	31.0	26 - 33.5	No
		Week 16	18MAY2016/12:20	30.5	26 - 33.5	No
		Week 20	15JUN2016/12:15	30.5	26 - 33.5	No
		Week 24	20JUL2016/13:50	30.6	26 - 33.5	Yes
		Week 28	09AUG2016/12:10	30.1	26 - 33.5	No
		Week 32	06SEP2016/13:10	30.1	26 - 33.5	No
		Week 36	04OCT2016/12:30	30.6	26 - 33.5	No
		Week 40	01NOV2016/12:30	31.2	26 - 33.5	No
		Week 44	29NOV2016/13:15	31.2	26 - 33.5	No
		Week 48	02JAN2017/12:00	32.0	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	06JAN2016/11:00	89.7	80 - 99	Yes
		Day 1	27JAN2016/11:00	89.8	80 - 99	No
		Week 1	02FEB2016/12:00	88.6	80 - 99	No
		Week 2	10FEB2016/12:45	89.5	80 - 99	No
		Week 4	25FEB2016/11:30	89.2	80 - 99	No
		Week 6	09MAR2016/12:00	89.3	80 - 99	Yes
		Week 8	22MAR2016/08:20	88.3	80 - 99	No
		Week 12	19APR2016/11:20	89.5	80 - 99	No
		Week 16	18MAY2016/12:20	93.6	80 - 99	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Ery. Mean Corpuscular Volume (fL)	Week 20	15JUN2016/12:15	89.9	80 - 99	No
		Week 24	20JUL2016/13:50	92.8	80 - 99	Yes
		Week 28	09AUG2016/12:10	87.6	80 - 99	No
		Week 32	06SEP2016/13:10	90.0	80 - 99	No
		Week 36	04OCT2016/12:30	92.7	80 - 99	No
		Week 40	01NOV2016/12:30	88.5	80 - 99	No
		Week 44	29NOV2016/13:15	87.8	80 - 99	No
		Week 48	02JAN2017/12:00	89.5	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	06JAN2016/11:00	5.17	4.4 - 5.8	Yes
		Day 1	27JAN2016/11:00	5.19	4.4 - 5.8	No
		Week 1	02FEB2016/12:00	5.42	4.4 - 5.8	No
		Week 2	10FEB2016/12:45	5.07	4.4 - 5.8	No
		Week 4	25FEB2016/11:30	5.07	4.4 - 5.8	No
		Week 6	09MAR2016/12:00	5.15	4.4 - 5.8	Yes
		Week 8	22MAR2016/08:20	4.88	4.4 - 5.8	No
		Week 12	19APR2016/11:20	5.06	4.4 - 5.8	No
		Week 16	18MAY2016/12:20	5.12	4.4 - 5.8	No
		Week 20	15JUN2016/12:15	5.05	4.4 - 5.8	No
		Week 24	20JUL2016/13:50	5.13	4.4 - 5.8	Yes
		Week 28	09AUG2016/12:10	5.34	4.4 - 5.8	No
		Week 32	06SEP2016/13:10	4.91	4.4 - 5.8	No
		Week 36	04OCT2016/12:30	5.07	4.4 - 5.8	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Erythrocytes (10 <sup>12</sup> /L)	Week 40	01NOV2016/12:30	5.04	4.4 - 5.8	No	
		Week 44	29NOV2016/13:15	5.42	4.4 - 5.8	No	
		Week 48	02JAN2017/12:00	4.84	4.4 - 5.8	No	
	Hematocrit (%)	Screening	06JAN2016/11:00	46.4	37 - 50	Yes	
		Day 1	27JAN2016/11:00	46.6	37 - 50	No	
		Week 1	02FEB2016/12:00	48.0	37 - 50	No	
		Week 2	10FEB2016/12:45	45.4	37 - 50	No	
		Week 4	25FEB2016/11:30	45.2	37 - 50	No	
		Week 6	09MAR2016/12:00	46.0	37 - 50	Yes	
		Week 8	22MAR2016/08:20	43.1	37 - 50	No	
		Week 12	19APR2016/11:20	45.3	37 - 50	No	
		Week 16	18MAY2016/12:20	47.9	37 - 50	No	
		Week 20	15JUN2016/12:15	45.4	37 - 50	No	
		Week 24	20JUL2016/13:50	47.6	37 - 50	Yes	
		Week 28	09AUG2016/12:10	46.8	37 - 50	No	
		Week 32	06SEP2016/13:10	44.2	37 - 50	No	
		Week 36	04OCT2016/12:30	47.0	37 - 50	No	
		Week 40	01NOV2016/12:30	44.6	37 - 50	No	
		Week 44	29NOV2016/13:15	47.6	37 - 50	No	
		Week 48	02JAN2017/12:00	43.3	37 - 50	No	
	Hemoglobin (g/L)	Screening	06JAN2016/11:00	165	130 - 170	Yes	0
		Day 1	27JAN2016/11:00	165	130 - 170	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Hemoglobin (g/L)	Week 1	02FEB2016/12:00	172 H	130 - 170	No	1
		Week 2	10FEB2016/12:45	162	130 - 170	No	0
		Week 4	25FEB2016/11:30	163	130 - 170	No	0
		Week 6	09MAR2016/12:00	160	130 - 170	Yes	0
		Week 8	22MAR2016/08:20	153	130 - 170	No	0
		Week 12	19APR2016/11:20	157	130 - 170	No	0
		Week 16	18MAY2016/12:20	156	130 - 170	No	0
		Week 20	15JUN2016/12:15	154	130 - 170	No	0
		Week 24	20JUL2016/13:50	157	130 - 170	Yes	0
		Week 28	09AUG2016/12:10	161	130 - 170	No	0
		Week 32	06SEP2016/13:10	148	130 - 170	No	0
		Week 36	04OCT2016/12:30	155	130 - 170	No	0
		Week 40	01NOV2016/12:30	157	130 - 170	No	0
		Week 44	29NOV2016/13:15	169	130 - 170	No	0
		Week 48	02JAN2017/12:00	155	130 - 170	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	4.72	3 - 10	Yes	0
		Day 1	27JAN2016/11:00	5.60	3 - 10	No	0
		Week 1	02FEB2016/12:00	7.46	3 - 10	No	0
		Week 2	10FEB2016/12:45	5.38	3 - 10	No	0
		Week 4	25FEB2016/11:30	4.28	3 - 10	No	0
		Week 6	09MAR2016/12:00	5.87	3 - 10	Yes	0
		Week 8	22MAR2016/08:20	5.73	3 - 10	No	0
		Week 12	19APR2016/11:20	5.90	3 - 10	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Leukocytes (10 <sup>9</sup> /L)	Week 16	18MAY2016/12:20	4.98	3 - 10	No	0
		Week 20	15JUN2016/12:15	5.85	3 - 10	No	0
		Week 24	20JUL2016/13:50	6.71	3 - 10	Yes	0
		Week 28	09AUG2016/12:10	4.30	3 - 10	No	0
		Week 32	06SEP2016/13:10	2.85 L	3 - 10	No	2
		Week 36	04OCT2016/12:30	5.24	3 - 10	No	0
		Week 40	01NOV2016/12:30	4.73	3 - 10	No	0
		Week 44	29NOV2016/13:15	5.45	3 - 10	No	0
		Week 48	02JAN2017/12:00	3.83	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	1.26	1.2 - 3.65	Yes	0
		Day 1	27JAN2016/11:00	2.24	1.2 - 3.65	No	0
		Week 1	02FEB2016/12:00	1.98	1.2 - 3.65	No	0
		Week 2	10FEB2016/12:45	2.00	1.2 - 3.65	No	0
		Week 4	25FEB2016/11:30	1.00 L	1.2 - 3.65	No	1
		Week 6	09MAR2016/12:00	2.41	1.2 - 3.65	Yes	0
		Week 8	22MAR2016/08:20	2.28	1.2 - 3.65	No	0
		Week 12	19APR2016/11:20	1.69	1.2 - 3.65	No	0
		Week 16	18MAY2016/12:20	1.51	1.2 - 3.65	No	0
		Week 20	15JUN2016/12:15	1.78	1.2 - 3.65	No	0
		Week 24	20JUL2016/13:50	2.75	1.2 - 3.65	Yes	0
		Week 28	09AUG2016/12:10	1.68	1.2 - 3.65	No	0
		Week 32	06SEP2016/13:10	0.80 L	1.2 - 3.65	No	1
		Week 36	04OCT2016/12:30	1.58	1.2 - 3.65	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Lymphocytes (10 <sup>9</sup> /L)	Week 40	01NOV2016/12:30	2.03	1.2 - 3.65	No	0
		Week 44	29NOV2016/13:15	2.03	1.2 - 3.65	No	0
		Week 48	02JAN2017/12:00	1.39	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	0.38	0.2 - 1	Yes	
		Day 1	27JAN2016/11:00	0.39	0.2 - 1	No	
		Week 1	02FEB2016/12:00	0.49	0.2 - 1	No	
		Week 2	10FEB2016/12:45	0.30	0.2 - 1	No	
		Week 4	25FEB2016/11:30	0.36	0.2 - 1	No	
		Week 6	09MAR2016/12:00	0.59	0.2 - 1	Yes	
		Week 8	22MAR2016/08:20	0.27	0.2 - 1	No	
		Week 12	19APR2016/11:20	0.35	0.2 - 1	No	
		Week 16	18MAY2016/12:20	0.24	0.2 - 1	No	
		Week 20	15JUN2016/12:15	0.27	0.2 - 1	No	
		Week 24	20JUL2016/13:50	0.54	0.2 - 1	Yes	
		Week 28	09AUG2016/12:10	0.17 L	0.2 - 1	No	
		Week 32	06SEP2016/13:10	0.18 L	0.2 - 1	No	
		Week 36	04OCT2016/12:30	0.39	0.2 - 1	No	
		Week 40	01NOV2016/12:30	0.95	0.2 - 1	No	
		Week 44	29NOV2016/13:15	0.24	0.2 - 1	No	
		Week 48	02JAN2017/12:00	0.23	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	0.00	0 - 0.38	Yes	4
		Day 1	27JAN2016/11:00	0.00	0 - 0.38	No	4

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Neutrophils Band Form (10 <sup>9</sup> /L)	Week 1	02FEB2016/12:00	0.00	0 - 0.38	No	4
		Week 2	10FEB2016/12:45	0.00	0 - 0.38	No	4
		Week 4	25FEB2016/11:30	0.00	0 - 0.38	No	4
		Week 6	09MAR2016/12:00	0.35	0 - 0.38	Yes	4
		Week 8	22MAR2016/08:20	0.00	0 - 0.38	No	4
		Week 12	19APR2016/11:20	0.00	0 - 0.38	No	4
		Week 16	18MAY2016/12:20	0.00	0 - 0.38	No	4
		Week 20	15JUN2016/12:15		0 - 0.38	No	
		Week 24	20JUL2016/13:50	0.34	0 - 0.38	Yes	4
		Week 28	09AUG2016/12:10	0.17	0 - 0.38	No	4
		Week 32	06SEP2016/13:10	0.00	0 - 0.38	No	4
		Week 36	04OCT2016/12:30	0.00	0 - 0.38	No	4
		Week 40	01NOV2016/12:30	0.00	0 - 0.38	No	4
		Week 44	29NOV2016/13:15	0.00	0 - 0.38	No	4
		Week 48	02JAN2017/12:00	0.00	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	2.88	2 - 7.5	Yes	0
		Day 1	27JAN2016/11:00	2.63	2 - 7.5	No	0
		Week 1	02FEB2016/12:00	4.71	2 - 7.5	No	0
		Week 2	10FEB2016/12:45	2.70	2 - 7.5	No	0
		Week 4	25FEB2016/11:30	2.67	2 - 7.5	No	0
		Week 6	09MAR2016/12:00	2.52	2 - 7.5	Yes	0
		Week 8	22MAR2016/08:20	2.87	2 - 7.5	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Neutrophils, Segmented (10 <sup>9</sup> /L)	Week 12	19APR2016/11:20	3.56	2 - 7.5	No	0
		Week 16	18MAY2016/12:20	2.95	2 - 7.5	No	0
		Week 20	15JUN2016/12:15		2 - 7.5	No	
		Week 24	20JUL2016/13:50	2.68	2 - 7.5	Yes	0
		Week 28	09AUG2016/12:10	2.24	2 - 7.5	No	0
		Week 32	06SEP2016/13:10	1.71 L	2 - 7.5	No	1
		Week 36	04OCT2016/12:30	3.01	2 - 7.5	No	0
		Week 40	01NOV2016/12:30	1.47 L	2 - 7.5	No	2
		Week 44	29NOV2016/13:15	2.90	2 - 7.5	No	0
		Week 48	02JAN2017/12:00	1.95 L	2 - 7.5	No	1
	Platelets (10 <sup>9</sup> /L)	Screening	06JAN2016/11:00	94 L	150 - 400	Yes	1
		Day 1	27JAN2016/11:00	111 L	150 - 400	No	1
		Week 1	02FEB2016/12:00	137 L	150 - 400	No	1
		Week 2	10FEB2016/12:45	116 L	150 - 400	No	1
		Week 4	25FEB2016/11:30	91 L	150 - 400	No	1
		Week 6	09MAR2016/12:00	167	150 - 400	Yes	0
		Week 8	22MAR2016/08:20	122 L	150 - 400	No	1
		Week 12	19APR2016/11:20		150 - 400	No	
		Week 16	18MAY2016/12:20	120 L	150 - 400	No	1
		Week 20	15JUN2016/12:15	125 L	150 - 400	No	1
		Week 24	20JUL2016/13:50	127 L	150 - 400	Yes	1
		Week 28	09AUG2016/12:10	113 L	150 - 400	No	1

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Platelets (10 <sup>9</sup> /L)	Week 32	06SEP2016/13:10	92 L	150 - 400	No	1
		Week 36	04OCT2016/12:30	112 L	150 - 400	No	1
		Week 40	01NOV2016/12:30	106 L	150 - 400	No	1
		Week 44	29NOV2016/13:15	117 L	150 - 400	No	1
		Week 48	02JAN2017/12:00	77 L	150 - 400	No	1
301-010	Basophils (10 <sup>9</sup> /L)	Screening	07JAN2016/09:30	0.06	0 - 0.1	Yes	
		Day 1	27JAN2016/10:00	0.00	0 - 0.1	Yes	
		Week 1	04FEB2016/10:30	0.03	0 - 0.1	No	
		Week 2	09FEB2016/12:00	0.02	0 - 0.1	No	
		Week 4	24FEB2016/14:00	0.02	0 - 0.1	No	
		Week 6	09MAR2016/11:30	0.01	0 - 0.1	No	
		Week 8	22MAR2016/08:30	0.02	0 - 0.1	No	
		Week 12	19APR2016/11:32	0.08	0 - 0.1	No	
		Week 16	17MAY2016/12:55	0.08	0 - 0.1	No	
		Week 20	20JUN2016/12:12	0.01	0 - 0.1	No	
		Week 24	12JUL2016/11:40	0.06	0 - 0.1	Yes	
		Week 28	08AUG2016/12:30	0.04	0 - 0.1	No	
		Week 32	06SEP2016/11:10	0.01	0 - 0.1	No	
		Week 36	04OCT2016/12:40	0.04	0 - 0.1	No	
		Week 40	01NOV2016/12:50	0.03	0 - 0.1	No	
		Week 44	28NOV2016/11:45	0.02	0 - 0.1	No	
		Week 48	03JAN2017/13:00	0.02	0 - 0.1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Blood film	Screening	07JAN2016/09:30			Yes
		Day 1	27JAN2016/10:00			Yes
		Week 1	04FEB2016/10:30			No
		Week 2	09FEB2016/12:00			No
		Week 4	24FEB2016/14:00			No
		Week 6	09MAR2016/11:30			No
		Week 8	22MAR2016/08:30			No
		Week 12	19APR2016/11:32			No
		Week 16	17MAY2016/12:55			No
		Week 20	20JUN2016/12:12			No
		Week 24	12JUL2016/11:40			Yes
		Week 28	08AUG2016/12:30			No
		Week 32	06SEP2016/11:10			No
		Week 36	04OCT2016/12:40			No
		Week 40	01NOV2016/12:50			No
		Week 44	28NOV2016/11:45			No
		Week 48	03JAN2017/13:00			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	07JAN2016/09:30	0.12	0 - 0.4	Yes
		Day 1	27JAN2016/10:00	0.10	0 - 0.4	Yes
		Week 1	04FEB2016/10:30	0.06	0 - 0.4	No
		Week 2	09FEB2016/12:00	0.04	0 - 0.4	No
		Week 4	24FEB2016/14:00	0.08	0 - 0.4	No
		Week 6	09MAR2016/11:30	0.02	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010 Eosinophils (10 <sup>9</sup> /L)	Week 8	22MAR2016/08:30	0.01	0 - 0.4	No
	Week 12	19APR2016/11:32	0.08	0 - 0.4	No
	Week 16	17MAY2016/12:55	0.18	0 - 0.4	No
	Week 20	20JUN2016/12:12	0.01	0 - 0.4	No
	Week 24	12JUL2016/11:40	0.06	0 - 0.4	Yes
	Week 28	08AUG2016/12:30	0.09	0 - 0.4	No
	Week 32	06SEP2016/11:10	0.03	0 - 0.4	No
	Week 36	04OCT2016/12:40	0.05	0 - 0.4	No
	Week 40	01NOV2016/12:50	0.10	0 - 0.4	No
	Week 44	28NOV2016/11:45	0.05	0 - 0.4	No
	Week 48	03JAN2017/13:00	0.06	0 - 0.4	No
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	350	300 - 350	Yes
		Day 1	344	300 - 350	Yes
		Week 1	349	300 - 350	No
		Week 2	349	300 - 350	No
		Week 4	352 H	300 - 350	No
		Week 6	344	300 - 350	No
		Week 8	351 H	300 - 350	No
		Week 12	329	300 - 350	No
		Week 16	340	300 - 350	No
		Week 20	322	300 - 350	No
		Week 24	321	300 - 350	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Ery. Mean Corpuscular HGB Concentration (g/L)	Week 28	08AUG2016/12:30	330	300 - 350	No
		Week 32	06SEP2016/11:10	326	300 - 350	No
		Week 36	04OCT2016/12:40	336	300 - 350	No
		Week 40	01NOV2016/12:50	341	300 - 350	No
		Week 44	28NOV2016/11:45	342	300 - 350	No
		Week 48	03JAN2017/13:00	328	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	07JAN2016/09:30	31.2	26 - 33.5	Yes
		Day 1	27JAN2016/10:00	30.3	26 - 33.5	Yes
		Week 1	04FEB2016/10:30	30.8	26 - 33.5	No
		Week 2	09FEB2016/12:00	30.3	26 - 33.5	No
		Week 4	24FEB2016/14:00	30.8	26 - 33.5	No
		Week 6	09MAR2016/11:30	30.2	26 - 33.5	No
		Week 8	22MAR2016/08:30	30.6	26 - 33.5	No
		Week 12	19APR2016/11:32	30.6	26 - 33.5	No
		Week 16	17MAY2016/12:55	30.7	26 - 33.5	No
		Week 20	20JUN2016/12:12	29.4	26 - 33.5	No
		Week 24	12JUL2016/11:40	28.7	26 - 33.5	Yes
		Week 28	08AUG2016/12:30	28.9	26 - 33.5	No
		Week 32	06SEP2016/11:10	28.8	26 - 33.5	No
		Week 36	04OCT2016/12:40	30.3	26 - 33.5	No
		Week 40	01NOV2016/12:50	30.4	26 - 33.5	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Ery. Mean Corpuscular Hemoglobin (pg)	Week 44	28NOV2016/11:45	30.9	26 - 33.5	No
		Week 48	03JAN2017/13:00	30.9	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	07JAN2016/09:30	89.2	80 - 99	Yes
		Day 1	27JAN2016/10:00	88.1	80 - 99	Yes
		Week 1	04FEB2016/10:30	88.3	80 - 99	No
		Week 2	09FEB2016/12:00	87.0	80 - 99	No
		Week 4	24FEB2016/14:00	87.5	80 - 99	No
		Week 6	09MAR2016/11:30	87.9	80 - 99	No
		Week 8	22MAR2016/08:30	87.1	80 - 99	No
		Week 12	19APR2016/11:32	93.0	80 - 99	No
		Week 16	17MAY2016/12:55	90.3	80 - 99	No
		Week 20	20JUN2016/12:12	91.3	80 - 99	No
		Week 24	12JUL2016/11:40	89.4	80 - 99	Yes
		Week 28	08AUG2016/12:30	87.6	80 - 99	No
		Week 32	06SEP2016/11:10	88.4	80 - 99	No
		Week 36	04OCT2016/12:40	90.2	80 - 99	No
		Week 40	01NOV2016/12:50	89.1	80 - 99	No
		Week 44	28NOV2016/11:45	90.4	80 - 99	No
		Week 48	03JAN2017/13:00	94.4	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	07JAN2016/09:30	4.93	4.4 - 5.8	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010 Erythrocytes (10 <sup>12</sup> /L)	Day 1	27JAN2016/10:00	5.12	4.4 - 5.8	Yes
	Week 1	04FEB2016/10:30	5.03	4.4 - 5.8	No
	Week 2	09FEB2016/12:00	4.91	4.4 - 5.8	No
	Week 4	24FEB2016/14:00	4.97	4.4 - 5.8	No
	Week 6	09MAR2016/11:30	4.63	4.4 - 5.8	No
	Week 8	22MAR2016/08:30	4.51	4.4 - 5.8	No
	Week 12	19APR2016/11:32	4.41	4.4 - 5.8	No
	Week 16	17MAY2016/12:55	4.76	4.4 - 5.8	No
	Week 20	20JUN2016/12:12	4.96	4.4 - 5.8	No
	Week 24	12JUL2016/11:40	5.19	4.4 - 5.8	Yes
	Week 28	08AUG2016/12:30	5.32	4.4 - 5.8	No
	Week 32	06SEP2016/11:10	5.00	4.4 - 5.8	No
	Week 36	04OCT2016/12:40	4.91	4.4 - 5.8	No
	Week 40	01NOV2016/12:50	4.87	4.4 - 5.8	No
	Week 44	28NOV2016/11:45	4.89	4.4 - 5.8	No
	Week 48	03JAN2017/13:00	4.98	4.4 - 5.8	No
Hematocrit (%)	Screening	07JAN2016/09:30	44.0	37 - 50	Yes
	Day 1	27JAN2016/10:00	45.1	37 - 50	Yes
	Week 1	04FEB2016/10:30	44.4	37 - 50	No
	Week 2	09FEB2016/12:00	42.7	37 - 50	No
	Week 4	24FEB2016/14:00	43.5	37 - 50	No
	Week 6	09MAR2016/11:30	40.7	37 - 50	No
	Week 8	22MAR2016/08:30	39.3	37 - 50	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Hematocrit (%)	Week 12	19APR2016/11:32	41.0	37 - 50	No	
		Week 16	17MAY2016/12:55	43.0	37 - 50	No	
		Week 20	20JUN2016/12:12	45.3	37 - 50	No	
		Week 24	12JUL2016/11:40	46.4	37 - 50	Yes	
		Week 28	08AUG2016/12:30	46.6	37 - 50	No	
		Week 32	06SEP2016/11:10	44.2	37 - 50	No	
		Week 36	04OCT2016/12:40	44.3	37 - 50	No	
		Week 40	01NOV2016/12:50	43.4	37 - 50	No	
		Week 44	28NOV2016/11:45	44.2	37 - 50	No	
		Week 48	03JAN2017/13:00	47.0	37 - 50	No	
	Hemoglobin (g/L)	Screening	07JAN2016/09:30	154	130 - 170	Yes	0
		Day 1	27JAN2016/10:00	155	130 - 170	Yes	0
		Week 1	04FEB2016/10:30	155	130 - 170	No	0
		Week 2	09FEB2016/12:00	149	130 - 170	No	0
		Week 4	24FEB2016/14:00	153	130 - 170	No	0
		Week 6	09MAR2016/11:30	140	130 - 170	No	0
		Week 8	22MAR2016/08:30	138	130 - 170	No	0
		Week 12	19APR2016/11:32	135	130 - 170	No	0
		Week 16	17MAY2016/12:55	146	130 - 170	No	0
		Week 20	20JUN2016/12:12	146	130 - 170	No	0
		Week 24	12JUL2016/11:40	149	130 - 170	Yes	0
		Week 28	08AUG2016/12:30	154	130 - 170	No	0
		Week 32	06SEP2016/11:10	144	130 - 170	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Hemoglobin (g/L)	Week 36	04OCT2016/12:40	149	130 - 170	No	0
		Week 40	01NOV2016/12:50	148	130 - 170	No	0
		Week 44	28NOV2016/11:45	151	130 - 170	No	0
		Week 48	03JAN2017/13:00	154	130 - 170	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	07JAN2016/09:30	5.83	3 - 10	Yes	0
		Day 1	27JAN2016/10:00	5.03	3 - 10	Yes	0
		Week 1	04FEB2016/10:30	5.60	3 - 10	No	0
		Week 2	09FEB2016/12:00	4.57	3 - 10	No	0
		Week 4	24FEB2016/14:00	5.79	3 - 10	No	0
		Week 6	09MAR2016/11:30	6.80	3 - 10	No	0
		Week 8	22MAR2016/08:30	4.51	3 - 10	No	0
		Week 12	19APR2016/11:32	2.18 L	3 - 10	No	2
		Week 16	17MAY2016/12:55	7.38	3 - 10	No	0
		Week 20	20JUN2016/12:12	6.79	3 - 10	No	0
		Week 24	12JUL2016/11:40	5.86	3 - 10	Yes	0
		Week 28	08AUG2016/12:30	6.07	3 - 10	No	0
		Week 32	06SEP2016/11:10	4.82	3 - 10	No	0
		Week 36	04OCT2016/12:40	4.61	3 - 10	No	0
		Week 40	01NOV2016/12:50	6.45	3 - 10	No	0
		Week 44	28NOV2016/11:45	4.48	3 - 10	No	0
		Week 48	03JAN2017/13:00	4.33	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	07JAN2016/09:30	1.46	1.2 - 3.65	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Lymphocytes (10 <sup>9</sup> /L)	Day 1	27JAN2016/10:00	1.21	1.2 - 3.65	Yes	0
		Week 1	04FEB2016/10:30	1.46	1.2 - 3.65	No	0
		Week 2	09FEB2016/12:00	1.22	1.2 - 3.65	No	0
		Week 4	24FEB2016/14:00	1.58	1.2 - 3.65	No	0
		Week 6	09MAR2016/11:30	1.56	1.2 - 3.65	No	0
		Week 8	22MAR2016/08:30	1.31	1.2 - 3.65	No	0
		Week 12	19APR2016/11:32	0.88 L	1.2 - 3.65	No	1
		Week 16	17MAY2016/12:55	1.46	1.2 - 3.65	No	0
		Week 20	20JUN2016/12:12	1.11 L	1.2 - 3.65	No	1
		Week 24	12JUL2016/11:40	2.40	1.2 - 3.65	Yes	0
		Week 28	08AUG2016/12:30	1.48	1.2 - 3.65	No	0
		Week 32	06SEP2016/11:10	1.19 L	1.2 - 3.65	No	1
		Week 36	04OCT2016/12:40	1.36	1.2 - 3.65	No	0
		Week 40	01NOV2016/12:50	1.47	1.2 - 3.65	No	0
		Week 44	28NOV2016/11:45	1.27	1.2 - 3.65	No	0
		Week 48	03JAN2017/13:00	1.30	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	07JAN2016/09:30	0.35	0.2 - 1	Yes	
		Day 1	27JAN2016/10:00	0.50	0.2 - 1	Yes	
		Week 1	04FEB2016/10:30	0.43	0.2 - 1	No	
		Week 2	09FEB2016/12:00	0.35	0.2 - 1	No	
		Week 4	24FEB2016/14:00	0.42	0.2 - 1	No	
		Week 6	09MAR2016/11:30	0.50	0.2 - 1	No	
		Week 8	22MAR2016/08:30	0.36	0.2 - 1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Monocytes (10 <sup>9</sup> /L)	Week 12	19APR2016/11:32	0.30	0.2 - 1	No	
		Week 16	17MAY2016/12:55	0.52	0.2 - 1	No	
		Week 20	20JUN2016/12:12	0.33	0.2 - 1	No	
		Week 24	12JUL2016/11:40	0.59	0.2 - 1	Yes	
		Week 28	08AUG2016/12:30	0.48	0.2 - 1	No	
		Week 32	06SEP2016/11:10	0.50	0.2 - 1	No	
		Week 36	04OCT2016/12:40	0.41	0.2 - 1	No	
		Week 40	01NOV2016/12:50	0.51	0.2 - 1	No	
		Week 44	28NOV2016/11:45	0.41	0.2 - 1	No	
		Week 48	03JAN2017/13:00	0.32	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	07JAN2016/09:30	0.06	0 - 0.38	Yes	4
		Day 1	27JAN2016/10:00	0.00	0 - 0.38	Yes	4
		Week 1	04FEB2016/10:30	0.00	0 - 0.38	No	4
		Week 2	09FEB2016/12:00	0.00	0 - 0.38	No	4
		Week 4	24FEB2016/14:00	0.00	0 - 0.38	No	4
		Week 6	09MAR2016/11:30	0.00	0 - 0.38	No	4
		Week 8	22MAR2016/08:30	0.00	0 - 0.38	No	4
		Week 12	19APR2016/11:32	0.00	0 - 0.38	No	4
		Week 16	17MAY2016/12:55	0.00	0 - 0.38	No	4
		Week 20	20JUN2016/12:12	0.00	0 - 0.38	No	4
		Week 24	12JUL2016/11:40	0.12	0 - 0.38	Yes	4
		Week 28	08AUG2016/12:30	0.00	0 - 0.38	No	4
		Week 32	06SEP2016/11:10	0.00	0 - 0.38	No	4

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Neutrophils Band Form (10 <sup>9</sup> /L)	Week 36	04OCT2016/12:40	0.00	0 - 0.38	No	4
		Week 40	01NOV2016/12:50	0.00	0 - 0.38	No	4
		Week 44	28NOV2016/11:45	0.00	0 - 0.38	No	4
		Week 48	03JAN2017/13:00	0.39 H	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	07JAN2016/09:30	3.79	2 - 7.5	Yes	0
		Day 1	27JAN2016/10:00	3.22	2 - 7.5	Yes	0
		Week 1	04FEB2016/10:30	3.62	2 - 7.5	No	0
		Week 2	09FEB2016/12:00	2.94	2 - 7.5	No	0
		Week 4	24FEB2016/14:00	3.69	2 - 7.5	No	0
		Week 6	09MAR2016/11:30	4.71	2 - 7.5	No	0
		Week 8	22MAR2016/08:30	2.81	2 - 7.5	No	0
		Week 12	19APR2016/11:32	0.84 L	2 - 7.5	No	3
		Week 16	17MAY2016/12:55	5.14	2 - 7.5	No	0
		Week 20	20JUN2016/12:12	5.34	2 - 7.5	No	0
		Week 24	12JUL2016/11:40	2.64	2 - 7.5	Yes	0
		Week 28	08AUG2016/12:30	3.98	2 - 7.5	No	0
		Week 32	06SEP2016/11:10	3.09	2 - 7.5	No	0
		Week 36	04OCT2016/12:40	2.75	2 - 7.5	No	0
		Week 40	01NOV2016/12:50	4.33	2 - 7.5	No	0
		Week 44	28NOV2016/11:45	2.73	2 - 7.5	No	0
		Week 48	03JAN2017/13:00	2.24	2 - 7.5	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Platelets (10 <sup>9</sup> /L)	Screening	07JAN2016/09:30	204	150 - 400	Yes	0
		Day 1	27JAN2016/10:00	203	150 - 400	Yes	0
		Week 1	04FEB2016/10:30	203	150 - 400	No	0
		Week 2	09FEB2016/12:00	207	150 - 400	No	0
		Week 4	24FEB2016/14:00	212	150 - 400	No	0
		Week 6	09MAR2016/11:30	205	150 - 400	No	0
		Week 8	22MAR2016/08:30	210	150 - 400	No	0
		Week 12	19APR2016/11:32	416 H	150 - 400	No	0
		Week 16	17MAY2016/12:55	219	150 - 400	No	0
		Week 20	20JUN2016/12:12	218	150 - 400	No	0
		Week 24	12JUL2016/11:40	228	150 - 400	Yes	0
		Week 28	08AUG2016/12:30	220	150 - 400	No	0
		Week 32	06SEP2016/11:10	202	150 - 400	No	0
		Week 36	04OCT2016/12:40	215	150 - 400	No	0
		Week 40	01NOV2016/12:50	203	150 - 400	No	0
		Week 44	28NOV2016/11:45	167	150 - 400	No	0
		Week 48	03JAN2017/13:00	211	150 - 400	No	0
301-014	Basophils (10 <sup>9</sup> /L)	Screening	27JAN2016/11:30	0.08	0 - 0.1	Yes	
		Day 1	23FEB2016/13:00	0.05	0 - 0.1	Yes	
		Week 1	01MAR2016/11:30	0.07	0 - 0.1	No	
		Week 2	09MAR2016/10:45	0.05	0 - 0.1	No	
		Week 4	22MAR2016/10:15	0.04	0 - 0.1	No	
		Week 6	05APR2016/11:47	0.06	0 - 0.1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Basophils (10 <sup>9</sup> /L)	Week 8	20APR2016/09:15	0.06	0 - 0.1	Yes
		Week 12	19MAY2016/11:55	0.02	0 - 0.1	No
		Week 16	14JUN2016/11:08	0.06	0 - 0.1	No
		Week 20	13JUL2016/11:20	0.08	0 - 0.1	No
		Week 24	10AUG2016/10:50	0.05	0 - 0.1	Yes
		Week 28	07SEP2016/11:30	0.03	0 - 0.1	No
		Week 32	05OCT2016/11:00	0.02	0 - 0.1	No
		Week 36	02NOV2016/12:00	0.03	0 - 0.1	No
		Week 40	30NOV2016/10:45	0.06	0 - 0.1	No
		Week 44	22DEC2016/12:00	0.04	0 - 0.1	No
		Week 48	25JAN2017/11:00	0.06	0 - 0.1	No
	Blood film	Screening	27JAN2016/11:30			Yes
		Day 1	23FEB2016/13:00			Yes
		Week 1	01MAR2016/11:30			No
		Week 4	22MAR2016/10:15			No
		Week 6	05APR2016/11:47			No
		Week 8	20APR2016/09:15			Yes
		Week 12	19MAY2016/11:55			No
		Week 16	14JUN2016/11:08			No
		Week 20	13JUL2016/11:20			No
		Week 24	10AUG2016/10:50			Yes
		Week 28	07SEP2016/11:30			No
		Week 32	05OCT2016/11:00			No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Blood film	Week 36	02NOV2016/12:00			No
		Week 40	30NOV2016/10:45			No
		Week 44	22DEC2016/12:00			No
		Week 48	25JAN2017/11:00			No
	Blood film (reflex)	Week 40	30NOV2016/10:45			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	27JAN2016/11:30	0.17	0 - 0.4	Yes
		Day 1	23FEB2016/13:00	0.31	0 - 0.4	Yes
		Week 1	01MAR2016/11:30	0.36	0 - 0.4	No
		Week 2	09MAR2016/10:45	0.31	0 - 0.4	No
		Week 4	22MAR2016/10:15	0.26	0 - 0.4	No
		Week 6	05APR2016/11:47	0.26	0 - 0.4	No
		Week 8	20APR2016/09:15	0.15	0 - 0.4	Yes
		Week 12	19MAY2016/11:55	0.13	0 - 0.4	No
		Week 16	14JUN2016/11:08	0.25	0 - 0.4	No
		Week 20	13JUL2016/11:20	0.14	0 - 0.4	No
		Week 24	10AUG2016/10:50	0.16	0 - 0.4	Yes
		Week 28	07SEP2016/11:30	0.28	0 - 0.4	No
		Week 32	05OCT2016/11:00	0.30	0 - 0.4	No
		Week 36	02NOV2016/12:00	0.44 H	0 - 0.4	No
		Week 40	30NOV2016/10:45	0.38	0 - 0.4	No
		Week 44	22DEC2016/12:00	0.26	0 - 0.4	No
		Week 48	25JAN2017/11:00	0.35	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	27JAN2016/11:30	323	300 - 350	Yes
		Day 1	23FEB2016/13:00	333	300 - 350	Yes
		Week 1	01MAR2016/11:30	341	300 - 350	No
		Week 2	09MAR2016/10:45	333	300 - 350	No
		Week 4	22MAR2016/10:15	340	300 - 350	No
		Week 6	05APR2016/11:47	341	300 - 350	No
		Week 8	20APR2016/09:15	341	300 - 350	Yes
		Week 12	19MAY2016/11:55	326	300 - 350	No
		Week 16	14JUN2016/11:08	326	300 - 350	No
		Week 20	13JUL2016/11:20	326	300 - 350	No
		Week 24	10AUG2016/10:50	329	300 - 350	Yes
		Week 28	07SEP2016/11:30	314	300 - 350	No
		Week 32	05OCT2016/11:00	315	300 - 350	No
		Week 36	02NOV2016/12:00	314	300 - 350	No
		Week 40	30NOV2016/10:45	317	300 - 350	No
		Week 44	22DEC2016/12:00	312	300 - 350	No
		Week 48	25JAN2017/11:00	321	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	27JAN2016/11:30	25.1 L	26 - 33.5	Yes
		Day 1	23FEB2016/13:00	25.7 L	26 - 33.5	Yes
		Week 1	01MAR2016/11:30	25.9 L	26 - 33.5	No
		Week 2	09MAR2016/10:45	25.2 L	26 - 33.5	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Ery. Mean Corpuscular Hemoglobin (pg)	Week 4	22MAR2016/10:15	25.9 L	26 - 33.5	No
		Week 6	05APR2016/11:47	25.8 L	26 - 33.5	No
		Week 8	20APR2016/09:15	26.3	26 - 33.5	Yes
		Week 12	19MAY2016/11:55	26.2	26 - 33.5	No
		Week 16	14JUN2016/11:08	26.6	26 - 33.5	No
		Week 20	13JUL2016/11:20	26.1	26 - 33.5	No
		Week 24	10AUG2016/10:50	25.8 L	26 - 33.5	Yes
		Week 28	07SEP2016/11:30	24.4 L	26 - 33.5	No
		Week 32	05OCT2016/11:00	23.7 L	26 - 33.5	No
		Week 36	02NOV2016/12:00	22.5 L	26 - 33.5	No
		Week 40	30NOV2016/10:45	22.2 L	26 - 33.5	No
		Week 44	22DEC2016/12:00	21.6 L	26 - 33.5	No
		Week 48	25JAN2017/11:00	22.1 L	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	27JAN2016/11:30	77.6 L	80 - 99	Yes
		Day 1	23FEB2016/13:00	77.2 L	80 - 99	Yes
		Week 1	01MAR2016/11:30	75.8 L	80 - 99	No
		Week 2	09MAR2016/10:45	75.7 L	80 - 99	No
		Week 4	22MAR2016/10:15	76.4 L	80 - 99	No
		Week 6	05APR2016/11:47	75.5 L	80 - 99	No
		Week 8	20APR2016/09:15	77.2 L	80 - 99	Yes
		Week 12	19MAY2016/11:55	80.5	80 - 99	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Ery. Mean Corpuscular Volume (fL)	Week 16	14JUN2016/11:08	81.7	80 - 99	No
		Week 20	13JUL2016/11:20	80.1	80 - 99	No
		Week 24	10AUG2016/10:50	78.4 L	80 - 99	Yes
		Week 28	07SEP2016/11:30	77.7 L	80 - 99	No
		Week 32	05OCT2016/11:00	75.2 L	80 - 99	No
		Week 36	02NOV2016/12:00	71.6 L	80 - 99	No
		Week 40	30NOV2016/10:45	70.1 L	80 - 99	No
		Week 44	22DEC2016/12:00	69.2 L	80 - 99	No
		Week 48	25JAN2017/11:00	68.9 L	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	27JAN2016/11:30	5.58	4.4 - 5.8	Yes
		Day 1	23FEB2016/13:00	5.36	4.4 - 5.8	Yes
		Week 1	01MAR2016/11:30	5.41	4.4 - 5.8	No
		Week 2	09MAR2016/10:45	5.75	4.4 - 5.8	No
		Week 4	22MAR2016/10:15	5.63	4.4 - 5.8	No
		Week 6	05APR2016/11:47	5.63	4.4 - 5.8	No
		Week 8	20APR2016/09:15	5.39	4.4 - 5.8	Yes
		Week 12	19MAY2016/11:55	5.07	4.4 - 5.8	No
		Week 16	14JUN2016/11:08	5.07	4.4 - 5.8	No
		Week 20	13JUL2016/11:20	5.02	4.4 - 5.8	No
		Week 24	10AUG2016/10:50	5.00	4.4 - 5.8	Yes
		Week 28	07SEP2016/11:30	5.12	4.4 - 5.8	No
		Week 32	05OCT2016/11:00	5.32	4.4 - 5.8	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Erythrocytes (10 <sup>12</sup> /L)	Week 36	02NOV2016/12:00	5.52	4.4 - 5.8	No	
		Week 40	30NOV2016/10:45	5.85 H	4.4 - 5.8	No	
		Week 44	22DEC2016/12:00	5.61	4.4 - 5.8	No	
		Week 48	25JAN2017/11:00	5.56	4.4 - 5.8	No	
	Hematocrit (%)	Screening	27JAN2016/11:30	43.3	37 - 50	Yes	
		Day 1	23FEB2016/13:00	41.4	37 - 50	Yes	
		Week 1	01MAR2016/11:30	41.0	37 - 50	No	
		Week 2	09MAR2016/10:45	43.5	37 - 50	No	
		Week 4	22MAR2016/10:15	43.0	37 - 50	No	
		Week 6	05APR2016/11:47	42.5	37 - 50	No	
		Week 8	20APR2016/09:15	40.6	37 - 50	Yes	
		Week 12	19MAY2016/11:55	40.8	37 - 50	No	
		Week 16	14JUN2016/11:08	41.4	37 - 50	No	
		Week 20	13JUL2016/11:20	40.2	37 - 50	No	
		Week 24	10AUG2016/10:50	39.2	37 - 50	Yes	
		Week 28	07SEP2016/11:30	39.8	37 - 50	No	
		Week 32	05OCT2016/11:00	40.0	37 - 50	No	
		Week 36	02NOV2016/12:00	39.5	37 - 50	No	
		Week 40	30NOV2016/10:45	41.0	37 - 50	No	
		Week 44	22DEC2016/12:00	38.8	37 - 50	No	
		Week 48	25JAN2017/11:00	38.3	37 - 50	No	
	Hemoglobin (g/L)	Screening	27JAN2016/11:30	140	130 - 170	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Hemoglobin (g/L)	Day 1	23FEB2016/13:00	138	130 - 170	Yes	0
		Week 1	01MAR2016/11:30	140	130 - 170	No	0
		Week 2	09MAR2016/10:45	145	130 - 170	No	0
		Week 4	22MAR2016/10:15	146	130 - 170	No	0
		Week 6	05APR2016/11:47	145	130 - 170	No	0
		Week 8	20APR2016/09:15	142	130 - 170	Yes	0
		Week 12	19MAY2016/11:55	133	130 - 170	No	0
		Week 16	14JUN2016/11:08	135	130 - 170	No	0
		Week 20	13JUL2016/11:20	131	130 - 170	No	0
		Week 24	10AUG2016/10:50	129 L	130 - 170	Yes	1
		Week 28	07SEP2016/11:30	125 L	130 - 170	No	1
		Week 32	05OCT2016/11:00	126 L	130 - 170	No	1
		Week 36	02NOV2016/12:00	124 L	130 - 170	No	1
		Week 40	30NOV2016/10:45	130	130 - 170	No	0
		Week 44	22DEC2016/12:00	121 L	130 - 170	No	1
		Week 48	25JAN2017/11:00	123 L	130 - 170	No	1
	Leukocytes (10 <sup>9</sup> /L)	Screening	27JAN2016/11:30	8.32	3 - 10	Yes	0
		Day 1	23FEB2016/13:00	5.04	3 - 10	Yes	0
		Week 1	01MAR2016/11:30	6.45	3 - 10	No	0
		Week 2	09MAR2016/10:45	6.43	3 - 10	No	0
		Week 4	22MAR2016/10:15	5.95	3 - 10	No	0
		Week 6	05APR2016/11:47	8.07	3 - 10	No	0
		Week 8	20APR2016/09:15	5.49	3 - 10	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Leukocytes (10 <sup>9</sup> /L)	Week 12	19MAY2016/11:55	5.30	3 - 10	No	0
		Week 16	14JUN2016/11:08	8.36	3 - 10	No	0
		Week 20	13JUL2016/11:20	4.54	3 - 10	No	0
		Week 24	10AUG2016/10:50	4.56	3 - 10	Yes	0
		Week 28	07SEP2016/11:30	4.94	3 - 10	No	0
		Week 32	05OCT2016/11:00	4.94	3 - 10	No	0
		Week 36	02NOV2016/12:00	5.24	3 - 10	No	0
		Week 40	30NOV2016/10:45	4.26	3 - 10	No	0
		Week 44	22DEC2016/12:00	5.71	3 - 10	No	0
		Week 48	25JAN2017/11:00	5.08	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	27JAN2016/11:30	1.50	1.2 - 3.65	Yes	0
		Day 1	23FEB2016/13:00	2.24	1.2 - 3.65	Yes	0
		Week 1	01MAR2016/11:30	2.60	1.2 - 3.65	No	0
		Week 2	09MAR2016/10:45	2.44	1.2 - 3.65	No	0
		Week 4	22MAR2016/10:15	2.41	1.2 - 3.65	No	0
		Week 6	05APR2016/11:47	3.32	1.2 - 3.65	No	0
		Week 8	20APR2016/09:15	2.18	1.2 - 3.65	Yes	0
		Week 12	19MAY2016/11:55	1.82	1.2 - 3.65	No	0
		Week 16	14JUN2016/11:08	2.43	1.2 - 3.65	No	0
		Week 20	13JUL2016/11:20	1.26	1.2 - 3.65	No	0
		Week 24	10AUG2016/10:50	1.43	1.2 - 3.65	Yes	0
		Week 28	07SEP2016/11:30	2.08	1.2 - 3.65	No	0
		Week 32	05OCT2016/11:00	2.04	1.2 - 3.65	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Lymphocytes (10 <sup>9</sup> /L)	Week 36	02NOV2016/12:00	2.31	1.2 - 3.65	No	0
		Week 40	30NOV2016/10:45	1.74	1.2 - 3.65	No	0
		Week 44	22DEC2016/12:00	1.40	1.2 - 3.65	No	0
		Week 48	25JAN2017/11:00	2.26	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	27JAN2016/11:30	0.58	0.2 - 1	Yes	
		Day 1	23FEB2016/13:00	0.42	0.2 - 1	Yes	
		Week 1	01MAR2016/11:30	0.38	0.2 - 1	No	
		Week 2	09MAR2016/10:45	0.41	0.2 - 1	No	
		Week 4	22MAR2016/10:15	0.43	0.2 - 1	No	
		Week 6	05APR2016/11:47	0.56	0.2 - 1	No	
		Week 8	20APR2016/09:15	0.48	0.2 - 1	Yes	
		Week 12	19MAY2016/11:55	0.46	0.2 - 1	No	
		Week 16	14JUN2016/11:08	0.78	0.2 - 1	No	
		Week 20	13JUL2016/11:20	0.53	0.2 - 1	No	
		Week 24	10AUG2016/10:50	0.35	0.2 - 1	Yes	
		Week 28	07SEP2016/11:30	0.44	0.2 - 1	No	
		Week 32	05OCT2016/11:00	0.39	0.2 - 1	No	
		Week 36	02NOV2016/12:00	0.42	0.2 - 1	No	
		Week 40	30NOV2016/10:45	0.36	0.2 - 1	No	
		Week 44	22DEC2016/12:00	0.59	0.2 - 1	No	
		Week 48	25JAN2017/11:00	0.35	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)		Screening	0.17	0 - 0.38	Yes	4

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Neutrophils Band Form (10 <sup>9</sup> /L)	Day 1	23FEB2016/13:00	0.00	0 - 0.38	Yes	4
		Week 1	01MAR2016/11:30	0.00	0 - 0.38	No	4
		Week 2	09MAR2016/10:45	0.00	0 - 0.38	No	4
		Week 4	22MAR2016/10:15	0.00	0 - 0.38	No	4
		Week 6	05APR2016/11:47	0.00	0 - 0.38	No	4
		Week 8	20APR2016/09:15	0.00	0 - 0.38	Yes	4
		Week 12	19MAY2016/11:55	0.00	0 - 0.38	No	4
		Week 16	14JUN2016/11:08	0.00	0 - 0.38	No	4
		Week 20	13JUL2016/11:20	0.00	0 - 0.38	No	4
		Week 24	10AUG2016/10:50	0.00	0 - 0.38	Yes	4
		Week 28	07SEP2016/11:30	0.00	0 - 0.38	No	4
		Week 32	05OCT2016/11:00	0.00	0 - 0.38	No	4
		Week 36	02NOV2016/12:00	0.00	0 - 0.38	No	4
		Week 40	30NOV2016/10:45	0.00	0 - 0.38	No	4
		Week 44	22DEC2016/12:00	0.00	0 - 0.38	No	4
		Week 48	25JAN2017/11:00	0.00	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	27JAN2016/11:30	5.82	2 - 7.5	Yes	0
		Day 1	23FEB2016/13:00	2.02	2 - 7.5	Yes	0
		Week 1	01MAR2016/11:30	3.04	2 - 7.5	No	0
		Week 2	09MAR2016/10:45	3.22	2 - 7.5	No	0
		Week 4	22MAR2016/10:15	2.81	2 - 7.5	No	0
		Week 6	05APR2016/11:47	3.88	2 - 7.5	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Neutrophils, Segmented (10 <sup>9</sup> /L)	Week 8	20APR2016/09:15	2.56	2 - 7.5	Yes	0
		Week 12	19MAY2016/11:55	2.87	2 - 7.5	No	0
		Week 16	14JUN2016/11:08	4.84	2 - 7.5	No	0
		Week 20	13JUL2016/11:20	2.52	2 - 7.5	No	0
		Week 24	10AUG2016/10:50	2.57	2 - 7.5	Yes	0
		Week 28	07SEP2016/11:30	2.11	2 - 7.5	No	0
		Week 32	05OCT2016/11:00	2.19	2 - 7.5	No	0
		Week 36	02NOV2016/12:00	2.04	2 - 7.5	No	0
		Week 40	30NOV2016/10:45	1.72 L	2 - 7.5	No	1
		Week 44	22DEC2016/12:00	3.42	2 - 7.5	No	0
		Week 48	25JAN2017/11:00	2.06	2 - 7.5	No	0
	Platelets (10 <sup>9</sup> /L)	Screening	27JAN2016/11:30	127 L	150 - 400	Yes	1
		Day 1	23FEB2016/13:00		150 - 400	Yes	
		Week 1	01MAR2016/11:30		150 - 400	No	
		Week 2	09MAR2016/10:45	105 L	150 - 400	No	1
		Week 4	22MAR2016/10:15	123 L	150 - 400	No	1
		Week 6	05APR2016/11:47	155	150 - 400	No	0
		Week 8	20APR2016/09:15	112 L	150 - 400	Yes	1
		Week 12	19MAY2016/11:55	135 L	150 - 400	No	1
		Week 16	14JUN2016/11:08	136 L	150 - 400	No	1
		Week 20	13JUL2016/11:20	120 L	150 - 400	No	1
		Week 24	10AUG2016/10:50		150 - 400	Yes	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Platelets (10 <sup>9</sup> /L)	Week 28	07SEP2016/11:30	123 L	150 - 400	No	1
		Week 32	05OCT2016/11:00	114 L	150 - 400	No	1
		Week 36	02NOV2016/12:00	99 L	150 - 400	No	1
		Week 40	30NOV2016/10:45	108 L	150 - 400	No	1
		Week 44	22DEC2016/12:00	94 L	150 - 400	No	1
		Week 48	25JAN2017/11:00	95 L	150 - 400	No	1
301-016	Basophils (10 <sup>9</sup> /L)	Screening	03FEB2016/13:00	0.03	0 - 0.1	Yes	
		Day 1	25FEB2016/11:50	0.03	0 - 0.1	No	
		Week 1	02MAR2016/11:30	0.03	0 - 0.1	No	
		Week 2	08MAR2016/11:00	0.03	0 - 0.1	No	
		Week 4	24MAR2016/11:35	0.01	0 - 0.1	No	
		Week 6	07APR2016/11:10	0.04	0 - 0.1	No	
		Week 8	19APR2016/09:00	0.05	0 - 0.1	Yes	
		Week 12	24MAY2016/11:56	0.06	0 - 0.1	No	
		Week 16	14JUN2016/10:30	0.04	0 - 0.1	No	
		Week 20	13JUL2016/11:50	0.03	0 - 0.1	No	
		Week 24	28JUL2016/11:00	0.07	0 - 0.1	Yes	
		Week 28	06SEP2016/10:10	0.04	0 - 0.1	No	
		Week 32	05OCT2016/11:30	0.01	0 - 0.1	No	
		Week 36	02NOV2016/11:45	0.02	0 - 0.1	No	
		Week 40	29NOV2016/11:00	0.03	0 - 0.1	No	
		Week 44	21DEC2016/11:30	0.02	0 - 0.1	No	
		Week 48	24JAN2017/12:00	0.05	0 - 0.1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Blood film	Screening	03FEB2016/13:00			Yes
		Day 1	25FEB2016/11:50			No
		Week 1	02MAR2016/11:30			No
		Week 2	08MAR2016/11:00			No
		Week 4	24MAR2016/11:35			No
		Week 6	07APR2016/11:10			No
		Week 8	19APR2016/09:00			Yes
		Week 12	24MAY2016/11:56			No
		Week 16	14JUN2016/10:30			No
		Week 20	13JUL2016/11:50			No
		Week 24	28JUL2016/11:00			Yes
		Week 28	06SEP2016/10:10			No
		Week 32	05OCT2016/11:30			No
		Week 36	02NOV2016/11:45			No
		Week 40	29NOV2016/11:00			No
		Week 44	21DEC2016/11:30			No
		Week 48	24JAN2017/12:00			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	03FEB2016/13:00	0.14	0 - 0.4	Yes
		Day 1	25FEB2016/11:50	0.14	0 - 0.4	No
		Week 1	02MAR2016/11:30	0.22	0 - 0.4	No
		Week 2	08MAR2016/11:00	0.19	0 - 0.4	No
		Week 4	24MAR2016/11:35	0.09	0 - 0.4	No
		Week 6	07APR2016/11:10	0.20	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016 Eosinophils (10 <sup>9</sup> /L)	Week 8	19APR2016/09:00	0.14	0 - 0.4	Yes
	Week 12	24MAY2016/11:56	0.25	0 - 0.4	No
	Week 16	14JUN2016/10:30	0.11	0 - 0.4	No
	Week 20	13JUL2016/11:50	0.12	0 - 0.4	No
	Week 24	28JUL2016/11:00	0.14	0 - 0.4	Yes
	Week 28	06SEP2016/10:10	0.14	0 - 0.4	No
	Week 32	05OCT2016/11:30	0.11	0 - 0.4	No
	Week 36	02NOV2016/11:45	0.16	0 - 0.4	No
	Week 40	29NOV2016/11:00	0.09	0 - 0.4	No
	Week 44	21DEC2016/11:30	0.18	0 - 0.4	No
	Week 48	24JAN2017/12:00	0.19	0 - 0.4	No
Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	03FEB2016/13:00	352 H	300 - 350	Yes
	Day 1	25FEB2016/11:50	353 H	300 - 350	No
	Week 1	02MAR2016/11:30	359 H	300 - 350	No
	Week 2	08MAR2016/11:00	354 H	300 - 350	No
	Week 4	24MAR2016/11:35	321	300 - 350	No
	Week 6	07APR2016/11:10	363 H	300 - 350	No
	Week 8	19APR2016/09:00	341	300 - 350	Yes
	Week 12	24MAY2016/11:56	354 H	300 - 350	No
	Week 16	14JUN2016/10:30	352 H	300 - 350	No
	Week 20	13JUL2016/11:50	342	300 - 350	No
	Week 24	28JUL2016/11:00	340	300 - 350	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Ery. Mean Corpuscular HGB Concentration (g/L)	Week 28	06SEP2016/10:10	325	300 - 350	No
		Week 32	05OCT2016/11:30	336	300 - 350	No
		Week 36	02NOV2016/11:45	347	300 - 350	No
		Week 40	29NOV2016/11:00	353 H	300 - 350	No
		Week 44	21DEC2016/11:30	355 H	300 - 350	No
		Week 48	24JAN2017/12:00	346	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	03FEB2016/13:00	29.8	26 - 33.5	Yes
		Day 1	25FEB2016/11:50	29.5	26 - 33.5	No
		Week 1	02MAR2016/11:30	29.9	26 - 33.5	No
		Week 2	08MAR2016/11:00	29.4	26 - 33.5	No
		Week 4	24MAR2016/11:35	29.3	26 - 33.5	No
		Week 6	07APR2016/11:10	30.1	26 - 33.5	No
		Week 8	19APR2016/09:00	29.1	26 - 33.5	Yes
		Week 12	24MAY2016/11:56	30.1	26 - 33.5	No
		Week 16	14JUN2016/10:30	30.2	26 - 33.5	No
		Week 20	13JUL2016/11:50	29.6	26 - 33.5	No
		Week 24	28JUL2016/11:00	29.8	26 - 33.5	Yes
		Week 28	06SEP2016/10:10	28.6	26 - 33.5	No
		Week 32	05OCT2016/11:30	29.5	26 - 33.5	No
		Week 36	02NOV2016/11:45	29.1	26 - 33.5	No
		Week 40	29NOV2016/11:00	29.3	26 - 33.5	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Ery. Mean Corpuscular Hemoglobin (pg)	Week 44	21DEC2016/11:30	29.8	26 - 33.5	No
		Week 48	24JAN2017/12:00	30.1	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	03FEB2016/13:00	84.7	80 - 99	Yes
		Day 1	25FEB2016/11:50	83.7	80 - 99	No
		Week 1	02MAR2016/11:30	83.1	80 - 99	No
		Week 2	08MAR2016/11:00	83.1	80 - 99	No
		Week 4	24MAR2016/11:35	91.4	80 - 99	No
		Week 6	07APR2016/11:10	82.8	80 - 99	No
		Week 8	19APR2016/09:00	85.2	80 - 99	Yes
		Week 12	24MAY2016/11:56	84.9	80 - 99	No
		Week 16	14JUN2016/10:30	85.7	80 - 99	No
		Week 20	13JUL2016/11:50	86.6	80 - 99	No
		Week 24	28JUL2016/11:00	87.8	80 - 99	Yes
		Week 28	06SEP2016/10:10	88.3	80 - 99	No
		Week 32	05OCT2016/11:30	87.8	80 - 99	No
		Week 36	02NOV2016/11:45	84.0	80 - 99	No
		Week 40	29NOV2016/11:00	83.1	80 - 99	No
		Week 44	21DEC2016/11:30	83.9	80 - 99	No
		Week 48	24JAN2017/12:00	86.8	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	03FEB2016/13:00	5.63	4.4 - 5.8	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016 Erythrocytes (10 <sup>12</sup> /L)	Day 1	25FEB2016/11:50	5.72	4.4 - 5.8	No
	Week 1	02MAR2016/11:30	5.56	4.4 - 5.8	No
	Week 2	08MAR2016/11:00	5.55	4.4 - 5.8	No
	Week 4	24MAR2016/11:35	5.49	4.4 - 5.8	No
	Week 6	07APR2016/11:10	5.75	4.4 - 5.8	No
	Week 8	19APR2016/09:00	4.88	4.4 - 5.8	Yes
	Week 12	24MAY2016/11:56	5.09	4.4 - 5.8	No
	Week 16	14JUN2016/10:30	4.97	4.4 - 5.8	No
	Week 20	13JUL2016/11:50	5.06	4.4 - 5.8	No
	Week 24	28JUL2016/11:00	5.26	4.4 - 5.8	Yes
	Week 28	06SEP2016/10:10	5.62	4.4 - 5.8	No
	Week 32	05OCT2016/11:30	5.32	4.4 - 5.8	No
	Week 36	02NOV2016/11:45	5.70	4.4 - 5.8	No
	Week 40	29NOV2016/11:00	5.73	4.4 - 5.8	No
	Week 44	21DEC2016/11:30	5.34	4.4 - 5.8	No
	Week 48	24JAN2017/12:00	5.29	4.4 - 5.8	No
Hematocrit (%)	Screening	03FEB2016/13:00	47.7	37 - 50	Yes
	Day 1	25FEB2016/11:50	47.9	37 - 50	No
	Week 1	02MAR2016/11:30	46.2	37 - 50	No
	Week 2	08MAR2016/11:00	46.1	37 - 50	No
	Week 4	24MAR2016/11:35	50.2 H	37 - 50	No
	Week 6	07APR2016/11:10	47.6	37 - 50	No
	Week 8	19APR2016/09:00	41.6	37 - 50	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Hematocrit (%)	Week 12	24MAY2016/11:56	43.2	37 - 50	No	
		Week 16	14JUN2016/10:30	42.6	37 - 50	No	
		Week 20	13JUL2016/11:50	43.8	37 - 50	No	
		Week 24	28JUL2016/11:00	46.2	37 - 50	Yes	
		Week 28	06SEP2016/10:10	49.6	37 - 50	No	
		Week 32	05OCT2016/11:30	46.7	37 - 50	No	
		Week 36	02NOV2016/11:45	47.9	37 - 50	No	
		Week 40	29NOV2016/11:00	47.6	37 - 50	No	
		Week 44	21DEC2016/11:30	44.8	37 - 50	No	
		Week 48	24JAN2017/12:00	45.9	37 - 50	No	
	Hemoglobin (g/L)	Screening	03FEB2016/13:00	168	130 - 170	Yes	0
		Day 1	25FEB2016/11:50	169	130 - 170	No	0
		Week 1	02MAR2016/11:30	166	130 - 170	No	0
		Week 2	08MAR2016/11:00	163	130 - 170	No	0
		Week 4	24MAR2016/11:35	161	130 - 170	No	0
		Week 6	07APR2016/11:10	173 H	130 - 170	No	1
		Week 8	19APR2016/09:00	142	130 - 170	Yes	0
		Week 12	24MAY2016/11:56	153	130 - 170	No	0
		Week 16	14JUN2016/10:30	150	130 - 170	No	0
		Week 20	13JUL2016/11:50	150	130 - 170	No	0
		Week 24	28JUL2016/11:00	157	130 - 170	Yes	0
		Week 28	06SEP2016/10:10	161	130 - 170	No	0
		Week 32	05OCT2016/11:30	157	130 - 170	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Hemoglobin (g/L)	Week 36	02NOV2016/11:45	166	130 - 170	No	0
		Week 40	29NOV2016/11:00	168	130 - 170	No	0
		Week 44	21DEC2016/11:30	159	130 - 170	No	0
		Week 48	24JAN2017/12:00	159	130 - 170	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	03FEB2016/13:00	7.71	3 - 10	Yes	0
		Day 1	25FEB2016/11:50	6.97	3 - 10	No	0
		Week 1	02MAR2016/11:30	8.45	3 - 10	No	0
		Week 2	08MAR2016/11:00	8.69	3 - 10	No	0
		Week 4	24MAR2016/11:35	6.88	3 - 10	No	0
		Week 6	07APR2016/11:10	9.24	3 - 10	No	0
		Week 8	19APR2016/09:00	9.05	3 - 10	Yes	0
		Week 12	24MAY2016/11:56	8.24	3 - 10	No	0
		Week 16	14JUN2016/10:30	6.67	3 - 10	No	0
		Week 20	13JUL2016/11:50	6.35	3 - 10	No	0
		Week 24	28JUL2016/11:00	7.02	3 - 10	Yes	0
		Week 28	06SEP2016/10:10	8.07	3 - 10	No	0
		Week 32	05OCT2016/11:30	6.19	3 - 10	No	0
		Week 36	02NOV2016/11:45	7.15	3 - 10	No	0
		Week 40	29NOV2016/11:00	7.57	3 - 10	No	0
		Week 44	21DEC2016/11:30	8.00	3 - 10	No	0
		Week 48	24JAN2017/12:00	7.98	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	03FEB2016/13:00	2.11	1.2 - 3.65	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Lymphocytes (10 <sup>9</sup> /L)	Day 1	25FEB2016/11:50	2.39	1.2 - 3.65	No	0
		Week 1	02MAR2016/11:30	2.75	1.2 - 3.65	No	0
		Week 2	08MAR2016/11:00	2.67	1.2 - 3.65	No	0
		Week 4	24MAR2016/11:35	2.46	1.2 - 3.65	No	0
		Week 6	07APR2016/11:10	3.62	1.2 - 3.65	No	0
		Week 8	19APR2016/09:00	2.86	1.2 - 3.65	Yes	0
		Week 12	24MAY2016/11:56	2.16	1.2 - 3.65	No	0
		Week 16	14JUN2016/10:30	1.98	1.2 - 3.65	No	0
		Week 20	13JUL2016/11:50	1.44	1.2 - 3.65	No	0
		Week 24	28JUL2016/11:00	2.25	1.2 - 3.65	Yes	0
		Week 28	06SEP2016/10:10	2.69	1.2 - 3.65	No	0
		Week 32	05OCT2016/11:30	1.98	1.2 - 3.65	No	0
		Week 36	02NOV2016/11:45	2.51	1.2 - 3.65	No	0
		Week 40	29NOV2016/11:00	2.15	1.2 - 3.65	No	0
		Week 44	21DEC2016/11:30	3.00	1.2 - 3.65	No	0
		Week 48	24JAN2017/12:00	2.03	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	03FEB2016/13:00	0.56	0.2 - 1	Yes	
		Day 1	25FEB2016/11:50	0.56	0.2 - 1	No	
		Week 1	02MAR2016/11:30	0.75	0.2 - 1	No	
		Week 2	08MAR2016/11:00	0.63	0.2 - 1	No	
		Week 4	24MAR2016/11:35	0.61	0.2 - 1	No	
		Week 6	07APR2016/11:10	0.58	0.2 - 1	No	
		Week 8	19APR2016/09:00	0.70	0.2 - 1	Yes	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Monocytes (10 <sup>9</sup> /L)	Week 12	24MAY2016/11:56	0.67	0.2 - 1	No	
		Week 16	14JUN2016/10:30	0.60	0.2 - 1	No	
		Week 20	13JUL2016/11:50	0.73	0.2 - 1	No	
		Week 24	28JUL2016/11:00	0.49	0.2 - 1	Yes	
		Week 28	06SEP2016/10:10	0.75	0.2 - 1	No	
		Week 32	05OCT2016/11:30	0.63	0.2 - 1	No	
		Week 36	02NOV2016/11:45	0.61	0.2 - 1	No	
		Week 40	29NOV2016/11:00	0.61	0.2 - 1	No	
		Week 44	21DEC2016/11:30	0.72	0.2 - 1	No	
		Week 48	24JAN2017/12:00	0.93	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	03FEB2016/13:00	0.00	0 - 0.38	Yes	4
		Day 1	25FEB2016/11:50	0.00	0 - 0.38	No	4
		Week 1	02MAR2016/11:30	0.00	0 - 0.38	No	4
		Week 2	08MAR2016/11:00	0.00	0 - 0.38	No	4
		Week 4	24MAR2016/11:35	0.00	0 - 0.38	No	4
		Week 6	07APR2016/11:10	0.00	0 - 0.38	No	4
		Week 8	19APR2016/09:00	0.00	0 - 0.38	Yes	4
		Week 12	24MAY2016/11:56	0.00	0 - 0.38	No	4
		Week 16	14JUN2016/10:30	0.00	0 - 0.38	No	4
		Week 20	13JUL2016/11:50	0.00	0 - 0.38	No	4
		Week 24	28JUL2016/11:00	0.07	0 - 0.38	Yes	4
		Week 28	06SEP2016/10:10	0.00	0 - 0.38	No	4
		Week 32	05OCT2016/11:30	0.00	0 - 0.38	No	4

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Neutrophils Band Form (10 <sup>9</sup> /L)	Week 36	02NOV2016/11:45	0.00	0 - 0.38	No	4
		Week 40	29NOV2016/11:00	0.00	0 - 0.38	No	4
		Week 44	21DEC2016/11:30	0.00	0 - 0.38	No	4
		Week 48	24JAN2017/12:00	0.00	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	03FEB2016/13:00	4.87	2 - 7.5	Yes	0
		Day 1	25FEB2016/11:50	3.85	2 - 7.5	No	0
		Week 1	02MAR2016/11:30	4.70	2 - 7.5	No	0
		Week 2	08MAR2016/11:00	5.18	2 - 7.5	No	0
		Week 4	24MAR2016/11:35	3.71	2 - 7.5	No	0
		Week 6	07APR2016/11:10	4.80	2 - 7.5	No	0
		Week 8	19APR2016/09:00	5.30	2 - 7.5	Yes	0
		Week 12	24MAY2016/11:56	5.11	2 - 7.5	No	0
		Week 16	14JUN2016/10:30	3.94	2 - 7.5	No	0
		Week 20	13JUL2016/11:50	4.03	2 - 7.5	No	0
		Week 24	28JUL2016/11:00	4.00	2 - 7.5	Yes	0
		Week 28	06SEP2016/10:10	4.45	2 - 7.5	No	0
		Week 32	05OCT2016/11:30	3.45	2 - 7.5	No	0
		Week 36	02NOV2016/11:45	3.85	2 - 7.5	No	0
		Week 40	29NOV2016/11:00	4.69	2 - 7.5	No	0
		Week 44	21DEC2016/11:30	4.07	2 - 7.5	No	0
		Week 48	24JAN2017/12:00	4.79	2 - 7.5	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Platelets (10 <sup>9</sup> /L)	Screening	03FEB2016/13:00	200	150 - 400	Yes	0
		Day 1	25FEB2016/11:50	191	150 - 400	No	0
		Week 1	02MAR2016/11:30	224	150 - 400	No	0
		Week 2	08MAR2016/11:00	255	150 - 400	No	0
		Week 4	24MAR2016/11:35	230	150 - 400	No	0
		Week 6	07APR2016/11:10	235	150 - 400	No	0
		Week 8	19APR2016/09:00	221	150 - 400	Yes	0
		Week 12	24MAY2016/11:56	249	150 - 400	No	0
		Week 16	14JUN2016/10:30	208	150 - 400	No	0
		Week 20	13JUL2016/11:50	233	150 - 400	No	0
		Week 24	28JUL2016/11:00	240	150 - 400	Yes	0
		Week 28	06SEP2016/10:10	205	150 - 400	No	0
		Week 32	05OCT2016/11:30	227	150 - 400	No	0
		Week 36	02NOV2016/11:45	199	150 - 400	No	0
		Week 40	29NOV2016/11:00	228	150 - 400	No	0
		Week 44	21DEC2016/11:30	213	150 - 400	No	0
		Week 48	24JAN2017/12:00	194	150 - 400	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Basophils (10 <sup>9</sup> /L)	Screening	02FEB2016/10:50	0.02	0 - 0.1	Yes
		Day 1	23FEB2016/13:40	0.01	0 - 0.1	Yes
		Week 1	03MAR2016/12:00	0.02	0 - 0.1	No
		Week 2	08MAR2016/10:10	0.01	0 - 0.1	No
		Week 4	23MAR2016/11:32	0.01	0 - 0.1	No
		Week 6	06APR2016/11:45	0.00	0 - 0.1	No
		Week 8	20APR2016/09:00	0.01	0 - 0.1	Yes
		Week 12	17MAY2016/11:55	0.01	0 - 0.1	No
		Week 16	16JUN2016/12:50	0.01	0 - 0.1	No
		Week 20	14JUL2016/11:50	0.05	0 - 0.1	No
		Week 24	10AUG2016/10:20	0.00	0 - 0.1	Yes
		Week 28	07SEP2016/09:45	0.01	0 - 0.1	No
		Week 40	30NOV2016/09:50	0.02	0 - 0.1	No
		Week 44	28DEC2016/11:00	0.01	0 - 0.1	No
		Week 48	26JAN2017/12:45	0.02	0 - 0.1	No
	Blood film	Screening	02FEB2016/10:50			Yes
		Day 1	23FEB2016/13:40			Yes
		Week 1	03MAR2016/12:00			No
		Week 2	08MAR2016/10:10			No
		Week 4	23MAR2016/11:32			No
		Week 6	06APR2016/11:45			No
		Week 8	20APR2016/09:00			Yes
		Week 12	17MAY2016/11:55			No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Blood film	Week 16	16JUN2016/12:50			No
		Week 20	14JUL2016/11:50			No
		Week 24	10AUG2016/10:20			Yes
		Week 28	07SEP2016/09:45			No
		Week 40	30NOV2016/09:50			No
		Week 44	28DEC2016/11:00			No
		Week 48	26JAN2017/12:45			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	02FEB2016/10:50	0.19	0 - 0.4	Yes
		Day 1	23FEB2016/13:40	0.19	0 - 0.4	Yes
		Week 1	03MAR2016/12:00	0.14	0 - 0.4	No
		Week 2	08MAR2016/10:10	0.12	0 - 0.4	No
		Week 4	23MAR2016/11:32	0.10	0 - 0.4	No
		Week 6	06APR2016/11:45	0.06	0 - 0.4	No
		Week 8	20APR2016/09:00	0.04	0 - 0.4	Yes
		Week 12	17MAY2016/11:55	0.04	0 - 0.4	No
		Week 16	16JUN2016/12:50	0.04	0 - 0.4	No
		Week 20	14JUL2016/11:50	0.05	0 - 0.4	No
		Week 24	10AUG2016/10:20	0.04	0 - 0.4	Yes
		Week 28	07SEP2016/09:45	0.06	0 - 0.4	No
		Week 40	30NOV2016/09:50	0.15	0 - 0.4	No
		Week 44	28DEC2016/11:00	0.10	0 - 0.4	No
		Week 48	26JAN2017/12:45	0.10	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	02FEB2016/10:50	352 H	300 - 350	Yes
		Day 1	23FEB2016/13:40	344	300 - 350	Yes
		Week 1	03MAR2016/12:00	351 H	300 - 350	No
		Week 2	08MAR2016/10:10	351 H	300 - 350	No
		Week 4	23MAR2016/11:32	347	300 - 350	No
		Week 6	06APR2016/11:45	347	300 - 350	No
		Week 8	20APR2016/09:00	356 H	300 - 350	Yes
		Week 12	17MAY2016/11:55	347	300 - 350	No
		Week 16	16JUN2016/12:50	342	300 - 350	No
		Week 20	14JUL2016/11:50	345	300 - 350	No
		Week 24	10AUG2016/10:20	332	300 - 350	Yes
		Week 28	07SEP2016/09:45	324	300 - 350	No
		Week 40	30NOV2016/09:50	353 H	300 - 350	No
		Week 44	28DEC2016/11:00	342	300 - 350	No
		Week 48	26JAN2017/12:45	351 H	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	02FEB2016/10:50	31.4	26 - 33.5	Yes
		Day 1	23FEB2016/13:40	30.9	26 - 33.5	Yes
		Week 1	03MAR2016/12:00	31.4	26 - 33.5	No
		Week 2	08MAR2016/10:10	31.5	26 - 33.5	No
		Week 4	23MAR2016/11:32	31.3	26 - 33.5	No
		Week 6	06APR2016/11:45	31.2	26 - 33.5	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Ery. Mean Corpuscular Hemoglobin (pg)	Week 8	20APR2016/09:00	31.3	26 - 33.5	Yes
		Week 12	17MAY2016/11:55	31.4	26 - 33.5	No
		Week 16	16JUN2016/12:50	31.5	26 - 33.5	No
		Week 20	14JUL2016/11:50	31.3	26 - 33.5	No
		Week 24	10AUG2016/10:20	31.6	26 - 33.5	Yes
		Week 28	07SEP2016/09:45	31.6	26 - 33.5	No
		Week 40	30NOV2016/09:50	31.4	26 - 33.5	No
		Week 44	28DEC2016/11:00	30.5	26 - 33.5	No
		Week 48	26JAN2017/12:45	31.6	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	02FEB2016/10:50	89.1	80 - 99	Yes
		Day 1	23FEB2016/13:40	89.7	80 - 99	Yes
		Week 1	03MAR2016/12:00	89.5	80 - 99	No
		Week 2	08MAR2016/10:10	89.5	80 - 99	No
		Week 4	23MAR2016/11:32	90.2	80 - 99	No
		Week 6	06APR2016/11:45	90.1	80 - 99	No
		Week 8	20APR2016/09:00	88.0	80 - 99	Yes
		Week 12	17MAY2016/11:55	90.6	80 - 99	No
		Week 16	16JUN2016/12:50	92.2	80 - 99	No
		Week 20	14JUL2016/11:50	90.9	80 - 99	No
		Week 24	10AUG2016/10:20	95.2	80 - 99	Yes
		Week 28	07SEP2016/09:45	97.6	80 - 99	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Ery. Mean Corpuscular Volume (fL)	Week 40	30NOV2016/09:50	89.0	80 - 99	No
		Week 44	28DEC2016/11:00	89.2	80 - 99	No
		Week 48	26JAN2017/12:45	89.9	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	02FEB2016/10:50	5.23	4.4 - 5.8	Yes
		Day 1	23FEB2016/13:40	5.15	4.4 - 5.8	Yes
		Week 1	03MAR2016/12:00	5.22	4.4 - 5.8	No
		Week 2	08MAR2016/10:10	5.15	4.4 - 5.8	No
		Week 4	23MAR2016/11:32	5.02	4.4 - 5.8	No
		Week 6	06APR2016/11:45	4.93	4.4 - 5.8	No
		Week 8	20APR2016/09:00	4.82	4.4 - 5.8	Yes
		Week 12	17MAY2016/11:55	4.68	4.4 - 5.8	No
		Week 16	16JUN2016/12:50	4.25 L	4.4 - 5.8	No
		Week 20	14JUL2016/11:50	4.18 L	4.4 - 5.8	No
		Week 24	10AUG2016/10:20	3.96 L	4.4 - 5.8	Yes
		Week 28	07SEP2016/09:45	4.21 L	4.4 - 5.8	No
		Week 40	30NOV2016/09:50	4.74	4.4 - 5.8	No
		Week 44	28DEC2016/11:00	4.62	4.4 - 5.8	No
		Week 48	26JAN2017/12:45	4.94	4.4 - 5.8	No
	Hematocrit (%)	Screening	02FEB2016/10:50	46.6	37 - 50	Yes
		Day 1	23FEB2016/13:40	46.2	37 - 50	Yes
		Week 1	03MAR2016/12:00	46.7	37 - 50	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Hematocrit (%)	Week 2	08MAR2016/10:10	46.1	37 - 50	No	
		Week 4	23MAR2016/11:32	45.3	37 - 50	No	
		Week 6	06APR2016/11:45	44.4	37 - 50	No	
		Week 8	20APR2016/09:00	42.4	37 - 50	Yes	
		Week 12	17MAY2016/11:55	42.4	37 - 50	No	
		Week 16	16JUN2016/12:50	39.2	37 - 50	No	
		Week 20	14JUL2016/11:50	38.0	37 - 50	No	
		Week 24	10AUG2016/10:20	37.7	37 - 50	Yes	
		Week 28	07SEP2016/09:45	41.1	37 - 50	No	
		Week 40	30NOV2016/09:50	42.2	37 - 50	No	
		Week 44	28DEC2016/11:00	41.2	37 - 50	No	
		Week 48	26JAN2017/12:45	44.4	37 - 50	No	
	Hemoglobin (g/L)	Screening	02FEB2016/10:50	164	130 - 170	Yes	0
		Day 1	23FEB2016/13:40	159	130 - 170	Yes	0
		Week 1	03MAR2016/12:00	164	130 - 170	No	0
		Week 2	08MAR2016/10:10	162	130 - 170	No	0
		Week 4	23MAR2016/11:32	157	130 - 170	No	0
		Week 6	06APR2016/11:45	154	130 - 170	No	0
		Week 8	20APR2016/09:00	151	130 - 170	Yes	0
		Week 12	17MAY2016/11:55	147	130 - 170	No	0
		Week 16	16JUN2016/12:50	134	130 - 170	No	0
		Week 20	14JUL2016/11:50	131	130 - 170	No	0
		Week 24	10AUG2016/10:20	125 L	130 - 170	Yes	1

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Hemoglobin (g/L)	Week 28	07SEP2016/09:45	133	130 - 170	No	0
		Week 40	30NOV2016/09:50	149	130 - 170	No	0
		Week 44	28DEC2016/11:00	141	130 - 170	No	0
		Week 48	26JAN2017/12:45	156	130 - 170	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	02FEB2016/10:50	5.81	3 - 10	Yes	0
		Day 1	23FEB2016/13:40	5.34	3 - 10	Yes	0
		Week 1	03MAR2016/12:00	5.48	3 - 10	No	0
		Week 2	08MAR2016/10:10	6.60	3 - 10	No	0
		Week 4	23MAR2016/11:32	5.12	3 - 10	No	0
		Week 6	06APR2016/11:45	5.70	3 - 10	No	0
		Week 8	20APR2016/09:00	6.09	3 - 10	Yes	0
		Week 12	17MAY2016/11:55	5.46	3 - 10	No	0
		Week 16	16JUN2016/12:50	4.72	3 - 10	No	0
		Week 20	14JUL2016/11:50	5.20	3 - 10	No	0
		Week 24	10AUG2016/10:20	4.16	3 - 10	Yes	0
		Week 28	07SEP2016/09:45	4.77	3 - 10	No	0
		Week 40	30NOV2016/09:50	5.06	3 - 10	No	0
		Week 44	28DEC2016/11:00	4.81	3 - 10	No	0
		Week 48	26JAN2017/12:45	6.53	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	02FEB2016/10:50	2.15	1.2 - 3.65	Yes	0
		Day 1	23FEB2016/13:40	1.80	1.2 - 3.65	Yes	0
		Week 1	03MAR2016/12:00	1.89	1.2 - 3.65	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Lymphocytes (10 <sup>9</sup> /L)	Week 2	08MAR2016/10:10	2.22	1.2 - 3.65	No	0
		Week 4	23MAR2016/11:32	1.97	1.2 - 3.65	No	0
		Week 6	06APR2016/11:45	2.34	1.2 - 3.65	No	0
		Week 8	20APR2016/09:00	2.01	1.2 - 3.65	Yes	0
		Week 12	17MAY2016/11:55	1.72	1.2 - 3.65	No	0
		Week 16	16JUN2016/12:50	1.18 L	1.2 - 3.65	No	1
		Week 20	14JUL2016/11:50	1.56	1.2 - 3.65	No	0
		Week 24	10AUG2016/10:20	1.25	1.2 - 3.65	Yes	0
		Week 28	07SEP2016/09:45	1.21	1.2 - 3.65	No	0
		Week 40	30NOV2016/09:50	1.32	1.2 - 3.65	No	0
		Week 44	28DEC2016/11:00	1.56	1.2 - 3.65	No	0
		Week 48	26JAN2017/12:45	1.69	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	02FEB2016/10:50	0.67	0.2 - 1	Yes	
		Day 1	23FEB2016/13:40	0.53	0.2 - 1	Yes	
		Week 1	03MAR2016/12:00	0.51	0.2 - 1	No	
		Week 2	08MAR2016/10:10	0.55	0.2 - 1	No	
		Week 4	23MAR2016/11:32	0.51	0.2 - 1	No	
		Week 6	06APR2016/11:45	0.63	0.2 - 1	No	
		Week 8	20APR2016/09:00	0.67	0.2 - 1	Yes	
		Week 12	17MAY2016/11:55	0.43	0.2 - 1	No	
		Week 16	16JUN2016/12:50	0.34	0.2 - 1	No	
		Week 20	14JUL2016/11:50	0.42	0.2 - 1	No	
		Week 24	10AUG2016/10:20	0.50	0.2 - 1	Yes	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Monocytes (10 <sup>9</sup> /L)	Week 28	07SEP2016/09:45	0.46	0.2 - 1	No	
		Week 40	30NOV2016/09:50	0.45	0.2 - 1	No	
		Week 44	28DEC2016/11:00	0.39	0.2 - 1	No	
		Week 48	26JAN2017/12:45	0.50	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	02FEB2016/10:50	0.00	0 - 0.38	Yes	4
		Day 1	23FEB2016/13:40	0.00	0 - 0.38	Yes	4
		Week 1	03MAR2016/12:00	0.00	0 - 0.38	No	4
		Week 2	08MAR2016/10:10	0.00	0 - 0.38	No	4
		Week 4	23MAR2016/11:32	0.00	0 - 0.38	No	4
		Week 6	06APR2016/11:45	0.34	0 - 0.38	No	4
		Week 8	20APR2016/09:00	0.00	0 - 0.38	Yes	4
		Week 12	17MAY2016/11:55	0.00	0 - 0.38	No	4
		Week 16	16JUN2016/12:50	0.00	0 - 0.38	No	4
		Week 20	14JUL2016/11:50	0.10	0 - 0.38	No	4
		Week 24	10AUG2016/10:20	0.12	0 - 0.38	Yes	4
		Week 28	07SEP2016/09:45	0.00	0 - 0.38	No	4
		Week 40	30NOV2016/09:50	0.00	0 - 0.38	No	4
		Week 44	28DEC2016/11:00	0.00	0 - 0.38	No	4
		Week 48	26JAN2017/12:45	0.00	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	02FEB2016/10:50	2.78	2 - 7.5	Yes	0
		Day 1	23FEB2016/13:40	2.81	2 - 7.5	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Neutrophils, Segmented (10 <sup>9</sup> /L)	Week 1	03MAR2016/12:00	2.92	2 - 7.5	No	0
		Week 2	08MAR2016/10:10	3.70	2 - 7.5	No	0
		Week 4	23MAR2016/11:32	2.52	2 - 7.5	No	0
		Week 6	06APR2016/11:45	2.34	2 - 7.5	No	0
		Week 8	20APR2016/09:00	3.36	2 - 7.5	Yes	0
		Week 12	17MAY2016/11:55	3.26	2 - 7.5	No	0
		Week 16	16JUN2016/12:50	3.15	2 - 7.5	No	0
		Week 20	14JUL2016/11:50	3.02	2 - 7.5	No	0
		Week 24	10AUG2016/10:20	2.25	2 - 7.5	Yes	0
		Week 28	07SEP2016/09:45	3.03	2 - 7.5	No	0
		Week 40	30NOV2016/09:50	3.12	2 - 7.5	No	0
		Week 44	28DEC2016/11:00	2.75	2 - 7.5	No	0
		Week 48	26JAN2017/12:45	4.22	2 - 7.5	No	0
	Platelets (10 <sup>9</sup> /L)	Screening	02FEB2016/10:50	190	150 - 400	Yes	0
		Day 1	23FEB2016/13:40	176	150 - 400	Yes	0
		Week 1	03MAR2016/12:00	212	150 - 400	No	0
		Week 2	08MAR2016/10:10	212	150 - 400	No	0
		Week 4	23MAR2016/11:32	186	150 - 400	No	0
		Week 6	06APR2016/11:45	178	150 - 400	No	0
		Week 8	20APR2016/09:00	181	150 - 400	Yes	0
		Week 12	17MAY2016/11:55	215	150 - 400	No	0
		Week 16	16JUN2016/12:50	173	150 - 400	No	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Platelets (10 <sup>9</sup> /L)	Week 20	14JUL2016/11:50	163	150 - 400	No	0
		Week 24	10AUG2016/10:20	174	150 - 400	Yes	0
		Week 28	07SEP2016/09:45	190	150 - 400	No	0
		Week 40	30NOV2016/09:50	178	150 - 400	No	0
		Week 44	28DEC2016/11:00	159	150 - 400	No	0
		Week 48	26JAN2017/12:45	200	150 - 400	No	0
301-018	Basophils (10 <sup>9</sup> /L)	Screening	17FEB2016/14:45	0.03	0 - 0.1	Yes	
		Day 1	09MAR2016/10:15	0.00	0 - 0.1	Yes	
		Week 1	16MAR2016/11:05	0.01	0 - 0.1	No	
		Week 2	23MAR2016/09:35	0.01	0 - 0.1	No	
		Week 4	06APR2016/10:10	0.15 H	0 - 0.1	No	
		Week 6	21APR2016/10:20	0.02	0 - 0.1	No	
		Week 8	28APR2016/09:45	0.01	0 - 0.1	No	
		Week 12	01JUN2016/08:40	0.02	0 - 0.1	Yes	
		Week 16	29JUN2016/09:45	0.03	0 - 0.1	No	
		Week 20	27JUL2016/09:50	0.01	0 - 0.1	No	
		Week 24	23AUG2016/10:00	0.01	0 - 0.1	Yes	
		Week 28	20SEP2016/11:30	0.01	0 - 0.1	No	
		Week 32	18OCT2016/11:00	0.01	0 - 0.1	No	
		Week 36	15NOV2016/12:00	0.01	0 - 0.1	No	
		Week 40	14DEC2016/12:00	0.01	0 - 0.1	No	
		Week 44	10JAN2017/11:30	0.01	0 - 0.1	No	
		Week 48	07FEB2017/10:30	0.01	0 - 0.1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Blood film	Screening	17FEB2016/14:45			Yes
		Day 1	09MAR2016/10:15			Yes
		Week 1	16MAR2016/11:05			No
		Week 2	23MAR2016/09:35			No
		Week 6	21APR2016/10:20			No
		Week 8	28APR2016/09:45			No
		Week 12	01JUN2016/08:40			Yes
		Week 16	29JUN2016/09:45			No
		Week 20	27JUL2016/09:50			No
		Week 24	23AUG2016/10:00			Yes
		Week 28	20SEP2016/11:30			No
		Week 32	18OCT2016/11:00			No
		Week 36	15NOV2016/12:00			No
		Week 40	14DEC2016/12:00			No
		Week 44	10JAN2017/11:30			No
		Week 48	07FEB2017/10:30			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	17FEB2016/14:45	0.07	0 - 0.4	Yes
		Day 1	09MAR2016/10:15	0.06	0 - 0.4	Yes
		Week 1	16MAR2016/11:05	0.07	0 - 0.4	No
		Week 2	23MAR2016/09:35	0.06	0 - 0.4	No
		Week 4	06APR2016/10:10	0.22	0 - 0.4	No
		Week 6	21APR2016/10:20	0.05	0 - 0.4	No
		Week 8	28APR2016/09:45	0.04	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Eosinophils (10 <sup>9</sup> /L)	Week 12	01JUN2016/08:40	0.07	0 - 0.4	Yes
		Week 16	29JUN2016/09:45	0.19	0 - 0.4	No
		Week 20	27JUL2016/09:50	0.12	0 - 0.4	No
		Week 24	23AUG2016/10:00	0.07	0 - 0.4	Yes
		Week 28	20SEP2016/11:30	0.07	0 - 0.4	No
		Week 32	18OCT2016/11:00	0.13	0 - 0.4	No
		Week 36	15NOV2016/12:00	0.10	0 - 0.4	No
		Week 40	14DEC2016/12:00	0.10	0 - 0.4	No
		Week 44	10JAN2017/11:30	0.08	0 - 0.4	No
		Week 48	07FEB2017/10:30	0.08	0 - 0.4	No
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	17FEB2016/14:45	356 H	300 - 350	Yes
		Day 1	09MAR2016/10:15	345	300 - 350	Yes
		Week 1	16MAR2016/11:05	349	300 - 350	No
		Week 2	23MAR2016/09:35	350	300 - 350	No
		Week 4	06APR2016/10:10	347	300 - 350	No
		Week 6	21APR2016/10:20	348	300 - 350	No
		Week 8	28APR2016/09:45	355 H	300 - 350	No
		Week 12	01JUN2016/08:40	333	300 - 350	Yes
		Week 16	29JUN2016/09:45	340	300 - 350	No
		Week 20	27JUL2016/09:50	325	300 - 350	No
		Week 24	23AUG2016/10:00	330	300 - 350	Yes
		Week 28	20SEP2016/11:30	350	300 - 350	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Ery. Mean Corpuscular HGB Concentration (g/L)	Week 32	18OCT2016/11:00	346	300 - 350	No
		Week 36	15NOV2016/12:00	348	300 - 350	No
		Week 40	14DEC2016/12:00	349	300 - 350	No
		Week 44	10JAN2017/11:30	358 H	300 - 350	No
		Week 48	07FEB2017/10:30	349	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	17FEB2016/14:45	31.2	26 - 33.5	Yes
		Day 1	09MAR2016/10:15	31.2	26 - 33.5	Yes
		Week 1	16MAR2016/11:05	31.1	26 - 33.5	No
		Week 2	23MAR2016/09:35	31.2	26 - 33.5	No
		Week 4	06APR2016/10:10	31.2	26 - 33.5	No
		Week 6	21APR2016/10:20	30.9	26 - 33.5	No
		Week 8	28APR2016/09:45	31.4	26 - 33.5	No
		Week 12	01JUN2016/08:40	32.1	26 - 33.5	Yes
		Week 16	29JUN2016/09:45	31.7	26 - 33.5	No
		Week 20	27JUL2016/09:50	30.6	26 - 33.5	No
		Week 24	23AUG2016/10:00	29.6	26 - 33.5	Yes
		Week 28	20SEP2016/11:30	31.3	26 - 33.5	No
		Week 32	18OCT2016/11:00	31.2	26 - 33.5	No
		Week 36	15NOV2016/12:00	31.2	26 - 33.5	No
		Week 40	14DEC2016/12:00	31.1	26 - 33.5	No
		Week 44	10JAN2017/11:30	31.9	26 - 33.5	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Ery. Mean Corpuscular Hemoglobin (pg)	Week 48	07FEB2017/10:30	31.1	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	17FEB2016/14:45	87.7	80 - 99	Yes
		Day 1	09MAR2016/10:15	90.3	80 - 99	Yes
		Week 1	16MAR2016/11:05	89.1	80 - 99	No
		Week 2	23MAR2016/09:35	89.1	80 - 99	No
		Week 4	06APR2016/10:10	89.8	80 - 99	No
		Week 6	21APR2016/10:20	88.7	80 - 99	No
		Week 8	28APR2016/09:45	88.3	80 - 99	No
		Week 12	01JUN2016/08:40	96.3	80 - 99	Yes
		Week 16	29JUN2016/09:45	93.3	80 - 99	No
		Week 20	27JUL2016/09:50	94.2	80 - 99	No
		Week 24	23AUG2016/10:00	89.7	80 - 99	Yes
		Week 28	20SEP2016/11:30	89.6	80 - 99	No
		Week 32	18OCT2016/11:00	90.2	80 - 99	No
		Week 36	15NOV2016/12:00	89.6	80 - 99	No
		Week 40	14DEC2016/12:00	89.1	80 - 99	No
		Week 44	10JAN2017/11:30	89.1	80 - 99	No
		Week 48	07FEB2017/10:30	89.0	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	17FEB2016/14:45	5.22	4.4 - 5.8	Yes
		Day 1	09MAR2016/10:15	5.07	4.4 - 5.8	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018 Erythrocytes (10 <sup>12</sup> /L)	Week 1	16MAR2016/11:05	5.12	4.4 - 5.8	No
	Week 2	23MAR2016/09:35	4.97	4.4 - 5.8	No
	Week 4	06APR2016/10:10	4.91	4.4 - 5.8	No
	Week 6	21APR2016/10:20	4.79	4.4 - 5.8	No
	Week 8	28APR2016/09:45	4.72	4.4 - 5.8	No
	Week 12	01JUN2016/08:40	4.27 L	4.4 - 5.8	Yes
	Week 16	29JUN2016/09:45	4.79	4.4 - 5.8	No
	Week 20	27JUL2016/09:50	4.83	4.4 - 5.8	No
	Week 24	23AUG2016/10:00	5.03	4.4 - 5.8	Yes
	Week 28	20SEP2016/11:30	5.17	4.4 - 5.8	No
	Week 32	18OCT2016/11:00	4.90	4.4 - 5.8	No
	Week 36	15NOV2016/12:00	5.29	4.4 - 5.8	No
	Week 40	14DEC2016/12:00	5.24	4.4 - 5.8	No
	Week 44	10JAN2017/11:30	5.23	4.4 - 5.8	No
	Week 48	07FEB2017/10:30	5.11	4.4 - 5.8	No
Hematocrit (%)	Screening	17FEB2016/14:45	45.8	37 - 50	Yes
	Day 1	09MAR2016/10:15	45.8	37 - 50	Yes
	Week 1	16MAR2016/11:05	45.6	37 - 50	No
	Week 2	23MAR2016/09:35	44.3	37 - 50	No
	Week 4	06APR2016/10:10	44.1	37 - 50	No
	Week 6	21APR2016/10:20	42.5	37 - 50	No
	Week 8	28APR2016/09:45	41.7	37 - 50	No
	Week 12	01JUN2016/08:40	41.1	37 - 50	Yes

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Hematocrit (%)	Week 16	29JUN2016/09:45	44.7	37 - 50	No	
		Week 20	27JUL2016/09:50	45.5	37 - 50	No	
		Week 24	23AUG2016/10:00	45.1	37 - 50	Yes	
		Week 28	20SEP2016/11:30	46.3	37 - 50	No	
		Week 32	18OCT2016/11:00	44.2	37 - 50	No	
		Week 36	15NOV2016/12:00	47.4	37 - 50	No	
		Week 40	14DEC2016/12:00	46.7	37 - 50	No	
		Week 44	10JAN2017/11:30	46.6	37 - 50	No	
		Week 48	07FEB2017/10:30	45.5	37 - 50	No	
	Hemoglobin (g/L)	Screening	17FEB2016/14:45	163	130 - 170	Yes	0
		Day 1	09MAR2016/10:15	158	130 - 170	Yes	0
		Week 1	16MAR2016/11:05	159	130 - 170	No	0
		Week 2	23MAR2016/09:35	155	130 - 170	No	0
		Week 4	06APR2016/10:10	153	130 - 170	No	0
		Week 6	21APR2016/10:20	148	130 - 170	No	0
		Week 8	28APR2016/09:45	148	130 - 170	No	0
		Week 12	01JUN2016/08:40	137	130 - 170	Yes	0
		Week 16	29JUN2016/09:45	152	130 - 170	No	0
		Week 20	27JUL2016/09:50	148	130 - 170	No	0
		Week 24	23AUG2016/10:00	149	130 - 170	Yes	0
		Week 28	20SEP2016/11:30	162	130 - 170	No	0
		Week 32	18OCT2016/11:00	153	130 - 170	No	0
		Week 36	15NOV2016/12:00	165	130 - 170	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Hemoglobin (g/L)	Week 40	14DEC2016/12:00	163	130 - 170	No	0
		Week 44	10JAN2017/11:30	167	130 - 170	No	0
		Week 48	07FEB2017/10:30	159	130 - 170	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	17FEB2016/14:45	6.76	3 - 10	Yes	0
		Day 1	09MAR2016/10:15	6.01	3 - 10	Yes	0
		Week 1	16MAR2016/11:05	7.63	3 - 10	No	0
		Week 2	23MAR2016/09:35	8.62	3 - 10	No	0
		Week 4	06APR2016/10:10	7.28	3 - 10	No	0
		Week 6	21APR2016/10:20	7.58	3 - 10	No	0
		Week 8	28APR2016/09:45	8.44	3 - 10	No	0
		Week 12	01JUN2016/08:40	3.83	3 - 10	Yes	0
		Week 16	29JUN2016/09:45	6.63	3 - 10	No	0
		Week 20	27JUL2016/09:50	6.30	3 - 10	No	0
		Week 24	23AUG2016/10:00	6.02	3 - 10	Yes	0
		Week 28	20SEP2016/11:30	5.51	3 - 10	No	0
		Week 32	18OCT2016/11:00	5.72	3 - 10	No	0
		Week 36	15NOV2016/12:00	5.87	3 - 10	No	0
		Week 40	14DEC2016/12:00	8.26	3 - 10	No	0
		Week 44	10JAN2017/11:30	6.72	3 - 10	No	0
		Week 48	07FEB2017/10:30	5.94	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	17FEB2016/14:45	1.59	1.2 - 3.65	Yes	0
		Day 1	09MAR2016/10:15	2.10	1.2 - 3.65	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Lymphocytes (10 <sup>9</sup> /L)	Week 1	16MAR2016/11:05	1.46	1.2 - 3.65	No	0
		Week 2	23MAR2016/09:35	1.63	1.2 - 3.65	No	0
		Week 4	06APR2016/10:10	2.26	1.2 - 3.65	No	0
		Week 6	21APR2016/10:20	1.77	1.2 - 3.65	No	0
		Week 8	28APR2016/09:45	1.82	1.2 - 3.65	No	0
		Week 12	01JUN2016/08:40	0.91 L	1.2 - 3.65	Yes	1
		Week 16	29JUN2016/09:45	1.46	1.2 - 3.65	No	0
		Week 20	27JUL2016/09:50	1.38	1.2 - 3.65	No	0
		Week 24	23AUG2016/10:00	1.19 L	1.2 - 3.65	Yes	1
		Week 28	20SEP2016/11:30	0.99 L	1.2 - 3.65	No	1
		Week 32	18OCT2016/11:00	1.18 L	1.2 - 3.65	No	1
		Week 36	15NOV2016/12:00	1.24	1.2 - 3.65	No	0
		Week 40	14DEC2016/12:00	1.64	1.2 - 3.65	No	0
		Week 44	10JAN2017/11:30	1.29	1.2 - 3.65	No	0
		Week 48	07FEB2017/10:30	1.52	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	17FEB2016/14:45	0.57	0.2 - 1	Yes	
		Day 1	09MAR2016/10:15	0.66	0.2 - 1	Yes	
		Week 1	16MAR2016/11:05	0.66	0.2 - 1	No	
		Week 2	23MAR2016/09:35	0.66	0.2 - 1	No	
		Week 4	06APR2016/10:10	0.58	0.2 - 1	No	
		Week 6	21APR2016/10:20	0.50	0.2 - 1	No	
		Week 8	28APR2016/09:45	0.64	0.2 - 1	No	
		Week 12	01JUN2016/08:40	0.31	0.2 - 1	Yes	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Monocytes (10 <sup>9</sup> /L)	Week 16	29JUN2016/09:45	0.44	0.2 - 1	No	
		Week 20	27JUL2016/09:50	0.51	0.2 - 1	No	
		Week 24	23AUG2016/10:00	0.53	0.2 - 1	Yes	
		Week 28	20SEP2016/11:30	0.60	0.2 - 1	No	
		Week 32	18OCT2016/11:00	0.66	0.2 - 1	No	
		Week 36	15NOV2016/12:00	0.50	0.2 - 1	No	
		Week 40	14DEC2016/12:00	0.63	0.2 - 1	No	
		Week 44	10JAN2017/11:30	0.59	0.2 - 1	No	
		Week 48	07FEB2017/10:30	0.52	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	17FEB2016/14:45	0.00	0 - 0.38	Yes	4
		Day 1	09MAR2016/10:15	0.54 H	0 - 0.38	Yes	3
		Week 1	16MAR2016/11:05	0.00	0 - 0.38	No	4
		Week 2	23MAR2016/09:35	0.00	0 - 0.38	No	4
		Week 4	06APR2016/10:10	0.58 H	0 - 0.38	No	3
		Week 6	21APR2016/10:20	0.08	0 - 0.38	No	4
		Week 8	28APR2016/09:45	0.00	0 - 0.38	No	4
		Week 12	01JUN2016/08:40	0.00	0 - 0.38	Yes	4
		Week 16	29JUN2016/09:45	0.00	0 - 0.38	No	4
		Week 20	27JUL2016/09:50	0.00	0 - 0.38	No	4
		Week 24	23AUG2016/10:00	0.00	0 - 0.38	Yes	4
		Week 28	20SEP2016/11:30	0.00	0 - 0.38	No	4
		Week 32	18OCT2016/11:00	0.17	0 - 0.38	No	4
		Week 36	15NOV2016/12:00	0.29	0 - 0.38	No	4

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Neutrophils Band Form (10 <sup>9</sup> /L)	Week 40	14DEC2016/12:00	0.00	0 - 0.38	No	4
		Week 44	10JAN2017/11:30	0.00	0 - 0.38	No	4
		Week 48	07FEB2017/10:30	0.77 H	0 - 0.38	No	3
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	17FEB2016/14:45	4.51	2 - 7.5	Yes	0
		Day 1	09MAR2016/10:15	2.64	2 - 7.5	Yes	0
		Week 1	16MAR2016/11:05	5.43	2 - 7.5	No	0
		Week 2	23MAR2016/09:35	6.26	2 - 7.5	No	0
		Week 4	06APR2016/10:10	3.49	2 - 7.5	No	0
		Week 6	21APR2016/10:20	5.15	2 - 7.5	No	0
		Week 8	28APR2016/09:45	5.92	2 - 7.5	No	0
		Week 12	01JUN2016/08:40	2.52	2 - 7.5	Yes	0
		Week 16	29JUN2016/09:45	4.51	2 - 7.5	No	0
		Week 20	27JUL2016/09:50	4.28	2 - 7.5	No	0
		Week 24	23AUG2016/10:00	4.21	2 - 7.5	Yes	0
		Week 28	20SEP2016/11:30	3.83	2 - 7.5	No	0
		Week 32	18OCT2016/11:00	3.57	2 - 7.5	No	0
		Week 36	15NOV2016/12:00	3.74	2 - 7.5	No	0
		Week 40	14DEC2016/12:00	5.88	2 - 7.5	No	0
		Week 44	10JAN2017/11:30	4.75	2 - 7.5	No	0
		Week 48	07FEB2017/10:30	3.03	2 - 7.5	No	0
	Platelets (10 <sup>9</sup> /L)	Screening	17FEB2016/14:45	140 L	150 - 400	Yes	1

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Platelets (10 <sup>9</sup> /L)	Day 1	09MAR2016/10:15	122 L	150 - 400	Yes	1
		Week 1	16MAR2016/11:05	131 L	150 - 400	No	1
		Week 2	23MAR2016/09:35	139 L	150 - 400	No	1
		Week 4	06APR2016/10:10	135 L	150 - 400	No	1
		Week 6	21APR2016/10:20	117 L	150 - 400	No	1
		Week 8	28APR2016/09:45		150 - 400	No	
		Week 12	01JUN2016/08:40	168	150 - 400	Yes	0
		Week 16	29JUN2016/09:45	99 L	150 - 400	No	1
		Week 20	27JUL2016/09:50	107 L	150 - 400	No	1
		Week 24	23AUG2016/10:00	114 L	150 - 400	Yes	1
		Week 28	20SEP2016/11:30	136 L	150 - 400	No	1
		Week 32	18OCT2016/11:00	130 L	150 - 400	No	1
		Week 36	15NOV2016/12:00	130 L	150 - 400	No	1
		Week 40	14DEC2016/12:00	127 L	150 - 400	No	1
		Week 44	10JAN2017/11:30	138 L	150 - 400	No	1
		Week 48	07FEB2017/10:30	113 L	150 - 400	No	1

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Basophils (10 <sup>9</sup> /L)	Screening	14JAN2016/13:30	0.01	0 - 0.1	Yes
		Day 1	04FEB2016/09:45	0.02	0 - 0.1	Yes
		Week 1	10FEB2016/13:00	0.01	0 - 0.1	No
		Week 2	16FEB2016/14:00	0.01	0 - 0.1	No
		Week 4	03MAR2016/12:15	0.02	0 - 0.1	No
		Week 6	17MAR2016/11:31	0.00	0 - 0.1	No
		Week 8	31MAR2016/11:22	0.05	0 - 0.1	No
		Week 12	26APR2016/08:15	0.03	0 - 0.1	Yes
		Week 16	25MAY2016/11:55	0.00	0 - 0.1	No
		Week 20	23JUN2016/12:45	0.01	0 - 0.1	No
		Week 24	19JUL2016/12:00	0.06	0 - 0.1	Yes
		Week 28	18AUG2016/12:15	0.00	0 - 0.1	No
		Week 32	13SEP2016/11:45	0.03	0 - 0.1	No
		Week 36	13OCT2016/12:10	0.01	0 - 0.1	No
		Week 40	08NOV2016/11:00	0.01	0 - 0.1	No
		Week 44	08DEC2016/11:00	0.01	0 - 0.1	No
		Week 48	03JAN2017/12:00	0.01	0 - 0.1	No
	Blood film	Screening	14JAN2016/13:30			Yes
		Day 1	04FEB2016/09:45			Yes
		Week 1	10FEB2016/13:00			No
		Week 2	16FEB2016/14:00			No
		Week 4	03MAR2016/12:15			No
		Week 8	31MAR2016/11:22			No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Blood film	Week 12	26APR2016/08:15			Yes
		Week 20	23JUN2016/12:45			No
		Week 24	19JUL2016/12:00			Yes
		Week 28	18AUG2016/12:15			No
		Week 32	13SEP2016/11:45			No
		Week 36	13OCT2016/12:10			No
		Week 40	08NOV2016/11:00			No
		Week 44	08DEC2016/11:00			No
		Week 48	03JAN2017/12:00			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	14JAN2016/13:30	0.08	0 - 0.4	Yes
		Day 1	04FEB2016/09:45	0.07	0 - 0.4	Yes
		Week 1	10FEB2016/13:00	0.06	0 - 0.4	No
		Week 2	16FEB2016/14:00	0.07	0 - 0.4	No
		Week 4	03MAR2016/12:15	0.07	0 - 0.4	No
		Week 6	17MAR2016/11:31	0.25	0 - 0.4	No
		Week 8	31MAR2016/11:22	0.05	0 - 0.4	No
		Week 12	26APR2016/08:15	0.02	0 - 0.4	Yes
		Week 16	25MAY2016/11:55	0.25	0 - 0.4	No
		Week 20	23JUN2016/12:45	0.08	0 - 0.4	No
		Week 24	19JUL2016/12:00	0.06	0 - 0.4	Yes
		Week 28	18AUG2016/12:15	0.04	0 - 0.4	No
		Week 32	13SEP2016/11:45	0.08	0 - 0.4	No
		Week 36	13OCT2016/12:10	0.07	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Eosinophils (10 <sup>9</sup> /L)	Week 40	08NOV2016/11:00	0.06	0 - 0.4	No
		Week 44	08DEC2016/11:00	0.14	0 - 0.4	No
		Week 48	03JAN2017/12:00	0.15	0 - 0.4	No
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	14JAN2016/13:30	349	300 - 350	Yes
		Day 1	04FEB2016/09:45	354 H	300 - 350	Yes
		Week 1	10FEB2016/13:00	339	300 - 350	No
		Week 2	16FEB2016/14:00	349	300 - 350	No
		Week 4	03MAR2016/12:15	346	300 - 350	No
		Week 6	17MAR2016/11:31	352 H	300 - 350	No
		Week 8	31MAR2016/11:22	348	300 - 350	No
		Week 12	26APR2016/08:15	349	300 - 350	Yes
		Week 16	25MAY2016/11:55	359 H	300 - 350	No
		Week 20	23JUN2016/12:45	312	300 - 350	No
		Week 24	19JUL2016/12:00	340	300 - 350	Yes
		Week 28	18AUG2016/12:15	344	300 - 350	No
		Week 32	13SEP2016/11:45	326	300 - 350	No
		Week 36	13OCT2016/12:10	346	300 - 350	No
		Week 40	08NOV2016/11:00	352 H	300 - 350	No
		Week 44	08DEC2016/11:00	338	300 - 350	No
		Week 48	03JAN2017/12:00	343	300 - 350	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	14JAN2016/13:30	31.4	26 - 33.5	Yes
		Day 1	04FEB2016/09:45	31.5	26 - 33.5	Yes
		Week 1	10FEB2016/13:00	31.0	26 - 33.5	No
		Week 2	16FEB2016/14:00	31.1	26 - 33.5	No
		Week 4	03MAR2016/12:15	30.3	26 - 33.5	No
		Week 6	17MAR2016/11:31	30.8	26 - 33.5	No
		Week 8	31MAR2016/11:22	30.8	26 - 33.5	No
		Week 12	26APR2016/08:15	31.1	26 - 33.5	Yes
		Week 16	25MAY2016/11:55	32.0	26 - 33.5	No
		Week 20	23JUN2016/12:45	32.0	26 - 33.5	No
		Week 24	19JUL2016/12:00	31.4	26 - 33.5	Yes
		Week 28	18AUG2016/12:15	31.2	26 - 33.5	No
		Week 32	13SEP2016/11:45	30.6	26 - 33.5	No
		Week 36	13OCT2016/12:10	31.1	26 - 33.5	No
		Week 40	08NOV2016/11:00	30.7	26 - 33.5	No
		Week 44	08DEC2016/11:00	30.9	26 - 33.5	No
		Week 48	03JAN2017/12:00	31.0	26 - 33.5	No
	Ery. Mean Corpuscular Volume (fL)	Screening	14JAN2016/13:30	89.8	80 - 99	Yes
		Day 1	04FEB2016/09:45	88.8	80 - 99	Yes
		Week 1	10FEB2016/13:00	91.6	80 - 99	No
		Week 2	16FEB2016/14:00	89.1	80 - 99	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Ery. Mean Corpuscular Volume (fL)	Week 4	03MAR2016/12:15	87.6	80 - 99	No
		Week 6	17MAR2016/11:31	87.5	80 - 99	No
		Week 8	31MAR2016/11:22	88.6	80 - 99	No
		Week 12	26APR2016/08:15	89.0	80 - 99	Yes
		Week 16	25MAY2016/11:55	89.1	80 - 99	No
		Week 20	23JUN2016/12:45	102.5 H	80 - 99	No
		Week 24	19JUL2016/12:00	92.3	80 - 99	Yes
		Week 28	18AUG2016/12:15	90.7	80 - 99	No
		Week 32	13SEP2016/11:45	93.8	80 - 99	No
		Week 36	13OCT2016/12:10	89.9	80 - 99	No
		Week 40	08NOV2016/11:00	87.3	80 - 99	No
		Week 44	08DEC2016/11:00	91.5	80 - 99	No
		Week 48	03JAN2017/12:00	90.4	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	14JAN2016/13:30	5.29	4.4 - 5.8	Yes
		Day 1	04FEB2016/09:45	5.34	4.4 - 5.8	Yes
		Week 1	10FEB2016/13:00	5.22	4.4 - 5.8	No
		Week 2	16FEB2016/14:00	5.12	4.4 - 5.8	No
		Week 4	03MAR2016/12:15	5.01	4.4 - 5.8	No
		Week 6	17MAR2016/11:31	5.10	4.4 - 5.8	No
		Week 8	31MAR2016/11:22	4.74	4.4 - 5.8	No
		Week 12	26APR2016/08:15	4.47	4.4 - 5.8	Yes
		Week 16	25MAY2016/11:55	4.69	4.4 - 5.8	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006 Erythrocytes (10 <sup>12</sup> /L)	Week 20	23JUN2016/12:45	4.85	4.4 - 5.8	No
	Week 24	19JUL2016/12:00	4.91	4.4 - 5.8	Yes
	Week 28	18AUG2016/12:15	4.97	4.4 - 5.8	No
	Week 32	13SEP2016/11:45	5.04	4.4 - 5.8	No
	Week 36	13OCT2016/12:10	5.17	4.4 - 5.8	No
	Week 40	08NOV2016/11:00	5.34	4.4 - 5.8	No
	Week 44	08DEC2016/11:00	5.08	4.4 - 5.8	No
	Week 48	03JAN2017/12:00	5.09	4.4 - 5.8	No
Hematocrit (%)	Screening	14JAN2016/13:30	47.5	37 - 50	Yes
	Day 1	04FEB2016/09:45	47.4	37 - 50	Yes
	Week 1	10FEB2016/13:00	47.8	37 - 50	No
	Week 2	16FEB2016/14:00	45.6	37 - 50	No
	Week 4	03MAR2016/12:15	43.9	37 - 50	No
	Week 6	17MAR2016/11:31	44.6	37 - 50	No
	Week 8	31MAR2016/11:22	42.0	37 - 50	No
	Week 12	26APR2016/08:15	39.8	37 - 50	Yes
	Week 16	25MAY2016/11:55	41.8	37 - 50	No
	Week 20	23JUN2016/12:45	49.7	37 - 50	No
	Week 24	19JUL2016/12:00	45.3	37 - 50	Yes
	Week 28	18AUG2016/12:15	45.1	37 - 50	No
	Week 32	13SEP2016/11:45	47.3	37 - 50	No
	Week 36	13OCT2016/12:10	46.5	37 - 50	No
	Week 40	08NOV2016/11:00	46.6	37 - 50	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Hematocrit (%)	Week 44	08DEC2016/11:00	46.5	37 - 50	No	
		Week 48	03JAN2017/12:00	46.0	37 - 50	No	
	Hemoglobin (g/L)	Screening	14JAN2016/13:30	166	130 - 170	Yes	0
		Day 1	04FEB2016/09:45	168	130 - 170	Yes	0
		Week 1	10FEB2016/13:00	162	130 - 170	No	0
		Week 2	16FEB2016/14:00	159	130 - 170	No	0
		Week 4	03MAR2016/12:15	152	130 - 170	No	0
		Week 6	17MAR2016/11:31	157	130 - 170	No	0
		Week 8	31MAR2016/11:22	146	130 - 170	No	0
		Week 12	26APR2016/08:15	139	130 - 170	Yes	0
		Week 16	25MAY2016/11:55	150	130 - 170	No	0
		Week 20	23JUN2016/12:45	155	130 - 170	No	0
		Week 24	19JUL2016/12:00	154	130 - 170	Yes	0
		Week 28	18AUG2016/12:15	155	130 - 170	No	0
		Week 32	13SEP2016/11:45	154	130 - 170	No	0
		Week 36	13OCT2016/12:10	161	130 - 170	No	0
		Week 40	08NOV2016/11:00	164	130 - 170	No	0
		Week 44	08DEC2016/11:00	157	130 - 170	No	0
		Week 48	03JAN2017/12:00	158	130 - 170	No	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	14JAN2016/13:30	5.78	3 - 10	Yes	0
		Day 1	04FEB2016/09:45	5.47	3 - 10	Yes	0
		Week 1	10FEB2016/13:00	6.25	3 - 10	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Leukocytes (10 <sup>9</sup> /L)	Week 2	16FEB2016/14:00	5.99	3 - 10	No	0
		Week 4	03MAR2016/12:15	6.42	3 - 10	No	0
		Week 6	17MAR2016/11:31	5.01	3 - 10	No	0
		Week 8	31MAR2016/11:22	4.98	3 - 10	No	0
		Week 12	26APR2016/08:15	2.76 L	3 - 10	Yes	2
		Week 16	25MAY2016/11:55	4.99	3 - 10	No	0
		Week 20	23JUN2016/12:45	6.05	3 - 10	No	0
		Week 24	19JUL2016/12:00	5.70	3 - 10	Yes	0
		Week 28	18AUG2016/12:15	4.15	3 - 10	No	0
		Week 32	13SEP2016/11:45	4.85	3 - 10	No	0
		Week 36	13OCT2016/12:10	5.73	3 - 10	No	0
		Week 40	08NOV2016/11:00	5.46	3 - 10	No	0
		Week 44	08DEC2016/11:00	6.85	3 - 10	No	0
		Week 48	03JAN2017/12:00	5.42	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	14JAN2016/13:30	2.57	1.2 - 3.65	Yes	0
		Day 1	04FEB2016/09:45	1.94	1.2 - 3.65	Yes	0
		Week 1	10FEB2016/13:00	1.95	1.2 - 3.65	No	0
		Week 2	16FEB2016/14:00	2.18	1.2 - 3.65	No	0
		Week 4	03MAR2016/12:15	2.16	1.2 - 3.65	No	0
		Week 6	17MAR2016/11:31	2.25	1.2 - 3.65	No	0
		Week 8	31MAR2016/11:22	1.94	1.2 - 3.65	No	0
		Week 12	26APR2016/08:15	1.41	1.2 - 3.65	Yes	0
		Week 16	25MAY2016/11:55	2.79	1.2 - 3.65	No	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Lymphocytes (10 <sup>9</sup> /L)	Week 20	23JUN2016/12:45	1.84	1.2 - 3.65	No	0
		Week 24	19JUL2016/12:00	1.60	1.2 - 3.65	Yes	0
		Week 28	18AUG2016/12:15	1.70	1.2 - 3.65	No	0
		Week 32	13SEP2016/11:45	2.53	1.2 - 3.65	No	0
		Week 36	13OCT2016/12:10	2.54	1.2 - 3.65	No	0
		Week 40	08NOV2016/11:00	2.30	1.2 - 3.65	No	0
		Week 44	08DEC2016/11:00	1.89	1.2 - 3.65	No	0
		Week 48	03JAN2017/12:00	2.40	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	14JAN2016/13:30	0.53	0.2 - 1	Yes	
		Day 1	04FEB2016/09:45	0.62	0.2 - 1	Yes	
		Week 1	10FEB2016/13:00	0.66	0.2 - 1	No	
		Week 2	16FEB2016/14:00	0.38	0.2 - 1	No	
		Week 4	03MAR2016/12:15	0.53	0.2 - 1	No	
		Week 6	17MAR2016/11:31	0.25	0.2 - 1	No	
		Week 8	31MAR2016/11:22	0.30	0.2 - 1	No	
		Week 12	26APR2016/08:15	0.15 L	0.2 - 1	Yes	
		Week 16	25MAY2016/11:55	0.30	0.2 - 1	No	
		Week 20	23JUN2016/12:45	0.32	0.2 - 1	No	
		Week 24	19JUL2016/12:00	0.51	0.2 - 1	Yes	
		Week 28	18AUG2016/12:15	0.42	0.2 - 1	No	
		Week 32	13SEP2016/11:45	0.31	0.2 - 1	No	
		Week 36	13OCT2016/12:10	0.43	0.2 - 1	No	
		Week 40	08NOV2016/11:00	0.41	0.2 - 1	No	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Monocytes (10 <sup>9</sup> /L)	Week 44	08DEC2016/11:00	0.54	0.2 - 1	No	
		Week 48	03JAN2017/12:00	0.51	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	14JAN2016/13:30	0.06	0 - 0.38	Yes	4
		Day 1	04FEB2016/09:45	0.00	0 - 0.38	Yes	4
		Week 1	10FEB2016/13:00	0.00	0 - 0.38	No	4
		Week 2	16FEB2016/14:00	0.00	0 - 0.38	No	4
		Week 4	03MAR2016/12:15	0.00	0 - 0.38	No	4
		Week 6	17MAR2016/11:31	0.55 H	0 - 0.38	No	3
		Week 8	31MAR2016/11:22	0.05	0 - 0.38	No	4
		Week 12	26APR2016/08:15	0.00	0 - 0.38	Yes	4
		Week 16	25MAY2016/11:55	0.35	0 - 0.38	No	4
		Week 20	23JUN2016/12:45	0.00	0 - 0.38	No	4
		Week 24	19JUL2016/12:00	0.06	0 - 0.38	Yes	4
		Week 28	18AUG2016/12:15	0.37	0 - 0.38	No	4
		Week 32	13SEP2016/11:45		0 - 0.38	No	
		Week 36	13OCT2016/12:10	0.34	0 - 0.38	No	4
		Week 40	08NOV2016/11:00	0.00	0 - 0.38	No	4
		Week 44	08DEC2016/11:00	0.00	0 - 0.38	No	4
		Week 48	03JAN2017/12:00	0.22	0 - 0.38	No	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	14JAN2016/13:30	2.49	2 - 7.5	Yes	0
		Day 1	04FEB2016/09:45	2.82	2 - 7.5	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Neutrophils, Segmented (10 <sup>9</sup> /L)	Week 1	10FEB2016/13:00	3.56	2 - 7.5	No	0
		Week 2	16FEB2016/14:00	3.35	2 - 7.5	No	0
		Week 4	03MAR2016/12:15	3.64	2 - 7.5	No	0
		Week 6	17MAR2016/11:31	1.70 L	2 - 7.5	No	1
		Week 8	31MAR2016/11:22	2.59	2 - 7.5	No	0
		Week 12	26APR2016/08:15	1.15 L	2 - 7.5	Yes	2
		Week 16	25MAY2016/11:55	1.30 L	2 - 7.5	No	2
		Week 20	23JUN2016/12:45	3.80	2 - 7.5	No	0
		Week 24	19JUL2016/12:00	3.42	2 - 7.5	Yes	0
		Week 28	18AUG2016/12:15	1.62 L	2 - 7.5	No	1
		Week 32	13SEP2016/11:45		2 - 7.5	No	
		Week 36	13OCT2016/12:10	2.34	2 - 7.5	No	0
		Week 40	08NOV2016/11:00	2.68	2 - 7.5	No	0
		Week 44	08DEC2016/11:00	4.27	2 - 7.5	No	0
		Week 48	03JAN2017/12:00	2.13	2 - 7.5	No	0
	Platelets (10 <sup>9</sup> /L)	Screening	14JAN2016/13:30	106 L	150 - 400	Yes	1
		Day 1	04FEB2016/09:45	85 L	150 - 400	Yes	1
		Week 1	10FEB2016/13:00	100 L	150 - 400	No	1
		Week 2	16FEB2016/14:00	118 L	150 - 400	No	1
		Week 4	03MAR2016/12:15	105 L	150 - 400	No	1
		Week 6	17MAR2016/11:31	119 L	150 - 400	No	1
		Week 8	31MAR2016/11:22	103 L	150 - 400	No	1

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Platelets (10 <sup>9</sup> /L)	Week 12	26APR2016/08:15		150 - 400	Yes	
		Week 16	25MAY2016/11:55	145 L	150 - 400	No	1
		Week 20	23JUN2016/12:45	126 L	150 - 400	No	1
		Week 24	19JUL2016/12:00		150 - 400	Yes	
		Week 28	18AUG2016/12:15	105 L	150 - 400	No	1
		Week 32	13SEP2016/11:45	84 L	150 - 400	No	1
		Week 36	13OCT2016/12:10	121 L	150 - 400	No	1
		Week 40	08NOV2016/11:00	94 L	150 - 400	No	1
		Week 44	08DEC2016/11:00	119 L	150 - 400	No	1
		Week 48	03JAN2017/12:00	100 L	150 - 400	No	1

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017 Basophils (10 <sup>9</sup> /L)	Screening	17FEB2016/13:00	0.04	0 - 0.1	Yes
	Day 1	08MAR2016/10:50	0.03	0 - 0.1	No
	Week 1	15MAR2016/09:25	0.05	0 - 0.1	No
	Week 2	23MAR2016/09:08	0.02	0 - 0.1	No
	Week 4	05APR2016/10:15	0.00	0 - 0.1	No
	Week 6	19APR2016/09:45	0.00	0 - 0.1	No
	Week 8	28APR2016/10:10	0.01	0 - 0.1	No
	Week 12	01JUN2016/08:30	0.02	0 - 0.1	Yes
	Week 16	29JUN2016/09:23	0.00	0 - 0.1	No
	Week 20	26JUL2016/09:45	0.02	0 - 0.1	No
	Week 24	24AUG2016/09:30	0.02	0 - 0.1	Yes
	Week 28	20SEP2016/12:00	0.03	0 - 0.1	No
	Week 32	19OCT2016/11:00	0.02	0 - 0.1	No
	Week 36	15NOV2016/11:15	0.02	0 - 0.1	No
	Week 40	14DEC2016/09:30	0.03	0 - 0.1	No
	Week 44	11JAN2017/11:00	0.02	0 - 0.1	No
	Week 48	08FEB2017/11:50	0.03	0 - 0.1	No
Blood film	Screening	17FEB2016/13:00			Yes
	Day 1	08MAR2016/10:50			No
	Week 2	23MAR2016/09:08			No
	Week 4	05APR2016/10:15			No
	Week 6	19APR2016/09:45			No
	Week 8	28APR2016/10:10			No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Blood film	Week 12	01JUN2016/08:30			Yes
		Week 16	29JUN2016/09:23			No
		Week 20	26JUL2016/09:45			No
		Week 24	24AUG2016/09:30			Yes
		Week 28	20SEP2016/12:00			No
		Week 32	19OCT2016/11:00			No
		Week 36	15NOV2016/11:15			No
		Week 40	14DEC2016/09:30			No
		Week 44	11JAN2017/11:00			No
		Week 48	08FEB2017/11:50			No
	Blood film (reflex)	Week 16	29JUN2016/09:23			No
		Week 36	15NOV2016/11:15			No
	Eosinophils (10 <sup>9</sup> /L)	Screening	17FEB2016/13:00	0.24	0 - 0.4	Yes
		Day 1	08MAR2016/10:50	0.12	0 - 0.4	No
		Week 1	15MAR2016/09:25	0.14	0 - 0.4	No
		Week 2	23MAR2016/09:08	0.05	0 - 0.4	No
		Week 4	05APR2016/10:15	0.03	0 - 0.4	No
		Week 6	19APR2016/09:45	0.00	0 - 0.4	No
		Week 8	28APR2016/10:10	0.02	0 - 0.4	No
		Week 12	01JUN2016/08:30	0.18	0 - 0.4	Yes
		Week 16	29JUN2016/09:23	0.04	0 - 0.4	No
		Week 20	26JUL2016/09:45	0.09	0 - 0.4	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Eosinophils (10 <sup>9</sup> /L)	Week 24	24AUG2016/09:30	0.11	0 - 0.4	Yes
		Week 28	20SEP2016/12:00	0.08	0 - 0.4	No
		Week 32	19OCT2016/11:00	0.13	0 - 0.4	No
		Week 36	15NOV2016/11:15	0.12	0 - 0.4	No
		Week 40	14DEC2016/09:30	0.15	0 - 0.4	No
		Week 44	11JAN2017/11:00	0.18	0 - 0.4	No
		Week 48	08FEB2017/11:50	0.21	0 - 0.4	No
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	17FEB2016/13:00	352 H	300 - 350	Yes
		Day 1	08MAR2016/10:50	355 H	300 - 350	No
		Week 1	15MAR2016/09:25	360 H	300 - 350	No
		Week 2	23MAR2016/09:08	350	300 - 350	No
		Week 4	05APR2016/10:15	369 H	300 - 350	No
		Week 6	19APR2016/09:45	357 H	300 - 350	No
		Week 8	28APR2016/10:10	354 H	300 - 350	No
		Week 12	01JUN2016/08:30	346	300 - 350	Yes
		Week 16	29JUN2016/09:23	344	300 - 350	No
		Week 20	26JUL2016/09:45	322	300 - 350	No
		Week 24	24AUG2016/09:30	330	300 - 350	Yes
		Week 28	20SEP2016/12:00	343	300 - 350	No
		Week 32	19OCT2016/11:00	341	300 - 350	No
		Week 36	15NOV2016/11:15	350	300 - 350	No
		Week 40	14DEC2016/09:30	346	300 - 350	No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Ery. Mean Corpuscular HGB Concentration (g/L)	Week 44	11JAN2017/11:00	341	300 - 350	No
		Week 48	08FEB2017/11:50	341	300 - 350	No
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	17FEB2016/13:00	33.4	26 - 33.5	Yes
		Day 1	08MAR2016/10:50	34.2 H	26 - 33.5	No
		Week 1	15MAR2016/09:25	34.4 H	26 - 33.5	No
		Week 2	23MAR2016/09:08	32.7	26 - 33.5	No
		Week 4	05APR2016/10:15	34.6 H	26 - 33.5	No
		Week 6	19APR2016/09:45	33.7 H	26 - 33.5	No
		Week 8	28APR2016/10:10	34.9 H	26 - 33.5	No
		Week 12	01JUN2016/08:30	34.8 H	26 - 33.5	Yes
		Week 16	29JUN2016/09:23	33.8 H	26 - 33.5	No
		Week 20	26JUL2016/09:45	31.7	26 - 33.5	No
		Week 24	24AUG2016/09:30	31.3	26 - 33.5	Yes
		Week 28	20SEP2016/12:00	32.1	26 - 33.5	No
		Week 32	19OCT2016/11:00	32.3	26 - 33.5	No
		Week 36	15NOV2016/11:15	32.5	26 - 33.5	No
		Week 40	14DEC2016/09:30	32.4	26 - 33.5	No
		Week 44	11JAN2017/11:00	31.9	26 - 33.5	No
		Week 48	08FEB2017/11:50	31.8	26 - 33.5	No

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Ery. Mean Corpuscular Volume (fL)	Screening	17FEB2016/13:00	95.0	80 - 99	Yes
		Day 1	08MAR2016/10:50	96.5	80 - 99	No
		Week 1	15MAR2016/09:25	95.5	80 - 99	No
		Week 2	23MAR2016/09:08	93.5	80 - 99	No
		Week 4	05APR2016/10:15	93.8	80 - 99	No
		Week 6	19APR2016/09:45	94.2	80 - 99	No
		Week 8	28APR2016/10:10	98.6	80 - 99	No
		Week 12	01JUN2016/08:30	100.6 H	80 - 99	Yes
		Week 16	29JUN2016/09:23	98.4	80 - 99	No
		Week 20	26JUL2016/09:45	98.7	80 - 99	No
		Week 24	24AUG2016/09:30	95.1	80 - 99	Yes
		Week 28	20SEP2016/12:00	93.6	80 - 99	No
		Week 32	19OCT2016/11:00	94.8	80 - 99	No
		Week 36	15NOV2016/11:15	92.8	80 - 99	No
		Week 40	14DEC2016/09:30	93.9	80 - 99	No
		Week 44	11JAN2017/11:00	93.6	80 - 99	No
		Week 48	08FEB2017/11:50	93.2	80 - 99	No
	Erythrocytes (10 <sup>12</sup> /L)	Screening	17FEB2016/13:00	3.83 L	3.95 - 5.15	Yes
		Day 1	08MAR2016/10:50	3.71 L	3.95 - 5.15	No
		Week 1	15MAR2016/09:25	3.81 L	3.95 - 5.15	No
		Week 2	23MAR2016/09:08	3.67 L	3.95 - 5.15	No
		Week 4	05APR2016/10:15	3.21 L	3.95 - 5.15	No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Erythrocytes (10 <sup>12</sup> /L)	Week 6	19APR2016/09:45	3.12 L	3.95 - 5.15	No
		Week 8	28APR2016/10:10	2.81 L	3.95 - 5.15	No
		Week 12	01JUN2016/08:30	3.36 L	3.95 - 5.15	Yes
		Week 16	29JUN2016/09:23	3.64 L	3.95 - 5.15	No
		Week 20	26JUL2016/09:45	3.78 L	3.95 - 5.15	No
		Week 24	24AUG2016/09:30	3.86 L	3.95 - 5.15	Yes
		Week 28	20SEP2016/12:00	3.89 L	3.95 - 5.15	No
		Week 32	19OCT2016/11:00	3.84 L	3.95 - 5.15	No
		Week 36	15NOV2016/11:15	3.88 L	3.95 - 5.15	No
		Week 40	14DEC2016/09:30	3.76 L	3.95 - 5.15	No
		Week 44	11JAN2017/11:00	3.92 L	3.95 - 5.15	No
		Week 48	08FEB2017/11:50	3.84 L	3.95 - 5.15	No
	Hematocrit (%)	Screening	17FEB2016/13:00	36.4	33 - 45	Yes
		Day 1	08MAR2016/10:50	35.8	33 - 45	No
		Week 1	15MAR2016/09:25	36.4	33 - 45	No
		Week 2	23MAR2016/09:08	34.3	33 - 45	No
		Week 4	05APR2016/10:15	30.1 L	33 - 45	No
		Week 6	19APR2016/09:45	29.4 L	33 - 45	No
		Week 8	28APR2016/10:10	27.7 L	33 - 45	No
		Week 12	01JUN2016/08:30	33.8	33 - 45	Yes
		Week 16	29JUN2016/09:23	35.8	33 - 45	No
		Week 20	26JUL2016/09:45	37.3	33 - 45	No
		Week 24	24AUG2016/09:30	36.7	33 - 45	Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Hematocrit (%)	Week 28	20SEP2016/12:00	36.4	33 - 45	No	
		Week 32	19OCT2016/11:00	36.4	33 - 45	No	
		Week 36	15NOV2016/11:15	36.0	33 - 45	No	
		Week 40	14DEC2016/09:30	35.3	33 - 45	No	
		Week 44	11JAN2017/11:00	36.7	33 - 45	No	
		Week 48	08FEB2017/11:50	35.8	33 - 45	No	
	Hemoglobin (g/L)	Screening	17FEB2016/13:00	128	115 - 155	Yes	0
		Day 1	08MAR2016/10:50	127	115 - 155	No	0
		Week 1	15MAR2016/09:25	131	115 - 155	No	0
		Week 2	23MAR2016/09:08	120	115 - 155	No	0
		Week 4	05APR2016/10:15	111 L	115 - 155	No	1
		Week 6	19APR2016/09:45	105 L	115 - 155	No	1
		Week 8	28APR2016/10:10	98 L	115 - 155	No	2
		Week 12	01JUN2016/08:30	117	115 - 155	Yes	0
		Week 16	29JUN2016/09:23	123	115 - 155	No	0
		Week 20	26JUL2016/09:45	120	115 - 155	No	0
		Week 24	24AUG2016/09:30	121	115 - 155	Yes	0
		Week 28	20SEP2016/12:00	125	115 - 155	No	0
		Week 32	19OCT2016/11:00	124	115 - 155	No	0
		Week 36	15NOV2016/11:15	126	115 - 155	No	0
		Week 40	14DEC2016/09:30	122	115 - 155	No	0
		Week 44	11JAN2017/11:00	125	115 - 155	No	0
		Week 48	08FEB2017/11:50	122	115 - 155	No	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Leukocytes (10 <sup>9</sup> /L)	Screening	17FEB2016/13:00	4.68	3 - 10	Yes	0
		Day 1	08MAR2016/10:50	3.82	3 - 10	No	0
		Week 1	15MAR2016/09:25	4.59	3 - 10	No	0
		Week 2	23MAR2016/09:08	4.93	3 - 10	No	0
		Week 4	05APR2016/10:15	3.45	3 - 10	No	0
		Week 6	19APR2016/09:45	2.08 L	3 - 10	No	2
		Week 8	28APR2016/10:10	2.57 L	3 - 10	No	2
		Week 12	01JUN2016/08:30	3.80	3 - 10	Yes	0
		Week 16	29JUN2016/09:23	3.86	3 - 10	No	0
		Week 20	26JUL2016/09:45	3.50	3 - 10	No	0
		Week 24	24AUG2016/09:30	4.02	3 - 10	Yes	0
		Week 28	20SEP2016/12:00	3.82	3 - 10	No	0
		Week 32	19OCT2016/11:00	3.46	3 - 10	No	0
		Week 36	15NOV2016/11:15	3.28	3 - 10	No	0
		Week 40	14DEC2016/09:30	3.46	3 - 10	No	0
		Week 44	11JAN2017/11:00	4.76	3 - 10	No	0
		Week 48	08FEB2017/11:50	7.17	3 - 10	No	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	17FEB2016/13:00	1.84	1.2 - 3.65	Yes	0
		Day 1	08MAR2016/10:50	1.78	1.2 - 3.65	No	0
		Week 1	15MAR2016/09:25	2.11	1.2 - 3.65	No	0
		Week 2	23MAR2016/09:08	2.04	1.2 - 3.65	No	0
		Week 4	05APR2016/10:15	2.31	1.2 - 3.65	No	0
		Week 6	19APR2016/09:45	1.87	1.2 - 3.65	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Lymphocytes (10 <sup>9</sup> /L)	Week 8	28APR2016/10:10	1.72	1.2 - 3.65	No	0
		Week 12	01JUN2016/08:30	1.58	1.2 - 3.65	Yes	0
		Week 16	29JUN2016/09:23	1.74	1.2 - 3.65	No	0
		Week 20	26JUL2016/09:45	1.58	1.2 - 3.65	No	0
		Week 24	24AUG2016/09:30	1.93	1.2 - 3.65	Yes	0
		Week 28	20SEP2016/12:00	1.62	1.2 - 3.65	No	0
		Week 32	19OCT2016/11:00	1.61	1.2 - 3.65	No	0
		Week 36	15NOV2016/11:15	1.36	1.2 - 3.65	No	0
		Week 40	14DEC2016/09:30	1.59	1.2 - 3.65	No	0
		Week 44	11JAN2017/11:00	2.28	1.2 - 3.65	No	0
		Week 48	08FEB2017/11:50	2.51	1.2 - 3.65	No	0
	Monocytes (10 <sup>9</sup> /L)	Screening	17FEB2016/13:00	0.52	0.2 - 1	Yes	
		Day 1	08MAR2016/10:50	0.48	0.2 - 1	No	
		Week 1	15MAR2016/09:25	0.46	0.2 - 1	No	
		Week 2	23MAR2016/09:08	0.59	0.2 - 1	No	
		Week 4	05APR2016/10:15	0.10 L	0.2 - 1	No	
		Week 6	19APR2016/09:45	0.04 L	0.2 - 1	No	
		Week 8	28APR2016/10:10	0.47	0.2 - 1	No	
		Week 12	01JUN2016/08:30	0.36	0.2 - 1	Yes	
		Week 16	29JUN2016/09:23	0.27	0.2 - 1	No	
		Week 20	26JUL2016/09:45	0.36	0.2 - 1	No	
		Week 24	24AUG2016/09:30	0.44	0.2 - 1	Yes	
		Week 28	20SEP2016/12:00	0.40	0.2 - 1	No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Monocytes (10 <sup>9</sup> /L)	Week 32	19OCT2016/11:00	0.38	0.2 - 1	No	
		Week 36	15NOV2016/11:15	0.38	0.2 - 1	No	
		Week 40	14DEC2016/09:30	0.38	0.2 - 1	No	
		Week 44	11JAN2017/11:00	0.48	0.2 - 1	No	
		Week 48	08FEB2017/11:50	0.81	0.2 - 1	No	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	17FEB2016/13:00	0.14	0 - 0.38	Yes	4
		Day 1	08MAR2016/10:50	0.00	0 - 0.38	No	4
		Week 1	15MAR2016/09:25	0.46 H	0 - 0.38	No	4
		Week 2	23MAR2016/09:08	0.00	0 - 0.38	No	4
		Week 4	05APR2016/10:15	0.55 H	0 - 0.38	No	3
		Week 6	19APR2016/09:45	0.17	0 - 0.38	No	4
		Week 8	28APR2016/10:10	0.35	0 - 0.38	No	4
		Week 12	01JUN2016/08:30	0.00	0 - 0.38	Yes	4
		Week 16	29JUN2016/09:23	1.58 H	0 - 0.38	No	0
		Week 20	26JUL2016/09:45	0.77 H	0 - 0.38	No	3
		Week 24	24AUG2016/09:30	0.00	0 - 0.38	Yes	4
		Week 28	20SEP2016/12:00	0.00	0 - 0.38	No	4
		Week 32	19OCT2016/11:00	0.52 H	0 - 0.38	No	3
		Week 36	15NOV2016/11:15	1.07 H	0 - 0.38	No	2
		Week 40	14DEC2016/09:30	0.00	0 - 0.38	No	4
		Week 44	11JAN2017/11:00	0.00	0 - 0.38	No	4
		Week 48	08FEB2017/11:50	0.00	0 - 0.38	No	4

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	17FEB2016/13:00	1.90 L	2 - 7.5	Yes	1
		Day 1	08MAR2016/10:50	1.41 L	2 - 7.5	No	2
		Week 1	15MAR2016/09:25	1.38 L	2 - 7.5	No	2
		Week 2	23MAR2016/09:08	2.23	2 - 7.5	No	0
		Week 4	05APR2016/10:15	0.45 L	2 - 7.5	No	4
		Week 6	19APR2016/09:45	0.00 L	2 - 7.5	No	4
		Week 8	28APR2016/10:10	0.00 L	2 - 7.5	No	4
		Week 12	01JUN2016/08:30	1.66 L	2 - 7.5	Yes	1
		Week 16	29JUN2016/09:23	0.23 L	2 - 7.5	No	4
		Week 20	26JUL2016/09:45	0.70 L	2 - 7.5	No	3
		Week 24	24AUG2016/09:30	1.52 L	2 - 7.5	Yes	1
		Week 28	20SEP2016/12:00	1.69 L	2 - 7.5	No	1
		Week 32	19OCT2016/11:00	0.80 L	2 - 7.5	No	3
		Week 36	15NOV2016/11:15	0.33 L	2 - 7.5	No	4
		Week 40	14DEC2016/09:30	1.31 L	2 - 7.5	No	2
		Week 44	11JAN2017/11:00	1.80 L	2 - 7.5	No	1
		Week 48	08FEB2017/11:50	3.61	2 - 7.5	No	0
	Platelets (10 <sup>9</sup> /L)	Screening	17FEB2016/13:00	157	150 - 400	Yes	0
		Day 1	08MAR2016/10:50	140 L	150 - 400	No	1
		Week 1	15MAR2016/09:25	132 L	150 - 400	No	1
		Week 2	23MAR2016/09:08	137 L	150 - 400	No	1
		Week 4	05APR2016/10:15	134 L	150 - 400	No	1

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Platelets (10 <sup>9</sup> /L)	Week 6	19APR2016/09:45	168	150 - 400	No	0
		Week 8	28APR2016/10:10	166	150 - 400	No	0
		Week 12	01JUN2016/08:30	104 L	150 - 400	Yes	1
		Week 16	29JUN2016/09:23	118 L	150 - 400	No	1
		Week 20	26JUL2016/09:45	108 L	150 - 400	No	1
		Week 24	24AUG2016/09:30	110 L	150 - 400	Yes	1
		Week 28	20SEP2016/12:00	128 L	150 - 400	No	1
		Week 32	19OCT2016/11:00	138 L	150 - 400	No	1
		Week 36	15NOV2016/11:15	114 L	150 - 400	No	1
		Week 40	14DEC2016/09:30	120 L	150 - 400	No	1
		Week 44	11JAN2017/11:00	140 L	150 - 400	No	1
		Week 48	08FEB2017/11:50	152	150 - 400	No	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-004	Basophils (10 <sup>9</sup> /L)	Screening	16DEC2015/11:50	0.01	0 - 0.1	Yes	
	Blood film	Screening	16DEC2015/11:50			Yes	
	Eosinophils (10 <sup>9</sup> /L)	Screening	16DEC2015/11:50	0.04	0 - 0.4	Yes	
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	16DEC2015/11:50	338	300 - 350	Yes	
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	16DEC2015/11:50	30.1	26 - 33.5	Yes	
	Ery. Mean Corpuscular Volume (fL)	Screening	16DEC2015/11:50	89.1	80 - 99	Yes	
	Erythrocytes (10 <sup>12</sup> /L)	Screening	16DEC2015/11:50	4.12	3.95 - 5.15	Yes	
	Hematocrit (%)	Screening	16DEC2015/11:50	36.7	33 - 45	Yes	
	Hemoglobin (g/L)	Screening	16DEC2015/11:50	124	115 - 155	Yes	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	16DEC2015/11:50	5.72	3 - 10	Yes	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	16DEC2015/11:50	2.50	1.2 - 3.65	Yes	0

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-004	Monocytes (10 <sup>9</sup> /L)	Screening	16DEC2015/11:50	0.50	0.2 - 1	Yes	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	16DEC2015/11:50	0.00	0 - 0.38	Yes	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	16DEC2015/11:50	2.67	2 - 7.5	Yes	0
	Platelets (10 <sup>9</sup> /L)	Screening	16DEC2015/11:50	217	150 - 400	Yes	0
301-012	Basophils (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	0.04	0 - 0.1	Yes	
	Blood film	Screening	26JAN2016/13:00			Yes	
	Eosinophils (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	0.17	0 - 0.4	Yes	
	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	26JAN2016/13:00	348	300 - 350	Yes	
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	26JAN2016/13:00	30.5	26 - 33.5	Yes	
	Ery. Mean Corpuscular Volume (fL)	Screening	26JAN2016/13:00	87.6	80 - 99	Yes	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-012	Erythrocytes (10 <sup>12</sup> /L)	Screening	26JAN2016/13:00	5.34	4.4 - 5.8	Yes	
	Hematocrit (%)	Screening	26JAN2016/13:00	46.8	37 - 50	Yes	
	Hemoglobin (g/L)	Screening	26JAN2016/13:00	163	130 - 170	Yes	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	5.26	3 - 10	Yes	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	2.60	1.2 - 3.65	Yes	0
	Monocytes (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	0.55	0.2 - 1	Yes	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	0.00	0 - 0.38	Yes	4
	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	1.90 L	2 - 7.5	Yes	1
	Platelets (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	154	150 - 400	Yes	0
301-013	Basophils (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	0.00	0 - 0.1	Yes	
	Blood film	Screening	26JAN2016/13:00			Yes	
	Eosinophils (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	0.00	0 - 0.4	Yes	

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-013	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	26JAN2016/13:00	355 H	300 - 350	Yes	
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	26JAN2016/13:00	30.0	26 - 33.5	Yes	
	Ery. Mean Corpuscular Volume (fL)	Screening	26JAN2016/13:00	84.5	80 - 99	Yes	
	Erythrocytes (10 <sup>12</sup> /L)	Screening	26JAN2016/13:00	4.83	4.4 - 5.8	Yes	
	Hematocrit (%)	Screening	26JAN2016/13:00	40.8	37 - 50	Yes	
	Hemoglobin (g/L)	Screening	26JAN2016/13:00	145	130 - 170	Yes	0
	Leukocytes (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	4.91	3 - 10	Yes	0
	Lymphocytes (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	2.16	1.2 - 3.65	Yes	0
	Monocytes (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	0.29	0.2 - 1	Yes	
	Neutrophils Band Form (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	0.25	0 - 0.38	Yes	4

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.1  
Laboratory Results - Hematology  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-013	Neutrophils, Segmented (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	2.21	2 - 7.5	Yes	0
	Platelets (10 <sup>9</sup> /L)	Screening	26JAN2016/13:00	195	150 - 400	Yes	0

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Alanine Aminotransferase (IU/L)	Screening	05JAN2016/11:00	52 H	10 - 35	Yes	1
		Day 1	26JAN2016/10:00	53 H	10 - 35	No	1
		Week 1	01FEB2016/10:30	41 H	10 - 35	No	1
		Week 2	11FEB2016/12:00	49 H	10 - 35	No	1
		Week 4	24FEB2016/13:00	62 H	10 - 35	No	1
		Week 6	08MAR2016/11:30	42 H	10 - 35	No	1
		Week 8	24MAR2016/10:52	36 H	10 - 35	No	1
		Early Term	21APR2016/08:00	31	10 - 35	Yes	0
		Week 28	19MAY2016/12:20	34	10 - 35	No	0
		Week 32	16JUN2016/10:25	41 H	10 - 35	No	1
		Week 40	11AUG2016/12:00	74 H	10 - 35	No	1
		Week 44	08SEP2016/12:10	706 H	10 - 35	No	4
		Week 48	06OCT2016/12:30	157 H	10 - 35	No	2
	Albumin (g/L)	Screening	05JAN2016/11:00	43	34 - 50	Yes	0
		Day 1	26JAN2016/10:00	46	34 - 50	No	0
		Week 1	01FEB2016/10:30	46	34 - 50	No	0
		Week 2	11FEB2016/12:00	45	34 - 50	No	0
		Week 4	24FEB2016/13:00	44	34 - 50	No	0
		Week 6	08MAR2016/11:30	41	34 - 50	No	0
		Week 8	24MAR2016/10:52	43	34 - 50	No	0
		Early Term	21APR2016/08:00	42	34 - 50	Yes	0
		Week 28	19MAY2016/12:20	46	34 - 50	No	0

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Albumin (g/L)	Week 32	16JUN2016/10:25	44	34 - 50	No	0
		Week 40	11AUG2016/12:00	45	34 - 50	No	0
		Week 44	08SEP2016/12:10	43	34 - 50	No	0
		Week 48	06OCT2016/12:30	44	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	05JAN2016/11:00	73	35 - 104	Yes	0
		Day 1	26JAN2016/10:00	69	35 - 104	No	0
		Week 1	01FEB2016/10:30	67	35 - 104	No	0
		Week 2	11FEB2016/12:00	70	35 - 104	No	0
		Week 4	24FEB2016/13:00	70	35 - 104	No	0
		Week 6	08MAR2016/11:30	77	35 - 104	No	0
		Week 8	24MAR2016/10:52	78	35 - 104	No	0
		Early Term	21APR2016/08:00	77	35 - 104	Yes	0
		Week 28	19MAY2016/12:20	83	35 - 104	No	0
		Week 32	16JUN2016/10:25	74	35 - 104	No	0
		Week 40	11AUG2016/12:00	73	35 - 104	No	0
		Week 44	08SEP2016/12:10	138 H	35 - 104	No	1
		Week 48	06OCT2016/12:30	86	35 - 104	No	0
	Amylase (IU/L)	Screening	05JAN2016/11:00	101 H	28 - 100	Yes	1
		Day 1	26JAN2016/10:00	85	28 - 100	No	0
		Week 1	01FEB2016/10:30	83	28 - 100	No	0
		Week 2	11FEB2016/12:00	91	28 - 100	No	0
		Week 4	24FEB2016/13:00	94	28 - 100	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Amylase (IU/L)	Week 6	08MAR2016/11:30	87	28 - 100	No	0
		Week 8	24MAR2016/10:52	99	28 - 100	No	0
		Early Term	21APR2016/08:00	90	28 - 100	Yes	0
		Week 28	19MAY2016/12:20	100	28 - 100	No	0
		Week 32	16JUN2016/10:25	84	28 - 100	No	0
		Week 40	11AUG2016/12:00	94	28 - 100	No	0
		Week 44	08SEP2016/12:10	88	28 - 100	No	0
		Week 48	06OCT2016/12:30	86	28 - 100	No	0
	Aspartate Aminotransferase (IU/L)	Screening	05JAN2016/11:00	37 H	0 - 31	Yes	1
		Day 1	26JAN2016/10:00	34 H	0 - 31	No	1
		Week 1	01FEB2016/10:30	35 H	0 - 31	No	1
		Week 2	11FEB2016/12:00	37 H	0 - 31	No	1
		Week 4	24FEB2016/13:00	39 H	0 - 31	No	1
		Week 6	08MAR2016/11:30	28	0 - 31	No	0
		Week 8	24MAR2016/10:52	27	0 - 31	No	0
		Early Term	21APR2016/08:00	25	0 - 31	Yes	0
		Week 28	19MAY2016/12:20	28	0 - 31	No	0
		Week 32	16JUN2016/10:25	31	0 - 31	No	0
		Week 40	11AUG2016/12:00	49 H	0 - 31	No	1
		Week 44	08SEP2016/12:10	342 H	0 - 31	No	3
		Week 48	06OCT2016/12:30	89 H	0 - 31	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Bicarbonate (mmol/L)	Screening	05JAN2016/11:00	23	22 - 29	Yes	
		Day 1	26JAN2016/10:00	22	22 - 29	No	
		Week 1	01FEB2016/10:30	21 L	22 - 29	No	
		Week 2	11FEB2016/12:00	24	22 - 29	No	
		Week 4	24FEB2016/13:00	21 L	22 - 29	No	
		Week 6	08MAR2016/11:30	22	22 - 29	No	
		Week 8	24MAR2016/10:52	23	22 - 29	No	
		Early Term	21APR2016/08:00	21 L	22 - 29	Yes	
		Week 28	19MAY2016/12:20	24	22 - 29	No	
		Week 32	16JUN2016/10:25	20 L	22 - 29	No	
		Week 40	11AUG2016/12:00	19 L	22 - 29	No	
		Week 44	08SEP2016/12:10	19 L	22 - 29	No	
		Week 48	06OCT2016/12:30	24	22 - 29	No	
	Bilirubin (umol/L)	Screening	05JAN2016/11:00	12	0 - 20	Yes	0
		Day 1	26JAN2016/10:00	5	0 - 20	No	0
		Week 1	01FEB2016/10:30	11	0 - 20	No	0
		Week 2	11FEB2016/12:00	6	0 - 20	No	0
		Week 4	24FEB2016/13:00	5	0 - 20	No	0
		Week 6	08MAR2016/11:30	4	0 - 20	No	0
		Week 8	24MAR2016/10:52	4	0 - 20	No	0
		Early Term	21APR2016/08:00	6	0 - 20	Yes	0
		Week 28	19MAY2016/12:20	6	0 - 20	No	0
		Week 32	16JUN2016/10:25	6	0 - 20	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Bilirubin (umol/L)	Week 40	11AUG2016/12:00	4	0 - 20	No	0
		Week 44	08SEP2016/12:10	13	0 - 20	No	0
		Week 48	06OCT2016/12:30	7	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	05JAN2016/11:00	8.96	4.76 - 23.24	Yes	
		Day 1	26JAN2016/10:00	5.60	4.76 - 23.24	No	
		Week 1	01FEB2016/10:30	12.32	4.76 - 23.24	No	
		Week 2	11FEB2016/12:00	13.16	4.76 - 23.24	No	
		Week 4	24FEB2016/13:00	11.48	4.76 - 23.24	No	
		Week 6	08MAR2016/11:30	8.96	4.76 - 23.24	No	
		Week 8	24MAR2016/10:52	10.36	4.76 - 23.24	No	
		Early Term	21APR2016/08:00	12.04	4.76 - 23.24	Yes	
		Week 28	19MAY2016/12:20	9.24	4.76 - 23.24	No	
		Week 32	16JUN2016/10:25	8.96	4.76 - 23.24	No	
		Week 40	11AUG2016/12:00	8.68	4.76 - 23.24	No	
		Week 44	08SEP2016/12:10	7.84	4.76 - 23.24	No	
		Week 48	06OCT2016/12:30	8.40	4.76 - 23.24	No	
	Calcium (mmol/L)	Screening	05JAN2016/11:00	2.36	2.2 - 2.6	Yes	0
		Day 1	26JAN2016/10:00	2.42	2.2 - 2.6	No	0
		Week 1	01FEB2016/10:30	2.41	2.2 - 2.6	No	0
		Week 2	11FEB2016/12:00	2.33	2.2 - 2.6	No	0
		Week 4	24FEB2016/13:00	2.35	2.2 - 2.6	No	0
		Week 6	08MAR2016/11:30	2.34	2.2 - 2.6	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Calcium (mmol/L)	Week 8	24MAR2016/10:52	2.43	2.2 - 2.6	No	0
		Early Term	21APR2016/08:00	2.38	2.2 - 2.6	Yes	0
		Week 28	19MAY2016/12:20	2.37	2.2 - 2.6	No	0
		Week 32	16JUN2016/10:25	2.42	2.2 - 2.6	No	0
		Week 40	11AUG2016/12:00	2.38	2.2 - 2.6	No	0
		Week 44	08SEP2016/12:10	2.34	2.2 - 2.6	No	0
		Week 48	06OCT2016/12:30	2.41	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	05JAN2016/11:00	97 L	98 - 107	Yes	
		Day 1	26JAN2016/10:00	103	98 - 107	No	
		Week 1	01FEB2016/10:30	100	98 - 107	No	
		Week 2	11FEB2016/12:00	102	98 - 107	No	
		Week 4	24FEB2016/13:00	100	98 - 107	No	
		Week 6	08MAR2016/11:30	102	98 - 107	No	
		Week 8	24MAR2016/10:52	102	98 - 107	No	
		Early Term	21APR2016/08:00	104	98 - 107	Yes	
		Week 28	19MAY2016/12:20	102	98 - 107	No	
		Week 32	16JUN2016/10:25	99	98 - 107	No	
		Week 40	11AUG2016/12:00	104	98 - 107	No	
		Week 44	08SEP2016/12:10	101	98 - 107	No	
		Week 48	06OCT2016/12:30	99	98 - 107	No	
	Cholesterol (mmol/L)	Screening	05JAN2016/11:00	4.8	0 - 4.9	Yes	0
		Day 1	26JAN2016/10:00	4.7	0 - 4.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007 Cholesterol (mmol/L)	Week 1	01FEB2016/10:30	4.2	0 - 4.9	No	0
	Week 2	11FEB2016/12:00	3.8	0 - 4.9	No	0
	Week 4	24FEB2016/13:00	3.7	0 - 4.9	No	0
	Week 6	08MAR2016/11:30	4.0	0 - 4.9	No	0
	Week 8	24MAR2016/10:52	4.2	0 - 4.9	No	0
	Early Term	21APR2016/08:00	4.2	0 - 4.9	Yes	0
	Week 28	19MAY2016/12:20	5.0 H	0 - 4.9	No	1
	Week 32	16JUN2016/10:25	5.3 H	0 - 4.9	No	1
	Week 40	11AUG2016/12:00	4.4	0 - 4.9	No	0
	Week 44	08SEP2016/12:10	4.2	0 - 4.9	No	0
	Week 48	06OCT2016/12:30	4.2	0 - 4.9	No	0
Creatine Kinase (IU/L)	Screening	05JAN2016/11:00	144 H	26 - 140	Yes	1
	Day 1	26JAN2016/10:00	120	26 - 140	No	0
	Week 1	01FEB2016/10:30	148 H	26 - 140	No	1
	Week 2	11FEB2016/12:00	123	26 - 140	No	0
	Week 4	24FEB2016/13:00	126	26 - 140	No	0
	Week 6	08MAR2016/11:30	128	26 - 140	No	0
	Week 8	24MAR2016/10:52	101	26 - 140	No	0
	Early Term	21APR2016/08:00	111	26 - 140	Yes	0
	Week 28	19MAY2016/12:20	134	26 - 140	No	0
	Week 32	16JUN2016/10:25	107	26 - 140	No	0
	Week 40	11AUG2016/12:00	75	26 - 140	No	0
	Week 44	08SEP2016/12:10	90	26 - 140	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Creatine Kinase (IU/L)	Week 48	06OCT2016/12:30	119	26 - 140	No	0
	Creatinine (umol/L)	Screening	05JAN2016/11:00	53	49 - 92	Yes	0
		Day 1	26JAN2016/10:00	54	49 - 92	No	0
		Week 1	01FEB2016/10:30	68	49 - 92	No	1
		Week 2	11FEB2016/12:00	66	49 - 92	No	1
		Week 4	24FEB2016/13:00	69	49 - 92	No	1
		Week 6	08MAR2016/11:30	54	49 - 92	No	0
		Week 8	24MAR2016/10:52	63	49 - 92	No	1
		Early Term	21APR2016/08:00	66	49 - 92	Yes	1
		Week 28	19MAY2016/12:20	58	49 - 92	No	1
		Week 32	16JUN2016/10:25	57	49 - 92	No	1
		Week 40	11AUG2016/12:00	54	49 - 92	No	0
		Week 44	08SEP2016/12:10	58	49 - 92	No	1
		Week 48	06OCT2016/12:30	53	49 - 92	No	0
	Direct Bilirubin (umol/L)	Screening	05JAN2016/11:00	5	0 - 5	Yes	
		Day 1	26JAN2016/10:00	2	0 - 5	No	
		Week 1	01FEB2016/10:30	4	0 - 5	No	
		Week 2	11FEB2016/12:00	2	0 - 5	No	
		Week 4	24FEB2016/13:00	2	0 - 5	No	
		Week 6	08MAR2016/11:30	<2	0 - 5	No	
		Week 8	24MAR2016/10:52	<2	0 - 5	No	
		Early Term	21APR2016/08:00	2	0 - 5	Yes	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Direct Bilirubin (umol/L)	Week 28	19MAY2016/12:20	3	0 - 5	No	
		Week 32	16JUN2016/10:25	3	0 - 5	No	
		Week 40	11AUG2016/12:00	2	0 - 5	No	
		Week 44	08SEP2016/12:10	6 H	0 - 5	No	
		Week 48	06OCT2016/12:30	3	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	05JAN2016/11:00	31	6 - 42	Yes	0
		Day 1	26JAN2016/10:00	27	6 - 42	No	0
		Week 1	01FEB2016/10:30	24	6 - 42	No	0
		Week 2	11FEB2016/12:00	28	6 - 42	No	0
		Week 4	24FEB2016/13:00	31	6 - 42	No	0
		Week 6	08MAR2016/11:30	29	6 - 42	No	0
		Week 8	24MAR2016/10:52	25	6 - 42	No	0
		Early Term	21APR2016/08:00	20	6 - 42	Yes	0
		Week 28	19MAY2016/12:20	23	6 - 42	No	0
		Week 32	16JUN2016/10:25	23	6 - 42	No	0
		Week 40	11AUG2016/12:00	30	6 - 42	No	0
		Week 44	08SEP2016/12:10	338 H	6 - 42	No	3
		Week 48	06OCT2016/12:30	172 H	6 - 42	No	2
	Globulin (g/L)	Screening	05JAN2016/11:00	39 H	19 - 35	Yes	
		Day 1	26JAN2016/10:00	36 H	19 - 35	No	
		Week 1	01FEB2016/10:30	36 H	19 - 35	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Globulin (g/L)	Week 2	11FEB2016/12:00	37 H	19 - 35	No	
		Week 4	24FEB2016/13:00	41 H	19 - 35	No	
		Week 6	08MAR2016/11:30	38 H	19 - 35	No	
		Week 8	24MAR2016/10:52	36 H	19 - 35	No	
		Early Term	21APR2016/08:00	35	19 - 35	Yes	
		Week 28	19MAY2016/12:20	38 H	19 - 35	No	
		Week 32	16JUN2016/10:25	37 H	19 - 35	No	
		Week 40	11AUG2016/12:00	37 H	19 - 35	No	
		Week 44	08SEP2016/12:10	43 H	19 - 35	No	
		Week 48	06OCT2016/12:30	44 H	19 - 35	No	
	Glucose (mmol/L)	Screening	05JAN2016/11:00	5.0	3.9 - 5.8	Yes	0
		Day 1	26JAN2016/10:00	5.1	3.5 - 7.9	No	0
		Week 1	01FEB2016/10:30	6.2	3.5 - 7.9	No	0
		Week 2	11FEB2016/12:00	6.6	3.5 - 7.9	No	0
		Week 4	24FEB2016/13:00	5.7	3.5 - 7.9	No	0
		Week 6	08MAR2016/11:30	6.0	3.5 - 7.9	No	0
		Week 8	24MAR2016/10:52	5.6	3.5 - 7.9	No	0
		Early Term	21APR2016/08:00	4.8	3.9 - 5.8	Yes	0
		Week 28	19MAY2016/12:20	4.4	3.5 - 7.9	No	0
		Week 32	16JUN2016/10:25	5.3	3.5 - 7.9	No	0
		Week 40	11AUG2016/12:00	5.0	3.5 - 7.9	No	0
		Week 44	08SEP2016/12:10	4.8	3.5 - 7.9	No	0
		Week 48	06OCT2016/12:30	5.2	3.5 - 7.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Indirect Bilirubin (umol/L)	Screening	05JAN2016/11:00	7	0 - 14	Yes
		Day 1	26JAN2016/10:00	3	0 - 14	No
		Week 1	01FEB2016/10:30	7	0 - 14	No
		Week 2	11FEB2016/12:00	4	0 - 14	No
		Week 4	24FEB2016/13:00	3	0 - 14	No
		Week 6	08MAR2016/11:30		0 - 14	No
		Week 8	24MAR2016/10:52		0 - 14	No
		Early Term	21APR2016/08:00	4	0 - 14	Yes
		Week 28	19MAY2016/12:20	3	0 - 14	No
		Week 32	16JUN2016/10:25	3	0 - 14	No
		Week 40	11AUG2016/12:00	2	0 - 14	No
		Week 44	08SEP2016/12:10	7	0 - 14	No
		Week 48	06OCT2016/12:30	4	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	05JAN2016/11:00	154	135 - 214	Yes
		Day 1	26JAN2016/10:00	160	135 - 214	No
		Week 1	01FEB2016/10:30	162	135 - 214	No
		Week 2	11FEB2016/12:00	149	135 - 214	No
		Week 4	24FEB2016/13:00	157	135 - 214	No
		Week 6	08MAR2016/11:30	140	135 - 214	No
		Week 8	24MAR2016/10:52	149	135 - 214	No
		Early Term	21APR2016/08:00	143	135 - 214	Yes
		Week 28	19MAY2016/12:20	176	135 - 214	No
		Week 32	16JUN2016/10:25	155	135 - 214	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Lactate Dehydrogenase (IU/L)	Week 40	11AUG2016/12:00	185	135 - 214	No	
		Week 44	08SEP2016/12:10	218 H	135 - 214	No	
		Week 48	06OCT2016/12:30	187	135 - 214	No	
	Magnesium (mmol/L)	Screening	05JAN2016/11:00	0.88	0.6 - 1	Yes	0
		Day 1	26JAN2016/10:00	0.89	0.6 - 1	No	0
		Week 1	01FEB2016/10:30	0.87	0.6 - 1	No	0
		Week 2	11FEB2016/12:00	0.86	0.6 - 1	No	0
		Week 4	24FEB2016/13:00	0.87	0.6 - 1	No	0
		Week 6	08MAR2016/11:30	0.88	0.6 - 1	No	0
		Week 8	24MAR2016/10:52	0.90	0.6 - 1	No	0
		Early Term	21APR2016/08:00	0.79	0.6 - 1	Yes	0
		Week 28	19MAY2016/12:20	0.91	0.6 - 1	No	0
		Week 32	16JUN2016/10:25	0.86	0.6 - 1	No	0
		Week 40	11AUG2016/12:00	0.91	0.6 - 1	No	0
		Week 44	08SEP2016/12:10	0.90	0.6 - 1	No	0
		Week 48	06OCT2016/12:30	0.86	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	05JAN2016/11:00	1.08	0.87 - 1.45	Yes	0
		Day 1	26JAN2016/10:00	1.21	0.87 - 1.45	No	0
		Week 1	01FEB2016/10:30	1.18	0.87 - 1.45	No	0
		Week 2	11FEB2016/12:00	1.01	0.87 - 1.45	No	0
		Week 4	24FEB2016/13:00	1.12	0.87 - 1.45	No	0
		Week 6	08MAR2016/11:30	1.21	0.87 - 1.45	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Phosphate (mmol/L)	Week 8	24MAR2016/10:52	1.23	0.87 - 1.45	No	0
		Early Term	21APR2016/08:00	1.40	0.87 - 1.45	Yes	0
		Week 28	19MAY2016/12:20	1.21	0.87 - 1.45	No	0
		Week 32	16JUN2016/10:25	1.13	0.87 - 1.45	No	0
		Week 40	11AUG2016/12:00	1.25	0.87 - 1.45	No	0
		Week 44	08SEP2016/12:10	1.16	0.87 - 1.45	No	0
		Week 48	06OCT2016/12:30	1.23	0.87 - 1.45	No	0
	Potassium (mmol/L)	Screening	05JAN2016/11:00	4.1	3.5 - 5.1	Yes	0
		Day 1	26JAN2016/10:00	4.2	3.5 - 5.1	No	0
		Week 1	01FEB2016/10:30	4.5	3.5 - 5.1	No	0
		Week 2	11FEB2016/12:00	4.2	3.5 - 5.1	No	0
		Week 4	24FEB2016/13:00	3.8	3.5 - 5.1	No	0
		Week 6	08MAR2016/11:30	4.2	3.5 - 5.1	No	0
		Week 8	24MAR2016/10:52	4.5	3.5 - 5.1	No	0
		Early Term	21APR2016/08:00	4.2	3.5 - 5.1	Yes	0
		Week 28	19MAY2016/12:20	4.4	3.5 - 5.1	No	0
		Week 32	16JUN2016/10:25	4.3	3.5 - 5.1	No	0
		Week 40	11AUG2016/12:00	4.9	3.5 - 5.1	No	0
		Week 44	08SEP2016/12:10	4.5	3.5 - 5.1	No	0
		Week 48	06OCT2016/12:30	4.4	3.5 - 5.1	No	0
		Protein (g/L)	Screening	05JAN2016/11:00	82	63 - 83	Yes
	Day 1		26JAN2016/10:00	82	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Protein (g/L)	Week 1	01FEB2016/10:30	82	63 - 83	No	
		Week 2	11FEB2016/12:00	82	63 - 83	No	
		Week 4	24FEB2016/13:00	85 H	63 - 83	No	
		Week 6	08MAR2016/11:30	79	63 - 83	No	
		Week 8	24MAR2016/10:52	79	63 - 83	No	
		Early Term	21APR2016/08:00	77	63 - 83	Yes	
		Week 28	19MAY2016/12:20	84 H	63 - 83	No	
		Week 32	16JUN2016/10:25	81	63 - 83	No	
		Week 40	11AUG2016/12:00	82	63 - 83	No	
		Week 44	08SEP2016/12:10	86 H	63 - 83	No	
		Week 48	06OCT2016/12:30	88 H	63 - 83	No	
	Sodium (mmol/L)	Screening	05JAN2016/11:00	135	135 - 145	Yes	0
		Day 1	26JAN2016/10:00	141	135 - 145	No	0
		Week 1	01FEB2016/10:30	136	135 - 145	No	0
		Week 2	11FEB2016/12:00	140	135 - 145	No	0
		Week 4	24FEB2016/13:00	137	135 - 145	No	0
		Week 6	08MAR2016/11:30	139	135 - 145	No	0
		Week 8	24MAR2016/10:52	139	135 - 145	No	0
		Early Term	21APR2016/08:00	140	135 - 145	Yes	0
		Week 28	19MAY2016/12:20	141	135 - 145	No	0
		Week 32	16JUN2016/10:25	139	135 - 145	No	0
		Week 40	11AUG2016/12:00	145	135 - 145	No	0
		Week 44	08SEP2016/12:10	139	135 - 145	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Sodium (mmol/L)	Week 48	06OCT2016/12:30	137	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	05JAN2016/11:00	0.93	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	05JAN2016/11:00	73	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	05JAN2016/11:00	0.7	0 - 2.2	Yes	0
		Day 1	26JAN2016/10:00	1.9	0 - 2.2	No	1
		Week 1	01FEB2016/10:30	1.3	0 - 2.2	No	0
		Week 2	11FEB2016/12:00	1.5	0 - 2.2	No	0
		Week 4	24FEB2016/13:00	1.5	0 - 2.2	No	0
		Week 6	08MAR2016/11:30	2.1	0 - 2.2	No	1
		Week 8	24MAR2016/10:52	1.3	0 - 2.2	No	0
		Early Term	21APR2016/08:00	1.6	0 - 2.2	Yes	0
		Week 28	19MAY2016/12:20	1.4	0 - 2.2	No	0
		Week 32	16JUN2016/10:25	1.4	0 - 2.2	No	0
		Week 40	11AUG2016/12:00	2.1	0 - 2.2	No	1
		Week 44	08SEP2016/12:10	1.6	0 - 2.2	No	0
		Week 48	06OCT2016/12:30	1.5	0 - 2.2	No	0
	Triiodothyronine (nmol/L)	Screening	05JAN2016/11:00	1.2 L	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	05JAN2016/11:00	3.2	1.7 - 8.3	Yes	
		Day 1	26JAN2016/10:00	2.0	1.7 - 8.3	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007 Urea (mmol/L)	Week 1	01FEB2016/10:30	4.4	1.7 - 8.3	No	
	Week 2	11FEB2016/12:00	4.7	1.7 - 8.3	No	
	Week 4	24FEB2016/13:00	4.1	1.7 - 8.3	No	
	Week 6	08MAR2016/11:30	3.2	1.7 - 8.3	No	
	Week 8	24MAR2016/10:52	3.7	1.7 - 8.3	No	
	Early Term	21APR2016/08:00	4.3	1.7 - 8.3	Yes	
	Week 28	19MAY2016/12:20	3.3	1.7 - 8.3	No	
	Week 32	16JUN2016/10:25	3.2	1.7 - 8.3	No	
	Week 40	11AUG2016/12:00	3.1	1.7 - 8.3	No	
	Week 44	08SEP2016/12:10	2.8	1.7 - 8.3	No	
	Week 48	06OCT2016/12:30	3.0	1.7 - 8.3	No	
Uric acid (umol/L)	Screening	05JAN2016/11:00	196	175 - 363	Yes	0
	Day 1	26JAN2016/10:00	210	175 - 363	No	0
	Week 1	01FEB2016/10:30	245	175 - 363	No	0
	Week 2	11FEB2016/12:00	211	175 - 363	No	0
	Week 4	24FEB2016/13:00	214	175 - 363	No	0
	Week 6	08MAR2016/11:30	182	175 - 363	No	0
	Week 8	24MAR2016/10:52	200	175 - 363	No	0
	Early Term	21APR2016/08:00	249	175 - 363	Yes	0
	Week 28	19MAY2016/12:20	255	175 - 363	No	0
	Week 32	16JUN2016/10:25	210	175 - 363	No	0
	Week 40	11AUG2016/12:00	233	175 - 363	No	0
	Week 44	08SEP2016/12:10	284	175 - 363	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Uric acid (umol/L)	Week 48	06OCT2016/12:30	226	175 - 363	No	0
301-011	Alanine Aminotransferase (IU/L)	Screening	07JAN2016/12:00	53 H	10 - 35	Yes	1
		Day 1	27JAN2016/08:30	54 H	10 - 35	Yes	1
		Week 1	03FEB2016/11:00	46 H	10 - 35	Yes	1
		Week 2	11FEB2016/11:30	66 H	10 - 35	Yes	1
		Week 4	26FEB2016/10:20	209 H	10 - 35	No	3
		Week 6	10MAR2016/10:45	486 H	10 - 35	No	3
		Week 8	24MAR2016/09:31	116 H	10 - 35	No	2
		Week 12	19APR2016/09:20	223 H	10 - 35	Yes	3
		Week 16	18MAY2016/10:10	373 H	10 - 35	No	3
		Week 20	21JUN2016/10:35	85 H	10 - 35	No	1
		Week 24	12JUL2016/10:00	954 H	10 - 35	Yes	4
		Week 28	09AUG2016/09:50	111 H	10 - 35	No	2
		Week 32	06SEP2016/09:00	104 H	10 - 35	No	1
		Week 36	06OCT2016/09:50	78 H	10 - 35	No	1
		Week 40	03NOV2016/11:00	49 H	10 - 35	No	1
		Week 44	06DEC2016/10:30	50 H	10 - 35	No	1
		Week 48	03JAN2017/10:45	56 H	10 - 35	No	1
	Albumin (g/L)	Screening	07JAN2016/12:00	42	34 - 50	Yes	0
		Day 1	27JAN2016/08:30	43	34 - 50	Yes	0
		Week 1	03FEB2016/11:00	42	34 - 50	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Albumin (g/L)	Week 2	11FEB2016/11:30	43	34 - 50	Yes	0
		Week 4	26FEB2016/10:20	44	34 - 50	No	0
		Week 6	10MAR2016/10:45	43	34 - 50	No	0
		Week 8	24MAR2016/09:31	42	34 - 50	No	0
		Week 12	19APR2016/09:20	43	34 - 50	Yes	0
		Week 16	18MAY2016/10:10	44	34 - 50	No	0
		Week 20	21JUN2016/10:35	40	34 - 50	No	0
		Week 24	12JUL2016/10:00	40	34 - 50	Yes	0
		Week 28	09AUG2016/09:50	38	34 - 50	No	0
		Week 32	06SEP2016/09:00	40	34 - 50	No	0
		Week 36	06OCT2016/09:50	41	34 - 50	No	0
		Week 40	03NOV2016/11:00	40	34 - 50	No	0
		Week 44	06DEC2016/10:30	43	34 - 50	No	0
		Week 48	03JAN2017/10:45	41	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	07JAN2016/12:00	62	35 - 104	Yes	0
		Day 1	27JAN2016/08:30	61	35 - 104	Yes	0
		Week 1	03FEB2016/11:00	62	35 - 104	Yes	0
		Week 2	11FEB2016/11:30	62	35 - 104	Yes	0
		Week 4	26FEB2016/10:20	59	35 - 104	No	0
		Week 6	10MAR2016/10:45	58	35 - 104	No	0
		Week 8	24MAR2016/09:31	65	35 - 104	No	0
		Week 12	19APR2016/09:20	71	35 - 104	Yes	0
		Week 16	18MAY2016/10:10	87	35 - 104	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Alkaline Phosphatase (IU/L)	Week 20	21JUN2016/10:35	91	35 - 104	No	0
		Week 24	12JUL2016/10:00	147 H	35 - 104	Yes	1
		Week 28	09AUG2016/09:50	117 H	35 - 104	No	1
		Week 32	06SEP2016/09:00	112 H	35 - 104	No	1
		Week 36	06OCT2016/09:50	101	35 - 104	No	0
		Week 40	03NOV2016/11:00	81	35 - 104	No	0
		Week 44	06DEC2016/10:30	81	35 - 104	No	0
		Week 48	03JAN2017/10:45	72	35 - 104	No	0
	Amylase (IU/L)	Screening	07JAN2016/12:00	40	28 - 100	Yes	0
		Day 1	27JAN2016/08:30	54	28 - 100	Yes	0
		Week 1	03FEB2016/11:00	55	28 - 100	Yes	0
		Week 2	11FEB2016/11:30	42	28 - 100	Yes	0
		Week 4	26FEB2016/10:20	35	28 - 100	No	0
		Week 6	10MAR2016/10:45	34	28 - 100	No	0
		Week 8	24MAR2016/09:31	53	28 - 100	No	0
		Week 12	19APR2016/09:20	40	28 - 100	Yes	0
		Week 16	18MAY2016/10:10	33	28 - 100	No	0
		Week 20	21JUN2016/10:35	54	28 - 100	No	0
		Week 24	12JUL2016/10:00	43	28 - 100	Yes	0
		Week 28	09AUG2016/09:50	54	28 - 100	No	0
		Week 32	06SEP2016/09:00	51	28 - 100	No	0
		Week 36	06OCT2016/09:50	49	28 - 100	No	0
		Week 40	03NOV2016/11:00	50	28 - 100	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Amylase (IU/L)	Week 44	06DEC2016/10:30	51	28 - 100	No	0
		Week 48	03JAN2017/10:45	70	28 - 100	No	0
	Aspartate Aminotransferase (IU/L)	Screening	07JAN2016/12:00	42 H	0 - 31	Yes	1
		Day 1	27JAN2016/08:30	40 H	0 - 31	Yes	1
		Week 1	03FEB2016/11:00	35 H	0 - 31	Yes	1
		Week 2	11FEB2016/11:30	41 H	0 - 31	Yes	1
		Week 4	26FEB2016/10:20	118 H	0 - 31	No	2
		Week 6	10MAR2016/10:45	182 H	0 - 31	No	3
		Week 8	24MAR2016/09:31	41 H	0 - 31	No	1
		Week 12	19APR2016/09:20	103 H	0 - 31	Yes	2
		Week 16	18MAY2016/10:10	204 H	0 - 31	No	3
		Week 20	21JUN2016/10:35	69 H	0 - 31	No	1
		Week 24	12JUL2016/10:00	676 H	0 - 31	Yes	4
		Week 28	09AUG2016/09:50	99 H	0 - 31	No	2
		Week 32	06SEP2016/09:00	91 H	0 - 31	No	1
		Week 36	06OCT2016/09:50	68 H	0 - 31	No	1
		Week 40	03NOV2016/11:00	51 H	0 - 31	No	1
		Week 44	06DEC2016/10:30	52 H	0 - 31	No	1
		Week 48	03JAN2017/10:45	48 H	0 - 31	No	1
	Bicarbonate (mmol/L)	Screening	07JAN2016/12:00	25	22 - 29	Yes	
		Day 1	27JAN2016/08:30	28	22 - 29	Yes	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011 Bicarbonate (mmol/L)	Week 1	03FEB2016/11:00	24	22 - 29	Yes	
	Week 2	11FEB2016/11:30	31 H	22 - 29	Yes	
	Week 4	26FEB2016/10:20	27	22 - 29	No	
	Week 6	10MAR2016/10:45	27	22 - 29	No	
	Week 8	24MAR2016/09:31	27	22 - 29	No	
	Week 12	19APR2016/09:20	28	22 - 29	Yes	
	Week 16	18MAY2016/10:10	25	22 - 29	No	
	Week 20	21JUN2016/10:35	29	22 - 29	No	
	Week 24	12JUL2016/10:00	29	22 - 29	Yes	
	Week 28	09AUG2016/09:50	32 H	22 - 29	No	
	Week 32	06SEP2016/09:00	26	22 - 29	No	
	Week 36	06OCT2016/09:50	30 H	22 - 29	No	
	Week 40	03NOV2016/11:00	26	22 - 29	No	
	Week 44	06DEC2016/10:30	26	22 - 29	No	
	Week 48	03JAN2017/10:45	27	22 - 29	No	
Bilirubin (umol/L)	Screening	07JAN2016/12:00	11	0 - 20	Yes	0
	Day 1	27JAN2016/08:30	7	0 - 20	Yes	0
	Week 1	03FEB2016/11:00	7	0 - 20	Yes	0
	Week 2	11FEB2016/11:30	7	0 - 20	Yes	0
	Week 4	26FEB2016/10:20	10	0 - 20	No	0
	Week 6	10MAR2016/10:45	8	0 - 20	No	0
	Week 8	24MAR2016/09:31	6	0 - 20	No	0
	Week 12	19APR2016/09:20	9	0 - 20	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Bilirubin (umol/L)	Week 16	18MAY2016/10:10	10	0 - 20	No	0
		Week 20	21JUN2016/10:35	7	0 - 20	No	0
		Week 24	12JUL2016/10:00	12	0 - 20	Yes	0
		Week 28	09AUG2016/09:50	9	0 - 20	No	0
		Week 32	06SEP2016/09:00	7	0 - 20	No	0
		Week 36	06OCT2016/09:50	10	0 - 20	No	0
		Week 40	03NOV2016/11:00	12	0 - 20	No	0
		Week 44	06DEC2016/10:30	8	0 - 20	No	0
		Week 48	03JAN2017/10:45	8	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	07JAN2016/12:00	14.00	4.76 - 23.24	Yes	
		Day 1	27JAN2016/08:30	17.64	4.76 - 23.24	Yes	
		Week 1	03FEB2016/11:00	19.04	4.76 - 23.24	Yes	
		Week 2	11FEB2016/11:30	14.84	4.76 - 23.24	Yes	
		Week 4	26FEB2016/10:20	15.68	4.76 - 23.24	No	
		Week 6	10MAR2016/10:45	14.00	4.76 - 23.24	No	
		Week 8	24MAR2016/09:31	14.00	4.76 - 23.24	No	
		Week 12	19APR2016/09:20	13.16	4.76 - 23.24	Yes	
		Week 16	18MAY2016/10:10	12.04	4.76 - 23.24	No	
		Week 20	21JUN2016/10:35	11.76	4.76 - 23.24	No	
		Week 24	12JUL2016/10:00	11.76	4.76 - 23.24	Yes	
		Week 28	09AUG2016/09:50	12.04	4.76 - 23.24	No	
		Week 32	06SEP2016/09:00	12.60	4.76 - 23.24	No	
		Week 36	06OCT2016/09:50	14.00	4.76 - 23.24	No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Blood Urea Nitrogen (mg/dL)	Week 40	03NOV2016/11:00	13.16	4.76 - 23.24	No	
		Week 44	06DEC2016/10:30	16.52	4.76 - 23.24	No	
		Week 48	03JAN2017/10:45	15.68	4.76 - 23.24	No	
	Calcium (mmol/L)	Screening	07JAN2016/12:00	2.36	2.2 - 2.6	Yes	0
		Day 1	27JAN2016/08:30	2.34	2.2 - 2.6	Yes	0
		Week 1	03FEB2016/11:00	2.32	2.2 - 2.6	Yes	0
		Week 2	11FEB2016/11:30	2.30	2.2 - 2.6	Yes	0
		Week 4	26FEB2016/10:20	2.37	2.2 - 2.6	No	0
		Week 6	10MAR2016/10:45	2.41	2.2 - 2.6	No	0
		Week 8	24MAR2016/09:31	2.45	2.2 - 2.6	No	0
		Week 12	19APR2016/09:20	2.33	2.2 - 2.6	Yes	0
		Week 16	18MAY2016/10:10	2.48	2.2 - 2.6	No	0
		Week 20	21JUN2016/10:35	2.38	2.2 - 2.6	No	0
		Week 24	12JUL2016/10:00	2.34	2.2 - 2.6	Yes	0
		Week 28	09AUG2016/09:50	2.35	2.2 - 2.6	No	0
		Week 32	06SEP2016/09:00	2.35	2.2 - 2.6	No	0
		Week 36	06OCT2016/09:50	2.36	2.2 - 2.6	No	0
		Week 40	03NOV2016/11:00	2.37	2.2 - 2.6	No	0
		Week 44	06DEC2016/10:30	2.33	2.2 - 2.6	No	0
		Week 48	03JAN2017/10:45	2.40	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	07JAN2016/12:00	97 L	98 - 107	Yes	
		Day 1	27JAN2016/08:30	101	98 - 107	Yes	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Chloride (mmol/L)	Week 1	03FEB2016/11:00	101	98 - 107	Yes	
		Week 2	11FEB2016/11:30	100	98 - 107	Yes	
		Week 4	26FEB2016/10:20	98	98 - 107	No	
		Week 6	10MAR2016/10:45	98	98 - 107	No	
		Week 8	24MAR2016/09:31	104	98 - 107	No	
		Week 12	19APR2016/09:20	100	98 - 107	Yes	
		Week 16	18MAY2016/10:10	97 L	98 - 107	No	
		Week 20	21JUN2016/10:35	100	98 - 107	No	
		Week 24	12JUL2016/10:00	98	98 - 107	Yes	
		Week 28	09AUG2016/09:50	101	98 - 107	No	
		Week 32	06SEP2016/09:00	102	98 - 107	No	
		Week 36	06OCT2016/09:50	101	98 - 107	No	
		Week 40	03NOV2016/11:00	101	98 - 107	No	
		Week 44	06DEC2016/10:30	104	98 - 107	No	
		Week 48	03JAN2017/10:45	100	98 - 107	No	
	Cholesterol (mmol/L)	Screening	07JAN2016/12:00	7.0 H	0 - 4.9	Yes	1
		Day 1	27JAN2016/08:30	6.6 H	0 - 4.9	Yes	1
		Week 1	03FEB2016/11:00	6.6 H	0 - 4.9	Yes	1
		Week 2	11FEB2016/11:30	6.0 H	0 - 4.9	Yes	1
		Week 4	26FEB2016/10:20	5.8 H	0 - 4.9	No	1
		Week 6	10MAR2016/10:45	5.3 H	0 - 4.9	No	1
		Week 8	24MAR2016/09:31	5.8 H	0 - 4.9	No	1
		Week 12	19APR2016/09:20	5.7 H	0 - 4.9	Yes	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011 Cholesterol (mmol/L)	Week 16	18MAY2016/10:10	5.0 H	0 - 4.9	No	1
	Week 20	21JUN2016/10:35	5.5 H	0 - 4.9	No	1
	Week 24	12JUL2016/10:00	5.6 H	0 - 4.9	Yes	1
	Week 28	09AUG2016/09:50	6.2 H	0 - 4.9	No	1
	Week 32	06SEP2016/09:00	5.8 H	0 - 4.9	No	1
	Week 36	06OCT2016/09:50	5.7 H	0 - 4.9	No	1
	Week 40	03NOV2016/11:00	5.8 H	0 - 4.9	No	1
	Week 44	06DEC2016/10:30	6.0 H	0 - 4.9	No	1
	Week 48	03JAN2017/10:45	6.0 H	0 - 4.9	No	1
Creatine Kinase (IU/L)	Screening	07JAN2016/12:00	331 H	26 - 140	Yes	1
	Day 1	27JAN2016/08:30	280 H	26 - 140	Yes	1
	Week 1	03FEB2016/11:00	261 H	26 - 140	Yes	1
	Week 2	11FEB2016/11:30	330 H	26 - 140	Yes	1
	Week 4	26FEB2016/10:20	270 H	26 - 140	No	1
	Week 6	10MAR2016/10:45	163 H	26 - 140	No	1
	Week 8	24MAR2016/09:31	198 H	26 - 140	No	1
	Week 12	19APR2016/09:20	168 H	26 - 140	Yes	1
	Week 16	18MAY2016/10:10	132	26 - 140	No	0
	Week 20	21JUN2016/10:35	141 H	26 - 140	No	1
	Week 24	12JUL2016/10:00	182 H	26 - 140	Yes	1
	Week 28	09AUG2016/09:50	184 H	26 - 140	No	1
	Week 32	06SEP2016/09:00	198 H	26 - 140	No	1
	Week 36	06OCT2016/09:50	185 H	26 - 140	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Creatine Kinase (IU/L)	Week 40	03NOV2016/11:00	195 H	26 - 140	No	1
		Week 44	06DEC2016/10:30	202 H	26 - 140	No	1
		Week 48	03JAN2017/10:45	166 H	26 - 140	No	1
	Creatinine (umol/L)	Screening	07JAN2016/12:00	73	49 - 92	Yes	0
		Day 1	27JAN2016/08:30	54	49 - 92	Yes	0
		Week 1	03FEB2016/11:00	67	49 - 92	Yes	1
		Week 2	11FEB2016/11:30	71	49 - 92	Yes	1
		Week 4	26FEB2016/10:20	81	49 - 92	No	1
		Week 6	10MAR2016/10:45	78	49 - 92	No	1
		Week 8	24MAR2016/09:31	58	49 - 92	No	1
		Week 12	19APR2016/09:20	68	49 - 92	Yes	1
		Week 16	18MAY2016/10:10	77	49 - 92	No	1
		Week 20	21JUN2016/10:35	62	49 - 92	No	1
		Week 24	12JUL2016/10:00	71	49 - 92	Yes	1
		Week 28	09AUG2016/09:50	56	49 - 92	No	1
		Week 32	06SEP2016/09:00	63	49 - 92	No	1
		Week 36	06OCT2016/09:50	62	49 - 92	No	1
		Week 40	03NOV2016/11:00	60	49 - 92	No	1
		Week 44	06DEC2016/10:30	64	49 - 92	No	1
		Week 48	03JAN2017/10:45	65	49 - 92	No	1
	Direct Bilirubin (umol/L)	Screening	07JAN2016/12:00	4	0 - 5	Yes	
		Day 1	27JAN2016/08:30	3	0 - 5	Yes	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Direct Bilirubin (umol/L)	Week 1	03FEB2016/11:00	2	0 - 5	Yes	
		Week 2	11FEB2016/11:30	3	0 - 5	Yes	
		Week 4	26FEB2016/10:20	4	0 - 5	No	
		Week 6	10MAR2016/10:45	3	0 - 5	No	
		Week 8	24MAR2016/09:31	3	0 - 5	No	
		Week 12	19APR2016/09:20	4	0 - 5	Yes	
		Week 16	18MAY2016/10:10	5	0 - 5	No	
		Week 20	21JUN2016/10:35	3	0 - 5	No	
		Week 24	12JUL2016/10:00	8 H	0 - 5	Yes	
		Week 28	09AUG2016/09:50	5	0 - 5	No	
		Week 32	06SEP2016/09:00	4	0 - 5	No	
		Week 36	06OCT2016/09:50	4	0 - 5	No	
		Week 40	03NOV2016/11:00	4	0 - 5	No	
		Week 44	06DEC2016/10:30	3	0 - 5	No	
		Week 48	03JAN2017/10:45	3	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	07JAN2016/12:00	35	6 - 42	Yes	0
		Day 1	27JAN2016/08:30	33	6 - 42	Yes	0
		Week 1	03FEB2016/11:00	34	6 - 42	Yes	0
		Week 2	11FEB2016/11:30	36	6 - 42	Yes	0
		Week 4	26FEB2016/10:20	37	6 - 42	No	0
		Week 6	10MAR2016/10:45	47 H	6 - 42	No	1
		Week 8	24MAR2016/09:31	50 H	6 - 42	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Gamma Glutamyl Transferase (IU/L)	Week 12	19APR2016/09:20	55 H	6 - 42	Yes	1
		Week 16	18MAY2016/10:10	77 H	6 - 42	No	1
		Week 20	21JUN2016/10:35	60 H	6 - 42	No	1
		Week 24	12JUL2016/10:00	199 H	6 - 42	Yes	2
		Week 28	09AUG2016/09:50	174 H	6 - 42	No	2
		Week 32	06SEP2016/09:00	162 H	6 - 42	No	2
		Week 36	06OCT2016/09:50	118 H	6 - 42	No	2
		Week 40	03NOV2016/11:00	78 H	6 - 42	No	1
		Week 44	06DEC2016/10:30	59 H	6 - 42	No	1
		Week 48	03JAN2017/10:45	44 H	6 - 42	No	1
	Globulin (g/L)	Screening	07JAN2016/12:00	24	19 - 35	Yes	
		Day 1	27JAN2016/08:30	24	19 - 35	Yes	
		Week 1	03FEB2016/11:00	28	19 - 35	Yes	
		Week 2	11FEB2016/11:30	24	19 - 35	Yes	
		Week 4	26FEB2016/10:20	29	19 - 35	No	
		Week 6	10MAR2016/10:45	26	19 - 35	No	
		Week 8	24MAR2016/09:31	27	19 - 35	No	
		Week 12	19APR2016/09:20	25	19 - 35	Yes	
		Week 16	18MAY2016/10:10	27	19 - 35	No	
		Week 20	21JUN2016/10:35	25	19 - 35	No	
		Week 24	12JUL2016/10:00	33	19 - 35	Yes	
		Week 28	09AUG2016/09:50	29	19 - 35	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Globulin (g/L)	Week 32	06SEP2016/09:00	31	19 - 35	No	
		Week 36	06OCT2016/09:50	30	19 - 35	No	
		Week 40	03NOV2016/11:00	30	19 - 35	No	
		Week 44	06DEC2016/10:30	26	19 - 35	No	
		Week 48	03JAN2017/10:45	27	19 - 35	No	
	Glucose (mmol/L)	Screening	07JAN2016/12:00	12.0 H	3.9 - 5.8	Yes	2
		Day 1	27JAN2016/08:30	4.7	3.9 - 5.8	Yes	0
		Week 1	03FEB2016/11:00	5.1	3.9 - 5.8	Yes	0
		Week 2	11FEB2016/11:30	5.3	3.9 - 5.8	Yes	0
		Week 4	26FEB2016/10:20	5.3	3.5 - 7.9	No	0
		Week 6	10MAR2016/10:45	5.5	3.5 - 7.9	No	0
		Week 8	24MAR2016/09:31	5.4	3.5 - 7.9	No	0
		Week 12	19APR2016/09:20	5.2	3.9 - 5.8	Yes	0
		Week 16	18MAY2016/10:10	5.8	3.5 - 7.9	No	0
		Week 20	21JUN2016/10:35	5.3	3.5 - 7.9	No	0
		Week 24	12JUL2016/10:00	4.3	3.9 - 5.8	Yes	0
		Week 28	09AUG2016/09:50	4.9	3.5 - 7.9	No	0
		Week 32	06SEP2016/09:00	4.9	3.5 - 7.9	No	0
		Week 36	06OCT2016/09:50	5.2	3.5 - 7.9	No	0
		Week 40	03NOV2016/11:00	4.5	3.5 - 7.9	No	0
		Week 44	06DEC2016/10:30	4.7	3.5 - 7.9	No	0
		Week 48	03JAN2017/10:45	4.5	3.5 - 7.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Indirect Bilirubin (umol/L)	Screening	07JAN2016/12:00	7	0 - 14	Yes
		Day 1	27JAN2016/08:30	4	0 - 14	Yes
		Week 1	03FEB2016/11:00	5	0 - 14	Yes
		Week 2	11FEB2016/11:30	4	0 - 14	Yes
		Week 4	26FEB2016/10:20	6	0 - 14	No
		Week 6	10MAR2016/10:45	5	0 - 14	No
		Week 8	24MAR2016/09:31	3	0 - 14	No
		Week 12	19APR2016/09:20	5	0 - 14	Yes
		Week 16	18MAY2016/10:10	5	0 - 14	No
		Week 20	21JUN2016/10:35	4	0 - 14	No
		Week 24	12JUL2016/10:00	4	0 - 14	Yes
		Week 28	09AUG2016/09:50	4	0 - 14	No
		Week 32	06SEP2016/09:00	3	0 - 14	No
		Week 36	06OCT2016/09:50	6	0 - 14	No
		Week 40	03NOV2016/11:00	8	0 - 14	No
		Week 44	06DEC2016/10:30	5	0 - 14	No
		Week 48	03JAN2017/10:45	5	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	07JAN2016/12:00	237 H	135 - 214	Yes
		Day 1	27JAN2016/08:30	228 H	135 - 214	Yes
		Week 1	03FEB2016/11:00	223 H	135 - 214	Yes
		Week 2	11FEB2016/11:30	233 H	135 - 214	Yes
		Week 4	26FEB2016/10:20	303 H	135 - 214	No
		Week 6	10MAR2016/10:45	284 H	135 - 214	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Lactate Dehydrogenase (IU/L)	Week 8	24MAR2016/09:31	261 H	135 - 214	No	
		Week 12	19APR2016/09:20	266 H	135 - 214	Yes	
		Week 16	18MAY2016/10:10	303 H	135 - 214	No	
		Week 20	21JUN2016/10:35	260 H	135 - 214	No	
		Week 24	12JUL2016/10:00	396 H	135 - 214	Yes	
		Week 28	09AUG2016/09:50	281 H	135 - 214	No	
		Week 32	06SEP2016/09:00	262 H	135 - 214	No	
		Week 36	06OCT2016/09:50	258 H	135 - 214	No	
		Week 40	03NOV2016/11:00	254 H	135 - 214	No	
		Week 44	06DEC2016/10:30	243 H	135 - 214	No	
		Week 48	03JAN2017/10:45	238 H	135 - 214	No	
	Magnesium (mmol/L)	Screening	07JAN2016/12:00	0.81	0.6 - 1	Yes	0
		Day 1	27JAN2016/08:30	0.85	0.6 - 1	Yes	0
		Week 1	03FEB2016/11:00	0.84	0.6 - 1	Yes	0
		Week 2	11FEB2016/11:30	0.87	0.6 - 1	Yes	0
		Week 4	26FEB2016/10:20	0.76	0.6 - 1	No	0
		Week 6	10MAR2016/10:45	0.82	0.6 - 1	No	0
		Week 8	24MAR2016/09:31	0.91	0.6 - 1	No	0
		Week 12	19APR2016/09:20	0.78	0.6 - 1	Yes	0
		Week 16	18MAY2016/10:10	0.79	0.6 - 1	No	0
		Week 20	21JUN2016/10:35	0.86	0.6 - 1	No	0
		Week 24	12JUL2016/10:00	0.87	0.6 - 1	Yes	0
		Week 28	09AUG2016/09:50	0.82	0.6 - 1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Magnesium (mmol/L)	Week 32	06SEP2016/09:00	0.89	0.6 - 1	No	0
		Week 36	06OCT2016/09:50	0.86	0.6 - 1	No	0
		Week 40	03NOV2016/11:00	0.77	0.6 - 1	No	0
		Week 44	06DEC2016/10:30	0.83	0.6 - 1	No	0
		Week 48	03JAN2017/10:45	0.78	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	07JAN2016/12:00	1.03	0.87 - 1.45	Yes	0
		Day 1	27JAN2016/08:30	1.23	0.87 - 1.45	Yes	0
		Week 1	03FEB2016/11:00	1.04	0.87 - 1.45	Yes	0
		Week 2	11FEB2016/11:30	0.95	0.87 - 1.45	Yes	0
		Week 4	26FEB2016/10:20	1.20	0.87 - 1.45	No	0
		Week 6	10MAR2016/10:45	1.18	0.87 - 1.45	No	0
		Week 8	24MAR2016/09:31	1.40	0.87 - 1.45	No	0
		Week 12	19APR2016/09:20	1.12	0.87 - 1.45	Yes	0
		Week 16	18MAY2016/10:10	1.06	0.87 - 1.45	No	0
		Week 20	21JUN2016/10:35	1.07	0.87 - 1.45	No	0
		Week 24	12JUL2016/10:00	1.12	0.87 - 1.45	Yes	0
		Week 28	09AUG2016/09:50	1.19	0.87 - 1.45	No	0
		Week 32	06SEP2016/09:00	1.19	0.87 - 1.45	No	0
		Week 36	06OCT2016/09:50	1.15	0.87 - 1.45	No	0
		Week 40	03NOV2016/11:00	1.12	0.87 - 1.45	No	0
		Week 44	06DEC2016/10:30	1.14	0.87 - 1.45	No	0
		Week 48	03JAN2017/10:45	1.24	0.87 - 1.45	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011 Potassium (mmol/L)	Screening	07JAN2016/12:00	4.5	3.5 - 5.1	Yes	0
	Day 1	27JAN2016/08:30	5.3 H	3.5 - 5.1	Yes	1
	Week 1	03FEB2016/11:00	5.3 H	3.5 - 5.1	Yes	1
	Week 2	11FEB2016/11:30	4.9	3.5 - 5.1	Yes	0
	Week 4	26FEB2016/10:20	4.8	3.5 - 5.1	No	0
	Week 6	10MAR2016/10:45	4.3	3.5 - 5.1	No	0
	Week 8	24MAR2016/09:31	5.2 H	3.5 - 5.1	No	1
	Week 12	19APR2016/09:20	4.1	3.5 - 5.1	Yes	0
	Week 16	18MAY2016/10:10	4.2	3.5 - 5.1	No	0
	Week 20	21JUN2016/10:35	4.7	3.5 - 5.1	No	0
	Week 24	12JUL2016/10:00	4.5	3.5 - 5.1	Yes	0
	Week 28	09AUG2016/09:50	5.0	3.5 - 5.1	No	0
	Week 32	06SEP2016/09:00	5.1	3.5 - 5.1	No	0
	Week 36	06OCT2016/09:50	5.1	3.5 - 5.1	No	0
	Week 40	03NOV2016/11:00	5.0	3.5 - 5.1	No	0
	Week 44	06DEC2016/10:30	4.8	3.5 - 5.1	No	0
	Week 48	03JAN2017/10:45	5.1	3.5 - 5.1	No	0
Protein (g/L)	Screening	07JAN2016/12:00	66	63 - 83	Yes	
	Day 1	27JAN2016/08:30	67	63 - 83	Yes	
	Week 1	03FEB2016/11:00	70	63 - 83	Yes	
	Week 2	11FEB2016/11:30	67	63 - 83	Yes	
	Week 4	26FEB2016/10:20	73	63 - 83	No	
	Week 6	10MAR2016/10:45	69	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Protein (g/L)	Week 8	24MAR2016/09:31	69	63 - 83	No	
		Week 12	19APR2016/09:20	68	63 - 83	Yes	
		Week 16	18MAY2016/10:10	71	63 - 83	No	
		Week 20	21JUN2016/10:35	65	63 - 83	No	
		Week 24	12JUL2016/10:00	73	63 - 83	Yes	
		Week 28	09AUG2016/09:50	67	63 - 83	No	
		Week 32	06SEP2016/09:00	71	63 - 83	No	
		Week 36	06OCT2016/09:50	71	63 - 83	No	
		Week 40	03NOV2016/11:00	70	63 - 83	No	
		Week 44	06DEC2016/10:30	69	63 - 83	No	
		Week 48	03JAN2017/10:45	68	63 - 83	No	
	Sodium (mmol/L)	Screening	07JAN2016/12:00	140	135 - 145	Yes	0
		Day 1	27JAN2016/08:30	140	135 - 145	Yes	0
		Week 1	03FEB2016/11:00	141	135 - 145	Yes	0
		Week 2	11FEB2016/11:30	142	135 - 145	Yes	0
		Week 4	26FEB2016/10:20	138	135 - 145	No	0
		Week 6	10MAR2016/10:45	139	135 - 145	No	0
		Week 8	24MAR2016/09:31	144	135 - 145	No	0
		Week 12	19APR2016/09:20	140	135 - 145	Yes	0
		Week 16	18MAY2016/10:10	142	135 - 145	No	0
		Week 20	21JUN2016/10:35	142	135 - 145	No	0
		Week 24	12JUL2016/10:00	139	135 - 145	Yes	0
		Week 28	09AUG2016/09:50	140	135 - 145	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Sodium (mmol/L)	Week 32	06SEP2016/09:00	143	135 - 145	No	0
		Week 36	06OCT2016/09:50	143	135 - 145	No	0
		Week 40	03NOV2016/11:00	143	135 - 145	No	0
		Week 44	06DEC2016/10:30	143	135 - 145	No	0
		Week 48	03JAN2017/10:45	142	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	07JAN2016/12:00	0.97	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	07JAN2016/12:00	95	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	07JAN2016/12:00	0.7	0 - 2.2	Yes	0
		Day 1	27JAN2016/08:30	0.9	0 - 2.2	Yes	0
		Week 1	03FEB2016/11:00	1.4	0 - 2.2	Yes	0
		Week 2	11FEB2016/11:30	1.6	0 - 2.2	Yes	0
		Week 4	26FEB2016/10:20	1.1	0 - 2.2	No	0
		Week 6	10MAR2016/10:45	1.2	0 - 2.2	No	0
		Week 8	24MAR2016/09:31	1.2	0 - 2.2	No	0
		Week 12	19APR2016/09:20	1.6	0 - 2.2	Yes	0
		Week 16	18MAY2016/10:10	1.2	0 - 2.2	No	0
		Week 20	21JUN2016/10:35	1.3	0 - 2.2	No	0
		Week 24	12JUL2016/10:00	1.2	0 - 2.2	Yes	0
		Week 28	09AUG2016/09:50	1.2	0 - 2.2	No	0
		Week 32	06SEP2016/09:00	1.1	0 - 2.2	No	0
		Week 36	06OCT2016/09:50	1.0	0 - 2.2	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Triglycerides (mmol/L)	Week 40	03NOV2016/11:00	1.0	0 - 2.2	No	0
		Week 44	06DEC2016/10:30	0.9	0 - 2.2	No	0
		Week 48	03JAN2017/10:45	0.8	0 - 2.2	No	0
	Triiodothyronine (nmol/L)	Screening	07JAN2016/12:00	1.6	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	07JAN2016/12:00	5.0	1.7 - 8.3	Yes	
		Day 1	27JAN2016/08:30	6.3	1.7 - 8.3	Yes	
		Week 1	03FEB2016/11:00	6.8	1.7 - 8.3	Yes	
		Week 2	11FEB2016/11:30	5.3	1.7 - 8.3	Yes	
		Week 4	26FEB2016/10:20	5.6	1.7 - 8.3	No	
		Week 6	10MAR2016/10:45	5.0	1.7 - 8.3	No	
		Week 8	24MAR2016/09:31	5.0	1.7 - 8.3	No	
		Week 12	19APR2016/09:20	4.7	1.7 - 8.3	Yes	
		Week 16	18MAY2016/10:10	4.3	1.7 - 8.3	No	
		Week 20	21JUN2016/10:35	4.2	1.7 - 8.3	No	
		Week 24	12JUL2016/10:00	4.2	1.7 - 8.3	Yes	
		Week 28	09AUG2016/09:50	4.3	1.7 - 8.3	No	
		Week 32	06SEP2016/09:00	4.5	1.7 - 8.3	No	
		Week 36	06OCT2016/09:50	5.0	1.7 - 8.3	No	
		Week 40	03NOV2016/11:00	4.7	1.7 - 8.3	No	
		Week 44	06DEC2016/10:30	5.9	1.7 - 8.3	No	
		Week 48	03JAN2017/10:45	5.6	1.7 - 8.3	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Uric acid (umol/L)	Screening	07JAN2016/12:00	387 H	175 - 363	Yes	1
		Day 1	27JAN2016/08:30	287	175 - 363	Yes	0
		Week 1	03FEB2016/11:00	298	175 - 363	Yes	0
		Week 2	11FEB2016/11:30	314	175 - 363	Yes	0
		Week 4	26FEB2016/10:20	337	175 - 363	No	0
		Week 6	10MAR2016/10:45	360	175 - 363	No	0
		Week 8	24MAR2016/09:31	296	175 - 363	No	0
		Week 12	19APR2016/09:20	295	175 - 363	Yes	0
		Week 16	18MAY2016/10:10	339	175 - 363	No	0
		Week 20	21JUN2016/10:35	295	175 - 363	No	0
		Week 24	12JUL2016/10:00	371 H	175 - 363	Yes	1
		Week 28	09AUG2016/09:50	348	175 - 363	No	0
		Week 32	06SEP2016/09:00	352	175 - 363	No	0
		Week 36	06OCT2016/09:50	341	175 - 363	No	0
		Week 40	03NOV2016/11:00	305	175 - 363	No	0
		Week 44	06DEC2016/10:30	293	175 - 363	No	0
		Week 48	03JAN2017/10:45	326	175 - 363	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Alanine Aminotransferase (IU/L)	Screening	06JAN2016/11:00	54 H	10 - 50	Yes	1
		Day 1	02FEB2016/11:10	59 H	10 - 50	Yes	1
		Week 1	09FEB2016/10:00	80 H	10 - 50	No	1
		Week 2	16FEB2016/11:00	132 H	10 - 50	No	1
		Week 4	01MAR2016/10:30	239 H	10 - 50	No	2
		Week 6	16MAR2016/11:45	294 H	10 - 50	No	3
		Week 8	31MAR2016/09:52	69 H	10 - 50	No	1
		Week 12	28APR2016/08:15	52 H	10 - 50	Yes	1
		Week 16	26MAY2016/12:10	49	10 - 50	No	0
		Week 20	22JUN2016/09:55	35	10 - 50	No	0
		Week 24	20JUL2016/09:30	46	10 - 50	Yes	0
		Week 28	18AUG2016/10:45	70 H	10 - 50	No	1
		Week 32	15SEP2016/10:00	87 H	10 - 50	No	1
		Week 36	13OCT2016/12:30	80 H	10 - 50	No	1
		Week 40	10NOV2016/10:15	101 H	10 - 50	No	1
		Week 44	06DEC2016/11:00	119 H	10 - 50	No	1
		Week 48	03JAN2017/12:00	134 H	10 - 50	No	1
	Albumin (g/L)	Screening	06JAN2016/11:00	39	34 - 50	Yes	0
		Day 1	02FEB2016/11:10	37	34 - 50	Yes	0
		Week 1	09FEB2016/10:00	40	34 - 50	No	0
		Week 2	16FEB2016/11:00	39	34 - 50	No	0
		Week 4	01MAR2016/10:30	39	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Albumin (g/L)	Week 6	16MAR2016/11:45	36	34 - 50	No	0
		Week 8	31MAR2016/09:52	35	34 - 50	No	0
		Week 12	28APR2016/08:15	38	34 - 50	Yes	0
		Week 16	26MAY2016/12:10	40	34 - 50	No	0
		Week 20	22JUN2016/09:55	37	34 - 50	No	0
		Week 24	20JUL2016/09:30	39	34 - 50	Yes	0
		Week 28	18AUG2016/10:45	39	34 - 50	No	0
		Week 32	15SEP2016/10:00	40	34 - 50	No	0
		Week 36	13OCT2016/12:30	40	34 - 50	No	0
		Week 40	10NOV2016/10:15	39	34 - 50	No	0
		Week 44	06DEC2016/11:00	40	34 - 50	No	0
		Week 48	03JAN2017/12:00	42	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	06JAN2016/11:00	106	40 - 129	Yes	0
		Day 1	02FEB2016/11:10	119	40 - 129	Yes	0
		Week 1	09FEB2016/10:00	135 H	40 - 129	No	1
		Week 2	16FEB2016/11:00	161 H	40 - 129	No	1
		Week 4	01MAR2016/10:30	165 H	40 - 129	No	1
		Week 6	16MAR2016/11:45	146 H	40 - 129	No	1
		Week 8	31MAR2016/09:52	146 H	40 - 129	No	1
		Week 12	28APR2016/08:15	174 H	40 - 129	Yes	1
		Week 16	26MAY2016/12:10	158 H	40 - 129	No	1
		Week 20	22JUN2016/09:55	185 H	40 - 129	No	1
		Week 24	20JUL2016/09:30	139 H	40 - 129	Yes	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Alkaline Phosphatase (IU/L)	Week 28	18AUG2016/10:45	141 H	40 - 129	No	1
		Week 32	15SEP2016/10:00	131 H	40 - 129	No	1
		Week 36	13OCT2016/12:30	119	40 - 129	No	0
		Week 40	10NOV2016/10:15	131 H	40 - 129	No	1
		Week 44	06DEC2016/11:00	115	40 - 129	No	0
		Week 48	03JAN2017/12:00	115	40 - 129	No	0
	Amylase (IU/L)	Screening	06JAN2016/11:00	81	28 - 100	Yes	0
		Day 1	02FEB2016/11:10	94	28 - 100	Yes	0
		Week 1	09FEB2016/10:00	87	28 - 100	No	0
		Week 2	16FEB2016/11:00	104 H	28 - 100	No	1
		Week 4	01MAR2016/10:30	93	28 - 100	No	0
		Week 6	16MAR2016/11:45	78	28 - 100	No	0
		Week 8	31MAR2016/09:52	82	28 - 100	No	0
		Week 12	28APR2016/08:15	101 H	28 - 100	Yes	1
		Week 16	26MAY2016/12:10	99	28 - 100	No	0
		Week 20	22JUN2016/09:55	87	28 - 100	No	0
		Week 24	20JUL2016/09:30	70	28 - 100	Yes	0
		Week 28	18AUG2016/10:45	75	28 - 100	No	0
		Week 32	15SEP2016/10:00	86	28 - 100	No	0
		Week 36	13OCT2016/12:30	92	28 - 100	No	0
		Week 40	10NOV2016/10:15	102 H	28 - 100	No	1
		Week 44	06DEC2016/11:00	94	28 - 100	No	0
		Week 48	03JAN2017/12:00	98	28 - 100	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Aspartate Aminotransferase (IU/L)	Screening	06JAN2016/11:00	50 H	0 - 37	Yes	1
		Day 1	02FEB2016/11:10	53 H	0 - 37	Yes	1
		Week 1	09FEB2016/10:00	60 H	0 - 37	No	1
		Week 2	16FEB2016/11:00	69 H	0 - 37	No	1
		Week 4	01MAR2016/10:30	103 H	0 - 37	No	1
		Week 6	16MAR2016/11:45	114 H	0 - 37	No	2
		Week 8	31MAR2016/09:52	39 H	0 - 37	No	1
		Week 12	28APR2016/08:15	40 H	0 - 37	Yes	1
		Week 16	26MAY2016/12:10	43 H	0 - 37	No	1
		Week 20	22JUN2016/09:55	35	0 - 37	No	0
		Week 24	20JUL2016/09:30	42 H	0 - 37	Yes	1
		Week 28	18AUG2016/10:45	67 H	0 - 37	No	1
		Week 32	15SEP2016/10:00	77 H	0 - 37	No	1
		Week 36	13OCT2016/12:30	71 H	0 - 37	No	1
		Week 40	10NOV2016/10:15	80 H	0 - 37	No	1
		Week 44	06DEC2016/11:00	100 H	0 - 37	No	1
		Week 48	03JAN2017/12:00	103 H	0 - 37	No	1
	Bicarbonate (mmol/L)	Screening	06JAN2016/11:00	21 L	22 - 29	Yes	
		Day 1	02FEB2016/11:10	24	22 - 29	Yes	
		Week 1	09FEB2016/10:00	23	22 - 29	No	
		Week 2	16FEB2016/11:00	28	22 - 29	No	
		Week 4	01MAR2016/10:30	26	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Bicarbonate (mmol/L)	Week 6	16MAR2016/11:45	24	22 - 29	No	
		Week 8	31MAR2016/09:52	25	22 - 29	No	
		Week 12	28APR2016/08:15	24	22 - 29	Yes	
		Week 16	26MAY2016/12:10	20 L	22 - 29	No	
		Week 20	22JUN2016/09:55	20 L	22 - 29	No	
		Week 24	20JUL2016/09:30	21 L	22 - 29	Yes	
		Week 28	18AUG2016/10:45	22	22 - 29	No	
		Week 32	15SEP2016/10:00	23	22 - 29	No	
		Week 36	13OCT2016/12:30	24	22 - 29	No	
		Week 40	10NOV2016/10:15	25	22 - 29	No	
		Week 44	06DEC2016/11:00	21 L	22 - 29	No	
		Week 48	03JAN2017/12:00	23	22 - 29	No	
	Bilirubin (umol/L)	Screening	06JAN2016/11:00	10	0 - 20	Yes	0
		Day 1	02FEB2016/11:10	6	0 - 20	Yes	0
		Week 1	09FEB2016/10:00	5	0 - 20	No	0
		Week 2	16FEB2016/11:00	4	0 - 20	No	0
		Week 4	01MAR2016/10:30	4	0 - 20	No	0
		Week 6	16MAR2016/11:45	3	0 - 20	No	0
		Week 8	31MAR2016/09:52	6	0 - 20	No	0
		Week 12	28APR2016/08:15	4	0 - 20	Yes	0
		Week 16	26MAY2016/12:10	3	0 - 20	No	0
		Week 20	22JUN2016/09:55	4	0 - 20	No	0
		Week 24	20JUL2016/09:30	6	0 - 20	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Bilirubin (umol/L)	Week 28	18AUG2016/10:45	7	0 - 20	No	0
		Week 32	15SEP2016/10:00	6	0 - 20	No	0
		Week 36	13OCT2016/12:30	8	0 - 20	No	0
		Week 40	10NOV2016/10:15	5	0 - 20	No	0
		Week 44	06DEC2016/11:00	6	0 - 20	No	0
		Week 48	03JAN2017/12:00	4	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	06JAN2016/11:00	23.52 H	4.76 - 23.24	Yes	
		Day 1	02FEB2016/11:10	21.28	4.76 - 23.24	Yes	
		Week 1	09FEB2016/10:00	19.60	4.76 - 23.24	No	
		Week 2	16FEB2016/11:00	18.76	4.76 - 23.24	No	
		Week 4	01MAR2016/10:30	21.84	4.76 - 23.24	No	
		Week 6	16MAR2016/11:45	17.92	4.76 - 23.24	No	
		Week 8	31MAR2016/09:52	15.40	4.76 - 23.24	No	
		Week 12	28APR2016/08:15	19.32	4.76 - 23.24	Yes	
		Week 16	26MAY2016/12:10	15.40	4.76 - 23.24	No	
		Week 20	22JUN2016/09:55	18.48	4.76 - 23.24	No	
		Week 24	20JUL2016/09:30	16.52	4.76 - 23.24	Yes	
		Week 28	18AUG2016/10:45	17.08	4.76 - 23.24	No	
		Week 32	15SEP2016/10:00	20.16	4.76 - 23.24	No	
		Week 36	13OCT2016/12:30	16.24	4.76 - 23.24	No	
		Week 40	10NOV2016/10:15	14.28	4.76 - 23.24	No	
		Week 44	06DEC2016/11:00	20.72	4.76 - 23.24	No	
		Week 48	03JAN2017/12:00	21.00	4.76 - 23.24	No	

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Calcium (mmol/L)	Screening	06JAN2016/11:00	2.33	2.2 - 2.6	Yes	0
		Day 1	02FEB2016/11:10	2.25	2.2 - 2.6	Yes	0
		Week 1	09FEB2016/10:00	2.26	2.2 - 2.6	No	0
		Week 2	16FEB2016/11:00	2.34	2.2 - 2.6	No	0
		Week 4	01MAR2016/10:30	2.23	2.2 - 2.6	No	0
		Week 6	16MAR2016/11:45	2.28	2.2 - 2.6	No	0
		Week 8	31MAR2016/09:52	2.19 L	2.2 - 2.6	No	1
		Week 12	28APR2016/08:15	2.21	2.2 - 2.6	Yes	0
		Week 16	26MAY2016/12:10	2.37	2.2 - 2.6	No	0
		Week 20	22JUN2016/09:55	2.15 L	2.2 - 2.6	No	1
		Week 24	20JUL2016/09:30	2.21	2.2 - 2.6	Yes	0
		Week 28	18AUG2016/10:45	2.24	2.2 - 2.6	No	0
		Week 32	15SEP2016/10:00	2.26	2.2 - 2.6	No	0
		Week 36	13OCT2016/12:30	2.33	2.2 - 2.6	No	0
		Week 40	10NOV2016/10:15	2.24	2.2 - 2.6	No	0
		Week 44	06DEC2016/11:00	2.22	2.2 - 2.6	No	0
		Week 48	03JAN2017/12:00	2.28	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	06JAN2016/11:00	99	98 - 107	Yes	
		Day 1	02FEB2016/11:10	102	98 - 107	Yes	
		Week 1	09FEB2016/10:00	102	98 - 107	No	
		Week 2	16FEB2016/11:00	103	98 - 107	No	
		Week 4	01MAR2016/10:30	101	98 - 107	No	
		Week 6	16MAR2016/11:45	101	98 - 107	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Chloride (mmol/L)	Week 8	31MAR2016/09:52	102	98 - 107	No	
		Week 12	28APR2016/08:15	104	98 - 107	Yes	
		Week 16	26MAY2016/12:10	102	98 - 107	No	
		Week 20	22JUN2016/09:55	103	98 - 107	No	
		Week 24	20JUL2016/09:30	100	98 - 107	Yes	
		Week 28	18AUG2016/10:45	104	98 - 107	No	
		Week 32	15SEP2016/10:00	101	98 - 107	No	
		Week 36	13OCT2016/12:30	102	98 - 107	No	
		Week 40	10NOV2016/10:15	102	98 - 107	No	
		Week 44	06DEC2016/11:00	104	98 - 107	No	
		Week 48	03JAN2017/12:00	102	98 - 107	No	
	Cholesterol (mmol/L)	Screening	06JAN2016/11:00	4.9	0 - 4.9	Yes	0
		Day 1	02FEB2016/11:10	4.7	0 - 4.9	Yes	0
		Week 1	09FEB2016/10:00	3.7	0 - 4.9	No	0
		Week 2	16FEB2016/11:00	4.3	0 - 4.9	No	0
		Week 4	01MAR2016/10:30	4.3	0 - 4.9	No	0
		Week 6	16MAR2016/11:45	4.1	0 - 4.9	No	0
		Week 8	31MAR2016/09:52	4.1	0 - 4.9	No	0
		Week 12	28APR2016/08:15	4.3	0 - 4.9	Yes	0
		Week 16	26MAY2016/12:10	4.3	0 - 4.9	No	0
		Week 20	22JUN2016/09:55	3.9	0 - 4.9	No	0
		Week 24	20JUL2016/09:30	3.9	0 - 4.9	Yes	0
		Week 28	18AUG2016/10:45	4.2	0 - 4.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Cholesterol (mmol/L)	Week 32	15SEP2016/10:00	4.2	0 - 4.9	No	0
		Week 36	13OCT2016/12:30	4.1	0 - 4.9	No	0
		Week 40	10NOV2016/10:15	4.3	0 - 4.9	No	0
		Week 44	06DEC2016/11:00	4.1	0 - 4.9	No	0
		Week 48	03JAN2017/12:00	4.3	0 - 4.9	No	0
	Creatine Kinase (IU/L)	Screening	06JAN2016/11:00	197	38 - 204	Yes	0
		Day 1	02FEB2016/11:10	105	38 - 204	Yes	0
		Week 1	09FEB2016/10:00	116	38 - 204	No	0
		Week 2	16FEB2016/11:00	93	38 - 204	No	0
		Week 4	01MAR2016/10:30	99	38 - 204	No	0
		Week 6	16MAR2016/11:45	109	38 - 204	No	0
		Week 8	31MAR2016/09:52	130	38 - 204	No	0
		Week 12	28APR2016/08:15	86	38 - 204	Yes	0
		Week 16	26MAY2016/12:10	93	38 - 204	No	0
		Week 20	22JUN2016/09:55	90	38 - 204	No	0
		Week 24	20JUL2016/09:30	128	38 - 204	Yes	0
		Week 28	18AUG2016/10:45	183	38 - 204	No	0
		Week 32	15SEP2016/10:00	111	38 - 204	No	0
		Week 36	13OCT2016/12:30	101	38 - 204	No	0
		Week 40	10NOV2016/10:15	109	38 - 204	No	0
		Week 44	06DEC2016/11:00	99	38 - 204	No	0
		Week 48	03JAN2017/12:00	131	38 - 204	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001 Creatinine (umol/L)	Screening	06JAN2016/11:00	106	66 - 112	Yes	0
	Day 1	02FEB2016/11:10	98	66 - 112	Yes	0
	Week 1	09FEB2016/10:00	89	66 - 112	No	0
	Week 2	16FEB2016/11:00	84	66 - 112	No	0
	Week 4	01MAR2016/10:30	89	66 - 112	No	0
	Week 6	16MAR2016/11:45	93	66 - 112	No	0
	Week 8	31MAR2016/09:52	98	66 - 112	No	0
	Week 12	28APR2016/08:15	94	66 - 112	Yes	0
	Week 16	26MAY2016/12:10	95	66 - 112	No	0
	Week 20	22JUN2016/09:55	83	66 - 112	No	0
	Week 24	20JUL2016/09:30	96	66 - 112	Yes	0
	Week 28	18AUG2016/10:45	95	66 - 112	No	0
	Week 32	15SEP2016/10:00	96	66 - 112	No	0
	Week 36	13OCT2016/12:30	96	66 - 112	No	0
	Week 40	10NOV2016/10:15	83	66 - 112	No	0
	Week 44	06DEC2016/11:00	95	66 - 112	No	0
	Week 48	03JAN2017/12:00	108	66 - 112	No	1
Direct Bilirubin (umol/L)	Screening	06JAN2016/11:00	4	0 - 5	Yes	
	Day 1	02FEB2016/11:10	2	0 - 5	Yes	
	Week 1	09FEB2016/10:00	3	0 - 5	No	
	Week 2	16FEB2016/11:00	<2	0 - 5	No	
	Week 4	01MAR2016/10:30	<2	0 - 5	No	
	Week 6	16MAR2016/11:45	<2	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Direct Bilirubin (umol/L)	Week 8	31MAR2016/09:52	3	0 - 5	No	
		Week 12	28APR2016/08:15	2	0 - 5	Yes	
		Week 16	26MAY2016/12:10	<2	0 - 5	No	
		Week 20	22JUN2016/09:55	<2	0 - 5	No	
		Week 24	20JUL2016/09:30	3	0 - 5	Yes	
		Week 28	18AUG2016/10:45	3	0 - 5	No	
		Week 32	15SEP2016/10:00	3	0 - 5	No	
		Week 36	13OCT2016/12:30	3	0 - 5	No	
		Week 40	10NOV2016/10:15	2	0 - 5	No	
		Week 44	06DEC2016/11:00	3	0 - 5	No	
		Week 48	03JAN2017/12:00	2	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	06JAN2016/11:00	80 H	10 - 71	Yes	1
		Day 1	02FEB2016/11:10	70	10 - 71	Yes	0
		Week 1	09FEB2016/10:00	69	10 - 71	No	0
		Week 2	16FEB2016/11:00	71	10 - 71	No	0
		Week 4	01MAR2016/10:30	87 H	10 - 71	No	1
		Week 6	16MAR2016/11:45	80 H	10 - 71	No	1
		Week 8	31MAR2016/09:52	69	10 - 71	No	0
		Week 12	28APR2016/08:15	66	10 - 71	Yes	0
		Week 16	26MAY2016/12:10	56	10 - 71	No	0
		Week 20	22JUN2016/09:55	52	10 - 71	No	0
		Week 24	20JUL2016/09:30	46	10 - 71	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Gamma Glutamyl Transferase (IU/L)	Week 28	18AUG2016/10:45	53	10 - 71	No	0
		Week 32	15SEP2016/10:00	55	10 - 71	No	0
		Week 36	13OCT2016/12:30	52	10 - 71	No	0
		Week 40	10NOV2016/10:15	58	10 - 71	No	0
		Week 44	06DEC2016/11:00	57	10 - 71	No	0
		Week 48	03JAN2017/12:00	68	10 - 71	No	0
	Globulin (g/L)	Screening	06JAN2016/11:00	31	19 - 35	Yes	
		Day 1	02FEB2016/11:10	31	19 - 35	Yes	
		Week 1	09FEB2016/10:00	31	19 - 35	No	
		Week 2	16FEB2016/11:00	29	19 - 35	No	
		Week 4	01MAR2016/10:30	31	19 - 35	No	
		Week 6	16MAR2016/11:45	31	19 - 35	No	
		Week 8	31MAR2016/09:52	27	19 - 35	No	
		Week 12	28APR2016/08:15	29	19 - 35	Yes	
		Week 16	26MAY2016/12:10	29	19 - 35	No	
		Week 20	22JUN2016/09:55	26	19 - 35	No	
		Week 24	20JUL2016/09:30	28	19 - 35	Yes	
		Week 28	18AUG2016/10:45	29	19 - 35	No	
		Week 32	15SEP2016/10:00	30	19 - 35	No	
		Week 36	13OCT2016/12:30	32	19 - 35	No	
		Week 40	10NOV2016/10:15	32	19 - 35	No	
		Week 44	06DEC2016/11:00	31	19 - 35	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Globulin (g/L)	Week 48	03JAN2017/12:00	32	19 - 35	No	
	Glucose (mmol/L)	Screening	06JAN2016/11:00	9.5 H	3.9 - 5.8	Yes	2
		Day 1	02FEB2016/11:10	4.5	3.9 - 5.8	Yes	0
		Week 1	09FEB2016/10:00	4.6	3.5 - 7.9	No	0
		Week 2	16FEB2016/11:00	3.8	3.5 - 7.9	No	0
		Week 4	01MAR2016/10:30	4.4	3.5 - 7.9	No	0
		Week 6	16MAR2016/11:45	6.9	3.5 - 7.9	No	0
		Week 8	31MAR2016/09:52	5.0	3.5 - 7.9	No	0
		Week 12	28APR2016/08:15	5.0	3.9 - 5.8	Yes	0
		Week 16	26MAY2016/12:10	5.1	3.5 - 7.9	No	0
		Week 20	22JUN2016/09:55	5.2	3.5 - 7.9	No	0
		Week 24	20JUL2016/09:30	4.3	3.9 - 5.8	Yes	0
		Week 28	18AUG2016/10:45	3.9	3.5 - 7.9	No	0
		Week 32	15SEP2016/10:00	4.6	3.5 - 7.9	No	0
		Week 36	13OCT2016/12:30	2.7 L	3.5 - 7.9	No	2
		Week 40	10NOV2016/10:15	4.4	3.5 - 7.9	No	0
		Week 44	06DEC2016/11:00	5.0	3.5 - 7.9	No	0
		Week 48	03JAN2017/12:00	4.3	3.5 - 7.9	No	0
	Indirect Bilirubin (umol/L)	Screening	06JAN2016/11:00	6	0 - 14	Yes	
		Day 1	02FEB2016/11:10	4	0 - 14	Yes	
		Week 1	09FEB2016/10:00	2	0 - 14	No	
		Week 2	16FEB2016/11:00		0 - 14	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Indirect Bilirubin (umol/L)	Week 4	01MAR2016/10:30		0 - 14	No
		Week 6	16MAR2016/11:45		0 - 14	No
		Week 8	31MAR2016/09:52	3	0 - 14	No
		Week 12	28APR2016/08:15	2	0 - 14	Yes
		Week 16	26MAY2016/12:10		0 - 14	No
		Week 20	22JUN2016/09:55		0 - 14	No
		Week 24	20JUL2016/09:30	3	0 - 14	Yes
		Week 28	18AUG2016/10:45	4	0 - 14	No
		Week 32	15SEP2016/10:00	3	0 - 14	No
		Week 36	13OCT2016/12:30	5	0 - 14	No
		Week 40	10NOV2016/10:15	3	0 - 14	No
		Week 44	06DEC2016/11:00	3	0 - 14	No
		Week 48	03JAN2017/12:00	2	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	06JAN2016/11:00	159	135 - 225	Yes
		Day 1	02FEB2016/11:10	163	135 - 225	Yes
		Week 1	09FEB2016/10:00	158	135 - 225	No
		Week 2	16FEB2016/11:00	155	135 - 225	No
		Week 4	01MAR2016/10:30	172	135 - 225	No
		Week 6	16MAR2016/11:45	173	135 - 225	No
		Week 8	31MAR2016/09:52	153	135 - 225	No
		Week 12	28APR2016/08:15	138	135 - 225	Yes
		Week 16	26MAY2016/12:10	162	135 - 225	No
		Week 20	22JUN2016/09:55	160	135 - 225	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Lactate Dehydrogenase (IU/L)	Week 24	20JUL2016/09:30	175	135 - 225	Yes	
		Week 28	18AUG2016/10:45	192	135 - 225	No	
		Week 32	15SEP2016/10:00	164	135 - 225	No	
		Week 36	13OCT2016/12:30	181	135 - 225	No	
		Week 40	10NOV2016/10:15	172	135 - 225	No	
		Week 44	06DEC2016/11:00	174	135 - 225	No	
		Week 48	03JAN2017/12:00	168	135 - 225	No	
	Magnesium (mmol/L)	Screening	06JAN2016/11:00	0.93	0.6 - 1	Yes	0
		Day 1	02FEB2016/11:10	0.91	0.6 - 1	Yes	0
		Week 1	09FEB2016/10:00	0.83	0.6 - 1	No	0
		Week 2	16FEB2016/11:00	0.83	0.6 - 1	No	0
		Week 4	01MAR2016/10:30	0.88	0.6 - 1	No	0
		Week 6	16MAR2016/11:45	0.86	0.6 - 1	No	0
		Week 8	31MAR2016/09:52	0.85	0.6 - 1	No	0
		Week 12	28APR2016/08:15	0.88	0.6 - 1	Yes	0
		Week 16	26MAY2016/12:10	0.92	0.6 - 1	No	0
		Week 20	22JUN2016/09:55	0.86	0.6 - 1	No	0
		Week 24	20JUL2016/09:30	0.87	0.6 - 1	Yes	0
		Week 28	18AUG2016/10:45	0.92	0.6 - 1	No	0
		Week 32	15SEP2016/10:00	0.91	0.6 - 1	No	0
		Week 36	13OCT2016/12:30	0.89	0.6 - 1	No	0
		Week 40	10NOV2016/10:15	0.92	0.6 - 1	No	0
		Week 44	06DEC2016/11:00	0.87	0.6 - 1	No	0

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Magnesium (mmol/L)	Week 48	03JAN2017/12:00	0.97	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	06JAN2016/11:00	0.89	0.87 - 1.45	Yes	0
		Day 1	02FEB2016/11:10	0.86 L	0.87 - 1.45	Yes	1
		Week 1	09FEB2016/10:00	0.98	0.87 - 1.45	No	0
		Week 2	16FEB2016/11:00	0.77 L	0.87 - 1.45	No	2
		Week 4	01MAR2016/10:30	0.91	0.87 - 1.45	No	0
		Week 6	16MAR2016/11:45	0.89	0.87 - 1.45	No	0
		Week 8	31MAR2016/09:52	0.91	0.87 - 1.45	No	0
		Week 12	28APR2016/08:15	0.92	0.87 - 1.45	Yes	0
		Week 16	26MAY2016/12:10	1.11	0.87 - 1.45	No	0
		Week 20	22JUN2016/09:55	0.77 L	0.87 - 1.45	No	2
		Week 24	20JUL2016/09:30	0.79 L	0.87 - 1.45	Yes	2
		Week 28	18AUG2016/10:45	0.98	0.87 - 1.45	No	0
		Week 32	15SEP2016/10:00	0.93	0.87 - 1.45	No	0
		Week 36	13OCT2016/12:30	0.76 L	0.87 - 1.45	No	2
		Week 40	10NOV2016/10:15	0.91	0.87 - 1.45	No	0
		Week 44	06DEC2016/11:00	0.94	0.87 - 1.45	No	0
		Week 48	03JAN2017/12:00	0.84 L	0.87 - 1.45	No	1
	Potassium (mmol/L)	Screening	06JAN2016/11:00	4.5	3.5 - 5.1	Yes	0
		Day 1	02FEB2016/11:10	4.4	3.5 - 5.1	Yes	0
		Week 1	09FEB2016/10:00	3.9	3.5 - 5.1	No	0
		Week 2	16FEB2016/11:00	4.0	3.5 - 5.1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Potassium (mmol/L)	Week 4	01MAR2016/10:30	4.1	3.5 - 5.1	No	0
		Week 6	16MAR2016/11:45	3.5	3.5 - 5.1	No	0
		Week 8	31MAR2016/09:52	4.1	3.5 - 5.1	No	0
		Week 12	28APR2016/08:15	4.1	3.5 - 5.1	Yes	0
		Week 16	26MAY2016/12:10	4.6	3.5 - 5.1	No	0
		Week 20	22JUN2016/09:55	4.2	3.5 - 5.1	No	0
		Week 24	20JUL2016/09:30	3.7	3.5 - 5.1	Yes	0
		Week 28	18AUG2016/10:45	4.2	3.5 - 5.1	No	0
		Week 32	15SEP2016/10:00	4.2	3.5 - 5.1	No	0
		Week 36	13OCT2016/12:30	4.5	3.5 - 5.1	No	0
		Week 40	10NOV2016/10:15	4.4	3.5 - 5.1	No	0
		Week 44	06DEC2016/11:00	4.4	3.5 - 5.1	No	0
		Week 48	03JAN2017/12:00	4.6	3.5 - 5.1	No	0
	Protein (g/L)	Screening	06JAN2016/11:00	70	63 - 83	Yes	
		Day 1	02FEB2016/11:10	68	63 - 83	Yes	
		Week 1	09FEB2016/10:00	71	63 - 83	No	
		Week 2	16FEB2016/11:00	68	63 - 83	No	
		Week 4	01MAR2016/10:30	70	63 - 83	No	
		Week 6	16MAR2016/11:45	67	63 - 83	No	
		Week 8	31MAR2016/09:52	62 L	63 - 83	No	
		Week 12	28APR2016/08:15	67	63 - 83	Yes	
		Week 16	26MAY2016/12:10	69	63 - 83	No	
		Week 20	22JUN2016/09:55	63	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Protein (g/L)	Week 24	20JUL2016/09:30	67	63 - 83	Yes	
		Week 28	18AUG2016/10:45	68	63 - 83	No	
		Week 32	15SEP2016/10:00	70	63 - 83	No	
		Week 36	13OCT2016/12:30	72	63 - 83	No	
		Week 40	10NOV2016/10:15	71	63 - 83	No	
		Week 44	06DEC2016/11:00	71	63 - 83	No	
		Week 48	03JAN2017/12:00	74	63 - 83	No	
	Sodium (mmol/L)	Screening	06JAN2016/11:00	140	135 - 145	Yes	0
		Day 1	02FEB2016/11:10	139	135 - 145	Yes	0
		Week 1	09FEB2016/10:00	139	135 - 145	No	0
		Week 2	16FEB2016/11:00	142	135 - 145	No	0
		Week 4	01MAR2016/10:30	142	135 - 145	No	0
		Week 6	16MAR2016/11:45	141	135 - 145	No	0
		Week 8	31MAR2016/09:52	139	135 - 145	No	0
		Week 12	28APR2016/08:15	142	135 - 145	Yes	0
		Week 16	26MAY2016/12:10	142	135 - 145	No	0
		Week 20	22JUN2016/09:55	139	135 - 145	No	0
		Week 24	20JUL2016/09:30	138	135 - 145	Yes	0
		Week 28	18AUG2016/10:45	141	135 - 145	No	0
		Week 32	15SEP2016/10:00	139	135 - 145	No	0
		Week 36	13OCT2016/12:30	143	135 - 145	No	0
		Week 40	10NOV2016/10:15	140	135 - 145	No	0
		Week 44	06DEC2016/11:00	139	135 - 145	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Sodium (mmol/L)	Week 48	03JAN2017/12:00	141	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	06JAN2016/11:00	1.10	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	06JAN2016/11:00	95	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	06JAN2016/11:00	1.1	0 - 2.2	Yes	0
		Day 1	02FEB2016/11:10	1.3	0 - 2.2	Yes	0
		Week 1	09FEB2016/10:00	1.1	0 - 2.2	No	0
		Week 2	16FEB2016/11:00	1.2	0 - 2.2	No	0
		Week 4	01MAR2016/10:30	1.4	0 - 2.2	No	0
		Week 6	16MAR2016/11:45	1.2	0 - 2.2	No	0
		Week 8	31MAR2016/09:52	1.4	0 - 2.2	No	0
		Week 12	28APR2016/08:15	1.2	0 - 2.2	Yes	0
		Week 16	26MAY2016/12:10	1.4	0 - 2.2	No	0
		Week 20	22JUN2016/09:55	1.2	0 - 2.2	No	0
		Week 24	20JUL2016/09:30	1.3	0 - 2.2	Yes	0
		Week 28	18AUG2016/10:45	0.9	0 - 2.2	No	0
		Week 32	15SEP2016/10:00	1.2	0 - 2.2	No	0
		Week 36	13OCT2016/12:30	1.0	0 - 2.2	No	0
		Week 40	10NOV2016/10:15	1.6	0 - 2.2	No	0
		Week 44	06DEC2016/11:00	1.1	0 - 2.2	No	0
		Week 48	03JAN2017/12:00	1.3	0 - 2.2	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Triiodothyronine (nmol/L)	Screening	06JAN2016/11:00	1.8	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	06JAN2016/11:00	8.4 H	1.7 - 8.3	Yes	
		Day 1	02FEB2016/11:10	7.6	1.7 - 8.3	Yes	
		Week 1	09FEB2016/10:00	7.0	1.7 - 8.3	No	
		Week 2	16FEB2016/11:00	6.7	1.7 - 8.3	No	
		Week 4	01MAR2016/10:30	7.8	1.7 - 8.3	No	
		Week 6	16MAR2016/11:45	6.4	1.7 - 8.3	No	
		Week 8	31MAR2016/09:52	5.5	1.7 - 8.3	No	
		Week 12	28APR2016/08:15	6.9	1.7 - 8.3	Yes	
		Week 16	26MAY2016/12:10	5.5	1.7 - 8.3	No	
		Week 20	22JUN2016/09:55	6.6	1.7 - 8.3	No	
		Week 24	20JUL2016/09:30	5.9	1.7 - 8.3	Yes	
		Week 28	18AUG2016/10:45	6.1	1.7 - 8.3	No	
		Week 32	15SEP2016/10:00	7.2	1.7 - 8.3	No	
		Week 36	13OCT2016/12:30	5.8	1.7 - 8.3	No	
		Week 40	10NOV2016/10:15	5.1	1.7 - 8.3	No	
		Week 44	06DEC2016/11:00	7.4	1.7 - 8.3	No	
		Week 48	03JAN2017/12:00	7.5	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	06JAN2016/11:00	367	266 - 474	Yes	0
		Day 1	02FEB2016/11:10	330	266 - 474	Yes	0
		Week 1	09FEB2016/10:00	308	266 - 474	No	0
		Week 2	16FEB2016/11:00	279	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Uric acid (umol/L)	Week 4	01MAR2016/10:30	296	266 - 474	No	0
		Week 6	16MAR2016/11:45	309	266 - 474	No	0
		Week 8	31MAR2016/09:52	313	266 - 474	No	0
		Week 12	28APR2016/08:15	259 L	266 - 474	Yes	0
		Week 16	26MAY2016/12:10	270	266 - 474	No	0
		Week 20	22JUN2016/09:55	260 L	266 - 474	No	0
		Week 24	20JUL2016/09:30	338	266 - 474	Yes	0
		Week 28	18AUG2016/10:45	360	266 - 474	No	0
		Week 32	15SEP2016/10:00	313	266 - 474	No	0
		Week 36	13OCT2016/12:30	338	266 - 474	No	0
		Week 40	10NOV2016/10:15	309	266 - 474	No	0
		Week 44	06DEC2016/11:00	326	266 - 474	No	0
		Week 48	03JAN2017/12:00	365	266 - 474	No	0
301-002	Alanine Aminotransferase (IU/L)	Screening	15DEC2015/09:00	98 H	10 - 50	Yes	1
		Day 1	05JAN2016/09:00	101 H	10 - 50	Yes	1
		Week 1	14JAN2016/10:00	188 H	10 - 50	No	2
		Week 2	20JAN2016/10:00	231 H	10 - 50	No	2
		Week 4	03FEB2016/09:45	197 H	10 - 50	No	2
		Week 6	17FEB2016/13:00	223 H	10 - 50	No	2
		Week 8	01MAR2016/09:00	135 H	10 - 50	No	1
		Week 12	30MAR2016/09:50	48	10 - 50	No	0
		Week 16	26APR2016/10:25	200 H	10 - 50	No	2

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Alanine Aminotransferase (IU/L)	Week 20	24MAY2016/11:40	48	10 - 50	No	0
		Week 24	21JUN2016/11:30	89 H	10 - 50	No	1
		Week 28	20JUL2016/11:45	45	10 - 50	No	0
		Week 32	18AUG2016/10:30	172 H	10 - 50	No	2
		Week 36	13SEP2016/11:00	121 H	10 - 50	No	1
		Week 40	11OCT2016/12:05	157 H	10 - 50	No	2
		Week 44	09NOV2016/12:30	125 H	10 - 50	No	1
		Week 48	06DEC2016/13:00	118 H	10 - 50	No	1
	Albumin (g/L)	Screening	15DEC2015/09:00	46	34 - 50	Yes	0
		Day 1	05JAN2016/09:00	46	34 - 50	Yes	0
		Week 1	14JAN2016/10:00	47	34 - 50	No	0
		Week 2	20JAN2016/10:00	49	34 - 50	No	0
		Week 4	03FEB2016/09:45	46	34 - 50	No	0
		Week 6	17FEB2016/13:00	44	34 - 50	No	0
		Week 8	01MAR2016/09:00	44	34 - 50	No	0
		Week 12	30MAR2016/09:50	43	34 - 50	No	0
		Week 16	26APR2016/10:25	45	34 - 50	No	0
		Week 20	24MAY2016/11:40	43	34 - 50	No	0
		Week 24	21JUN2016/11:30	48	34 - 50	No	0
		Week 28	20JUL2016/11:45	43	34 - 50	No	0
		Week 32	18AUG2016/10:30	43	34 - 50	No	0
		Week 36	13SEP2016/11:00	43	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Albumin (g/L)	Week 40	11OCT2016/12:05	44	34 - 50	No	0
		Week 44	09NOV2016/12:30	43	34 - 50	No	0
		Week 48	06DEC2016/13:00	44	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	15DEC2015/09:00	69	40 - 129	Yes	0
		Day 1	05JAN2016/09:00	70	40 - 129	Yes	0
		Week 1	14JAN2016/10:00	68	40 - 129	No	0
		Week 2	20JAN2016/10:00	70	40 - 129	No	0
		Week 4	03FEB2016/09:45	63	40 - 129	No	0
		Week 6	17FEB2016/13:00	70	40 - 129	No	0
		Week 8	01MAR2016/09:00	74	40 - 129	No	0
		Week 12	30MAR2016/09:50	80	40 - 129	No	0
		Week 16	26APR2016/10:25	97	40 - 129	No	0
		Week 20	24MAY2016/11:40	94	40 - 129	No	0
		Week 24	21JUN2016/11:30	129	40 - 129	No	0
		Week 28	20JUL2016/11:45	124	40 - 129	No	0
		Week 32	18AUG2016/10:30	132 H	40 - 129	No	1
		Week 36	13SEP2016/11:00	107	40 - 129	No	0
		Week 40	11OCT2016/12:05	97	40 - 129	No	0
		Week 44	09NOV2016/12:30	86	40 - 129	No	0
		Week 48	06DEC2016/13:00	81	40 - 129	No	0
	Amylase (IU/L)	Screening	15DEC2015/09:00	147 H	28 - 100	Yes	1
		Day 1	05JAN2016/09:00	109 H	28 - 100	Yes	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002 Amylase (IU/L)	Week 1	14JAN2016/10:00	149 H	28 - 100	No	1
	Week 2	20JAN2016/10:00	135 H	28 - 100	No	1
	Week 4	03FEB2016/09:45	88	28 - 100	No	0
	Week 6	17FEB2016/13:00	118 H	28 - 100	No	1
	Week 8	01MAR2016/09:00	120 H	28 - 100	No	1
	Week 12	30MAR2016/09:50	152 H	28 - 100	No	2
	Week 16	26APR2016/10:25	118 H	28 - 100	No	1
	Week 20	24MAY2016/11:40	103 H	28 - 100	No	1
	Week 24	21JUN2016/11:30	113 H	28 - 100	No	1
	Week 28	20JUL2016/11:45	107 H	28 - 100	No	1
	Week 32	18AUG2016/10:30	117 H	28 - 100	No	1
	Week 36	13SEP2016/11:00	122 H	28 - 100	No	1
	Week 40	11OCT2016/12:05	120 H	28 - 100	No	1
	Week 44	09NOV2016/12:30	128 H	28 - 100	No	1
	Week 48	06DEC2016/13:00	123 H	28 - 100	No	1
Aspartate Aminotransferase (IU/L)	Screening	15DEC2015/09:00	57 H	0 - 37	Yes	1
	Day 1	05JAN2016/09:00	43 H	0 - 37	Yes	1
	Week 1	14JAN2016/10:00	94 H	0 - 37	No	1
	Week 2	20JAN2016/10:00	81 H	0 - 37	No	1
	Week 4	03FEB2016/09:45	71 H	0 - 37	No	1
	Week 6	17FEB2016/13:00	72 H	0 - 37	No	1
	Week 8	01MAR2016/09:00	43 H	0 - 37	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Aspartate Aminotransferase (IU/L)	Week 12	30MAR2016/09:50	21	0 - 37	No	0
		Week 16	26APR2016/10:25	90 H	0 - 37	No	1
		Week 20	24MAY2016/11:40	26	0 - 37	No	0
		Week 24	21JUN2016/11:30	40 H	0 - 37	No	1
		Week 28	20JUL2016/11:45	25	0 - 37	No	0
		Week 32	18AUG2016/10:30	71 H	0 - 37	No	1
		Week 36	13SEP2016/11:00	65 H	0 - 37	No	1
		Week 40	11OCT2016/12:05	76 H	0 - 37	No	1
		Week 44	09NOV2016/12:30	67 H	0 - 37	No	1
		Week 48	06DEC2016/13:00	64 H	0 - 37	No	1
	Bicarbonate (mmol/L)	Screening	15DEC2015/09:00	26	22 - 29	Yes	
		Day 1	05JAN2016/09:00	26	22 - 29	Yes	
		Week 1	14JAN2016/10:00	28	22 - 29	No	
		Week 2	20JAN2016/10:00	25	22 - 29	No	
		Week 4	03FEB2016/09:45	28	22 - 29	No	
		Week 6	17FEB2016/13:00	28	22 - 29	No	
		Week 8	01MAR2016/09:00	26	22 - 29	No	
		Week 12	30MAR2016/09:50	26	22 - 29	No	
		Week 16	26APR2016/10:25	24	22 - 29	No	
		Week 20	24MAY2016/11:40	26	22 - 29	No	
		Week 24	21JUN2016/11:30	20 L	22 - 29	No	
		Week 28	20JUL2016/11:45	23	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Bicarbonate (mmol/L)	Week 32	18AUG2016/10:30	20 L	22 - 29	No	
		Week 36	13SEP2016/11:00	25	22 - 29	No	
		Week 40	11OCT2016/12:05	26	22 - 29	No	
		Week 44	09NOV2016/12:30	21 L	22 - 29	No	
		Week 48	06DEC2016/13:00	24	22 - 29	No	
	Bilirubin (umol/L)	Screening	15DEC2015/09:00	7	0 - 20	Yes	0
		Day 1	05JAN2016/09:00	7	0 - 20	Yes	0
		Week 1	14JAN2016/10:00	7	0 - 20	No	0
		Week 2	20JAN2016/10:00	8	0 - 20	No	0
		Week 4	03FEB2016/09:45	8	0 - 20	No	0
		Week 6	17FEB2016/13:00	6	0 - 20	No	0
		Week 8	01MAR2016/09:00	5	0 - 20	No	0
		Week 12	30MAR2016/09:50	5	0 - 20	No	0
		Week 16	26APR2016/10:25	6	0 - 20	No	0
		Week 20	24MAY2016/11:40	6	0 - 20	No	0
		Week 24	21JUN2016/11:30	6	0 - 20	No	0
		Week 28	20JUL2016/11:45	7	0 - 20	No	0
		Week 32	18AUG2016/10:30	9	0 - 20	No	0
		Week 36	13SEP2016/11:00	7	0 - 20	No	0
		Week 40	11OCT2016/12:05	4	0 - 20	No	0
		Week 44	09NOV2016/12:30	6	0 - 20	No	0
		Week 48	06DEC2016/13:00	8	0 - 20	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Blood Urea Nitrogen (mg/dL)	Screening	15DEC2015/09:00	11.20	4.76 - 23.24	Yes	
		Day 1	05JAN2016/09:00	10.08	4.76 - 23.24	Yes	
		Week 1	14JAN2016/10:00	12.60	4.76 - 23.24	No	
		Week 2	20JAN2016/10:00	10.36	4.76 - 23.24	No	
		Week 4	03FEB2016/09:45	11.76	4.76 - 23.24	No	
		Week 6	17FEB2016/13:00	9.24	4.76 - 23.24	No	
		Week 8	01MAR2016/09:00	6.16	4.76 - 23.24	No	
		Week 12	30MAR2016/09:50	10.08	4.76 - 23.24	No	
		Week 16	26APR2016/10:25	6.44	4.76 - 23.24	No	
		Week 20	24MAY2016/11:40	10.08	4.76 - 23.24	No	
		Week 24	21JUN2016/11:30	9.52	4.76 - 23.24	No	
		Week 28	20JUL2016/11:45	10.36	4.76 - 23.24	No	
		Week 32	18AUG2016/10:30	11.20	4.76 - 23.24	No	
		Week 36	13SEP2016/11:00	12.04	4.76 - 23.24	No	
		Week 40	11OCT2016/12:05	10.08	4.76 - 23.24	No	
		Week 44	09NOV2016/12:30	9.80	4.76 - 23.24	No	
		Week 48	06DEC2016/13:00	12.32	4.76 - 23.24	No	
	Calcium (mmol/L)	Screening	15DEC2015/09:00	2.47	2.2 - 2.6	Yes	0
		Day 1	05JAN2016/09:00	2.44	2.2 - 2.6	Yes	0
		Week 1	14JAN2016/10:00	2.46	2.2 - 2.6	No	0
		Week 2	20JAN2016/10:00	2.54	2.2 - 2.6	No	0
		Week 4	03FEB2016/09:45	2.41	2.2 - 2.6	No	0
		Week 6	17FEB2016/13:00	2.42	2.2 - 2.6	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Calcium (mmol/L)	Week 8	01MAR2016/09:00	2.30	2.2 - 2.6	No	0
		Week 12	30MAR2016/09:50	2.40	2.2 - 2.6	No	0
		Week 16	26APR2016/10:25	2.43	2.2 - 2.6	No	0
		Week 20	24MAY2016/11:40	2.34	2.2 - 2.6	No	0
		Week 24	21JUN2016/11:30	2.37	2.2 - 2.6	No	0
		Week 28	20JUL2016/11:45	2.32	2.2 - 2.6	No	0
		Week 32	18AUG2016/10:30	2.43	2.2 - 2.6	No	0
		Week 36	13SEP2016/11:00	2.56	2.2 - 2.6	No	0
		Week 40	11OCT2016/12:05	2.57	2.2 - 2.6	No	0
		Week 44	09NOV2016/12:30	2.37	2.2 - 2.6	No	0
		Week 48	06DEC2016/13:00	2.34	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	15DEC2015/09:00	101	98 - 107	Yes	
		Day 1	05JAN2016/09:00	101	98 - 107	Yes	
		Week 1	14JAN2016/10:00	100	98 - 107	No	
		Week 2	20JAN2016/10:00	96 L	98 - 107	No	
		Week 4	03FEB2016/09:45	99	98 - 107	No	
		Week 6	17FEB2016/13:00	99	98 - 107	No	
		Week 8	01MAR2016/09:00	104	98 - 107	No	
		Week 12	30MAR2016/09:50	102	98 - 107	No	
		Week 16	26APR2016/10:25	102	98 - 107	No	
		Week 20	24MAY2016/11:40	102	98 - 107	No	
		Week 24	21JUN2016/11:30	98	98 - 107	No	
		Week 28	20JUL2016/11:45	104	98 - 107	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Chloride (mmol/L)	Week 32	18AUG2016/10:30	105	98 - 107	No	
		Week 36	13SEP2016/11:00	100	98 - 107	No	
		Week 40	11OCT2016/12:05	100	98 - 107	No	
		Week 44	09NOV2016/12:30	102	98 - 107	No	
		Week 48	06DEC2016/13:00	103	98 - 107	No	
	Cholesterol (mmol/L)	Screening	15DEC2015/09:00	4.8	0 - 4.9	Yes	0
		Day 1	05JAN2016/09:00	4.6	0 - 4.9	Yes	0
		Week 1	14JAN2016/10:00	3.6	0 - 4.9	No	0
		Week 2	20JAN2016/10:00	3.8	0 - 4.9	No	0
		Week 4	03FEB2016/09:45	3.7	0 - 4.9	No	0
		Week 6	17FEB2016/13:00	3.3	0 - 4.9	No	0
		Week 8	01MAR2016/09:00	2.7	0 - 4.9	No	0
		Week 12	30MAR2016/09:50	4.1	0 - 4.9	No	0
		Week 16	26APR2016/10:25	3.4	0 - 4.9	No	0
		Week 20	24MAY2016/11:40	3.6	0 - 4.9	No	0
		Week 24	21JUN2016/11:30	3.6	0 - 4.9	No	0
		Week 28	20JUL2016/11:45	4.6	0 - 4.9	No	0
		Week 32	18AUG2016/10:30	4.0	0 - 4.9	No	0
		Week 36	13SEP2016/11:00	4.8	0 - 4.9	No	0
		Week 40	11OCT2016/12:05	4.8	0 - 4.9	No	0
		Week 44	09NOV2016/12:30	4.3	0 - 4.9	No	0
		Week 48	06DEC2016/13:00	4.3	0 - 4.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Creatine Kinase (IU/L)	Screening	15DEC2015/09:00	226 H	38 - 204	Yes	1
		Day 1	05JAN2016/09:00	219 H	38 - 204	Yes	1
		Week 1	14JAN2016/10:00	244 H	38 - 204	No	1
		Week 2	20JAN2016/10:00	236 H	38 - 204	No	1
		Week 4	03FEB2016/09:45	424 H	38 - 204	No	1
		Week 6	17FEB2016/13:00	149	38 - 204	No	0
		Week 8	01MAR2016/09:00	260 H	38 - 204	No	1
		Week 12	30MAR2016/09:50	108	38 - 204	No	0
		Week 16	26APR2016/10:25	157	38 - 204	No	0
		Week 20	24MAY2016/11:40	163	38 - 204	No	0
		Week 24	21JUN2016/11:30	154	38 - 204	No	0
		Week 28	20JUL2016/11:45	238 H	38 - 204	No	1
		Week 32	18AUG2016/10:30	738 H	38 - 204	No	2
		Week 36	13SEP2016/11:00	172	38 - 204	No	0
		Week 40	11OCT2016/12:05	216 H	38 - 204	No	1
		Week 44	09NOV2016/12:30	312 H	38 - 204	No	1
		Week 48	06DEC2016/13:00	439 H	38 - 204	No	1
	Creatinine (umol/L)	Screening	15DEC2015/09:00	99	66 - 112	Yes	0
		Day 1	05JAN2016/09:00	85	66 - 112	Yes	0
		Week 1	14JAN2016/10:00	105	66 - 112	No	1
		Week 2	20JAN2016/10:00	103	66 - 112	No	1
		Week 4	03FEB2016/09:45	113 H	66 - 112	No	1
		Week 6	17FEB2016/13:00	114 H	66 - 112	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Creatinine (umol/L)	Week 8	01MAR2016/09:00	97	66 - 112	No	1
		Week 12	30MAR2016/09:50	92	66 - 112	No	1
		Week 16	26APR2016/10:25	95	66 - 112	No	1
		Week 20	24MAY2016/11:40	88	66 - 112	No	1
		Week 24	21JUN2016/11:30	91	66 - 112	No	1
		Week 28	20JUL2016/11:45	88	66 - 112	No	1
		Week 32	18AUG2016/10:30	79	66 - 112	No	0
		Week 36	13SEP2016/11:00	76	66 - 112	No	0
		Week 40	11OCT2016/12:05	85	66 - 112	No	0
		Week 44	09NOV2016/12:30	74	66 - 112	No	0
		Week 48	06DEC2016/13:00	92	66 - 112	No	1
	Direct Bilirubin (umol/L)	Screening	15DEC2015/09:00	3	0 - 5	Yes	
		Day 1	05JAN2016/09:00	3	0 - 5	Yes	
		Week 1	14JAN2016/10:00	3	0 - 5	No	
		Week 2	20JAN2016/10:00	3	0 - 5	No	
		Week 4	03FEB2016/09:45	4	0 - 5	No	
		Week 6	17FEB2016/13:00	3	0 - 5	No	
		Week 8	01MAR2016/09:00	2	0 - 5	No	
		Week 12	30MAR2016/09:50	2	0 - 5	No	
		Week 16	26APR2016/10:25	2	0 - 5	No	
		Week 20	24MAY2016/11:40	3	0 - 5	No	
		Week 24	21JUN2016/11:30	2	0 - 5	No	
		Week 28	20JUL2016/11:45	3	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Direct Bilirubin (umol/L)	Week 32	18AUG2016/10:30	4	0 - 5	No	
		Week 36	13SEP2016/11:00	3	0 - 5	No	
		Week 40	11OCT2016/12:05	2	0 - 5	No	
		Week 44	09NOV2016/12:30	3	0 - 5	No	
		Week 48	06DEC2016/13:00	4	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	15DEC2015/09:00	56	10 - 71	Yes	0
		Day 1	05JAN2016/09:00	61	10 - 71	Yes	0
		Week 1	14JAN2016/10:00	52	10 - 71	No	0
		Week 2	20JAN2016/10:00	62	10 - 71	No	0
		Week 4	03FEB2016/09:45	47	10 - 71	No	0
		Week 6	17FEB2016/13:00	45	10 - 71	No	0
		Week 8	01MAR2016/09:00	38	10 - 71	No	0
		Week 12	30MAR2016/09:50	37	10 - 71	No	0
		Week 16	26APR2016/10:25	58	10 - 71	No	0
		Week 20	24MAY2016/11:40	41	10 - 71	No	0
		Week 24	21JUN2016/11:30	41	10 - 71	No	0
		Week 28	20JUL2016/11:45	26	10 - 71	No	0
		Week 32	18AUG2016/10:30	76 H	10 - 71	No	1
		Week 36	13SEP2016/11:00	70	10 - 71	No	0
		Week 40	11OCT2016/12:05	74 H	10 - 71	No	1
		Week 44	09NOV2016/12:30	68	10 - 71	No	0
		Week 48	06DEC2016/13:00	63	10 - 71	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Globulin (g/L)	Screening	15DEC2015/09:00	29	19 - 35	Yes	
		Day 1	05JAN2016/09:00	32	19 - 35	Yes	
		Week 1	14JAN2016/10:00	31	19 - 35	No	
		Week 2	20JAN2016/10:00	30	19 - 35	No	
		Week 4	03FEB2016/09:45	29	19 - 35	No	
		Week 6	17FEB2016/13:00	29	19 - 35	No	
		Week 8	01MAR2016/09:00	26	19 - 35	No	
		Week 12	30MAR2016/09:50	28	19 - 35	No	
		Week 16	26APR2016/10:25	29	19 - 35	No	
		Week 20	24MAY2016/11:40	27	19 - 35	No	
		Week 24	21JUN2016/11:30	28	19 - 35	No	
		Week 28	20JUL2016/11:45	27	19 - 35	No	
		Week 32	18AUG2016/10:30	34	19 - 35	No	
		Week 36	13SEP2016/11:00	36 H	19 - 35	No	
		Week 40	11OCT2016/12:05	36 H	19 - 35	No	
		Week 44	09NOV2016/12:30	30	19 - 35	No	
		Week 48	06DEC2016/13:00	32	19 - 35	No	
	Glucose (mmol/L)	Screening	15DEC2015/09:00	5.1	3.9 - 5.8	Yes	0
		Day 1	05JAN2016/09:00	4.8	3.9 - 5.8	Yes	0
		Week 1	14JAN2016/10:00	4.3	3.5 - 7.9	No	0
		Week 2	20JAN2016/10:00	4.5	3.5 - 7.9	No	0
		Week 4	03FEB2016/09:45	4.6	3.5 - 7.9	No	0
		Week 6	17FEB2016/13:00	4.9	3.5 - 7.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Glucose (mmol/L)	Week 8	01MAR2016/09:00	3.5	3.5 - 7.9	No	0
		Week 12	30MAR2016/09:50	4.8	3.5 - 7.9	No	0
		Week 16	26APR2016/10:25	4.5	3.5 - 7.9	No	0
		Week 20	24MAY2016/11:40	3.6	3.5 - 7.9	No	0
		Week 24	21JUN2016/11:30	4.5	3.5 - 7.9	No	0
		Week 28	20JUL2016/11:45	4.7	3.5 - 7.9	No	0
		Week 32	18AUG2016/10:30	4.3	3.5 - 7.9	No	0
		Week 36	13SEP2016/11:00	4.6	3.5 - 7.9	No	0
		Week 40	11OCT2016/12:05	4.1	3.5 - 7.9	No	0
		Week 44	09NOV2016/12:30	4.6	3.5 - 7.9	No	0
		Week 48	06DEC2016/13:00	4.0	3.5 - 7.9	No	0
	Indirect Bilirubin (umol/L)	Screening	15DEC2015/09:00	4	0 - 14	Yes	
		Day 1	05JAN2016/09:00	4	0 - 14	Yes	
		Week 1	14JAN2016/10:00	4	0 - 14	No	
		Week 2	20JAN2016/10:00	5	0 - 14	No	
		Week 4	03FEB2016/09:45	4	0 - 14	No	
		Week 6	17FEB2016/13:00	3	0 - 14	No	
		Week 8	01MAR2016/09:00	3	0 - 14	No	
		Week 12	30MAR2016/09:50	3	0 - 14	No	
		Week 16	26APR2016/10:25	4	0 - 14	No	
		Week 20	24MAY2016/11:40	3	0 - 14	No	
		Week 24	21JUN2016/11:30	4	0 - 14	No	
		Week 28	20JUL2016/11:45	4	0 - 14	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Indirect Bilirubin (umol/L)	Week 32	18AUG2016/10:30	5	0 - 14	No
		Week 36	13SEP2016/11:00	4	0 - 14	No
		Week 40	11OCT2016/12:05	2	0 - 14	No
		Week 44	09NOV2016/12:30	3	0 - 14	No
		Week 48	06DEC2016/13:00	4	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	15DEC2015/09:00	204	135 - 225	Yes
		Day 1	05JAN2016/09:00	181	135 - 225	Yes
		Week 1	14JAN2016/10:00	199	135 - 225	No
		Week 2	20JAN2016/10:00	196	135 - 225	No
		Week 4	03FEB2016/09:45	218	135 - 225	No
		Week 6	17FEB2016/13:00	193	135 - 225	No
		Week 8	01MAR2016/09:00	210	135 - 225	No
		Week 12	30MAR2016/09:50	171	135 - 225	No
		Week 16	26APR2016/10:25	209	135 - 225	No
		Week 20	24MAY2016/11:40	190	135 - 225	No
		Week 24	21JUN2016/11:30	217	135 - 225	No
		Week 28	20JUL2016/11:45	203	135 - 225	No
		Week 32	18AUG2016/10:30	246 H	135 - 225	No
		Week 36	13SEP2016/11:00	194	135 - 225	No
		Week 40	11OCT2016/12:05	216	135 - 225	No
		Week 44	09NOV2016/12:30	200	135 - 225	No
		Week 48	06DEC2016/13:00	209	135 - 225	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Magnesium (mmol/L)	Screening	15DEC2015/09:00	0.80	0.6 - 1	Yes	0
		Day 1	05JAN2016/09:00	0.77	0.6 - 1	Yes	0
		Week 1	14JAN2016/10:00	0.82	0.6 - 1	No	0
		Week 2	20JAN2016/10:00	0.89	0.6 - 1	No	0
		Week 4	03FEB2016/09:45	0.86	0.6 - 1	No	0
		Week 6	17FEB2016/13:00	0.75	0.6 - 1	No	0
		Week 8	01MAR2016/09:00	0.87	0.6 - 1	No	0
		Week 12	30MAR2016/09:50	0.83	0.6 - 1	No	0
		Week 16	26APR2016/10:25	0.89	0.6 - 1	No	0
		Week 20	24MAY2016/11:40	0.85	0.6 - 1	No	0
		Week 24	21JUN2016/11:30	0.77	0.6 - 1	No	0
		Week 28	20JUL2016/11:45	0.81	0.6 - 1	No	0
		Week 32	18AUG2016/10:30	0.85	0.6 - 1	No	0
		Week 36	13SEP2016/11:00	0.75	0.6 - 1	No	0
		Week 40	11OCT2016/12:05	0.88	0.6 - 1	No	0
		Week 44	09NOV2016/12:30	0.75	0.6 - 1	No	0
		Week 48	06DEC2016/13:00	0.88	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	15DEC2015/09:00	0.87	0.87 - 1.45	Yes	0
		Day 1	05JAN2016/09:00	1.39	0.87 - 1.45	Yes	0
		Week 1	14JAN2016/10:00	1.17	0.87 - 1.45	No	0
		Week 2	20JAN2016/10:00	0.80 L	0.87 - 1.45	No	1
		Week 4	03FEB2016/09:45	0.94	0.87 - 1.45	No	0
		Week 6	17FEB2016/13:00	1.13	0.87 - 1.45	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Phosphate (mmol/L)	Week 8	01MAR2016/09:00	1.08	0.87 - 1.45	No	0
		Week 12	30MAR2016/09:50	1.27	0.87 - 1.45	No	0
		Week 16	26APR2016/10:25	0.80 L	0.87 - 1.45	No	1
		Week 20	24MAY2016/11:40	0.91	0.87 - 1.45	No	0
		Week 24	21JUN2016/11:30	1.07	0.87 - 1.45	No	0
		Week 28	20JUL2016/11:45	0.94	0.87 - 1.45	No	0
		Week 32	18AUG2016/10:30	1.23	0.87 - 1.45	No	0
		Week 36	13SEP2016/11:00	0.98	0.87 - 1.45	No	0
		Week 40	11OCT2016/12:05	0.81 L	0.87 - 1.45	No	1
		Week 44	09NOV2016/12:30	0.86 L	0.87 - 1.45	No	1
		Week 48	06DEC2016/13:00	1.18	0.87 - 1.45	No	0
	Potassium (mmol/L)	Screening	15DEC2015/09:00	4.3	3.5 - 5.1	Yes	0
		Day 1	05JAN2016/09:00	4.2	3.5 - 5.1	Yes	0
		Week 1	14JAN2016/10:00	4.3	3.5 - 5.1	No	0
		Week 2	20JAN2016/10:00	4.5	3.5 - 5.1	No	0
		Week 4	03FEB2016/09:45	4.5	3.5 - 5.1	No	0
		Week 6	17FEB2016/13:00	4.3	3.5 - 5.1	No	0
		Week 8	01MAR2016/09:00	4.3	3.5 - 5.1	No	0
		Week 12	30MAR2016/09:50	4.5	3.5 - 5.1	No	0
		Week 16	26APR2016/10:25	5.3 H	3.5 - 5.1	No	1
		Week 20	24MAY2016/11:40	4.7	3.5 - 5.1	No	0
		Week 24	21JUN2016/11:30	4.2	3.5 - 5.1	No	0
		Week 28	20JUL2016/11:45	4.7	3.5 - 5.1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Potassium (mmol/L)	Week 32	18AUG2016/10:30	4.4	3.5 - 5.1	No	0
		Week 36	13SEP2016/11:00	4.4	3.5 - 5.1	No	0
		Week 40	11OCT2016/12:05	4.8	3.5 - 5.1	No	0
		Week 44	09NOV2016/12:30	4.3	3.5 - 5.1	No	0
		Week 48	06DEC2016/13:00	4.5	3.5 - 5.1	No	0
	Protein (g/L)	Screening	15DEC2015/09:00	75	63 - 83	Yes	
		Day 1	05JAN2016/09:00	78	63 - 83	Yes	
		Week 1	14JAN2016/10:00	78	63 - 83	No	
		Week 2	20JAN2016/10:00	79	63 - 83	No	
		Week 4	03FEB2016/09:45	75	63 - 83	No	
		Week 6	17FEB2016/13:00	73	63 - 83	No	
		Week 8	01MAR2016/09:00	70	63 - 83	No	
		Week 12	30MAR2016/09:50	71	63 - 83	No	
		Week 16	26APR2016/10:25	74	63 - 83	No	
		Week 20	24MAY2016/11:40	70	63 - 83	No	
		Week 24	21JUN2016/11:30	76	63 - 83	No	
		Week 28	20JUL2016/11:45	70	63 - 83	No	
		Week 32	18AUG2016/10:30	77	63 - 83	No	
		Week 36	13SEP2016/11:00	79	63 - 83	No	
		Week 40	11OCT2016/12:05	80	63 - 83	No	
		Week 44	09NOV2016/12:30	73	63 - 83	No	
		Week 48	06DEC2016/13:00	76	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Sodium (mmol/L)	Screening	15DEC2015/09:00	142	135 - 145	Yes	0
		Day 1	05JAN2016/09:00	142	135 - 145	Yes	0
		Week 1	14JAN2016/10:00	141	135 - 145	No	0
		Week 2	20JAN2016/10:00	141	135 - 145	No	0
		Week 4	03FEB2016/09:45	140	135 - 145	No	0
		Week 6	17FEB2016/13:00	140	135 - 145	No	0
		Week 8	01MAR2016/09:00	143	135 - 145	No	0
		Week 12	30MAR2016/09:50	142	135 - 145	No	0
		Week 16	26APR2016/10:25	139	135 - 145	No	0
		Week 20	24MAY2016/11:40	142	135 - 145	No	0
		Week 24	21JUN2016/11:30	138	135 - 145	No	0
		Week 28	20JUL2016/11:45	141	135 - 145	No	0
		Week 32	18AUG2016/10:30	144	135 - 145	No	0
		Week 36	13SEP2016/11:00	141	135 - 145	No	0
		Week 40	11OCT2016/12:05	141	135 - 145	No	0
		Week 44	09NOV2016/12:30	140	135 - 145	No	0
		Week 48	06DEC2016/13:00	142	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	15DEC2015/09:00	1.23	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	15DEC2015/09:00	122	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	15DEC2015/09:00	0.6	0 - 2.2	Yes	0
		Day 1	05JAN2016/09:00	1.0	0 - 2.2	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Triglycerides (mmol/L)	Week 1	14JAN2016/10:00	0.6	0 - 2.2	No	0
		Week 2	20JAN2016/10:00	0.7	0 - 2.2	No	0
		Week 4	03FEB2016/09:45	0.6	0 - 2.2	No	0
		Week 6	17FEB2016/13:00	0.9	0 - 2.2	No	0
		Week 8	01MAR2016/09:00	0.4	0 - 2.2	No	0
		Week 12	30MAR2016/09:50	1.0	0 - 2.2	No	0
		Week 16	26APR2016/10:25	0.6	0 - 2.2	No	0
		Week 20	24MAY2016/11:40	0.6	0 - 2.2	No	0
		Week 24	21JUN2016/11:30	0.8	0 - 2.2	No	0
		Week 28	20JUL2016/11:45	0.6	0 - 2.2	No	0
		Week 32	18AUG2016/10:30	0.7	0 - 2.2	No	0
		Week 36	13SEP2016/11:00	1.1	0 - 2.2	No	0
		Week 40	11OCT2016/12:05	1.0	0 - 2.2	No	0
		Week 44	09NOV2016/12:30	0.6	0 - 2.2	No	0
		Week 48	06DEC2016/13:00	0.7	0 - 2.2	No	0
	Triiodothyronine (nmol/L)	Screening	15DEC2015/09:00	2.0	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	15DEC2015/09:00	4.0	1.7 - 8.3	Yes	
		Day 1	05JAN2016/09:00	3.6	1.7 - 8.3	Yes	
		Week 1	14JAN2016/10:00	4.5	1.7 - 8.3	No	
		Week 2	20JAN2016/10:00	3.7	1.7 - 8.3	No	
		Week 4	03FEB2016/09:45	4.2	1.7 - 8.3	No	
		Week 6	17FEB2016/13:00	3.3	1.7 - 8.3	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Urea (mmol/L)	Week 8	01MAR2016/09:00	2.2	1.7 - 8.3	No	
		Week 12	30MAR2016/09:50	3.6	1.7 - 8.3	No	
		Week 16	26APR2016/10:25	2.3	1.7 - 8.3	No	
		Week 20	24MAY2016/11:40	3.6	1.7 - 8.3	No	
		Week 24	21JUN2016/11:30	3.4	1.7 - 8.3	No	
		Week 28	20JUL2016/11:45	3.7	1.7 - 8.3	No	
		Week 32	18AUG2016/10:30	4.0	1.7 - 8.3	No	
		Week 36	13SEP2016/11:00	4.3	1.7 - 8.3	No	
		Week 40	11OCT2016/12:05	3.6	1.7 - 8.3	No	
		Week 44	09NOV2016/12:30	3.5	1.7 - 8.3	No	
		Week 48	06DEC2016/13:00	4.4	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	15DEC2015/09:00	329	266 - 474	Yes	0
		Day 1	05JAN2016/09:00	328	266 - 474	Yes	0
		Week 1	14JAN2016/10:00	324	266 - 474	No	0
		Week 2	20JAN2016/10:00	347	266 - 474	No	0
		Week 4	03FEB2016/09:45	390	266 - 474	No	0
		Week 6	17FEB2016/13:00	367	266 - 474	No	0
		Week 8	01MAR2016/09:00	296	266 - 474	No	0
		Week 12	30MAR2016/09:50	266	266 - 474	No	0
		Week 16	26APR2016/10:25	261 L	266 - 474	No	0
		Week 20	24MAY2016/11:40	268	266 - 474	No	0
		Week 24	21JUN2016/11:30	282	266 - 474	No	0
		Week 28	20JUL2016/11:45	304	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Uric acid (umol/L)	Week 32	18AUG2016/10:30	306	266 - 474	No	0
		Week 36	13SEP2016/11:00	300	266 - 474	No	0
		Week 40	11OCT2016/12:05	306	266 - 474	No	0
		Week 44	09NOV2016/12:30	263 L	266 - 474	No	0
		Week 48	06DEC2016/13:00	304	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Alanine Aminotransferase (IU/L)	Screening	15DEC2015/12:00	69 H	10 - 35	Yes	1
		Day 1	06JAN2016/11:00	63 H	10 - 35	Yes	1
		Week 1	13JAN2016/11:00	45 H	10 - 35	No	1
		Week 2	20JAN2016/11:00	45 H	10 - 35	No	1
		Week 4	03FEB2016/11:00	45 H	10 - 35	No	1
		Week 6	18FEB2016/13:30	47 H	10 - 35	No	1
		Week 8	08MAR2016/08:35	49 H	10 - 35	No	1
		Week 12	29MAR2016/09:15	45 H	10 - 35	No	1
		Week 16	25APR2016/08:50	29	10 - 35	No	0
		Week 20	26MAY2016/12:50	38 H	10 - 35	No	1
		Week 24	22JUN2016/12:30	32	10 - 35	No	0
		Week 28	19JUL2016/10:10	57 H	10 - 35	No	1
		Week 32	16AUG2016/12:10	55 H	10 - 35	No	1
		Week 36	15SEP2016/12:35	49 H	10 - 35	No	1
		Week 40	12OCT2016/11:20	41 H	10 - 35	Yes	1
		Week 44	09NOV2016/12:00	57 H	10 - 35	No	1
		Week 48	14DEC2016/12:00	63 H	10 - 35	No	1
	Albumin (g/L)	Screening	15DEC2015/12:00	45	34 - 50	Yes	0
		Day 1	06JAN2016/11:00	45	34 - 50	Yes	0
		Week 1	13JAN2016/11:00	45	34 - 50	No	0
		Week 2	20JAN2016/11:00	48	34 - 50	No	0
		Week 4	03FEB2016/11:00	46	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Albumin (g/L)	Week 6	18FEB2016/13:30	49	34 - 50	No	0
		Week 8	08MAR2016/08:35	44	34 - 50	No	0
		Week 12	29MAR2016/09:15	42	34 - 50	No	0
		Week 16	25APR2016/08:50	45	34 - 50	No	0
		Week 20	26MAY2016/12:50	45	34 - 50	No	0
		Week 24	22JUN2016/12:30	45	34 - 50	No	0
		Week 28	19JUL2016/10:10	45	34 - 50	No	0
		Week 32	16AUG2016/12:10	44	34 - 50	No	0
		Week 36	15SEP2016/12:35	43	34 - 50	No	0
		Week 40	12OCT2016/11:20	41	34 - 50	Yes	0
		Week 44	09NOV2016/12:00	44	34 - 50	No	0
		Week 48	14DEC2016/12:00	44	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	15DEC2015/12:00	71	35 - 104	Yes	0
		Day 1	06JAN2016/11:00	68	35 - 104	Yes	0
		Week 1	13JAN2016/11:00	64	35 - 104	No	0
		Week 2	20JAN2016/11:00	68	35 - 104	No	0
		Week 4	03FEB2016/11:00	61	35 - 104	No	0
		Week 6	18FEB2016/13:30	61	35 - 104	No	0
		Week 8	08MAR2016/08:35	58	35 - 104	No	0
		Week 12	29MAR2016/09:15	63	35 - 104	No	0
		Week 16	25APR2016/08:50	68	35 - 104	No	0
		Week 20	26MAY2016/12:50	62	35 - 104	No	0
		Week 24	22JUN2016/12:30	51	35 - 104	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Alkaline Phosphatase (IU/L)	Week 28	19JUL2016/10:10	56	35 - 104	No	0
		Week 32	16AUG2016/12:10	47	35 - 104	No	0
		Week 36	15SEP2016/12:35	57	35 - 104	No	0
		Week 40	12OCT2016/11:20	56	35 - 104	Yes	0
		Week 44	09NOV2016/12:00	65	35 - 104	No	0
		Week 48	14DEC2016/12:00	56	35 - 104	No	0
	Amylase (IU/L)	Screening	15DEC2015/12:00	118 H	28 - 100	Yes	1
		Day 1	06JAN2016/11:00	81	28 - 100	Yes	0
		Week 1	13JAN2016/11:00	86	28 - 100	No	0
		Week 2	20JAN2016/11:00	97	28 - 100	No	0
		Week 4	03FEB2016/11:00	93	28 - 100	No	0
		Week 6	18FEB2016/13:30	99	28 - 100	No	0
		Week 8	08MAR2016/08:35	83	28 - 100	No	0
		Week 12	29MAR2016/09:15	90	28 - 100	No	0
		Week 16	25APR2016/08:50	95	28 - 100	No	0
		Week 20	26MAY2016/12:50	94	28 - 100	No	0
		Week 24	22JUN2016/12:30	114 H	28 - 100	No	1
		Week 28	19JUL2016/10:10	106 H	28 - 100	No	1
		Week 32	16AUG2016/12:10	102 H	28 - 100	No	1
		Week 36	15SEP2016/12:35	84	28 - 100	No	0
		Week 40	12OCT2016/11:20	93	28 - 100	Yes	0
		Week 44	09NOV2016/12:00	81	28 - 100	No	0
		Week 48	14DEC2016/12:00	109 H	28 - 100	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Aspartate Aminotransferase (IU/L)	Screening	15DEC2015/12:00	40 H	0 - 31	Yes	1
		Day 1	06JAN2016/11:00	32 H	0 - 31	Yes	1
		Week 1	13JAN2016/11:00	33 H	0 - 31	No	1
		Week 2	20JAN2016/11:00	28	0 - 31	No	0
		Week 4	03FEB2016/11:00	33 H	0 - 31	No	1
		Week 6	18FEB2016/13:30	30	0 - 31	No	0
		Week 8	08MAR2016/08:35	30	0 - 31	No	0
		Week 12	29MAR2016/09:15	29	0 - 31	No	0
		Week 16	25APR2016/08:50	23	0 - 31	No	0
		Week 20	26MAY2016/12:50	27	0 - 31	No	0
		Week 24	22JUN2016/12:30	24	0 - 31	No	0
		Week 28	19JUL2016/10:10	28	0 - 31	No	0
		Week 32	16AUG2016/12:10	28	0 - 31	No	0
		Week 36	15SEP2016/12:35	29	0 - 31	No	0
		Week 40	12OCT2016/11:20	25	0 - 31	Yes	0
		Week 44	09NOV2016/12:00	30	0 - 31	No	0
		Week 48	14DEC2016/12:00	28	0 - 31	No	0
	Bicarbonate (mmol/L)	Screening	15DEC2015/12:00	22	22 - 29	Yes	
		Day 1	06JAN2016/11:00	24	22 - 29	Yes	
		Week 1	13JAN2016/11:00	23	22 - 29	No	
		Week 2	20JAN2016/11:00	24	22 - 29	No	
		Week 4	03FEB2016/11:00	22	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Bicarbonate (mmol/L)	Week 6	18FEB2016/13:30	20 L	22 - 29	No	
		Week 8	08MAR2016/08:35	21 L	22 - 29	No	
		Week 12	29MAR2016/09:15	22	22 - 29	No	
		Week 16	25APR2016/08:50	22	22 - 29	No	
		Week 20	26MAY2016/12:50	17 L	22 - 29	No	
		Week 24	22JUN2016/12:30	19 L	22 - 29	No	
		Week 28	19JUL2016/10:10	19 L	22 - 29	No	
		Week 32	16AUG2016/12:10	20 L	22 - 29	No	
		Week 36	15SEP2016/12:35	21 L	22 - 29	No	
		Week 40	12OCT2016/11:20	20 L	22 - 29	Yes	
		Week 44	09NOV2016/12:00	20 L	22 - 29	No	
		Week 48	14DEC2016/12:00	18 L	22 - 29	No	
	Bilirubin (umol/L)	Screening	15DEC2015/12:00	3	0 - 20	Yes	0
		Day 1	06JAN2016/11:00	5	0 - 20	Yes	0
		Week 1	13JAN2016/11:00	6	0 - 20	No	0
		Week 2	20JAN2016/11:00	2	0 - 20	No	0
		Week 4	03FEB2016/11:00	3	0 - 20	No	0
		Week 6	18FEB2016/13:30	5	0 - 20	No	0
		Week 8	08MAR2016/08:35	5	0 - 20	No	0
		Week 12	29MAR2016/09:15	2	0 - 20	No	0
		Week 16	25APR2016/08:50	<2	0 - 20	No	0
		Week 20	26MAY2016/12:50	4	0 - 20	No	0
		Week 24	22JUN2016/12:30	3	0 - 20	No	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Bilirubin (umol/L)	Week 28	19JUL2016/10:10	2	0 - 20	No	0
		Week 32	16AUG2016/12:10	4	0 - 20	No	0
		Week 36	15SEP2016/12:35	3	0 - 20	No	0
		Week 40	12OCT2016/11:20	2	0 - 20	Yes	0
		Week 44	09NOV2016/12:00	4	0 - 20	No	0
		Week 48	14DEC2016/12:00	6	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	15DEC2015/12:00	22.12	4.76 - 23.24	Yes	
		Day 1	06JAN2016/11:00	18.76	4.76 - 23.24	Yes	
		Week 1	13JAN2016/11:00	21.56	4.76 - 23.24	No	
		Week 2	20JAN2016/11:00	20.44	4.76 - 23.24	No	
		Week 4	03FEB2016/11:00	26.04 H	4.76 - 23.24	No	
		Week 6	18FEB2016/13:30	19.60	4.76 - 23.24	No	
		Week 8	08MAR2016/08:35	20.16	4.76 - 23.24	No	
		Week 12	29MAR2016/09:15	23.80 H	4.76 - 23.24	No	
		Week 16	25APR2016/08:50	17.92	4.76 - 23.24	No	
		Week 20	26MAY2016/12:50	20.16	4.76 - 23.24	No	
		Week 24	22JUN2016/12:30	19.32	4.76 - 23.24	No	
		Week 28	19JUL2016/10:10	30.80 H	4.76 - 23.24	No	
		Week 32	16AUG2016/12:10	15.12	4.76 - 23.24	No	
		Week 36	15SEP2016/12:35	12.60	4.76 - 23.24	No	
		Week 40	12OCT2016/11:20	11.20	4.76 - 23.24	Yes	
		Week 44	09NOV2016/12:00	11.48	4.76 - 23.24	No	
		Week 48	14DEC2016/12:00	15.40	4.76 - 23.24	No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Calcium (mmol/L)	Screening	15DEC2015/12:00	2.44	2.2 - 2.6	Yes	0
		Day 1	06JAN2016/11:00	2.43	2.2 - 2.6	Yes	0
		Week 1	13JAN2016/11:00	2.41	2.2 - 2.6	No	0
		Week 2	20JAN2016/11:00	2.54	2.2 - 2.6	No	0
		Week 4	03FEB2016/11:00	2.47	2.2 - 2.6	No	0
		Week 6	18FEB2016/13:30	2.44	2.2 - 2.6	No	0
		Week 8	08MAR2016/08:35	2.38	2.2 - 2.6	No	0
		Week 12	29MAR2016/09:15	2.39	2.2 - 2.6	No	0
		Week 16	25APR2016/08:50	2.36	2.2 - 2.6	No	0
		Week 20	26MAY2016/12:50	2.44	2.2 - 2.6	No	0
		Week 24	22JUN2016/12:30	2.38	2.2 - 2.6	No	0
		Week 28	19JUL2016/10:10	2.43	2.2 - 2.6	No	0
		Week 32	16AUG2016/12:10	2.38	2.2 - 2.6	No	0
		Week 36	15SEP2016/12:35	2.34	2.2 - 2.6	No	0
		Week 40	12OCT2016/11:20	2.30	2.2 - 2.6	Yes	0
		Week 44	09NOV2016/12:00	2.40	2.2 - 2.6	No	0
		Week 48	14DEC2016/12:00	2.49	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	15DEC2015/12:00	103	98 - 107	Yes	
		Day 1	06JAN2016/11:00	99	98 - 107	Yes	
		Week 1	13JAN2016/11:00	100	98 - 107	No	
		Week 2	20JAN2016/11:00	98	98 - 107	No	
		Week 4	03FEB2016/11:00	100	98 - 107	No	
		Week 6	18FEB2016/13:30	100	98 - 107	No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Chloride (mmol/L)	Week 8	08MAR2016/08:35	100	98 - 107	No	
		Week 12	29MAR2016/09:15	100	98 - 107	No	
		Week 16	25APR2016/08:50	101	98 - 107	No	
		Week 20	26MAY2016/12:50	100	98 - 107	No	
		Week 24	22JUN2016/12:30	102	98 - 107	No	
		Week 28	19JUL2016/10:10	100	98 - 107	No	
		Week 32	16AUG2016/12:10	104	98 - 107	No	
		Week 36	15SEP2016/12:35	104	98 - 107	No	
		Week 40	12OCT2016/11:20	107	98 - 107	Yes	
		Week 44	09NOV2016/12:00	105	98 - 107	No	
		Week 48	14DEC2016/12:00	101	98 - 107	No	
	Cholesterol (mmol/L)	Screening	15DEC2015/12:00	5.3 H	0 - 4.9	Yes	1
		Day 1	06JAN2016/11:00	5.4 H	0 - 4.9	Yes	1
		Week 1	13JAN2016/11:00	5.2 H	0 - 4.9	No	1
		Week 2	20JAN2016/11:00	6.0 H	0 - 4.9	No	1
		Week 4	03FEB2016/11:00	5.8 H	0 - 4.9	No	1
		Week 6	18FEB2016/13:30	5.8 H	0 - 4.9	No	1
		Week 8	08MAR2016/08:35	4.7	0 - 4.9	No	0
		Week 12	29MAR2016/09:15	5.2 H	0 - 4.9	No	1
		Week 16	25APR2016/08:50	5.3 H	0 - 4.9	No	1
		Week 20	26MAY2016/12:50	5.1 H	0 - 4.9	No	1
		Week 24	22JUN2016/12:30	4.8	0 - 4.9	No	0
		Week 28	19JUL2016/10:10	5.5 H	0 - 4.9	No	1

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Cholesterol (mmol/L)	Week 32	16AUG2016/12:10	4.4	0 - 4.9	No	0
		Week 36	15SEP2016/12:35	3.9	0 - 4.9	No	0
		Week 40	12OCT2016/11:20	3.6	0 - 4.9	Yes	0
		Week 44	09NOV2016/12:00	4.3	0 - 4.9	No	0
		Week 48	14DEC2016/12:00	4.0	0 - 4.9	No	0
	Creatine Kinase (IU/L)	Screening	15DEC2015/12:00	177 H	26 - 140	Yes	1
		Day 1	06JAN2016/11:00	141 H	26 - 140	Yes	1
		Week 1	13JAN2016/11:00	148 H	26 - 140	No	1
		Week 2	20JAN2016/11:00	94	26 - 140	No	0
		Week 4	03FEB2016/11:00	102	26 - 140	No	0
		Week 6	18FEB2016/13:30	122	26 - 140	No	0
		Week 8	08MAR2016/08:35	212 H	26 - 140	No	1
		Week 12	29MAR2016/09:15	779 H	26 - 140	No	3
		Week 16	25APR2016/08:50	158 H	26 - 140	No	1
		Week 20	26MAY2016/12:50	104	26 - 140	No	0
		Week 24	22JUN2016/12:30	103	26 - 140	No	0
		Week 28	19JUL2016/10:10	74	26 - 140	No	0
		Week 32	16AUG2016/12:10	187 H	26 - 140	No	1
		Week 36	15SEP2016/12:35	95	26 - 140	No	0
		Week 40	12OCT2016/11:20	83	26 - 140	Yes	0
		Week 44	09NOV2016/12:00	89	26 - 140	No	0
		Week 48	14DEC2016/12:00	112	26 - 140	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Creatinine (umol/L)	Screening	15DEC2015/12:00	66	49 - 92	Yes	0
		Day 1	06JAN2016/11:00	71	49 - 92	Yes	0
		Week 1	13JAN2016/11:00	63	49 - 92	No	0
		Week 2	20JAN2016/11:00	63	49 - 92	No	0
		Week 4	03FEB2016/11:00	75	49 - 92	No	1
		Week 6	18FEB2016/13:30	60	49 - 92	No	0
		Week 8	08MAR2016/08:35	64	49 - 92	No	0
		Week 12	29MAR2016/09:15	65	49 - 92	No	0
		Week 16	25APR2016/08:50	64	49 - 92	No	0
		Week 20	26MAY2016/12:50	71	49 - 92	No	0
		Week 24	22JUN2016/12:30	76	49 - 92	No	1
		Week 28	19JUL2016/10:10	63	49 - 92	No	0
		Week 32	16AUG2016/12:10	72	49 - 92	No	1
		Week 36	15SEP2016/12:35	68	49 - 92	No	0
		Week 40	12OCT2016/11:20	71	49 - 92	Yes	0
		Week 44	09NOV2016/12:00	66	49 - 92	No	0
		Week 48	14DEC2016/12:00	73	49 - 92	No	1
	Direct Bilirubin (umol/L)	Screening	15DEC2015/12:00	<2	0 - 5	Yes	
		Day 1	06JAN2016/11:00	3	0 - 5	Yes	
		Week 1	13JAN2016/11:00	2	0 - 5	No	
		Week 2	20JAN2016/11:00	<2	0 - 5	No	
		Week 4	03FEB2016/11:00	<2	0 - 5	No	
		Week 6	18FEB2016/13:30	<2	0 - 5	No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Direct Bilirubin (umol/L)	Week 8	08MAR2016/08:35	<2	0 - 5	No	
		Week 12	29MAR2016/09:15	<2	0 - 5	No	
		Week 16	25APR2016/08:50	<2	0 - 5	No	
		Week 20	26MAY2016/12:50	<2	0 - 5	No	
		Week 24	22JUN2016/12:30	<2	0 - 5	No	
		Week 28	19JUL2016/10:10	<2	0 - 5	No	
		Week 32	16AUG2016/12:10	2	0 - 5	No	
		Week 36	15SEP2016/12:35	<2	0 - 5	No	
		Week 40	12OCT2016/11:20	<2	0 - 5	Yes	
		Week 44	09NOV2016/12:00	2	0 - 5	No	
		Week 48	14DEC2016/12:00	3	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	15DEC2015/12:00	13	6 - 42	Yes	0
		Day 1	06JAN2016/11:00	16	6 - 42	Yes	0
		Week 1	13JAN2016/11:00	12	6 - 42	No	0
		Week 2	20JAN2016/11:00	16	6 - 42	No	0
		Week 4	03FEB2016/11:00	16	6 - 42	No	0
		Week 6	18FEB2016/13:30	14	6 - 42	No	0
		Week 8	08MAR2016/08:35	11	6 - 42	No	0
		Week 12	29MAR2016/09:15	12	6 - 42	No	0
		Week 16	25APR2016/08:50	12	6 - 42	No	0
		Week 20	26MAY2016/12:50	15	6 - 42	No	0
		Week 24	22JUN2016/12:30	17	6 - 42	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Gamma Glutamyl Transferase (IU/L)	Week 28	19JUL2016/10:10	17	6 - 42	No	0
		Week 32	16AUG2016/12:10	17	6 - 42	No	0
		Week 36	15SEP2016/12:35	26	6 - 42	No	0
		Week 40	12OCT2016/11:20	23	6 - 42	Yes	0
		Week 44	09NOV2016/12:00	18	6 - 42	No	0
		Week 48	14DEC2016/12:00	28	6 - 42	No	0
	Globulin (g/L)	Screening	15DEC2015/12:00	30	19 - 35	Yes	
		Day 1	06JAN2016/11:00	31	19 - 35	Yes	
		Week 1	13JAN2016/11:00	32	19 - 35	No	
		Week 2	20JAN2016/11:00	32	19 - 35	No	
		Week 4	03FEB2016/11:00	33	19 - 35	No	
		Week 6	18FEB2016/13:30	31	19 - 35	No	
		Week 8	08MAR2016/08:35	31	19 - 35	No	
		Week 12	29MAR2016/09:15	31	19 - 35	No	
		Week 16	25APR2016/08:50	30	19 - 35	No	
		Week 20	26MAY2016/12:50	32	19 - 35	No	
		Week 24	22JUN2016/12:30	32	19 - 35	No	
		Week 28	19JUL2016/10:10	32	19 - 35	No	
		Week 32	16AUG2016/12:10	28	19 - 35	No	
		Week 36	15SEP2016/12:35	29	19 - 35	No	
		Week 40	12OCT2016/11:20	30	19 - 35	Yes	
		Week 44	09NOV2016/12:00	27	19 - 35	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Globulin (g/L)	Week 48	14DEC2016/12:00	31	19 - 35	No	
	Glucose (mmol/L)	Screening	15DEC2015/12:00	4.3	3.9 - 5.8	Yes	0
		Day 1	06JAN2016/11:00	4.3	3.9 - 5.8	Yes	0
		Week 1	13JAN2016/11:00	3.3 L	3.5 - 7.9	No	1
		Week 2	20JAN2016/11:00	3.2 L	3.5 - 7.9	No	1
		Week 4	03FEB2016/11:00	4.1	3.5 - 7.9	No	0
		Week 6	18FEB2016/13:30	4.6	3.5 - 7.9	No	0
		Week 8	08MAR2016/08:35	4.7	3.5 - 7.9	No	0
		Week 12	29MAR2016/09:15	4.4	3.5 - 7.9	No	0
		Week 16	25APR2016/08:50	4.9	3.5 - 7.9	No	0
		Week 20	26MAY2016/12:50	4.6	3.5 - 7.9	No	0
		Week 24	22JUN2016/12:30	4.5	3.5 - 7.9	No	0
		Week 28	19JUL2016/10:10	4.2	3.5 - 7.9	No	0
		Week 32	16AUG2016/12:10	6.3	3.5 - 7.9	No	0
		Week 36	15SEP2016/12:35	5.1	3.5 - 7.9	No	0
		Week 40	12OCT2016/11:20	5.0	3.9 - 5.8	Yes	0
		Week 44	09NOV2016/12:00	4.6	3.5 - 7.9	No	0
		Week 48	14DEC2016/12:00	5.2	3.5 - 7.9	No	0
	Indirect Bilirubin (umol/L)	Screening	15DEC2015/12:00		0 - 14	Yes	
		Day 1	06JAN2016/11:00	2	0 - 14	Yes	
		Week 1	13JAN2016/11:00	4	0 - 14	No	
		Week 2	20JAN2016/11:00		0 - 14	No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Indirect Bilirubin (umol/L)	Week 4	03FEB2016/11:00		0 - 14	No
		Week 6	18FEB2016/13:30		0 - 14	No
		Week 8	08MAR2016/08:35		0 - 14	No
		Week 12	29MAR2016/09:15		0 - 14	No
		Week 16	25APR2016/08:50		0 - 14	No
		Week 20	26MAY2016/12:50		0 - 14	No
		Week 24	22JUN2016/12:30		0 - 14	No
		Week 28	19JUL2016/10:10		0 - 14	No
		Week 32	16AUG2016/12:10	2	0 - 14	No
		Week 36	15SEP2016/12:35		0 - 14	No
		Week 40	12OCT2016/11:20		0 - 14	Yes
		Week 44	09NOV2016/12:00	2	0 - 14	No
		Week 48	14DEC2016/12:00	3	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	15DEC2015/12:00	225 H	135 - 214	Yes
		Day 1	06JAN2016/11:00	218 H	135 - 214	Yes
		Week 1	13JAN2016/11:00	195	135 - 214	No
		Week 2	20JAN2016/11:00	193	135 - 214	No
		Week 4	03FEB2016/11:00	201	135 - 214	No
		Week 6	18FEB2016/13:30	220 H	135 - 214	No
		Week 8	08MAR2016/08:35	210	135 - 214	No
		Week 12	29MAR2016/09:15	214	135 - 214	No
		Week 16	25APR2016/08:50	201	135 - 214	No
		Week 20	26MAY2016/12:50	194	135 - 214	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Lactate Dehydrogenase (IU/L)	Week 24	22JUN2016/12:30	198	135 - 214	No	
		Week 28	19JUL2016/10:10	214	135 - 214	No	
		Week 32	16AUG2016/12:10	216 H	135 - 214	No	
		Week 36	15SEP2016/12:35	191	135 - 214	No	
		Week 40	12OCT2016/11:20	204	135 - 214	Yes	
		Week 44	09NOV2016/12:00	177	135 - 214	No	
		Week 48	14DEC2016/12:00	167	135 - 214	No	
	Magnesium (mmol/L)	Screening	15DEC2015/12:00	0.83	0.6 - 1	Yes	0
		Day 1	06JAN2016/11:00	0.87	0.6 - 1	Yes	0
		Week 1	13JAN2016/11:00	0.87	0.6 - 1	No	0
		Week 2	20JAN2016/11:00	0.86	0.6 - 1	No	0
		Week 4	03FEB2016/11:00	0.90	0.6 - 1	No	0
		Week 6	18FEB2016/13:30	0.90	0.6 - 1	No	0
		Week 8	08MAR2016/08:35	0.83	0.6 - 1	No	0
		Week 12	29MAR2016/09:15	0.83	0.6 - 1	No	0
		Week 16	25APR2016/08:50	0.82	0.6 - 1	No	0
		Week 20	26MAY2016/12:50	0.82	0.6 - 1	No	0
		Week 24	22JUN2016/12:30	0.87	0.6 - 1	No	0
		Week 28	19JUL2016/10:10	0.85	0.6 - 1	No	0
		Week 32	16AUG2016/12:10	0.89	0.6 - 1	No	0
		Week 36	15SEP2016/12:35	0.91	0.6 - 1	No	0
		Week 40	12OCT2016/11:20	0.90	0.6 - 1	Yes	0
		Week 44	09NOV2016/12:00	0.85	0.6 - 1	No	0

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Magnesium (mmol/L)	Week 48	14DEC2016/12:00	0.91	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	15DEC2015/12:00	1.26	0.87 - 1.45	Yes	0
		Day 1	06JAN2016/11:00	1.13	0.87 - 1.45	Yes	0
		Week 1	13JAN2016/11:00	1.03	0.87 - 1.45	No	0
		Week 2	20JAN2016/11:00	1.18	0.87 - 1.45	No	0
		Week 4	03FEB2016/11:00	1.19	0.87 - 1.45	No	0
		Week 6	18FEB2016/13:30	1.23	0.87 - 1.45	No	0
		Week 8	08MAR2016/08:35	1.09	0.87 - 1.45	No	0
		Week 12	29MAR2016/09:15	1.24	0.87 - 1.45	No	0
		Week 16	25APR2016/08:50	0.97	0.87 - 1.45	No	0
		Week 20	26MAY2016/12:50	1.24	0.87 - 1.45	No	0
		Week 24	22JUN2016/12:30	1.06	0.87 - 1.45	No	0
		Week 28	19JUL2016/10:10	1.32	0.87 - 1.45	No	0
		Week 32	16AUG2016/12:10	1.13	0.87 - 1.45	No	0
		Week 36	15SEP2016/12:35	1.29	0.87 - 1.45	No	0
		Week 40	12OCT2016/11:20	0.77 L	0.87 - 1.45	Yes	2
		Week 44	09NOV2016/12:00	1.06	0.87 - 1.45	No	0
		Week 48	14DEC2016/12:00	1.32	0.87 - 1.45	No	0
	Potassium (mmol/L)	Screening	15DEC2015/12:00	4.5	3.5 - 5.1	Yes	0
		Day 1	06JAN2016/11:00	4.2	3.5 - 5.1	Yes	0
		Week 1	13JAN2016/11:00	4.2	3.5 - 5.1	No	0
		Week 2	20JAN2016/11:00	4.7	3.5 - 5.1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Potassium (mmol/L)	Week 4	03FEB2016/11:00	4.7	3.5 - 5.1	No	0
		Week 6	18FEB2016/13:30	4.2	3.5 - 5.1	No	0
		Week 8	08MAR2016/08:35	4.4	3.5 - 5.1	No	0
		Week 12	29MAR2016/09:15	4.8	3.5 - 5.1	No	0
		Week 16	25APR2016/08:50	5.0	3.5 - 5.1	No	0
		Week 20	26MAY2016/12:50	4.7	3.5 - 5.1	No	0
		Week 24	22JUN2016/12:30	4.7	3.5 - 5.1	No	0
		Week 28	19JUL2016/10:10	4.4	3.5 - 5.1	No	0
		Week 32	16AUG2016/12:10	4.5	3.5 - 5.1	No	0
		Week 36	15SEP2016/12:35	4.2	3.5 - 5.1	No	0
		Week 40	12OCT2016/11:20	4.9	3.5 - 5.1	Yes	0
		Week 44	09NOV2016/12:00	4.5	3.5 - 5.1	No	0
		Week 48	14DEC2016/12:00	4.7	3.5 - 5.1	No	0
	Protein (g/L)	Screening	15DEC2015/12:00	75	63 - 83	Yes	
		Day 1	06JAN2016/11:00	76	63 - 83	Yes	
		Week 1	13JAN2016/11:00	77	63 - 83	No	
		Week 2	20JAN2016/11:00	80	63 - 83	No	
		Week 4	03FEB2016/11:00	79	63 - 83	No	
		Week 6	18FEB2016/13:30	80	63 - 83	No	
		Week 8	08MAR2016/08:35	75	63 - 83	No	
		Week 12	29MAR2016/09:15	73	63 - 83	No	
		Week 16	25APR2016/08:50	75	63 - 83	No	
		Week 20	26MAY2016/12:50	77	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Protein (g/L)	Week 24	22JUN2016/12:30	77	63 - 83	No	
		Week 28	19JUL2016/10:10	77	63 - 83	No	
		Week 32	16AUG2016/12:10	72	63 - 83	No	
		Week 36	15SEP2016/12:35	72	63 - 83	No	
		Week 40	12OCT2016/11:20	71	63 - 83	Yes	
		Week 44	09NOV2016/12:00	71	63 - 83	No	
		Week 48	14DEC2016/12:00	75	63 - 83	No	
	Sodium (mmol/L)	Screening	15DEC2015/12:00	141	135 - 145	Yes	0
		Day 1	06JAN2016/11:00	139	135 - 145	Yes	0
		Week 1	13JAN2016/11:00	138	135 - 145	No	0
		Week 2	20JAN2016/11:00	141	135 - 145	No	0
		Week 4	03FEB2016/11:00	138	135 - 145	No	0
		Week 6	18FEB2016/13:30	140	135 - 145	No	0
		Week 8	08MAR2016/08:35	137	135 - 145	No	0
		Week 12	29MAR2016/09:15	137	135 - 145	No	0
		Week 16	25APR2016/08:50	137	135 - 145	No	0
		Week 20	26MAY2016/12:50	141	135 - 145	No	0
		Week 24	22JUN2016/12:30	141	135 - 145	No	0
		Week 28	19JUL2016/10:10	138	135 - 145	No	0
		Week 32	16AUG2016/12:10	142	135 - 145	No	0
		Week 36	15SEP2016/12:35	143	135 - 145	No	0
		Week 40	12OCT2016/11:20	145	135 - 145	Yes	0
		Week 44	09NOV2016/12:00	142	135 - 145	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Sodium (mmol/L)	Week 48	14DEC2016/12:00	140	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	15DEC2015/12:00	1.10	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	15DEC2015/12:00	89	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	15DEC2015/12:00	1.2	0 - 2.2	Yes	0
		Day 1	06JAN2016/11:00	0.9	0 - 2.2	Yes	0
		Week 1	13JAN2016/11:00	1.6	0 - 2.2	No	0
		Week 2	20JAN2016/11:00	2.7 H	0 - 2.2	No	1
		Week 4	03FEB2016/11:00	1.4	0 - 2.2	No	0
		Week 6	18FEB2016/13:30	1.6	0 - 2.2	No	0
		Week 8	08MAR2016/08:35	1.1	0 - 2.2	No	0
		Week 12	29MAR2016/09:15	1.3	0 - 2.2	No	0
		Week 16	25APR2016/08:50	1.1	0 - 2.2	No	0
		Week 20	26MAY2016/12:50	1.4	0 - 2.2	No	0
		Week 24	22JUN2016/12:30	1.5	0 - 2.2	No	0
		Week 28	19JUL2016/10:10	1.6	0 - 2.2	No	0
		Week 32	16AUG2016/12:10	0.9	0 - 2.2	No	0
		Week 36	15SEP2016/12:35	1.0	0 - 2.2	No	0
		Week 40	12OCT2016/11:20	1.3	0 - 2.2	Yes	0
		Week 44	09NOV2016/12:00	0.5	0 - 2.2	No	0
		Week 48	14DEC2016/12:00	1.0	0 - 2.2	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Triiodothyronine (nmol/L)	Screening	15DEC2015/12:00	1.3	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	15DEC2015/12:00	7.9	1.7 - 8.3	Yes	
		Day 1	06JAN2016/11:00	6.7	1.7 - 8.3	Yes	
		Week 1	13JAN2016/11:00	7.7	1.7 - 8.3	No	
		Week 2	20JAN2016/11:00	7.3	1.7 - 8.3	No	
		Week 4	03FEB2016/11:00	9.3 H	1.7 - 8.3	No	
		Week 6	18FEB2016/13:30	7.0	1.7 - 8.3	No	
		Week 8	08MAR2016/08:35	7.2	1.7 - 8.3	No	
		Week 12	29MAR2016/09:15	8.5 H	1.7 - 8.3	No	
		Week 16	25APR2016/08:50	6.4	1.7 - 8.3	No	
		Week 20	26MAY2016/12:50	7.2	1.7 - 8.3	No	
		Week 24	22JUN2016/12:30	6.9	1.7 - 8.3	No	
		Week 28	19JUL2016/10:10	11.0 H	1.7 - 8.3	No	
		Week 32	16AUG2016/12:10	5.4	1.7 - 8.3	No	
		Week 36	15SEP2016/12:35	4.5	1.7 - 8.3	No	
		Week 40	12OCT2016/11:20	4.0	1.7 - 8.3	Yes	
		Week 44	09NOV2016/12:00	4.1	1.7 - 8.3	No	
		Week 48	14DEC2016/12:00	5.5	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	15DEC2015/12:00	208	175 - 363	Yes	0
		Day 1	06JAN2016/11:00	262	175 - 363	Yes	0
		Week 1	13JAN2016/11:00	199	175 - 363	No	0
		Week 2	20JAN2016/11:00	210	175 - 363	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Uric acid (umol/L)	Week 4	03FEB2016/11:00	237	175 - 363	No	0
		Week 6	18FEB2016/13:30	218	175 - 363	No	0
		Week 8	08MAR2016/08:35	223	175 - 363	No	0
		Week 12	29MAR2016/09:15	175	175 - 363	No	0
		Week 16	25APR2016/08:50	187	175 - 363	No	0
		Week 20	26MAY2016/12:50	189	175 - 363	No	0
		Week 24	22JUN2016/12:30	211	175 - 363	No	0
		Week 28	19JUL2016/10:10	177	175 - 363	No	0
		Week 32	16AUG2016/12:10	190	175 - 363	No	0
		Week 36	15SEP2016/12:35	205	175 - 363	No	0
		Week 40	12OCT2016/11:20	189	175 - 363	Yes	0
		Week 44	09NOV2016/12:00	183	175 - 363	No	0
		Week 48	14DEC2016/12:00	217	175 - 363	No	0
301-005	Alanine Aminotransferase (IU/L)	Screening	16DEC2015/08:45	348 H	10 - 50	Yes	3
		Day 1	07JAN2016/10:00	362 H	10 - 50	Yes	3
		Week 1	13JAN2016/09:30	367 H	10 - 50	No	3
		Week 2	21JAN2016/10:00	343 H	10 - 50	No	3
		Week 4	02FEB2016/09:00	270 H	10 - 50	No	3
		Week 6	17FEB2016/13:00	230 H	10 - 50	No	2
		Week 8	02MAR2016/09:15	274 H	10 - 50	No	3
		Week 12	31MAR2016/10:15	156 H	10 - 50	No	2
		Week 16	26APR2016/10:00	206 H	10 - 50	No	2

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Alanine Aminotransferase (IU/L)	Week 20	26MAY2016/12:30	279 H	10 - 50	No	3
		Week 24	23JUN2016/11:45	323 H	10 - 50	No	3
		Week 28	26JUL2016/09:15	629 H	10 - 50	No	3
		Week 32	16AUG2016/10:45	938 H	10 - 50	No	3
		Week 36	14SEP2016/12:00	357 H	10 - 50	No	3
		Week 40	12OCT2016/12:10	156 H	10 - 50	No	2
		Week 44	10NOV2016/11:00	108 H	10 - 50	No	1
		Week 48	07DEC2016/12:00	97 H	10 - 50	No	1
	Albumin (g/L)	Screening	16DEC2015/08:45	48	34 - 50	Yes	0
		Day 1	07JAN2016/10:00	45	34 - 50	Yes	0
		Week 1	13JAN2016/09:30	43	34 - 50	No	0
		Week 2	21JAN2016/10:00	44	34 - 50	No	0
		Week 4	02FEB2016/09:00	43	34 - 50	No	0
		Week 6	17FEB2016/13:00	47	34 - 50	No	0
		Week 8	02MAR2016/09:15	46	34 - 50	No	0
		Week 12	31MAR2016/10:15	45	34 - 50	No	0
		Week 16	26APR2016/10:00	46	34 - 50	No	0
		Week 20	26MAY2016/12:30	46	34 - 50	No	0
		Week 24	23JUN2016/11:45	47	34 - 50	No	0
		Week 28	26JUL2016/09:15	43	34 - 50	No	0
		Week 32	16AUG2016/10:45	44	34 - 50	No	0
		Week 36	14SEP2016/12:00	44	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Albumin (g/L)	Week 40	12OCT2016/12:10	44	34 - 50	No	0
		Week 44	10NOV2016/11:00	46	34 - 50	No	0
		Week 48	07DEC2016/12:00	47	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	16DEC2015/08:45	59	40 - 129	Yes	0
		Day 1	07JAN2016/10:00	53	40 - 129	Yes	0
		Week 1	13JAN2016/09:30	53	40 - 129	No	0
		Week 2	21JAN2016/10:00	53	40 - 129	No	0
		Week 4	02FEB2016/09:00	59	40 - 129	No	0
		Week 6	17FEB2016/13:00	66	40 - 129	No	0
		Week 8	02MAR2016/09:15	75	40 - 129	No	0
		Week 12	31MAR2016/10:15	80	40 - 129	No	0
		Week 16	26APR2016/10:00	71	40 - 129	No	0
		Week 20	26MAY2016/12:30	83	40 - 129	No	0
		Week 24	23JUN2016/11:45	80	40 - 129	No	0
		Week 28	26JUL2016/09:15	90	40 - 129	No	0
		Week 32	16AUG2016/10:45	90	40 - 129	No	0
		Week 36	14SEP2016/12:00	63	40 - 129	No	0
		Week 40	12OCT2016/12:10	55	40 - 129	No	0
		Week 44	10NOV2016/11:00	56	40 - 129	No	0
		Week 48	07DEC2016/12:00	47	40 - 129	No	0
	Amylase (IU/L)	Screening	16DEC2015/08:45	92	28 - 100	Yes	0
		Day 1	07JAN2016/10:00	91	28 - 100	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005 Amylase (IU/L)	Week 1	13JAN2016/09:30	73	28 - 100	No	0
	Week 2	21JAN2016/10:00	90	28 - 100	No	0
	Week 4	02FEB2016/09:00	85	28 - 100	No	0
	Week 6	17FEB2016/13:00	83	28 - 100	No	0
	Week 8	02MAR2016/09:15	102 H	28 - 100	No	1
	Week 12	31MAR2016/10:15	88	28 - 100	No	0
	Week 16	26APR2016/10:00	80	28 - 100	No	0
	Week 20	26MAY2016/12:30	89	28 - 100	No	0
	Week 24	23JUN2016/11:45	102 H	28 - 100	No	1
	Week 28	26JUL2016/09:15	103 H	28 - 100	No	1
	Week 32	16AUG2016/10:45	87	28 - 100	No	0
	Week 36	14SEP2016/12:00	85	28 - 100	No	0
	Week 40	12OCT2016/12:10	109 H	28 - 100	No	1
	Week 44	10NOV2016/11:00	84	28 - 100	No	0
	Week 48	07DEC2016/12:00	83	28 - 100	No	0
Aspartate Aminotransferase (IU/L)	Screening	16DEC2015/08:45	141 H	0 - 37	Yes	2
	Day 1	07JAN2016/10:00	135 H	0 - 37	Yes	2
	Week 1	13JAN2016/09:30	133 H	0 - 37	No	2
	Week 2	21JAN2016/10:00	115 H	0 - 37	No	2
	Week 4	02FEB2016/09:00	90 H	0 - 37	No	1
	Week 6	17FEB2016/13:00	96 H	0 - 37	No	1
	Week 8	02MAR2016/09:15	100 H	0 - 37	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Aspartate Aminotransferase (IU/L)	Week 12	31MAR2016/10:15	81 H	0 - 37	No	1
		Week 16	26APR2016/10:00	103 H	0 - 37	No	1
		Week 20	26MAY2016/12:30	135 H	0 - 37	No	2
		Week 24	23JUN2016/11:45	177 H	0 - 37	No	2
		Week 28	26JUL2016/09:15	311 H	0 - 37	No	3
		Week 32	16AUG2016/10:45	402 H	0 - 37	No	3
		Week 36	14SEP2016/12:00	143 H	0 - 37	No	2
		Week 40	12OCT2016/12:10	73 H	0 - 37	No	1
		Week 44	10NOV2016/11:00	63 H	0 - 37	No	1
		Week 48	07DEC2016/12:00	59 H	0 - 37	No	1
	Bicarbonate (mmol/L)	Screening	16DEC2015/08:45	20 L	22 - 29	Yes	
		Day 1	07JAN2016/10:00	20 L	22 - 29	Yes	
		Week 1	13JAN2016/09:30	22	22 - 29	No	
		Week 2	21JAN2016/10:00	22	22 - 29	No	
		Week 4	02FEB2016/09:00	22	22 - 29	No	
		Week 6	17FEB2016/13:00	20 L	22 - 29	No	
		Week 8	02MAR2016/09:15	18 L	22 - 29	No	
		Week 12	31MAR2016/10:15	21 L	22 - 29	No	
		Week 16	26APR2016/10:00	22	22 - 29	No	
		Week 20	26MAY2016/12:30	18 L	22 - 29	No	
		Week 24	23JUN2016/11:45	19 L	22 - 29	No	
		Week 28	26JUL2016/09:15	19 L	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Bicarbonate (mmol/L)	Week 32	16AUG2016/10:45	19 L	22 - 29	No	
		Week 36	14SEP2016/12:00	24	22 - 29	No	
		Week 40	12OCT2016/12:10	20 L	22 - 29	No	
		Week 44	10NOV2016/11:00	20 L	22 - 29	No	
		Week 48	07DEC2016/12:00	20 L	22 - 29	No	
	Bilirubin (umol/L)	Screening	16DEC2015/08:45	16	0 - 20	Yes	0
		Day 1	07JAN2016/10:00	15	0 - 20	Yes	0
		Week 1	13JAN2016/09:30	13	0 - 20	No	0
		Week 2	21JAN2016/10:00	10	0 - 20	No	0
		Week 4	02FEB2016/09:00	17	0 - 20	No	0
		Week 6	17FEB2016/13:00	20	0 - 20	No	0
		Week 8	02MAR2016/09:15	9	0 - 20	No	0
		Week 12	31MAR2016/10:15	8	0 - 20	No	0
		Week 16	26APR2016/10:00	14	0 - 20	No	0
		Week 20	26MAY2016/12:30	9	0 - 20	No	0
		Week 24	23JUN2016/11:45	9	0 - 20	No	0
		Week 28	26JUL2016/09:15	10	0 - 20	No	0
		Week 32	16AUG2016/10:45	15	0 - 20	No	0
		Week 36	14SEP2016/12:00	20	0 - 20	No	0
		Week 40	12OCT2016/12:10	9	0 - 20	No	0
		Week 44	10NOV2016/11:00	19	0 - 20	No	0
		Week 48	07DEC2016/12:00	25 H	0 - 20	No	1

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Blood Urea Nitrogen (mg/dL)	Screening	16DEC2015/08:45	16.24	4.76 - 23.24	Yes	
		Day 1	07JAN2016/10:00	13.44	4.76 - 23.24	Yes	
		Week 1	13JAN2016/09:30	11.48	4.76 - 23.24	No	
		Week 2	21JAN2016/10:00	12.04	4.76 - 23.24	No	
		Week 4	02FEB2016/09:00	13.16	4.76 - 23.24	No	
		Week 6	17FEB2016/13:00	12.88	4.76 - 23.24	No	
		Week 8	02MAR2016/09:15	12.88	4.76 - 23.24	No	
		Week 12	31MAR2016/10:15	12.60	4.76 - 23.24	No	
		Week 16	26APR2016/10:00	12.04	4.76 - 23.24	No	
		Week 20	26MAY2016/12:30	12.88	4.76 - 23.24	No	
		Week 24	23JUN2016/11:45	17.64	4.76 - 23.24	No	
		Week 28	26JUL2016/09:15	12.88	4.76 - 23.24	No	
		Week 32	16AUG2016/10:45	10.64	4.76 - 23.24	No	
		Week 36	14SEP2016/12:00	13.44	4.76 - 23.24	No	
		Week 40	12OCT2016/12:10	10.08	4.76 - 23.24	No	
		Week 44	10NOV2016/11:00	12.04	4.76 - 23.24	No	
		Week 48	07DEC2016/12:00	14.00	4.76 - 23.24	No	
	Calcium (mmol/L)	Screening	16DEC2015/08:45	2.43	2.2 - 2.6	Yes	0
		Day 1	07JAN2016/10:00	2.37	2.2 - 2.6	Yes	0
		Week 1	13JAN2016/09:30	2.27	2.2 - 2.6	No	0
		Week 2	21JAN2016/10:00	2.36	2.2 - 2.6	No	0
		Week 4	02FEB2016/09:00	2.36	2.2 - 2.6	No	0
		Week 6	17FEB2016/13:00	2.39	2.2 - 2.6	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Calcium (mmol/L)	Week 8	02MAR2016/09:15	2.42	2.2 - 2.6	No	0
		Week 12	31MAR2016/10:15	2.41	2.2 - 2.6	No	0
		Week 16	26APR2016/10:00	2.42	2.2 - 2.6	No	0
		Week 20	26MAY2016/12:30	2.40	2.2 - 2.6	No	0
		Week 24	23JUN2016/11:45	2.30	2.2 - 2.6	No	0
		Week 28	26JUL2016/09:15	2.44	2.2 - 2.6	No	0
		Week 32	16AUG2016/10:45	2.34	2.2 - 2.6	No	0
		Week 36	14SEP2016/12:00	2.40	2.2 - 2.6	No	0
		Week 40	12OCT2016/12:10	2.34	2.2 - 2.6	No	0
		Week 44	10NOV2016/11:00	2.32	2.2 - 2.6	No	0
		Week 48	07DEC2016/12:00	2.32	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	16DEC2015/08:45	98	98 - 107	Yes	
		Day 1	07JAN2016/10:00	96 L	98 - 107	Yes	
		Week 1	13JAN2016/09:30	98	98 - 107	No	
		Week 2	21JAN2016/10:00	99	98 - 107	No	
		Week 4	02FEB2016/09:00	97 L	98 - 107	No	
		Week 6	17FEB2016/13:00	100	98 - 107	No	
		Week 8	02MAR2016/09:15	101	98 - 107	No	
		Week 12	31MAR2016/10:15	101	98 - 107	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Chloride (mmol/L)	Week 32	16AUG2016/10:45	99	98 - 107	No	
		Week 36	14SEP2016/12:00	100	98 - 107	No	
		Week 40	12OCT2016/12:10	99	98 - 107	No	
		Week 44	10NOV2016/11:00	99	98 - 107	No	
		Week 48	07DEC2016/12:00	98	98 - 107	No	
	Cholesterol (mmol/L)	Screening	16DEC2015/08:45	4.5	0 - 4.9	Yes	0
		Day 1	07JAN2016/10:00	4.2	0 - 4.9	Yes	0
		Week 1	13JAN2016/09:30	2.8	0 - 4.9	No	0
		Week 2	21JAN2016/10:00	3.1	0 - 4.9	No	0
		Week 4	02FEB2016/09:00	4.0	0 - 4.9	No	0
		Week 6	17FEB2016/13:00	4.5	0 - 4.9	No	0
		Week 8	02MAR2016/09:15	2.9	0 - 4.9	No	0
		Week 12	31MAR2016/10:15	4.6	0 - 4.9	No	0
		Week 16	26APR2016/10:00	4.1	0 - 4.9	No	0
		Week 20	26MAY2016/12:30	4.6	0 - 4.9	No	0
		Week 24	23JUN2016/11:45	4.6	0 - 4.9	No	0
		Week 28	26JUL2016/09:15	4.3	0 - 4.9	No	0
		Week 32	16AUG2016/10:45	3.8	0 - 4.9	No	0
		Week 36	14SEP2016/12:00	4.4	0 - 4.9	No	0
		Week 40	12OCT2016/12:10	4.4	0 - 4.9	No	0
		Week 44	10NOV2016/11:00	4.1	0 - 4.9	No	0
		Week 48	07DEC2016/12:00	4.6	0 - 4.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Creatine Kinase (IU/L)	Screening	16DEC2015/08:45	192	38 - 204	Yes	0
		Day 1	07JAN2016/10:00	129	38 - 204	Yes	0
		Week 1	13JAN2016/09:30	145	38 - 204	No	0
		Week 2	21JAN2016/10:00	103	38 - 204	No	0
		Week 4	02FEB2016/09:00	151	38 - 204	No	0
		Week 6	17FEB2016/13:00	141	38 - 204	No	0
		Week 8	02MAR2016/09:15	124	38 - 204	No	0
		Week 12	31MAR2016/10:15	122	38 - 204	No	0
		Week 16	26APR2016/10:00	165	38 - 204	No	0
		Week 20	26MAY2016/12:30	122	38 - 204	No	0
		Week 24	23JUN2016/11:45	130	38 - 204	No	0
		Week 28	26JUL2016/09:15	138	38 - 204	No	0
		Week 32	16AUG2016/10:45	110	38 - 204	No	0
		Week 36	14SEP2016/12:00	119	38 - 204	No	0
		Week 40	12OCT2016/12:10	183	38 - 204	No	0
		Week 44	10NOV2016/11:00	194	38 - 204	No	0
		Week 48	07DEC2016/12:00	155	38 - 204	No	0
	Creatinine (umol/L)	Screening	16DEC2015/08:45	77	66 - 112	Yes	0
		Day 1	07JAN2016/10:00	84	66 - 112	Yes	0
		Week 1	13JAN2016/09:30	82	66 - 112	No	0
		Week 2	21JAN2016/10:00	86	66 - 112	No	1
		Week 4	02FEB2016/09:00	95	66 - 112	No	1
		Week 6	17FEB2016/13:00	81	66 - 112	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Creatinine (umol/L)	Week 8	02MAR2016/09:15	88	66 - 112	No	1
		Week 12	31MAR2016/10:15	77	66 - 112	No	0
		Week 16	26APR2016/10:00	80	66 - 112	No	0
		Week 20	26MAY2016/12:30	85	66 - 112	No	1
		Week 24	23JUN2016/11:45	76	66 - 112	No	0
		Week 28	26JUL2016/09:15	77	66 - 112	No	0
		Week 32	16AUG2016/10:45	80	66 - 112	No	0
		Week 36	14SEP2016/12:00	80	66 - 112	No	0
		Week 40	12OCT2016/12:10	78	66 - 112	No	0
		Week 44	10NOV2016/11:00	81	66 - 112	No	0
		Week 48	07DEC2016/12:00	79	66 - 112	No	0
	Direct Bilirubin (umol/L)	Screening	16DEC2015/08:45	6 H	0 - 5	Yes	
		Day 1	07JAN2016/10:00	6 H	0 - 5	Yes	
		Week 1	13JAN2016/09:30	5	0 - 5	No	
		Week 2	21JAN2016/10:00	4	0 - 5	No	
		Week 4	02FEB2016/09:00	6 H	0 - 5	No	
		Week 6	17FEB2016/13:00	7 H	0 - 5	No	
		Week 8	02MAR2016/09:15	4	0 - 5	No	
		Week 12	31MAR2016/10:15	3	0 - 5	No	
		Week 16	26APR2016/10:00	5	0 - 5	No	
		Week 20	26MAY2016/12:30	3	0 - 5	No	
		Week 24	23JUN2016/11:45	4	0 - 5	No	
		Week 28	26JUL2016/09:15	4	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Direct Bilirubin (umol/L)	Week 32	16AUG2016/10:45	6 H	0 - 5	No	
		Week 36	14SEP2016/12:00	7 H	0 - 5	No	
		Week 40	12OCT2016/12:10	3	0 - 5	No	
		Week 44	10NOV2016/11:00	7 H	0 - 5	No	
		Week 48	07DEC2016/12:00	8 H	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	16DEC2015/08:45	188 H	10 - 71	Yes	2
		Day 1	07JAN2016/10:00	186 H	10 - 71	Yes	2
		Week 1	13JAN2016/09:30	136 H	10 - 71	No	1
		Week 2	21JAN2016/10:00	100 H	10 - 71	No	1
		Week 4	02FEB2016/09:00	73 H	10 - 71	No	1
		Week 6	17FEB2016/13:00	92 H	10 - 71	No	1
		Week 8	02MAR2016/09:15	63	10 - 71	No	0
		Week 12	31MAR2016/10:15	95 H	10 - 71	No	1
		Week 16	26APR2016/10:00	120 H	10 - 71	No	1
		Week 20	26MAY2016/12:30	116 H	10 - 71	No	1
		Week 24	23JUN2016/11:45	179 H	10 - 71	No	2
		Week 28	26JUL2016/09:15	410 H	10 - 71	No	3
		Week 32	16AUG2016/10:45	318 H	10 - 71	No	2
		Week 36	14SEP2016/12:00	212 H	10 - 71	No	2
		Week 40	12OCT2016/12:10	160 H	10 - 71	No	1
		Week 44	10NOV2016/11:00	172 H	10 - 71	No	1
		Week 48	07DEC2016/12:00	153 H	10 - 71	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Globulin (g/L)	Screening	16DEC2015/08:45	41 H	19 - 35	Yes	
		Day 1	07JAN2016/10:00	34	19 - 35	Yes	
		Week 1	13JAN2016/09:30	36 H	19 - 35	No	
		Week 2	21JAN2016/10:00	35	19 - 35	No	
		Week 4	02FEB2016/09:00	37 H	19 - 35	No	
		Week 6	17FEB2016/13:00	41 H	19 - 35	No	
		Week 8	02MAR2016/09:15	41 H	19 - 35	No	
		Week 12	31MAR2016/10:15	37 H	19 - 35	No	
		Week 16	26APR2016/10:00	36 H	19 - 35	No	
		Week 20	26MAY2016/12:30	37 H	19 - 35	No	
		Week 24	23JUN2016/11:45	37 H	19 - 35	No	
		Week 28	26JUL2016/09:15	41 H	19 - 35	No	
		Week 32	16AUG2016/10:45	42 H	19 - 35	No	
		Week 36	14SEP2016/12:00	41 H	19 - 35	No	
		Week 40	12OCT2016/12:10	38 H	19 - 35	No	
		Week 44	10NOV2016/11:00	38 H	19 - 35	No	
		Week 48	07DEC2016/12:00	32	19 - 35	No	
	Glucose (mmol/L)	Screening	16DEC2015/08:45	5.1	3.9 - 5.8	Yes	0
		Day 1	07JAN2016/10:00	6.2 H	3.9 - 5.8	Yes	1
		Week 1	13JAN2016/09:30	5.0	3.5 - 7.9	No	0
		Week 2	21JAN2016/10:00	5.2	3.5 - 7.9	No	0
		Week 4	02FEB2016/09:00	8.9 H	3.5 - 7.9	No	1
		Week 6	17FEB2016/13:00	5.1	3.5 - 7.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Glucose (mmol/L)	Week 8	02MAR2016/09:15	5.6	3.5 - 7.9	No	0
		Week 12	31MAR2016/10:15	5.0	3.5 - 7.9	No	0
		Week 16	26APR2016/10:00	5.2	3.5 - 7.9	No	0
		Week 20	26MAY2016/12:30	4.4	3.5 - 7.9	No	0
		Week 24	23JUN2016/11:45	4.7	3.5 - 7.9	No	0
		Week 28	26JUL2016/09:15	4.7	3.5 - 7.9	No	0
		Week 32	16AUG2016/10:45	4.5	3.5 - 7.9	No	0
		Week 36	14SEP2016/12:00	5.3	3.5 - 7.9	No	0
		Week 40	12OCT2016/12:10	4.7	3.5 - 7.9	No	0
		Week 44	10NOV2016/11:00	5.3	3.5 - 7.9	No	0
		Week 48	07DEC2016/12:00	4.9	3.5 - 7.9	No	0
	Indirect Bilirubin (umol/L)	Screening	16DEC2015/08:45	10	0 - 14	Yes	
		Day 1	07JAN2016/10:00	9	0 - 14	Yes	
		Week 1	13JAN2016/09:30	8	0 - 14	No	
		Week 2	21JAN2016/10:00	6	0 - 14	No	
		Week 4	02FEB2016/09:00	11	0 - 14	No	
		Week 6	17FEB2016/13:00	13	0 - 14	No	
		Week 8	02MAR2016/09:15	5	0 - 14	No	
		Week 12	31MAR2016/10:15	5	0 - 14	No	
		Week 16	26APR2016/10:00	9	0 - 14	No	
		Week 20	26MAY2016/12:30	6	0 - 14	No	
		Week 24	23JUN2016/11:45	5	0 - 14	No	
		Week 28	26JUL2016/09:15	6	0 - 14	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Indirect Bilirubin (umol/L)	Week 32	16AUG2016/10:45	9	0 - 14	No
		Week 36	14SEP2016/12:00	13	0 - 14	No
		Week 40	12OCT2016/12:10	6	0 - 14	No
		Week 44	10NOV2016/11:00	12	0 - 14	No
		Week 48	07DEC2016/12:00	17 H	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	16DEC2015/08:45	181	135 - 225	Yes
		Day 1	07JAN2016/10:00	150	135 - 225	Yes
		Week 1	13JAN2016/09:30	144	135 - 225	No
		Week 2	21JAN2016/10:00	140	135 - 225	No
		Week 4	02FEB2016/09:00	136	135 - 225	No
		Week 6	17FEB2016/13:00	160	135 - 225	No
		Week 8	02MAR2016/09:15	156	135 - 225	No
		Week 12	31MAR2016/10:15	152	135 - 225	No
		Week 16	26APR2016/10:00	139	135 - 225	No
		Week 20	26MAY2016/12:30	161	135 - 225	No
		Week 24	23JUN2016/11:45	195	135 - 225	No
		Week 28	26JUL2016/09:15	219	135 - 225	No
		Week 32	16AUG2016/10:45	214	135 - 225	No
		Week 36	14SEP2016/12:00	174	135 - 225	No
		Week 40	12OCT2016/12:10	157	135 - 225	No
		Week 44	10NOV2016/11:00	145	135 - 225	No
		Week 48	07DEC2016/12:00	141	135 - 225	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Magnesium (mmol/L)	Screening	16DEC2015/08:45	0.94	0.6 - 1	Yes	0
		Day 1	07JAN2016/10:00	0.88	0.6 - 1	Yes	0
		Week 1	13JAN2016/09:30	0.85	0.6 - 1	No	0
		Week 2	21JAN2016/10:00	0.85	0.6 - 1	No	0
		Week 4	02FEB2016/09:00	0.83	0.6 - 1	No	0
		Week 6	17FEB2016/13:00	0.86	0.6 - 1	No	0
		Week 8	02MAR2016/09:15	0.88	0.6 - 1	No	0
		Week 12	31MAR2016/10:15	0.84	0.6 - 1	No	0
		Week 16	26APR2016/10:00	0.86	0.6 - 1	No	0
		Week 20	26MAY2016/12:30	0.92	0.6 - 1	No	0
		Week 24	23JUN2016/11:45	0.88	0.6 - 1	No	0
		Week 28	26JUL2016/09:15	0.82	0.6 - 1	No	0
		Week 32	16AUG2016/10:45	0.96	0.6 - 1	No	0
		Week 36	14SEP2016/12:00	0.87	0.6 - 1	No	0
		Week 40	12OCT2016/12:10	0.83	0.6 - 1	No	0
		Week 44	10NOV2016/11:00	0.88	0.6 - 1	No	0
		Week 48	07DEC2016/12:00	0.88	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	16DEC2015/08:45	1.26	0.87 - 1.45	Yes	0
		Day 1	07JAN2016/10:00	1.01	0.87 - 1.45	Yes	0
		Week 1	13JAN2016/09:30	0.87	0.87 - 1.45	No	0
		Week 2	21JAN2016/10:00	1.08	0.87 - 1.45	No	0
		Week 4	02FEB2016/09:00	0.96	0.87 - 1.45	No	0
		Week 6	17FEB2016/13:00	0.94	0.87 - 1.45	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Phosphate (mmol/L)	Week 8	02MAR2016/09:15	0.84 L	0.87 - 1.45	No	1
		Week 12	31MAR2016/10:15	1.21	0.87 - 1.45	No	0
		Week 16	26APR2016/10:00	1.01	0.87 - 1.45	No	0
		Week 20	26MAY2016/12:30	1.26	0.87 - 1.45	No	0
		Week 24	23JUN2016/11:45	1.14	0.87 - 1.45	No	0
		Week 28	26JUL2016/09:15	1.30	0.87 - 1.45	No	0
		Week 32	16AUG2016/10:45	1.09	0.87 - 1.45	No	0
		Week 36	14SEP2016/12:00	0.93	0.87 - 1.45	No	0
		Week 40	12OCT2016/12:10	1.09	0.87 - 1.45	No	0
		Week 44	10NOV2016/11:00	0.95	0.87 - 1.45	No	0
		Week 48	07DEC2016/12:00	0.98	0.87 - 1.45	No	0
	Potassium (mmol/L)	Screening	16DEC2015/08:45	4.3	3.5 - 5.1	Yes	0
		Day 1	07JAN2016/10:00	3.9	3.5 - 5.1	Yes	0
		Week 1	13JAN2016/09:30	4.2	3.5 - 5.1	No	0
		Week 2	21JAN2016/10:00	4.4	3.5 - 5.1	No	0
		Week 4	02FEB2016/09:00	4.0	3.5 - 5.1	No	0
		Week 6	17FEB2016/13:00	4.7	3.5 - 5.1	No	0
		Week 8	02MAR2016/09:15	4.1	3.5 - 5.1	No	0
		Week 12	31MAR2016/10:15	4.4	3.5 - 5.1	No	0
		Week 16	26APR2016/10:00	4.3	3.5 - 5.1	No	0
		Week 20	26MAY2016/12:30	4.3	3.5 - 5.1	No	0
		Week 24	23JUN2016/11:45	4.0	3.5 - 5.1	No	0
		Week 28	26JUL2016/09:15	4.4	3.5 - 5.1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Potassium (mmol/L)	Week 32	16AUG2016/10:45	4.4	3.5 - 5.1	No	0
		Week 36	14SEP2016/12:00	4.2	3.5 - 5.1	No	0
		Week 40	12OCT2016/12:10	4.6	3.5 - 5.1	No	0
		Week 44	10NOV2016/11:00	4.2	3.5 - 5.1	No	0
		Week 48	07DEC2016/12:00	4.1	3.5 - 5.1	No	0
	Protein (g/L)	Screening	16DEC2015/08:45	89 H	63 - 83	Yes	
		Day 1	07JAN2016/10:00	79	63 - 83	Yes	
		Week 1	13JAN2016/09:30	79	63 - 83	No	
		Week 2	21JAN2016/10:00	79	63 - 83	No	
		Week 4	02FEB2016/09:00	80	63 - 83	No	
		Week 6	17FEB2016/13:00	88 H	63 - 83	No	
		Week 8	02MAR2016/09:15	87 H	63 - 83	No	
		Week 12	31MAR2016/10:15	82	63 - 83	No	
		Week 16	26APR2016/10:00	82	63 - 83	No	
		Week 20	26MAY2016/12:30	83	63 - 83	No	
		Week 24	23JUN2016/11:45	84 H	63 - 83	No	
		Week 28	26JUL2016/09:15	84 H	63 - 83	No	
		Week 32	16AUG2016/10:45	86 H	63 - 83	No	
		Week 36	14SEP2016/12:00	85 H	63 - 83	No	
		Week 40	12OCT2016/12:10	82	63 - 83	No	
		Week 44	10NOV2016/11:00	84 H	63 - 83	No	
		Week 48	07DEC2016/12:00	79	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Sodium (mmol/L)	Screening	16DEC2015/08:45	136	135 - 145	Yes	0
		Day 1	07JAN2016/10:00	137	135 - 145	Yes	0
		Week 1	13JAN2016/09:30	136	135 - 145	No	0
		Week 2	21JAN2016/10:00	137	135 - 145	No	0
		Week 4	02FEB2016/09:00	135	135 - 145	No	0
		Week 6	17FEB2016/13:00	135	135 - 145	No	0
		Week 8	02MAR2016/09:15	135	135 - 145	No	0
		Week 12	31MAR2016/10:15	138	135 - 145	No	0
		Week 16	26APR2016/10:00	137	135 - 145	No	0
		Week 20	26MAY2016/12:30	137	135 - 145	No	0
		Week 24	23JUN2016/11:45	137	135 - 145	No	0
		Week 28	26JUL2016/09:15	136	135 - 145	No	0
		Week 32	16AUG2016/10:45	137	135 - 145	No	0
		Week 36	14SEP2016/12:00	136	135 - 145	No	0
		Week 40	12OCT2016/12:10	140	135 - 145	No	0
		Week 44	10NOV2016/11:00	137	135 - 145	No	0
		Week 48	07DEC2016/12:00	137	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	16DEC2015/08:45	3.85	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	16DEC2015/08:45	176 H	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	16DEC2015/08:45	0.9	0 - 2.2	Yes	0
		Day 1	07JAN2016/10:00	0.8	0 - 2.2	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Triglycerides (mmol/L)	Week 1	13JAN2016/09:30	1.2	0 - 2.2	No	0
		Week 2	21JAN2016/10:00	1.3	0 - 2.2	No	0
		Week 4	02FEB2016/09:00	1.8	0 - 2.2	No	1
		Week 6	17FEB2016/13:00	1.2	0 - 2.2	No	0
		Week 8	02MAR2016/09:15	1.4	0 - 2.2	No	0
		Week 12	31MAR2016/10:15	1.4	0 - 2.2	No	0
		Week 16	26APR2016/10:00	1.4	0 - 2.2	No	0
		Week 20	26MAY2016/12:30	1.9	0 - 2.2	No	1
		Week 24	23JUN2016/11:45	1.8	0 - 2.2	No	1
		Week 28	26JUL2016/09:15	2.1	0 - 2.2	No	1
		Week 32	16AUG2016/10:45	1.1	0 - 2.2	No	0
		Week 36	14SEP2016/12:00	1.3	0 - 2.2	No	0
		Week 40	12OCT2016/12:10	1.6	0 - 2.2	No	0
		Week 44	10NOV2016/11:00	0.9	0 - 2.2	No	0
		Week 48	07DEC2016/12:00	1.5	0 - 2.2	No	0
	Triiodothyronine (nmol/L)	Screening	16DEC2015/08:45	3.2 H	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	16DEC2015/08:45	5.8	1.7 - 8.3	Yes	
		Day 1	07JAN2016/10:00	4.8	1.7 - 8.3	Yes	
		Week 1	13JAN2016/09:30	4.1	1.7 - 8.3	No	
		Week 2	21JAN2016/10:00	4.3	1.7 - 8.3	No	
		Week 4	02FEB2016/09:00	4.7	1.7 - 8.3	No	
		Week 6	17FEB2016/13:00	4.6	1.7 - 8.3	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Urea (mmol/L)	Week 8	02MAR2016/09:15	4.6	1.7 - 8.3	No	
		Week 12	31MAR2016/10:15	4.5	1.7 - 8.3	No	
		Week 16	26APR2016/10:00	4.3	1.7 - 8.3	No	
		Week 20	26MAY2016/12:30	4.6	1.7 - 8.3	No	
		Week 24	23JUN2016/11:45	6.3	1.7 - 8.3	No	
		Week 28	26JUL2016/09:15	4.6	1.7 - 8.3	No	
		Week 32	16AUG2016/10:45	3.8	1.7 - 8.3	No	
		Week 36	14SEP2016/12:00	4.8	1.7 - 8.3	No	
		Week 40	12OCT2016/12:10	3.6	1.7 - 8.3	No	
		Week 44	10NOV2016/11:00	4.3	1.7 - 8.3	No	
		Week 48	07DEC2016/12:00	5.0	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	16DEC2015/08:45	295	266 - 474	Yes	0
		Day 1	07JAN2016/10:00	302	266 - 474	Yes	0
		Week 1	13JAN2016/09:30	261 L	266 - 474	No	0
		Week 2	21JAN2016/10:00	266	266 - 474	No	0
		Week 4	02FEB2016/09:00	274	266 - 474	No	0
		Week 6	17FEB2016/13:00	268	266 - 474	No	0
		Week 8	02MAR2016/09:15	272	266 - 474	No	0
		Week 12	31MAR2016/10:15	291	266 - 474	No	0
		Week 16	26APR2016/10:00	282	266 - 474	No	0
		Week 20	26MAY2016/12:30	309	266 - 474	No	0
		Week 24	23JUN2016/11:45	311	266 - 474	No	0
		Week 28	26JUL2016/09:15	330	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Uric acid (umol/L)	Week 32	16AUG2016/10:45	334	266 - 474	No	0
		Week 36	14SEP2016/12:00	336	266 - 474	No	0
		Week 40	12OCT2016/12:10	328	266 - 474	No	0
		Week 44	10NOV2016/11:00	314	266 - 474	No	0
		Week 48	07DEC2016/12:00	341	266 - 474	No	0
301-008	Alanine Aminotransferase (IU/L)	Screening	19JAN2016/12:00	84 H	10 - 50	Yes	1
		Day 1	11FEB2016/09:00	83 H	10 - 50	No	1
		Week 1	17FEB2016/11:00	86 H	10 - 50	No	1
		Week 2	24FEB2016/08:35	108 H	10 - 50	No	1
		Week 4	10MAR2016/08:00	131 H	10 - 50	No	1
		Week 6	24MAR2016/08:02	112 H	10 - 50	No	1
		Week 8	07APR2016/08:30	93 H	10 - 50	Yes	1
		Early Term	13APR2016/12:20	120 H	10 - 50	Yes	1
		Week 28	17MAY2016/08:30	47	10 - 50	No	0
		Week 32	09JUN2016/08:30	193 H	10 - 50	No	2
		Week 36	06JUL2016/08:25	148 H	10 - 50	No	1
		Week 40	03AUG2016/08:45	116 H	10 - 50	No	1
		Week 44	07SEP2016/07:55	120 H	10 - 50	No	1
		Week 48	19OCT2016/07:20	77 H	10 - 50	No	1
	Albumin (g/L)	Screening	19JAN2016/12:00	44	34 - 50	Yes	0
		Day 1	11FEB2016/09:00	45	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008 Albumin (g/L)	Week 1	17FEB2016/11:00	45	34 - 50	No	0
	Week 2	24FEB2016/08:35	42	34 - 50	No	0
	Week 4	10MAR2016/08:00	42	34 - 50	No	0
	Week 6	24MAR2016/08:02	42	34 - 50	No	0
	Week 8	07APR2016/08:30	41	34 - 50	Yes	0
	Early Term	13APR2016/12:20	37	34 - 50	Yes	0
	Week 28	17MAY2016/08:30	42	34 - 50	No	0
	Week 32	09JUN2016/08:30	42	34 - 50	No	0
	Week 36	06JUL2016/08:25	40	34 - 50	No	0
	Week 40	03AUG2016/08:45	43	34 - 50	No	0
	Week 44	07SEP2016/07:55	41	34 - 50	No	0
	Week 48	19OCT2016/07:20	42	34 - 50	No	0
Alkaline Phosphatase (IU/L)	Screening	19JAN2016/12:00	56	40 - 129	Yes	0
	Day 1	11FEB2016/09:00	54	40 - 129	No	0
	Week 1	17FEB2016/11:00	52	40 - 129	No	0
	Week 2	24FEB2016/08:35	54	40 - 129	No	0
	Week 4	10MAR2016/08:00	61	40 - 129	No	0
	Week 6	24MAR2016/08:02	59	40 - 129	No	0
	Week 8	07APR2016/08:30	59	40 - 129	Yes	0
	Early Term	13APR2016/12:20	57	40 - 129	Yes	0
	Week 28	17MAY2016/08:30	68	40 - 129	No	0
	Week 32	09JUN2016/08:30	63	40 - 129	No	0
	Week 36	06JUL2016/08:25	58	40 - 129	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Alkaline Phosphatase (IU/L)	Week 40	03AUG2016/08:45	65	40 - 129	No	0
		Week 44	07SEP2016/07:55	64	40 - 129	No	0
		Week 48	19OCT2016/07:20	55	40 - 129	No	0
	Amylase (IU/L)	Screening	19JAN2016/12:00	48	28 - 100	Yes	0
		Day 1	11FEB2016/09:00	52	28 - 100	No	0
		Week 1	17FEB2016/11:00	53	28 - 100	No	0
		Week 2	24FEB2016/08:35	52	28 - 100	No	0
		Week 4	10MAR2016/08:00	55	28 - 100	No	0
		Week 6	24MAR2016/08:02	57	28 - 100	No	0
		Week 8	07APR2016/08:30	44	28 - 100	Yes	0
		Early Term	13APR2016/12:20	66	28 - 100	Yes	0
		Week 28	17MAY2016/08:30	58	28 - 100	No	0
		Week 32	09JUN2016/08:30	51	28 - 100	No	0
		Week 36	06JUL2016/08:25	52	28 - 100	No	0
		Week 40	03AUG2016/08:45	55	28 - 100	No	0
		Week 44	07SEP2016/07:55	56	28 - 100	No	0
		Week 48	19OCT2016/07:20	63	28 - 100	No	0
	Aspartate Aminotransferase (IU/L)	Screening	19JAN2016/12:00	38 H	0 - 37	Yes	1
		Day 1	11FEB2016/09:00	35	0 - 37	No	0
		Week 1	17FEB2016/11:00	38 H	0 - 37	No	1
		Week 2	24FEB2016/08:35	43 H	0 - 37	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Aspartate Aminotransferase (IU/L)	Week 4	10MAR2016/08:00	53 H	0 - 37	No	1
		Week 6	24MAR2016/08:02	42 H	0 - 37	No	1
		Week 8	07APR2016/08:30	44 H	0 - 37	Yes	1
		Early Term	13APR2016/12:20	37	0 - 37	Yes	0
		Week 28	17MAY2016/08:30	28	0 - 37	No	0
		Week 32	09JUN2016/08:30	94 H	0 - 37	No	1
		Week 36	06JUL2016/08:25	64 H	0 - 37	No	1
		Week 40	03AUG2016/08:45	62 H	0 - 37	No	1
		Week 44	07SEP2016/07:55	60 H	0 - 37	No	1
		Week 48	19OCT2016/07:20	41 H	0 - 37	No	1
	Bicarbonate (mmol/L)	Screening	19JAN2016/12:00	25	22 - 29	Yes	
		Day 1	11FEB2016/09:00	26	22 - 29	No	
		Week 1	17FEB2016/11:00	25	22 - 29	No	
		Week 2	24FEB2016/08:35	22	22 - 29	No	
		Week 4	10MAR2016/08:00	24	22 - 29	No	
		Week 6	24MAR2016/08:02	24	22 - 29	No	
		Week 8	07APR2016/08:30	25	22 - 29	Yes	
		Early Term	13APR2016/12:20	26	22 - 29	Yes	
		Week 28	17MAY2016/08:30	24	22 - 29	No	
		Week 32	09JUN2016/08:30	26	22 - 29	No	
		Week 36	06JUL2016/08:25	23	22 - 29	No	
		Week 40	03AUG2016/08:45	26	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Bicarbonate (mmol/L)	Week 44	07SEP2016/07:55	23	22 - 29	No	
		Week 48	19OCT2016/07:20	24	22 - 29	No	
	Bilirubin (umol/L)	Screening	19JAN2016/12:00	12	0 - 20	Yes	0
		Day 1	11FEB2016/09:00	12	0 - 20	No	0
		Week 1	17FEB2016/11:00	12	0 - 20	No	0
		Week 2	24FEB2016/08:35	8	0 - 20	No	0
		Week 4	10MAR2016/08:00	6	0 - 20	No	0
		Week 6	24MAR2016/08:02	5	0 - 20	No	0
		Week 8	07APR2016/08:30	6	0 - 20	Yes	0
		Early Term	13APR2016/12:20	7	0 - 20	Yes	0
		Week 28	17MAY2016/08:30	11	0 - 20	No	0
		Week 32	09JUN2016/08:30	10	0 - 20	No	0
		Week 36	06JUL2016/08:25	8	0 - 20	No	0
		Week 40	03AUG2016/08:45	10	0 - 20	No	0
		Week 44	07SEP2016/07:55	8	0 - 20	No	0
		Week 48	19OCT2016/07:20	6	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	19JAN2016/12:00	14.84	4.76 - 23.24	Yes	
		Day 1	11FEB2016/09:00	14.00	4.76 - 23.24	No	
		Week 1	17FEB2016/11:00	15.40	4.76 - 23.24	No	
		Week 2	24FEB2016/08:35	15.68	4.76 - 23.24	No	
		Week 4	10MAR2016/08:00	15.96	4.76 - 23.24	No	
		Week 6	24MAR2016/08:02	14.28	4.76 - 23.24	No	

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Blood Urea Nitrogen (mg/dL)	Week 8	07APR2016/08:30	16.80	4.76 - 23.24	Yes	
		Early Term	13APR2016/12:20	16.52	4.76 - 23.24	Yes	
		Week 28	17MAY2016/08:30	15.40	4.76 - 23.24	No	
		Week 32	09JUN2016/08:30	13.16	4.76 - 23.24	No	
		Week 36	06JUL2016/08:25	15.40	4.76 - 23.24	No	
		Week 40	03AUG2016/08:45	11.76	4.76 - 23.24	No	
		Week 44	07SEP2016/07:55	16.24	4.76 - 23.24	No	
		Week 48	19OCT2016/07:20	13.16	4.76 - 23.24	No	
	Calcium (mmol/L)	Screening	19JAN2016/12:00	2.40	2.2 - 2.6	Yes	0
		Day 1	11FEB2016/09:00	2.39	2.2 - 2.6	No	0
		Week 1	17FEB2016/11:00	2.42	2.2 - 2.6	No	0
		Week 2	24FEB2016/08:35	2.28	2.2 - 2.6	No	0
		Week 4	10MAR2016/08:00	2.34	2.2 - 2.6	No	0
		Week 6	24MAR2016/08:02	2.31	2.2 - 2.6	No	0
		Week 8	07APR2016/08:30	2.16 L	2.2 - 2.6	Yes	1
		Early Term	13APR2016/12:20	2.30	2.2 - 2.6	Yes	0
		Week 28	17MAY2016/08:30	2.37	2.2 - 2.6	No	0
		Week 32	09JUN2016/08:30	2.35	2.2 - 2.6	No	0
		Week 36	06JUL2016/08:25	2.31	2.2 - 2.6	No	0
		Week 40	03AUG2016/08:45	2.41	2.2 - 2.6	No	0
		Week 44	07SEP2016/07:55	2.29	2.2 - 2.6	No	0
		Week 48	19OCT2016/07:20	2.40	2.2 - 2.6	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Chloride (mmol/L)	Screening	19JAN2016/12:00	99	98 - 107	Yes	
		Day 1	11FEB2016/09:00	102	98 - 107	No	
		Week 1	17FEB2016/11:00	101	98 - 107	No	
		Week 2	24FEB2016/08:35	102	98 - 107	No	
		Week 4	10MAR2016/08:00	105	98 - 107	No	
		Week 6	24MAR2016/08:02	107	98 - 107	No	
		Week 8	07APR2016/08:30	99	98 - 107	Yes	
		Early Term	13APR2016/12:20	106	98 - 107	Yes	
		Week 28	17MAY2016/08:30	101	98 - 107	No	
		Week 32	09JUN2016/08:30	101	98 - 107	No	
		Week 36	06JUL2016/08:25	102	98 - 107	No	
		Week 40	03AUG2016/08:45	101	98 - 107	No	
		Week 44	07SEP2016/07:55	100	98 - 107	No	
		Week 48	19OCT2016/07:20	102	98 - 107	No	
	Cholesterol (mmol/L)	Screening	19JAN2016/12:00	4.5	0 - 4.9	Yes	0
		Day 1	11FEB2016/09:00	4.3	0 - 4.9	No	0
		Week 1	17FEB2016/11:00	3.6	0 - 4.9	No	0
		Week 2	24FEB2016/08:35	2.8	0 - 4.9	No	0
		Week 4	10MAR2016/08:00	3.0	0 - 4.9	No	0
		Week 6	24MAR2016/08:02	2.5	0 - 4.9	No	0
		Week 8	07APR2016/08:30	2.6	0 - 4.9	Yes	0
		Early Term	13APR2016/12:20	2.5	0 - 4.9	Yes	0
		Week 28	17MAY2016/08:30	4.6	0 - 4.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Cholesterol (mmol/L)	Week 32	09JUN2016/08:30	3.9	0 - 4.9	No	0
		Week 36	06JUL2016/08:25	4.3	0 - 4.9	No	0
		Week 40	03AUG2016/08:45	4.4	0 - 4.9	No	0
		Week 44	07SEP2016/07:55	4.2	0 - 4.9	No	0
		Week 48	19OCT2016/07:20	3.7	0 - 4.9	No	0
	Creatine Kinase (IU/L)	Screening	19JAN2016/12:00	94	38 - 204	Yes	0
		Day 1	11FEB2016/09:00	85	38 - 204	No	0
		Week 1	17FEB2016/11:00	98	38 - 204	No	0
		Week 2	24FEB2016/08:35	119	38 - 204	No	0
		Week 4	10MAR2016/08:00	142	38 - 204	No	0
		Week 6	24MAR2016/08:02	119	38 - 204	No	0
		Week 8	07APR2016/08:30	122	38 - 204	Yes	0
		Early Term	13APR2016/12:20	103	38 - 204	Yes	0
		Week 28	17MAY2016/08:30	80	38 - 204	No	0
		Week 32	09JUN2016/08:30	118	38 - 204	No	0
		Week 36	06JUL2016/08:25	96	38 - 204	No	0
		Week 40	03AUG2016/08:45	108	38 - 204	No	0
		Week 44	07SEP2016/07:55	83	38 - 204	No	0
		Week 48	19OCT2016/07:20	70	38 - 204	No	0
	Creatinine (umol/L)	Screening	19JAN2016/12:00	89	66 - 112	Yes	0
		Day 1	11FEB2016/09:00	82	66 - 112	No	0
		Week 1	17FEB2016/11:00	97	66 - 112	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008 Creatinine (umol/L)	Week 2	24FEB2016/08:35	93	66 - 112	No	1
	Week 4	10MAR2016/08:00	97	66 - 112	No	1
	Week 6	24MAR2016/08:02	94	66 - 112	No	1
	Week 8	07APR2016/08:30	116 H	66 - 112	Yes	1
	Early Term	13APR2016/12:20	89	66 - 112	Yes	1
	Week 28	17MAY2016/08:30	87	66 - 112	No	1
	Week 32	09JUN2016/08:30	93	66 - 112	No	1
	Week 36	06JUL2016/08:25	85	66 - 112	No	1
	Week 40	03AUG2016/08:45	89	66 - 112	No	1
	Week 44	07SEP2016/07:55	92	66 - 112	No	1
	Week 48	19OCT2016/07:20	90	66 - 112	No	1
Direct Bilirubin (umol/L)	Screening	19JAN2016/12:00	5	0 - 5	Yes	
	Day 1	11FEB2016/09:00	4	0 - 5	No	
	Week 1	17FEB2016/11:00	4	0 - 5	No	
	Week 2	24FEB2016/08:35	3	0 - 5	No	
	Week 4	10MAR2016/08:00	3	0 - 5	No	
	Week 6	24MAR2016/08:02	2	0 - 5	No	
	Week 8	07APR2016/08:30	3	0 - 5	Yes	
	Early Term	13APR2016/12:20	3	0 - 5	Yes	
	Week 28	17MAY2016/08:30	4	0 - 5	No	
	Week 32	09JUN2016/08:30	3	0 - 5	No	
	Week 36	06JUL2016/08:25	4	0 - 5	No	
	Week 40	03AUG2016/08:45	4	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Direct Bilirubin (umol/L)	Week 44	07SEP2016/07:55	2	0 - 5	No	
		Week 48	19OCT2016/07:20	3	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	19JAN2016/12:00	23	10 - 71	Yes	0
		Day 1	11FEB2016/09:00	25	10 - 71	No	0
		Week 1	17FEB2016/11:00	22	10 - 71	No	0
		Week 2	24FEB2016/08:35	23	10 - 71	No	0
		Week 4	10MAR2016/08:00	26	10 - 71	No	0
		Week 6	24MAR2016/08:02	24	10 - 71	No	0
		Week 8	07APR2016/08:30	27	10 - 71	Yes	0
		Early Term	13APR2016/12:20	26	10 - 71	Yes	0
		Week 28	17MAY2016/08:30	24	10 - 71	No	0
		Week 32	09JUN2016/08:30	33	10 - 71	No	0
		Week 36	06JUL2016/08:25	39	10 - 71	No	0
		Week 40	03AUG2016/08:45	31	10 - 71	No	0
		Week 44	07SEP2016/07:55	36	10 - 71	No	0
		Week 48	19OCT2016/07:20	28	10 - 71	No	0
	Globulin (g/L)	Screening	19JAN2016/12:00	29	19 - 35	Yes	
		Day 1	11FEB2016/09:00	25	19 - 35	No	
		Week 1	17FEB2016/11:00	26	19 - 35	No	
		Week 2	24FEB2016/08:35	29	19 - 35	No	
		Week 4	10MAR2016/08:00	30	19 - 35	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008 Globulin (g/L)	Week 6	24MAR2016/08:02	25	19 - 35	No	
	Week 8	07APR2016/08:30	28	19 - 35	Yes	
	Early Term	13APR2016/12:20	25	19 - 35	Yes	
	Week 28	17MAY2016/08:30	28	19 - 35	No	
	Week 32	09JUN2016/08:30	26	19 - 35	No	
	Week 36	06JUL2016/08:25	30	19 - 35	No	
	Week 40	03AUG2016/08:45	30	19 - 35	No	
	Week 44	07SEP2016/07:55	30	19 - 35	No	
	Week 48	19OCT2016/07:20	27	19 - 35	No	
	Glucose (mmol/L)	Screening	5.4	3.9 - 5.8	Yes	0
		Day 1	5.2	3.5 - 7.9	No	0
		Week 1	5.4	3.5 - 7.9	No	0
		Week 2	5.4	3.5 - 7.9	No	0
		Week 4	5.3	3.5 - 7.9	No	0
		Week 6	5.4	3.5 - 7.9	No	0
		Week 8	5.5	3.9 - 5.8	Yes	0
		Early Term	7.1 H	3.9 - 5.8	Yes	1
		Week 28	5.6	3.5 - 7.9	No	0
		Week 32	4.9	3.5 - 7.9	No	0
		Week 36	5.1	3.5 - 7.9	No	0
		Week 40	5.2	3.5 - 7.9	No	0
		Week 44	4.7	3.5 - 7.9	No	0
		Week 48	4.9	3.5 - 7.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Indirect Bilirubin (umol/L)	Screening	19JAN2016/12:00	7	0 - 14	Yes
		Day 1	11FEB2016/09:00	8	0 - 14	No
		Week 1	17FEB2016/11:00	8	0 - 14	No
		Week 2	24FEB2016/08:35	5	0 - 14	No
		Week 4	10MAR2016/08:00	3	0 - 14	No
		Week 6	24MAR2016/08:02	3	0 - 14	No
		Week 8	07APR2016/08:30	3	0 - 14	Yes
		Early Term	13APR2016/12:20	4	0 - 14	Yes
		Week 28	17MAY2016/08:30	7	0 - 14	No
		Week 32	09JUN2016/08:30	7	0 - 14	No
		Week 36	06JUL2016/08:25	4	0 - 14	No
		Week 40	03AUG2016/08:45	6	0 - 14	No
		Week 44	07SEP2016/07:55	6	0 - 14	No
		Week 48	19OCT2016/07:20	3	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	19JAN2016/12:00	139	135 - 225	Yes
		Day 1	11FEB2016/09:00	126 L	135 - 225	No
		Week 1	17FEB2016/11:00	130 L	135 - 225	No
		Week 2	24FEB2016/08:35	130 L	135 - 225	No
		Week 4	10MAR2016/08:00	136	135 - 225	No
		Week 6	24MAR2016/08:02	145	135 - 225	No
		Week 8	07APR2016/08:30	177	135 - 225	Yes
		Early Term	13APR2016/12:20	149	135 - 225	Yes
		Week 28	17MAY2016/08:30	127 L	135 - 225	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Lactate Dehydrogenase (IU/L)	Week 32	09JUN2016/08:30	172	135 - 225	No	
		Week 36	06JUL2016/08:25	132 L	135 - 225	No	
		Week 40	03AUG2016/08:45	140	135 - 225	No	
		Week 44	07SEP2016/07:55	178	135 - 225	No	
		Week 48	19OCT2016/07:20	133 L	135 - 225	No	
	Magnesium (mmol/L)	Screening	19JAN2016/12:00	0.79	0.6 - 1	Yes	0
		Day 1	11FEB2016/09:00	0.76	0.6 - 1	No	0
		Week 1	17FEB2016/11:00	0.75	0.6 - 1	No	0
		Week 2	24FEB2016/08:35	0.78	0.6 - 1	No	0
		Week 4	10MAR2016/08:00	0.85	0.6 - 1	No	0
		Week 6	24MAR2016/08:02	0.84	0.6 - 1	No	0
		Week 8	07APR2016/08:30	0.78	0.6 - 1	Yes	0
		Early Term	13APR2016/12:20	0.81	0.6 - 1	Yes	0
		Week 28	17MAY2016/08:30	0.78	0.6 - 1	No	0
		Week 32	09JUN2016/08:30	0.80	0.6 - 1	No	0
		Week 36	06JUL2016/08:25	0.76	0.6 - 1	No	0
		Week 40	03AUG2016/08:45	0.80	0.6 - 1	No	0
		Week 44	07SEP2016/07:55	0.81	0.6 - 1	No	0
		Week 48	19OCT2016/07:20	0.84	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	19JAN2016/12:00	0.84 L	0.87 - 1.45	Yes	1
		Day 1	11FEB2016/09:00	0.80 L	0.87 - 1.45	No	1
		Week 1	17FEB2016/11:00	0.92	0.87 - 1.45	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Phosphate (mmol/L)	Week 2	24FEB2016/08:35	0.98	0.87 - 1.45	No	0
		Week 4	10MAR2016/08:00	0.86 L	0.87 - 1.45	No	1
		Week 6	24MAR2016/08:02	0.68 L	0.87 - 1.45	No	2
		Week 8	07APR2016/08:30	0.90	0.87 - 1.45	Yes	0
		Early Term	13APR2016/12:20	0.97	0.87 - 1.45	Yes	0
		Week 28	17MAY2016/08:30	0.91	0.87 - 1.45	No	0
		Week 32	09JUN2016/08:30	0.96	0.87 - 1.45	No	0
		Week 36	06JUL2016/08:25	0.83 L	0.87 - 1.45	No	1
		Week 40	03AUG2016/08:45	0.77 L	0.87 - 1.45	No	2
		Week 44	07SEP2016/07:55	0.96	0.87 - 1.45	No	0
		Week 48	19OCT2016/07:20	0.94	0.87 - 1.45	No	0
	Potassium (mmol/L)	Screening	19JAN2016/12:00	4.3	3.5 - 5.1	Yes	0
		Day 1	11FEB2016/09:00	4.8	3.5 - 5.1	No	0
		Week 1	17FEB2016/11:00	4.5	3.5 - 5.1	No	0
		Week 2	24FEB2016/08:35	4.5	3.5 - 5.1	No	0
		Week 4	10MAR2016/08:00	4.5	3.5 - 5.1	No	0
		Week 6	24MAR2016/08:02	4.8	3.5 - 5.1	No	0
		Week 8	07APR2016/08:30	3.9	3.5 - 5.1	Yes	0
		Early Term	13APR2016/12:20	3.6	3.5 - 5.1	Yes	0
		Week 28	17MAY2016/08:30	4.6	3.5 - 5.1	No	0
		Week 32	09JUN2016/08:30	4.5	3.5 - 5.1	No	0
		Week 36	06JUL2016/08:25	4.4	3.5 - 5.1	No	0
		Week 40	03AUG2016/08:45	4.7	3.5 - 5.1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Potassium (mmol/L)	Week 44	07SEP2016/07:55	4.9	3.5 - 5.1	No	0
		Week 48	19OCT2016/07:20	4.8	3.5 - 5.1	No	0
	Protein (g/L)	Screening	19JAN2016/12:00	73	63 - 83	Yes	
		Day 1	11FEB2016/09:00	70	63 - 83	No	
		Week 1	17FEB2016/11:00	71	63 - 83	No	
		Week 2	24FEB2016/08:35	71	63 - 83	No	
		Week 4	10MAR2016/08:00	72	63 - 83	No	
		Week 6	24MAR2016/08:02	67	63 - 83	No	
		Week 8	07APR2016/08:30	69	63 - 83	Yes	
		Early Term	13APR2016/12:20	62 L	63 - 83	Yes	
		Week 28	17MAY2016/08:30	70	63 - 83	No	
		Week 32	09JUN2016/08:30	68	63 - 83	No	
		Week 36	06JUL2016/08:25	70	63 - 83	No	
		Week 40	03AUG2016/08:45	73	63 - 83	No	
		Week 44	07SEP2016/07:55	71	63 - 83	No	
		Week 48	19OCT2016/07:20	69	63 - 83	No	
	Sodium (mmol/L)	Screening	19JAN2016/12:00	141	135 - 145	Yes	0
		Day 1	11FEB2016/09:00	143	135 - 145	No	0
		Week 1	17FEB2016/11:00	141	135 - 145	No	0
		Week 2	24FEB2016/08:35	140	135 - 145	No	0
		Week 4	10MAR2016/08:00	143	135 - 145	No	0
		Week 6	24MAR2016/08:02	143	135 - 145	No	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Sodium (mmol/L)	Week 8	07APR2016/08:30	142	135 - 145	Yes	0
		Early Term	13APR2016/12:20	145	135 - 145	Yes	0
		Week 28	17MAY2016/08:30	141	135 - 145	No	0
		Week 32	09JUN2016/08:30	143	135 - 145	No	0
		Week 36	06JUL2016/08:25	140	135 - 145	No	0
		Week 40	03AUG2016/08:45	141	135 - 145	No	0
		Week 44	07SEP2016/07:55	138	135 - 145	No	0
		Week 48	19OCT2016/07:20	143	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	19JAN2016/12:00	1.51	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	19JAN2016/12:00	111	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	19JAN2016/12:00	1.1	0 - 2.2	Yes	0
		Day 1	11FEB2016/09:00	1.1	0 - 2.2	No	0
		Week 1	17FEB2016/11:00	1.1	0 - 2.2	No	0
		Week 2	24FEB2016/08:35	0.9	0 - 2.2	No	0
		Week 4	10MAR2016/08:00	1.3	0 - 2.2	No	0
		Week 6	24MAR2016/08:02	1.1	0 - 2.2	No	0
		Week 8	07APR2016/08:30	1.1	0 - 2.2	Yes	0
		Early Term	13APR2016/12:20	1.2	0 - 2.2	Yes	0
		Week 28	17MAY2016/08:30	1.6	0 - 2.2	No	0
		Week 32	09JUN2016/08:30	1.2	0 - 2.2	No	0
		Week 36	06JUL2016/08:25	1.3	0 - 2.2	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Triglycerides (mmol/L)	Week 40	03AUG2016/08:45	1.2	0 - 2.2	No	0
		Week 44	07SEP2016/07:55	0.9	0 - 2.2	No	0
		Week 48	19OCT2016/07:20	1.0	0 - 2.2	No	0
	Triiodothyronine (nmol/L)	Screening	19JAN2016/12:00	2.3	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	19JAN2016/12:00	5.3	1.7 - 8.3	Yes	
		Day 1	11FEB2016/09:00	5.0	1.7 - 8.3	No	
		Week 1	17FEB2016/11:00	5.5	1.7 - 8.3	No	
		Week 2	24FEB2016/08:35	5.6	1.7 - 8.3	No	
		Week 4	10MAR2016/08:00	5.7	1.7 - 8.3	No	
		Week 6	24MAR2016/08:02	5.1	1.7 - 8.3	No	
		Week 8	07APR2016/08:30	6.0	1.7 - 8.3	Yes	
		Early Term	13APR2016/12:20	5.9	1.7 - 8.3	Yes	
		Week 28	17MAY2016/08:30	5.5	1.7 - 8.3	No	
		Week 32	09JUN2016/08:30	4.7	1.7 - 8.3	No	
		Week 36	06JUL2016/08:25	5.5	1.7 - 8.3	No	
		Week 40	03AUG2016/08:45	4.2	1.7 - 8.3	No	
		Week 44	07SEP2016/07:55	5.8	1.7 - 8.3	No	
		Week 48	19OCT2016/07:20	4.7	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	19JAN2016/12:00	301	266 - 474	Yes	0
		Day 1	11FEB2016/09:00	298	266 - 474	No	0
		Week 1	17FEB2016/11:00	292	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Uric acid (umol/L)	Week 2	24FEB2016/08:35	292	266 - 474	No	0
		Week 4	10MAR2016/08:00	324	266 - 474	No	0
		Week 6	24MAR2016/08:02	339	266 - 474	No	0
		Week 8	07APR2016/08:30	443	266 - 474	Yes	0
		Early Term	13APR2016/12:20	368	266 - 474	Yes	0
		Week 28	17MAY2016/08:30	334	266 - 474	No	0
		Week 32	09JUN2016/08:30	339	266 - 474	No	0
		Week 36	06JUL2016/08:25	321	266 - 474	No	0
		Week 40	03AUG2016/08:45	329	266 - 474	No	0
		Week 44	07SEP2016/07:55	336	266 - 474	No	0
		Week 48	19OCT2016/07:20	339	266 - 474	No	0
301-009	Alanine Aminotransferase (IU/L)	Screening	06JAN2016/11:00	161 H	10 - 50	Yes	2
		Day 1	27JAN2016/11:00	211 H	10 - 50	No	2
		Week 1	02FEB2016/12:00	125 H	10 - 50	No	1
		Week 2	10FEB2016/12:45	147 H	10 - 50	No	1
		Week 4	25FEB2016/11:30	107 H	10 - 50	No	1
		Week 6	09MAR2016/12:00	120 H	10 - 50	Yes	1
		Week 8	22MAR2016/08:20	80 H	10 - 50	No	1
		Week 12	19APR2016/11:20	69 H	10 - 50	No	1
		Week 16	18MAY2016/12:20	63 H	10 - 50	No	1
		Week 20	15JUN2016/12:15	66 H	10 - 50	No	1
		Week 24	20JUL2016/13:50	75 H	10 - 50	Yes	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Alanine Aminotransferase (IU/L)	Week 28	09AUG2016/12:10	140 H	10 - 50	No	1
		Week 32	06SEP2016/13:10	590 H	10 - 50	No	3
		Week 36	04OCT2016/12:30	423 H	10 - 50	No	3
		Week 40	01NOV2016/12:30	75 H	10 - 50	No	1
		Week 44	29NOV2016/13:15	64 H	10 - 50	No	1
		Week 48	02JAN2017/12:00	65 H	10 - 50	No	1
	Albumin (g/L)	Screening	06JAN2016/11:00	45	34 - 50	Yes	0
		Day 1	27JAN2016/11:00	46	34 - 50	No	0
		Week 1	02FEB2016/12:00	47	34 - 50	No	0
		Week 2	10FEB2016/12:45	43	34 - 50	No	0
		Week 4	25FEB2016/11:30	42	34 - 50	No	0
		Week 6	09MAR2016/12:00	44	34 - 50	Yes	0
		Week 8	22MAR2016/08:20	42	34 - 50	No	0
		Week 12	19APR2016/11:20	46	34 - 50	No	0
		Week 16	18MAY2016/12:20	44	34 - 50	No	0
		Week 20	15JUN2016/12:15	45	34 - 50	No	0
		Week 24	20JUL2016/13:50	47	34 - 50	Yes	0
		Week 28	09AUG2016/12:10	46	34 - 50	No	0
		Week 32	06SEP2016/13:10	43	34 - 50	No	0
		Week 36	04OCT2016/12:30	41	34 - 50	No	0
		Week 40	01NOV2016/12:30	45	34 - 50	No	0
		Week 44	29NOV2016/13:15	46	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Albumin (g/L)	Week 48	02JAN2017/12:00	45	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	06JAN2016/11:00	64	40 - 129	Yes	0
		Day 1	27JAN2016/11:00	60	40 - 129	No	0
		Week 1	02FEB2016/12:00	64	40 - 129	No	0
		Week 2	10FEB2016/12:45	64	40 - 129	No	0
		Week 4	25FEB2016/11:30	77	40 - 129	No	0
		Week 6	09MAR2016/12:00	85	40 - 129	Yes	0
		Week 8	22MAR2016/08:20	86	40 - 129	No	0
		Week 12	19APR2016/11:20	105	40 - 129	No	0
		Week 16	18MAY2016/12:20	99	40 - 129	No	0
		Week 20	15JUN2016/12:15	94	40 - 129	No	0
		Week 24	20JUL2016/13:50	98	40 - 129	Yes	0
		Week 28	09AUG2016/12:10	91	40 - 129	No	0
		Week 32	06SEP2016/13:10	77	40 - 129	No	0
		Week 36	04OCT2016/12:30	87	40 - 129	No	0
		Week 40	01NOV2016/12:30	69	40 - 129	No	0
		Week 44	29NOV2016/13:15	66	40 - 129	No	0
		Week 48	02JAN2017/12:00	58	40 - 129	No	0
	Amylase (IU/L)	Screening	06JAN2016/11:00	46	28 - 100	Yes	0
		Day 1	27JAN2016/11:00	53	28 - 100	No	0
		Week 1	02FEB2016/12:00	43	28 - 100	No	0
		Week 2	10FEB2016/12:45	44	28 - 100	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Amylase (IU/L)	Week 4	25FEB2016/11:30	58	28 - 100	No	0
		Week 6	09MAR2016/12:00	73	28 - 100	Yes	0
		Week 8	22MAR2016/08:20	59	28 - 100	No	0
		Week 12	19APR2016/11:20	55	28 - 100	No	0
		Week 16	18MAY2016/12:20	53	28 - 100	No	0
		Week 20	15JUN2016/12:15	57	28 - 100	No	0
		Week 24	20JUL2016/13:50	50	28 - 100	Yes	0
		Week 28	09AUG2016/12:10	49	28 - 100	No	0
		Week 32	06SEP2016/13:10	53	28 - 100	No	0
		Week 36	04OCT2016/12:30	67	28 - 100	No	0
		Week 40	01NOV2016/12:30	57	28 - 100	No	0
		Week 44	29NOV2016/13:15	55	28 - 100	No	0
		Week 48	02JAN2017/12:00	49	28 - 100	No	0
	Aspartate Aminotransferase (IU/L)	Screening	06JAN2016/11:00	89 H	0 - 37	Yes	1
		Day 1	27JAN2016/11:00	105 H	0 - 37	No	1
		Week 1	02FEB2016/12:00	60 H	0 - 37	No	1
		Week 2	10FEB2016/12:45	67 H	0 - 37	No	1
		Week 4	25FEB2016/11:30	53 H	0 - 37	No	1
		Week 6	09MAR2016/12:00	53 H	0 - 37	Yes	1
		Week 8	22MAR2016/08:20	42 H	0 - 37	No	1
		Week 12	19APR2016/11:20	45 H	0 - 37	No	1
		Week 16	18MAY2016/12:20	42 H	0 - 37	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Aspartate Aminotransferase (IU/L)	Week 20	15JUN2016/12:15	45 H	0 - 37	No	1
		Week 24	20JUL2016/13:50	51 H	0 - 37	Yes	1
		Week 28	09AUG2016/12:10	92 H	0 - 37	No	1
		Week 32	06SEP2016/13:10	322 H	0 - 37	No	3
		Week 36	04OCT2016/12:30	214 H	0 - 37	No	3
		Week 40	01NOV2016/12:30	53 H	0 - 37	No	1
		Week 44	29NOV2016/13:15	51 H	0 - 37	No	1
		Week 48	02JAN2017/12:00	45 H	0 - 37	No	1
	Bicarbonate (mmol/L)	Screening	06JAN2016/11:00	23	22 - 29	Yes	
		Day 1	27JAN2016/11:00	22	22 - 29	No	
		Week 1	02FEB2016/12:00	18 L	22 - 29	No	
		Week 2	10FEB2016/12:45	24	22 - 29	No	
		Week 4	25FEB2016/11:30	26	22 - 29	No	
		Week 6	09MAR2016/12:00	19 L	22 - 29	Yes	
		Week 8	22MAR2016/08:20	22	22 - 29	No	
		Week 12	19APR2016/11:20	20 L	22 - 29	No	
		Week 16	18MAY2016/12:20	21 L	22 - 29	No	
		Week 20	15JUN2016/12:15	21 L	22 - 29	No	
		Week 24	20JUL2016/13:50	18 L	22 - 29	Yes	
		Week 28	09AUG2016/12:10	25	22 - 29	No	
		Week 32	06SEP2016/13:10	24	22 - 29	No	
		Week 36	04OCT2016/12:30	21 L	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Bicarbonate (mmol/L)	Week 40	01NOV2016/12:30	23	22 - 29	No	
		Week 44	29NOV2016/13:15	21 L	22 - 29	No	
		Week 48	02JAN2017/12:00	24	22 - 29	No	
	Bilirubin (umol/L)	Screening	06JAN2016/11:00	15	0 - 20	Yes	0
		Day 1	27JAN2016/11:00	15	0 - 20	No	0
		Week 1	02FEB2016/12:00	11	0 - 20	No	0
		Week 2	10FEB2016/12:45	9	0 - 20	No	0
		Week 4	25FEB2016/11:30	10	0 - 20	No	0
		Week 6	09MAR2016/12:00	8	0 - 20	Yes	0
		Week 8	22MAR2016/08:20	7	0 - 20	No	0
		Week 12	19APR2016/11:20	12	0 - 20	No	0
		Week 16	18MAY2016/12:20	8	0 - 20	No	0
		Week 20	15JUN2016/12:15	8	0 - 20	No	0
		Week 24	20JUL2016/13:50	12	0 - 20	Yes	0
		Week 28	09AUG2016/12:10	12	0 - 20	No	0
		Week 32	06SEP2016/13:10	13	0 - 20	No	0
		Week 36	04OCT2016/12:30	13	0 - 20	No	0
		Week 40	01NOV2016/12:30	14	0 - 20	No	0
		Week 44	29NOV2016/13:15	14	0 - 20	No	0
		Week 48	02JAN2017/12:00	10	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	06JAN2016/11:00	14.28	4.76 - 23.24	Yes	
		Day 1	27JAN2016/11:00	13.44	4.76 - 23.24	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Blood Urea Nitrogen (mg/dL)	Week 1	02FEB2016/12:00	17.36	4.76 - 23.24	No	
		Week 2	10FEB2016/12:45	12.88	4.76 - 23.24	No	
		Week 4	25FEB2016/11:30	10.92	4.76 - 23.24	No	
		Week 6	09MAR2016/12:00	17.64	4.76 - 23.24	Yes	
		Week 8	22MAR2016/08:20	15.96	4.76 - 23.24	No	
		Week 12	19APR2016/11:20	15.68	4.76 - 23.24	No	
		Week 16	18MAY2016/12:20	11.20	4.76 - 23.24	No	
		Week 20	15JUN2016/12:15	13.44	4.76 - 23.24	No	
		Week 24	20JUL2016/13:50	22.68	4.76 - 23.24	Yes	
		Week 28	09AUG2016/12:10	13.72	4.76 - 23.24	No	
		Week 32	06SEP2016/13:10	14.00	4.76 - 23.24	No	
		Week 36	04OCT2016/12:30	12.32	4.76 - 23.24	No	
		Week 40	01NOV2016/12:30	13.72	4.76 - 23.24	No	
		Week 44	29NOV2016/13:15	7.56	4.76 - 23.24	No	
		Week 48	02JAN2017/12:00	11.76	4.76 - 23.24	No	
	Calcium (mmol/L)	Screening	06JAN2016/11:00	2.31	2.2 - 2.6	Yes	0
		Day 1	27JAN2016/11:00	2.35	2.2 - 2.6	No	0
		Week 1	02FEB2016/12:00	2.31	2.2 - 2.6	No	0
		Week 2	10FEB2016/12:45	2.28	2.2 - 2.6	No	0
		Week 4	25FEB2016/11:30	2.34	2.2 - 2.6	No	0
		Week 6	09MAR2016/12:00	2.28	2.2 - 2.6	Yes	0
		Week 8	22MAR2016/08:20	2.32	2.2 - 2.6	No	0
		Week 12	19APR2016/11:20	2.32	2.2 - 2.6	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Calcium (mmol/L)	Week 16	18MAY2016/12:20	2.24	2.2 - 2.6	No	0
		Week 20	15JUN2016/12:15	2.30	2.2 - 2.6	No	0
		Week 24	20JUL2016/13:50	2.26	2.2 - 2.6	Yes	0
		Week 28	09AUG2016/12:10	2.32	2.2 - 2.6	No	0
		Week 32	06SEP2016/13:10	2.30	2.2 - 2.6	No	0
		Week 36	04OCT2016/12:30	2.32	2.2 - 2.6	No	0
		Week 40	01NOV2016/12:30	2.30	2.2 - 2.6	No	0
		Week 44	29NOV2016/13:15	2.27	2.2 - 2.6	No	0
		Week 48	02JAN2017/12:00	2.33	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	06JAN2016/11:00	101	98 - 107	Yes	
		Day 1	27JAN2016/11:00	103	98 - 107	No	
		Week 1	02FEB2016/12:00	101	98 - 107	No	
		Week 2	10FEB2016/12:45	102	98 - 107	No	
		Week 4	25FEB2016/11:30	101	98 - 107	No	
		Week 6	09MAR2016/12:00	102	98 - 107	Yes	
		Week 8	22MAR2016/08:20	100	98 - 107	No	
		Week 12	19APR2016/11:20	100	98 - 107	No	
		Week 16	18MAY2016/12:20	103	98 - 107	No	
		Week 20	15JUN2016/12:15	101	98 - 107	No	
		Week 24	20JUL2016/13:50	102	98 - 107	Yes	
		Week 28	09AUG2016/12:10	100	98 - 107	No	
		Week 32	06SEP2016/13:10	102	98 - 107	No	
		Week 36	04OCT2016/12:30	101	98 - 107	No	

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Chloride (mmol/L)	Week 40	01NOV2016/12:30	101	98 - 107	No	
		Week 44	29NOV2016/13:15	100	98 - 107	No	
		Week 48	02JAN2017/12:00	101	98 - 107	No	
	Cholesterol (mmol/L)	Screening	06JAN2016/11:00	4.1	0 - 4.9	Yes	0
		Day 1	27JAN2016/11:00	4.1	0 - 4.9	No	0
		Week 1	02FEB2016/12:00	3.1	0 - 4.9	No	0
		Week 2	10FEB2016/12:45	3.2	0 - 4.9	No	0
		Week 4	25FEB2016/11:30	2.9	0 - 4.9	No	0
		Week 6	09MAR2016/12:00	2.8	0 - 4.9	Yes	0
		Week 8	22MAR2016/08:20	2.4	0 - 4.9	No	0
		Week 12	19APR2016/11:20	2.8	0 - 4.9	No	0
		Week 16	18MAY2016/12:20	2.8	0 - 4.9	No	0
		Week 20	15JUN2016/12:15	2.6	0 - 4.9	No	0
		Week 24	20JUL2016/13:50	3.2	0 - 4.9	Yes	0
		Week 28	09AUG2016/12:10	4.6	0 - 4.9	No	0
		Week 32	06SEP2016/13:10	3.2	0 - 4.9	No	0
		Week 36	04OCT2016/12:30	3.9	0 - 4.9	No	0
		Week 40	01NOV2016/12:30	4.4	0 - 4.9	No	0
		Week 44	29NOV2016/13:15	4.0	0 - 4.9	No	0
		Week 48	02JAN2017/12:00	4.2	0 - 4.9	No	0
	Creatine Kinase (IU/L)	Screening	06JAN2016/11:00	176	38 - 204	Yes	0
		Day 1	27JAN2016/11:00	182	38 - 204	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Creatine Kinase (IU/L)	Week 1	02FEB2016/12:00	208 H	38 - 204	No	1
		Week 2	10FEB2016/12:45	143	38 - 204	No	0
		Week 4	25FEB2016/11:30	117	38 - 204	No	0
		Week 6	09MAR2016/12:00	96	38 - 204	Yes	0
		Week 8	22MAR2016/08:20	184	38 - 204	No	0
		Week 12	19APR2016/11:20	120	38 - 204	No	0
		Week 16	18MAY2016/12:20	112	38 - 204	No	0
		Week 20	15JUN2016/12:15	224 H	38 - 204	No	1
		Week 24	20JUL2016/13:50	407 H	38 - 204	Yes	1
		Week 28	09AUG2016/12:10	152	38 - 204	No	0
		Week 32	06SEP2016/13:10	168	38 - 204	No	0
		Week 36	04OCT2016/12:30	149	38 - 204	No	0
		Week 40	01NOV2016/12:30	197	38 - 204	No	0
		Week 44	29NOV2016/13:15	173	38 - 204	No	0
		Week 48	02JAN2017/12:00	161	38 - 204	No	0
	Creatinine (umol/L)	Screening	06JAN2016/11:00	75	66 - 112	Yes	0
		Day 1	27JAN2016/11:00	66	66 - 112	No	0
		Week 1	02FEB2016/12:00	67	66 - 112	No	1
		Week 2	10FEB2016/12:45	71	66 - 112	No	1
		Week 4	25FEB2016/11:30	61 L	66 - 112	No	0
		Week 6	09MAR2016/12:00	80	66 - 112	Yes	1
		Week 8	22MAR2016/08:20	78	66 - 112	No	1
		Week 12	19APR2016/11:20	80	66 - 112	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Creatinine (umol/L)	Week 16	18MAY2016/12:20	64 L	66 - 112	No	0
		Week 20	15JUN2016/12:15	66	66 - 112	No	0
		Week 24	20JUL2016/13:50	81	66 - 112	Yes	1
		Week 28	09AUG2016/12:10	72	66 - 112	No	1
		Week 32	06SEP2016/13:10	65 L	66 - 112	No	0
		Week 36	04OCT2016/12:30	68	66 - 112	No	1
		Week 40	01NOV2016/12:30	69	66 - 112	No	1
		Week 44	29NOV2016/13:15	82	66 - 112	No	1
		Week 48	02JAN2017/12:00	62 L	66 - 112	No	0
	Direct Bilirubin (umol/L)	Screening	06JAN2016/11:00	6 H	0 - 5	Yes	
		Day 1	27JAN2016/11:00	6 H	0 - 5	No	
		Week 1	02FEB2016/12:00	4	0 - 5	No	
		Week 2	10FEB2016/12:45	4	0 - 5	No	
		Week 4	25FEB2016/11:30	4	0 - 5	No	
		Week 6	09MAR2016/12:00	4	0 - 5	Yes	
		Week 8	22MAR2016/08:20	4	0 - 5	No	
		Week 12	19APR2016/11:20	5	0 - 5	No	
		Week 16	18MAY2016/12:20	4	0 - 5	No	
		Week 20	15JUN2016/12:15	3	0 - 5	No	
		Week 24	20JUL2016/13:50	5	0 - 5	Yes	
		Week 28	09AUG2016/12:10	5	0 - 5	No	
		Week 32	06SEP2016/13:10	6 H	0 - 5	No	
		Week 36	04OCT2016/12:30	7 H	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Direct Bilirubin (umol/L)	Week 40	01NOV2016/12:30	6 H	0 - 5	No	
		Week 44	29NOV2016/13:15	5	0 - 5	No	
		Week 48	02JAN2017/12:00	5	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	06JAN2016/11:00	36	10 - 71	Yes	0
		Day 1	27JAN2016/11:00	40	10 - 71	No	0
		Week 1	02FEB2016/12:00	37	10 - 71	No	0
		Week 2	10FEB2016/12:45	33	10 - 71	No	0
		Week 4	25FEB2016/11:30	32	10 - 71	No	0
		Week 6	09MAR2016/12:00	32	10 - 71	Yes	0
		Week 8	22MAR2016/08:20	29	10 - 71	No	0
		Week 12	19APR2016/11:20	26	10 - 71	No	0
		Week 16	18MAY2016/12:20	25	10 - 71	No	0
		Week 20	15JUN2016/12:15	22	10 - 71	No	0
		Week 24	20JUL2016/13:50	21	10 - 71	Yes	0
		Week 28	09AUG2016/12:10	25	10 - 71	No	0
		Week 32	06SEP2016/13:10	31	10 - 71	No	0
		Week 36	04OCT2016/12:30	94 H	10 - 71	No	1
		Week 40	01NOV2016/12:30	46	10 - 71	No	0
		Week 44	29NOV2016/13:15	30	10 - 71	No	0
		Week 48	02JAN2017/12:00	26	10 - 71	No	0
	Globulin (g/L)	Screening	06JAN2016/11:00	32	19 - 35	Yes	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Globulin (g/L)	Day 1	27JAN2016/11:00	31	19 - 35	No	
		Week 1	02FEB2016/12:00	35	19 - 35	No	
		Week 2	10FEB2016/12:45	31	19 - 35	No	
		Week 4	25FEB2016/11:30	30	19 - 35	No	
		Week 6	09MAR2016/12:00	32	19 - 35	Yes	
		Week 8	22MAR2016/08:20	31	19 - 35	No	
		Week 12	19APR2016/11:20	28	19 - 35	No	
		Week 16	18MAY2016/12:20	29	19 - 35	No	
		Week 20	15JUN2016/12:15	27	19 - 35	No	
		Week 24	20JUL2016/13:50	26	19 - 35	Yes	
		Week 28	09AUG2016/12:10	26	19 - 35	No	
		Week 32	06SEP2016/13:10	27	19 - 35	No	
		Week 36	04OCT2016/12:30	43 H	19 - 35	No	
		Week 40	01NOV2016/12:30	33	19 - 35	No	
		Week 44	29NOV2016/13:15	31	19 - 35	No	
		Week 48	02JAN2017/12:00	27	19 - 35	No	
	Glucose (mmol/L)	Screening	06JAN2016/11:00	5.1	3.9 - 5.8	Yes	0
		Day 1	27JAN2016/11:00	4.8	3.5 - 7.9	No	0
		Week 1	02FEB2016/12:00	5.2	3.5 - 7.9	No	0
		Week 2	10FEB2016/12:45	4.8	3.5 - 7.9	No	0
		Week 4	25FEB2016/11:30	4.7	3.5 - 7.9	No	0
		Week 6	09MAR2016/12:00	6.2 H	3.9 - 5.8	Yes	1
		Week 8	22MAR2016/08:20	4.6	3.5 - 7.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Glucose (mmol/L)	Week 12	19APR2016/11:20	6.0	3.5 - 7.9	No	0
		Week 16	18MAY2016/12:20	5.1	3.5 - 7.9	No	0
		Week 20	15JUN2016/12:15	4.8	3.5 - 7.9	No	0
		Week 24	20JUL2016/13:50	4.7	3.9 - 5.8	Yes	0
		Week 28	09AUG2016/12:10	4.6	3.5 - 7.9	No	0
		Week 32	06SEP2016/13:10	5.8	3.5 - 7.9	No	0
		Week 36	04OCT2016/12:30	4.5	3.5 - 7.9	No	0
		Week 40	01NOV2016/12:30	4.5	3.5 - 7.9	No	0
		Week 44	29NOV2016/13:15	4.7	3.5 - 7.9	No	0
		Week 48	02JAN2017/12:00	5.9	3.5 - 7.9	No	0
	Indirect Bilirubin (umol/L)	Screening	06JAN2016/11:00	9	0 - 14	Yes	
		Day 1	27JAN2016/11:00	9	0 - 14	No	
		Week 1	02FEB2016/12:00	7	0 - 14	No	
		Week 2	10FEB2016/12:45	5	0 - 14	No	
		Week 4	25FEB2016/11:30	6	0 - 14	No	
		Week 6	09MAR2016/12:00	4	0 - 14	Yes	
		Week 8	22MAR2016/08:20	3	0 - 14	No	
		Week 12	19APR2016/11:20	7	0 - 14	No	
		Week 16	18MAY2016/12:20	4	0 - 14	No	
		Week 20	15JUN2016/12:15	5	0 - 14	No	
		Week 24	20JUL2016/13:50	7	0 - 14	Yes	
		Week 28	09AUG2016/12:10	7	0 - 14	No	
		Week 32	06SEP2016/13:10	7	0 - 14	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Indirect Bilirubin (umol/L)	Week 36	04OCT2016/12:30	6	0 - 14	No	
		Week 40	01NOV2016/12:30	8	0 - 14	No	
		Week 44	29NOV2016/13:15	9	0 - 14	No	
		Week 48	02JAN2017/12:00	5	0 - 14	No	
	Lactate Dehydrogenase (IU/L)	Screening	06JAN2016/11:00	214	135 - 225	Yes	
		Day 1	27JAN2016/11:00	219	135 - 225	No	
		Week 1	02FEB2016/12:00	203	135 - 225	No	
		Week 2	10FEB2016/12:45	178	135 - 225	No	
		Week 4	25FEB2016/11:30	179	135 - 225	No	
		Week 6	09MAR2016/12:00	171	135 - 225	Yes	
		Week 8	22MAR2016/08:20	184	135 - 225	No	
		Week 12	19APR2016/11:20	184	135 - 225	No	
		Week 16	18MAY2016/12:20	166	135 - 225	No	
		Week 20	15JUN2016/12:15	195	135 - 225	No	
		Week 24	20JUL2016/13:50	235 H	135 - 225	Yes	
		Week 28	09AUG2016/12:10	229 H	135 - 225	No	
		Week 32	06SEP2016/13:10	311 H	135 - 225	No	
		Week 36	04OCT2016/12:30	224	135 - 225	No	
		Week 40	01NOV2016/12:30	194	135 - 225	No	
		Week 44	29NOV2016/13:15	211	135 - 225	No	
		Week 48	02JAN2017/12:00	187	135 - 225	No	
	Magnesium (mmol/L)	Screening	06JAN2016/11:00	0.82	0.6 - 1	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Magnesium (mmol/L)	Day 1	27JAN2016/11:00	0.86	0.6 - 1	No	0
		Week 1	02FEB2016/12:00	0.89	0.6 - 1	No	0
		Week 2	10FEB2016/12:45	0.82	0.6 - 1	No	0
		Week 4	25FEB2016/11:30	0.74	0.6 - 1	No	0
		Week 6	09MAR2016/12:00	0.82	0.6 - 1	Yes	0
		Week 8	22MAR2016/08:20	0.82	0.6 - 1	No	0
		Week 12	19APR2016/11:20	0.72	0.6 - 1	No	0
		Week 16	18MAY2016/12:20	0.85	0.6 - 1	No	0
		Week 20	15JUN2016/12:15	0.88	0.6 - 1	No	0
		Week 24	20JUL2016/13:50	0.80	0.6 - 1	Yes	0
		Week 28	09AUG2016/12:10	0.81	0.6 - 1	No	0
		Week 32	06SEP2016/13:10	0.76	0.6 - 1	No	0
		Week 36	04OCT2016/12:30	0.82	0.6 - 1	No	0
		Week 40	01NOV2016/12:30	0.81	0.6 - 1	No	0
		Week 44	29NOV2016/13:15	0.80	0.6 - 1	No	0
		Week 48	02JAN2017/12:00	0.77	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	06JAN2016/11:00	0.93	0.87 - 1.45	Yes	0
		Day 1	27JAN2016/11:00	1.16	0.87 - 1.45	No	0
		Week 1	02FEB2016/12:00	1.09	0.87 - 1.45	No	0
		Week 2	10FEB2016/12:45	1.19	0.87 - 1.45	No	0
		Week 4	25FEB2016/11:30	1.14	0.87 - 1.45	No	0
		Week 6	09MAR2016/12:00	0.90	0.87 - 1.45	Yes	0
		Week 8	22MAR2016/08:20	1.42	0.87 - 1.45	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Phosphate (mmol/L)	Week 12	19APR2016/11:20	0.96	0.87 - 1.45	No	0
		Week 16	18MAY2016/12:20	1.10	0.87 - 1.45	No	0
		Week 20	15JUN2016/12:15	0.80 L	0.87 - 1.45	No	1
		Week 24	20JUL2016/13:50	1.04	0.87 - 1.45	Yes	0
		Week 28	09AUG2016/12:10	1.25	0.87 - 1.45	No	0
		Week 32	06SEP2016/13:10	0.95	0.87 - 1.45	No	0
		Week 36	04OCT2016/12:30	1.16	0.87 - 1.45	No	0
		Week 40	01NOV2016/12:30	1.18	0.87 - 1.45	No	0
		Week 44	29NOV2016/13:15	1.04	0.87 - 1.45	No	0
		Week 48	02JAN2017/12:00	0.63 L	0.87 - 1.45	No	2
	Potassium (mmol/L)	Screening	06JAN2016/11:00	4.4	3.5 - 5.1	Yes	0
		Day 1	27JAN2016/11:00	4.4	3.5 - 5.1	No	0
		Week 1	02FEB2016/12:00	4.9	3.5 - 5.1	No	0
		Week 2	10FEB2016/12:45	4.4	3.5 - 5.1	No	0
		Week 4	25FEB2016/11:30	4.1	3.5 - 5.1	No	0
		Week 6	09MAR2016/12:00	4.2	3.5 - 5.1	Yes	0
		Week 8	22MAR2016/08:20	4.3	3.5 - 5.1	No	0
		Week 12	19APR2016/11:20	3.9	3.5 - 5.1	No	0
		Week 16	18MAY2016/12:20	4.4	3.5 - 5.1	No	0
		Week 20	15JUN2016/12:15	4.0	3.5 - 5.1	No	0
		Week 24	20JUL2016/13:50	4.0	3.5 - 5.1	Yes	0
		Week 28	09AUG2016/12:10	4.2	3.5 - 5.1	No	0
		Week 32	06SEP2016/13:10	3.9	3.5 - 5.1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Potassium (mmol/L)	Week 36	04OCT2016/12:30	4.6	3.5 - 5.1	No	0
		Week 40	01NOV2016/12:30	4.6	3.5 - 5.1	No	0
		Week 44	29NOV2016/13:15	4.7	3.5 - 5.1	No	0
		Week 48	02JAN2017/12:00	4.2	3.5 - 5.1	No	0
	Protein (g/L)	Screening	06JAN2016/11:00	77	63 - 83	Yes	
		Day 1	27JAN2016/11:00	77	63 - 83	No	
		Week 1	02FEB2016/12:00	82	63 - 83	No	
		Week 2	10FEB2016/12:45	74	63 - 83	No	
		Week 4	25FEB2016/11:30	72	63 - 83	No	
		Week 6	09MAR2016/12:00	76	63 - 83	Yes	
		Week 8	22MAR2016/08:20	73	63 - 83	No	
		Week 12	19APR2016/11:20	74	63 - 83	No	
		Week 16	18MAY2016/12:20	73	63 - 83	No	
		Week 20	15JUN2016/12:15	72	63 - 83	No	
		Week 24	20JUL2016/13:50	73	63 - 83	Yes	
		Week 28	09AUG2016/12:10	72	63 - 83	No	
		Week 32	06SEP2016/13:10	70	63 - 83	No	
		Week 36	04OCT2016/12:30	84 H	63 - 83	No	
		Week 40	01NOV2016/12:30	78	63 - 83	No	
		Week 44	29NOV2016/13:15	77	63 - 83	No	
		Week 48	02JAN2017/12:00	72	63 - 83	No	
	Sodium (mmol/L)	Screening	06JAN2016/11:00	140	135 - 145	Yes	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Sodium (mmol/L)	Day 1	27JAN2016/11:00	140	135 - 145	No	0
		Week 1	02FEB2016/12:00	136	135 - 145	No	0
		Week 2	10FEB2016/12:45	141	135 - 145	No	0
		Week 4	25FEB2016/11:30	139	135 - 145	No	0
		Week 6	09MAR2016/12:00	140	135 - 145	Yes	0
		Week 8	22MAR2016/08:20	140	135 - 145	No	0
		Week 12	19APR2016/11:20	139	135 - 145	No	0
		Week 16	18MAY2016/12:20	142	135 - 145	No	0
		Week 20	15JUN2016/12:15	140	135 - 145	No	0
		Week 24	20JUL2016/13:50	143	135 - 145	Yes	0
		Week 28	09AUG2016/12:10	141	135 - 145	No	0
		Week 32	06SEP2016/13:10	142	135 - 145	No	0
		Week 36	04OCT2016/12:30	141	135 - 145	No	0
		Week 40	01NOV2016/12:30	141	135 - 145	No	0
		Week 44	29NOV2016/13:15	143	135 - 145	No	0
		Week 48	02JAN2017/12:00	142	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	06JAN2016/11:00	1.08	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	06JAN2016/11:00	73	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	06JAN2016/11:00	1.0	0 - 2.2	Yes	0
		Day 1	27JAN2016/11:00	1.0	0 - 2.2	No	0
		Week 1	02FEB2016/12:00	1.0	0 - 2.2	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Triglycerides (mmol/L)	Week 2	10FEB2016/12:45	1.7	0 - 2.2	No	0
		Week 4	25FEB2016/11:30	1.4	0 - 2.2	No	0
		Week 6	09MAR2016/12:00	1.5	0 - 2.2	Yes	0
		Week 8	22MAR2016/08:20	0.9	0 - 2.2	No	0
		Week 12	19APR2016/11:20	1.0	0 - 2.2	No	0
		Week 16	18MAY2016/12:20	1.2	0 - 2.2	No	0
		Week 20	15JUN2016/12:15	1.2	0 - 2.2	No	0
		Week 24	20JUL2016/13:50	0.9	0 - 2.2	Yes	0
		Week 28	09AUG2016/12:10	1.0	0 - 2.2	No	0
		Week 32	06SEP2016/13:10	1.0	0 - 2.2	No	0
		Week 36	04OCT2016/12:30	1.6	0 - 2.2	No	0
		Week 40	01NOV2016/12:30	1.2	0 - 2.2	No	0
		Week 44	29NOV2016/13:15	1.4	0 - 2.2	No	0
		Week 48	02JAN2017/12:00	1.7	0 - 2.2	No	0
	Triiodothyronine (nmol/L)	Screening	06JAN2016/11:00	2.0	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	06JAN2016/11:00	5.1	1.7 - 8.3	Yes	
		Day 1	27JAN2016/11:00	4.8	1.7 - 8.3	No	
		Week 1	02FEB2016/12:00	6.2	1.7 - 8.3	No	
		Week 2	10FEB2016/12:45	4.6	1.7 - 8.3	No	
		Week 4	25FEB2016/11:30	3.9	1.7 - 8.3	No	
		Week 6	09MAR2016/12:00	6.3	1.7 - 8.3	Yes	
		Week 8	22MAR2016/08:20	5.7	1.7 - 8.3	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Urea (mmol/L)	Week 12	19APR2016/11:20	5.6	1.7 - 8.3	No	
		Week 16	18MAY2016/12:20	4.0	1.7 - 8.3	No	
		Week 20	15JUN2016/12:15	4.8	1.7 - 8.3	No	
		Week 24	20JUL2016/13:50	8.1	1.7 - 8.3	Yes	
		Week 28	09AUG2016/12:10	4.9	1.7 - 8.3	No	
		Week 32	06SEP2016/13:10	5.0	1.7 - 8.3	No	
		Week 36	04OCT2016/12:30	4.4	1.7 - 8.3	No	
		Week 40	01NOV2016/12:30	4.9	1.7 - 8.3	No	
		Week 44	29NOV2016/13:15	2.7	1.7 - 8.3	No	
		Week 48	02JAN2017/12:00	4.2	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	06JAN2016/11:00	392	266 - 474	Yes	0
		Day 1	27JAN2016/11:00	359	266 - 474	No	0
		Week 1	02FEB2016/12:00	415	266 - 474	No	0
		Week 2	10FEB2016/12:45	345	266 - 474	No	0
		Week 4	25FEB2016/11:30	306	266 - 474	No	0
		Week 6	09MAR2016/12:00	321	266 - 474	Yes	0
		Week 8	22MAR2016/08:20	354	266 - 474	No	0
		Week 12	19APR2016/11:20	400	266 - 474	No	0
		Week 16	18MAY2016/12:20	305	266 - 474	No	0
		Week 20	15JUN2016/12:15	336	266 - 474	No	0
		Week 24	20JUL2016/13:50	333	266 - 474	Yes	0
		Week 28	09AUG2016/12:10	339	266 - 474	No	0
		Week 32	06SEP2016/13:10	362	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Uric acid (umol/L)	Week 36	04OCT2016/12:30	363	266 - 474	No	0
		Week 40	01NOV2016/12:30	380	266 - 474	No	0
		Week 44	29NOV2016/13:15	350	266 - 474	No	0
		Week 48	02JAN2017/12:00	315	266 - 474	No	0
301-010	Alanine Aminotransferase (IU/L)	Screening	07JAN2016/09:30	24	10 - 50	Yes	0
		Day 1	27JAN2016/10:00	82 H	10 - 50	Yes	1
		Week 1	04FEB2016/10:30	71 H	10 - 50	No	1
		Week 2	09FEB2016/12:00	81 H	10 - 50	No	1
		Week 4	24FEB2016/14:00	76 H	10 - 50	No	1
		Week 6	09MAR2016/11:30	47	10 - 50	No	0
		Week 8	22MAR2016/08:30	71 H	10 - 50	No	1
		Week 12	19APR2016/11:32	44	10 - 50	No	0
		Week 16	17MAY2016/12:55	35	10 - 50	No	0
		Week 20	20JUN2016/12:12	35	10 - 50	No	0
		Week 24	12JUL2016/11:40	36	10 - 50	Yes	0
		Week 28	08AUG2016/12:30	57 H	10 - 50	No	1
		Week 32	06SEP2016/11:10	672 H	10 - 50	No	3
		Week 36	04OCT2016/12:40	137 H	10 - 50	No	1
		Week 40	01NOV2016/12:50	73 H	10 - 50	No	1
		Week 44	28NOV2016/11:45	91 H	10 - 50	No	1
		Week 48	03JAN2017/13:00	160 H	10 - 50	No	2

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Albumin (g/L)	Screening	07JAN2016/09:30	47	34 - 50	Yes	0
		Day 1	27JAN2016/10:00	46	34 - 50	Yes	0
		Week 1	04FEB2016/10:30	48	34 - 50	No	0
		Week 2	09FEB2016/12:00	46	34 - 50	No	0
		Week 4	24FEB2016/14:00	46	34 - 50	No	0
		Week 6	09MAR2016/11:30	45	34 - 50	No	0
		Week 8	22MAR2016/08:30	45	34 - 50	No	0
		Week 12	19APR2016/11:32	47	34 - 50	No	0
		Week 16	17MAY2016/12:55	46	34 - 50	No	0
		Week 20	20JUN2016/12:12	46	34 - 50	No	0
		Week 24	12JUL2016/11:40	47	34 - 50	Yes	0
		Week 28	08AUG2016/12:30	46	34 - 50	No	0
		Week 32	06SEP2016/11:10	47	34 - 50	No	0
		Week 36	04OCT2016/12:40	45	34 - 50	No	0
		Week 40	01NOV2016/12:50	44	34 - 50	No	0
		Week 44	28NOV2016/11:45	46	34 - 50	No	0
		Week 48	03JAN2017/13:00	47	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	07JAN2016/09:30	65	40 - 129	Yes	0
		Day 1	27JAN2016/10:00	67	40 - 129	Yes	0
		Week 1	04FEB2016/10:30	67	40 - 129	No	0
		Week 2	09FEB2016/12:00	66	40 - 129	No	0
		Week 4	24FEB2016/14:00	78	40 - 129	No	0
		Week 6	09MAR2016/11:30	75	40 - 129	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Alkaline Phosphatase (IU/L)	Week 8	22MAR2016/08:30	86	40 - 129	No	0
		Week 12	19APR2016/11:32	95	40 - 129	No	0
		Week 16	17MAY2016/12:55	103	40 - 129	No	0
		Week 20	20JUN2016/12:12	103	40 - 129	No	0
		Week 24	12JUL2016/11:40	111	40 - 129	Yes	0
		Week 28	08AUG2016/12:30	108	40 - 129	No	0
		Week 32	06SEP2016/11:10	122	40 - 129	No	0
		Week 36	04OCT2016/12:40	86	40 - 129	No	0
		Week 40	01NOV2016/12:50	76	40 - 129	No	0
		Week 44	28NOV2016/11:45	76	40 - 129	No	0
		Week 48	03JAN2017/13:00	77	40 - 129	No	0
	Amylase (IU/L)	Screening	07JAN2016/09:30	73	28 - 100	Yes	0
		Day 1	27JAN2016/10:00	82	28 - 100	Yes	0
		Week 1	04FEB2016/10:30	57	28 - 100	No	0
		Week 2	09FEB2016/12:00	68	28 - 100	No	0
		Week 4	24FEB2016/14:00	75	28 - 100	No	0
		Week 6	09MAR2016/11:30	67	28 - 100	No	0
		Week 8	22MAR2016/08:30	64	28 - 100	No	0
		Week 12	19APR2016/11:32	67	28 - 100	No	0
		Week 16	17MAY2016/12:55	59	28 - 100	No	0
		Week 20	20JUN2016/12:12	48	28 - 100	No	0
		Week 24	12JUL2016/11:40	61	28 - 100	Yes	0
		Week 28	08AUG2016/12:30	79	28 - 100	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Amylase (IU/L)	Week 32	06SEP2016/11:10	66	28 - 100	No	0
		Week 36	04OCT2016/12:40	69	28 - 100	No	0
		Week 40	01NOV2016/12:50	67	28 - 100	No	0
		Week 44	28NOV2016/11:45	68	28 - 100	No	0
		Week 48	03JAN2017/13:00	71	28 - 100	No	0
	Aspartate Aminotransferase (IU/L)	Screening	07JAN2016/09:30	23	0 - 37	Yes	0
		Day 1	27JAN2016/10:00	39 H	0 - 37	Yes	1
		Week 1	04FEB2016/10:30	33	0 - 37	No	0
		Week 2	09FEB2016/12:00	36	0 - 37	No	0
		Week 4	24FEB2016/14:00	28	0 - 37	No	0
		Week 6	09MAR2016/11:30	28	0 - 37	No	0
		Week 8	22MAR2016/08:30	31	0 - 37	No	0
		Week 12	19APR2016/11:32	20	0 - 37	No	0
		Week 16	17MAY2016/12:55	21	0 - 37	No	0
		Week 20	20JUN2016/12:12	23	0 - 37	No	0
		Week 24	12JUL2016/11:40	20	0 - 37	Yes	0
		Week 28	08AUG2016/12:30	30	0 - 37	No	0
		Week 32	06SEP2016/11:10	269 H	0 - 37	No	3
		Week 36	04OCT2016/12:40	56 H	0 - 37	No	1
		Week 40	01NOV2016/12:50	38 H	0 - 37	No	1
		Week 44	28NOV2016/11:45	45 H	0 - 37	No	1
		Week 48	03JAN2017/13:00	63 H	0 - 37	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Bicarbonate (mmol/L)	Screening	07JAN2016/09:30	22	22 - 29	Yes	
		Day 1	27JAN2016/10:00	22	22 - 29	Yes	
		Week 1	04FEB2016/10:30	27	22 - 29	No	
		Week 2	09FEB2016/12:00	26	22 - 29	No	
		Week 4	24FEB2016/14:00	24	22 - 29	No	
		Week 6	09MAR2016/11:30	24	22 - 29	No	
		Week 8	22MAR2016/08:30	22	22 - 29	No	
		Week 12	19APR2016/11:32	25	22 - 29	No	
		Week 16	17MAY2016/12:55	23	22 - 29	No	
		Week 20	20JUN2016/12:12	25	22 - 29	No	
		Week 24	12JUL2016/11:40	22	22 - 29	Yes	
		Week 28	08AUG2016/12:30	25	22 - 29	No	
		Week 32	06SEP2016/11:10	22	22 - 29	No	
		Week 36	04OCT2016/12:40	24	22 - 29	No	
		Week 40	01NOV2016/12:50	23	22 - 29	No	
		Week 44	28NOV2016/11:45	25	22 - 29	No	
		Week 48	03JAN2017/13:00	24	22 - 29	No	
	Bilirubin (umol/L)	Screening	07JAN2016/09:30	7	0 - 20	Yes	0
		Day 1	27JAN2016/10:00	13	0 - 20	Yes	0
		Week 1	04FEB2016/10:30	12	0 - 20	No	0
		Week 2	09FEB2016/12:00	9	0 - 20	No	0
		Week 4	24FEB2016/14:00	6	0 - 20	No	0
		Week 6	09MAR2016/11:30	5	0 - 20	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Bilirubin (umol/L)	Week 8	22MAR2016/08:30	9	0 - 20	No	0
		Week 12	19APR2016/11:32	6	0 - 20	No	0
		Week 16	17MAY2016/12:55	5	0 - 20	No	0
		Week 20	20JUN2016/12:12	7	0 - 20	No	0
		Week 24	12JUL2016/11:40	6	0 - 20	Yes	0
		Week 28	08AUG2016/12:30	5	0 - 20	No	0
		Week 32	06SEP2016/11:10	8	0 - 20	No	0
		Week 36	04OCT2016/12:40	9	0 - 20	No	0
		Week 40	01NOV2016/12:50	11	0 - 20	No	0
		Week 44	28NOV2016/11:45	10	0 - 20	No	0
		Week 48	03JAN2017/13:00	11	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	07JAN2016/09:30	16.24	4.76 - 23.24	Yes	
		Day 1	27JAN2016/10:00	14.84	4.76 - 23.24	Yes	
		Week 1	04FEB2016/10:30	12.04	4.76 - 23.24	No	
		Week 2	09FEB2016/12:00	13.44	4.76 - 23.24	No	
		Week 4	24FEB2016/14:00	11.76	4.76 - 23.24	No	
		Week 6	09MAR2016/11:30	8.12	4.76 - 23.24	No	
		Week 8	22MAR2016/08:30	14.28	4.76 - 23.24	No	
		Week 12	19APR2016/11:32	8.68	4.76 - 23.24	No	
		Week 16	17MAY2016/12:55	10.36	4.76 - 23.24	No	
		Week 20	20JUN2016/12:12	12.04	4.76 - 23.24	No	
		Week 24	12JUL2016/11:40	8.40	4.76 - 23.24	Yes	
		Week 28	08AUG2016/12:30	12.60	4.76 - 23.24	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Blood Urea Nitrogen (mg/dL)	Week 32	06SEP2016/11:10	10.36	4.76 - 23.24	No	
		Week 36	04OCT2016/12:40	10.92	4.76 - 23.24	No	
		Week 40	01NOV2016/12:50	11.48	4.76 - 23.24	No	
		Week 44	28NOV2016/11:45	11.48	4.76 - 23.24	No	
		Week 48	03JAN2017/13:00	11.76	4.76 - 23.24	No	
	Calcium (mmol/L)	Screening	07JAN2016/09:30	2.35	2.2 - 2.6	Yes	0
		Day 1	27JAN2016/10:00	2.40	2.2 - 2.6	Yes	0
		Week 1	04FEB2016/10:30	2.41	2.2 - 2.6	No	0
		Week 2	09FEB2016/12:00	2.44	2.2 - 2.6	No	0
		Week 4	24FEB2016/14:00	2.35	2.2 - 2.6	No	0
		Week 6	09MAR2016/11:30	2.36	2.2 - 2.6	No	0
		Week 8	22MAR2016/08:30	2.40	2.2 - 2.6	No	0
		Week 12	19APR2016/11:32	2.44	2.2 - 2.6	No	0
		Week 16	17MAY2016/12:55	2.38	2.2 - 2.6	No	0
		Week 20	20JUN2016/12:12	2.42	2.2 - 2.6	No	0
		Week 24	12JUL2016/11:40	2.35	2.2 - 2.6	Yes	0
		Week 28	08AUG2016/12:30	2.37	2.2 - 2.6	No	0
		Week 32	06SEP2016/11:10	2.42	2.2 - 2.6	No	0
		Week 36	04OCT2016/12:40	2.37	2.2 - 2.6	No	0
		Week 40	01NOV2016/12:50	2.41	2.2 - 2.6	No	0
		Week 44	28NOV2016/11:45	2.38	2.2 - 2.6	No	0
		Week 48	03JAN2017/13:00	2.43	2.2 - 2.6	No	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Chloride (mmol/L)	Screening	07JAN2016/09:30	99	98 - 107	Yes	
		Day 1	27JAN2016/10:00	99	98 - 107	Yes	
		Week 1	04FEB2016/10:30	100	98 - 107	No	
		Week 2	09FEB2016/12:00	98	98 - 107	No	
		Week 4	24FEB2016/14:00	99	98 - 107	No	
		Week 6	09MAR2016/11:30	100	98 - 107	No	
		Week 8	22MAR2016/08:30	101	98 - 107	No	
		Week 12	19APR2016/11:32	103	98 - 107	No	
		Week 16	17MAY2016/12:55	102	98 - 107	No	
		Week 20	20JUN2016/12:12	101	98 - 107	No	
		Week 24	12JUL2016/11:40	101	98 - 107	Yes	
		Week 28	08AUG2016/12:30	99	98 - 107	No	
		Week 32	06SEP2016/11:10	99	98 - 107	No	
		Week 36	04OCT2016/12:40	100	98 - 107	No	
		Week 40	01NOV2016/12:50	97 L	98 - 107	No	
		Week 44	28NOV2016/11:45	102	98 - 107	No	
		Week 48	03JAN2017/13:00	98	98 - 107	No	
	Cholesterol (mmol/L)	Screening	07JAN2016/09:30	4.9	0 - 4.9	Yes	0
		Day 1	27JAN2016/10:00	5.0 H	0 - 4.9	Yes	1
		Week 1	04FEB2016/10:30	3.6	0 - 4.9	No	0
		Week 2	09FEB2016/12:00	3.0	0 - 4.9	No	0
		Week 4	24FEB2016/14:00	3.2	0 - 4.9	No	0
		Week 6	09MAR2016/11:30	2.9	0 - 4.9	No	0

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010 Cholesterol (mmol/L)	Week 8	22MAR2016/08:30	3.1	0 - 4.9	No	0
	Week 12	19APR2016/11:32	3.3	0 - 4.9	No	0
	Week 16	17MAY2016/12:55	2.9	0 - 4.9	No	0
	Week 20	20JUN2016/12:12	3.1	0 - 4.9	No	0
	Week 24	12JUL2016/11:40	3.0	0 - 4.9	Yes	0
	Week 28	08AUG2016/12:30	4.8	0 - 4.9	No	0
	Week 32	06SEP2016/11:10	3.9	0 - 4.9	No	0
	Week 36	04OCT2016/12:40	4.5	0 - 4.9	No	0
	Week 40	01NOV2016/12:50	4.5	0 - 4.9	No	0
	Week 44	28NOV2016/11:45	4.7	0 - 4.9	No	0
	Week 48	03JAN2017/13:00	5.1 H	0 - 4.9	No	1
Creatine Kinase (IU/L)	Screening	07JAN2016/09:30	117	38 - 204	Yes	0
	Day 1	27JAN2016/10:00	118	38 - 204	Yes	0
	Week 1	04FEB2016/10:30	105	38 - 204	No	0
	Week 2	09FEB2016/12:00	96	38 - 204	No	0
	Week 4	24FEB2016/14:00	100	38 - 204	No	0
	Week 6	09MAR2016/11:30	90	38 - 204	No	0
	Week 8	22MAR2016/08:30	91	38 - 204	No	0
	Week 12	19APR2016/11:32	61	38 - 204	No	0
	Week 16	17MAY2016/12:55	85	38 - 204	No	0
	Week 20	20JUN2016/12:12	84	38 - 204	No	0
	Week 24	12JUL2016/11:40	95	38 - 204	Yes	0
	Week 28	08AUG2016/12:30	77	38 - 204	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Creatine Kinase (IU/L)	Week 32	06SEP2016/11:10	109	38 - 204	No	0
		Week 36	04OCT2016/12:40	81	38 - 204	No	0
		Week 40	01NOV2016/12:50	130	38 - 204	No	0
		Week 44	28NOV2016/11:45	118	38 - 204	No	0
		Week 48	03JAN2017/13:00	119	38 - 204	No	0
	Creatinine (umol/L)	Screening	07JAN2016/09:30	105	66 - 112	Yes	0
		Day 1	27JAN2016/10:00	80	66 - 112	Yes	0
		Week 1	04FEB2016/10:30	82	66 - 112	No	1
		Week 2	09FEB2016/12:00	101	66 - 112	No	1
		Week 4	24FEB2016/14:00	73	66 - 112	No	0
		Week 6	09MAR2016/11:30	79	66 - 112	No	0
		Week 8	22MAR2016/08:30	86	66 - 112	No	1
		Week 12	19APR2016/11:32	76	66 - 112	No	0
		Week 16	17MAY2016/12:55	76	66 - 112	No	0
		Week 20	20JUN2016/12:12	69	66 - 112	No	0
		Week 24	12JUL2016/11:40	80	66 - 112	Yes	0
		Week 28	08AUG2016/12:30	82	66 - 112	No	1
		Week 32	06SEP2016/11:10	84	66 - 112	No	1
		Week 36	04OCT2016/12:40	77	66 - 112	No	0
		Week 40	01NOV2016/12:50	76	66 - 112	No	0
		Week 44	28NOV2016/11:45	74	66 - 112	No	0
		Week 48	03JAN2017/13:00	90	66 - 112	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Direct Bilirubin (umol/L)	Screening	07JAN2016/09:30	3	0 - 5	Yes	
		Day 1	27JAN2016/10:00	5	0 - 5	Yes	
		Week 1	04FEB2016/10:30	5	0 - 5	No	
		Week 2	09FEB2016/12:00	4	0 - 5	No	
		Week 4	24FEB2016/14:00	3	0 - 5	No	
		Week 6	09MAR2016/11:30	2	0 - 5	No	
		Week 8	22MAR2016/08:30	4	0 - 5	No	
		Week 12	19APR2016/11:32	3	0 - 5	No	
		Week 16	17MAY2016/12:55	2	0 - 5	No	
		Week 20	20JUN2016/12:12	4	0 - 5	No	
		Week 24	12JUL2016/11:40	3	0 - 5	Yes	
		Week 28	08AUG2016/12:30	2	0 - 5	No	
		Week 32	06SEP2016/11:10	4	0 - 5	No	
		Week 36	04OCT2016/12:40	4	0 - 5	No	
		Week 40	01NOV2016/12:50	5	0 - 5	No	
		Week 44	28NOV2016/11:45	4	0 - 5	No	
		Week 48	03JAN2017/13:00	4	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	07JAN2016/09:30	57	10 - 71	Yes	0
		Day 1	27JAN2016/10:00	54	10 - 71	Yes	0
		Week 1	04FEB2016/10:30	57	10 - 71	No	0
		Week 2	09FEB2016/12:00	49	10 - 71	No	0
		Week 4	24FEB2016/14:00	58	10 - 71	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Gamma Glutamyl Transferase (IU/L)	Week 6	09MAR2016/11:30	55	10 - 71	No	0
		Week 8	22MAR2016/08:30	56	10 - 71	No	0
		Week 12	19APR2016/11:32	53	10 - 71	No	0
		Week 16	17MAY2016/12:55	44	10 - 71	No	0
		Week 20	20JUN2016/12:12	34	10 - 71	No	0
		Week 24	12JUL2016/11:40	40	10 - 71	Yes	0
		Week 28	08AUG2016/12:30	53	10 - 71	No	0
		Week 32	06SEP2016/11:10	179 H	10 - 71	No	2
		Week 36	04OCT2016/12:40	165 H	10 - 71	No	1
		Week 40	01NOV2016/12:50	100 H	10 - 71	No	1
		Week 44	28NOV2016/11:45	74 H	10 - 71	No	1
		Week 48	03JAN2017/13:00	85 H	10 - 71	No	1
	Globulin (g/L)	Screening	07JAN2016/09:30	30	19 - 35	Yes	
		Day 1	27JAN2016/10:00	32	19 - 35	Yes	
		Week 1	04FEB2016/10:30	33	19 - 35	No	
		Week 2	09FEB2016/12:00	32	19 - 35	No	
		Week 4	24FEB2016/14:00	32	19 - 35	No	
		Week 6	09MAR2016/11:30	29	19 - 35	No	
		Week 8	22MAR2016/08:30	31	19 - 35	No	
		Week 12	19APR2016/11:32	28	19 - 35	No	
		Week 16	17MAY2016/12:55	29	19 - 35	No	
		Week 20	20JUN2016/12:12	27	19 - 35	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Globulin (g/L)	Week 24	12JUL2016/11:40	26	19 - 35	Yes	
		Week 28	08AUG2016/12:30	29	19 - 35	No	
		Week 32	06SEP2016/11:10	35	19 - 35	No	
		Week 36	04OCT2016/12:40	38 H	19 - 35	No	
		Week 40	01NOV2016/12:50	39 H	19 - 35	No	
		Week 44	28NOV2016/11:45	32	19 - 35	No	
		Week 48	03JAN2017/13:00	38 H	19 - 35	No	
	Glucose (mmol/L)	Screening	07JAN2016/09:30	5.4	3.9 - 5.8	Yes	0
		Day 1	27JAN2016/10:00	4.0	3.9 - 5.8	Yes	0
		Week 1	04FEB2016/10:30	4.9	3.5 - 7.9	No	0
		Week 2	09FEB2016/12:00	5.2	3.5 - 7.9	No	0
		Week 4	24FEB2016/14:00	5.1	3.5 - 7.9	No	0
		Week 6	09MAR2016/11:30	5.0	3.5 - 7.9	No	0
		Week 8	22MAR2016/08:30	5.1	3.5 - 7.9	No	0
		Week 12	19APR2016/11:32	5.5	3.5 - 7.9	No	0
		Week 16	17MAY2016/12:55	4.8	3.5 - 7.9	No	0
		Week 20	20JUN2016/12:12	5.5	3.5 - 7.9	No	0
		Week 24	12JUL2016/11:40	4.7	3.9 - 5.8	Yes	0
		Week 28	08AUG2016/12:30	5.4	3.5 - 7.9	No	0
		Week 32	06SEP2016/11:10	4.5	3.5 - 7.9	No	0
		Week 36	04OCT2016/12:40	4.2	3.5 - 7.9	No	0
		Week 40	01NOV2016/12:50	4.7	3.5 - 7.9	No	0
		Week 44	28NOV2016/11:45	3.9	3.5 - 7.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Glucose (mmol/L)	Week 48	03JAN2017/13:00	4.4	3.5 - 7.9	No	0
	Indirect Bilirubin (umol/L)	Screening	07JAN2016/09:30	4	0 - 14	Yes	
		Day 1	27JAN2016/10:00	8	0 - 14	Yes	
		Week 1	04FEB2016/10:30	7	0 - 14	No	
		Week 2	09FEB2016/12:00	5	0 - 14	No	
		Week 4	24FEB2016/14:00	3	0 - 14	No	
		Week 6	09MAR2016/11:30	3	0 - 14	No	
		Week 8	22MAR2016/08:30	5	0 - 14	No	
		Week 12	19APR2016/11:32	3	0 - 14	No	
		Week 16	17MAY2016/12:55	3	0 - 14	No	
		Week 20	20JUN2016/12:12	3	0 - 14	No	
		Week 24	12JUL2016/11:40	3	0 - 14	Yes	
		Week 28	08AUG2016/12:30	3	0 - 14	No	
		Week 32	06SEP2016/11:10	4	0 - 14	No	
		Week 36	04OCT2016/12:40	5	0 - 14	No	
		Week 40	01NOV2016/12:50	6	0 - 14	No	
		Week 44	28NOV2016/11:45	6	0 - 14	No	
		Week 48	03JAN2017/13:00	7	0 - 14	No	
	Lactate Dehydrogenase (IU/L)	Screening	07JAN2016/09:30	183	135 - 225	Yes	
		Day 1	27JAN2016/10:00	186	135 - 225	Yes	
		Week 1	04FEB2016/10:30	158	135 - 225	No	
		Week 2	09FEB2016/12:00	163	135 - 225	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Lactate Dehydrogenase (IU/L)	Week 4	24FEB2016/14:00	184	135 - 225	No	
		Week 6	09MAR2016/11:30	179	135 - 225	No	
		Week 8	22MAR2016/08:30	176	135 - 225	No	
		Week 12	19APR2016/11:32	165	135 - 225	No	
		Week 16	17MAY2016/12:55	180	135 - 225	No	
		Week 20	20JUN2016/12:12	165	135 - 225	No	
		Week 24	12JUL2016/11:40	161	135 - 225	Yes	
		Week 28	08AUG2016/12:30	182	135 - 225	No	
		Week 32	06SEP2016/11:10	238 H	135 - 225	No	
		Week 36	04OCT2016/12:40	174	135 - 225	No	
		Week 40	01NOV2016/12:50	179	135 - 225	No	
		Week 44	28NOV2016/11:45	175	135 - 225	No	
		Week 48	03JAN2017/13:00	168	135 - 225	No	
	Magnesium (mmol/L)	Screening	07JAN2016/09:30	0.81	0.6 - 1	Yes	0
		Day 1	27JAN2016/10:00	0.88	0.6 - 1	Yes	0
		Week 1	04FEB2016/10:30	0.87	0.6 - 1	No	0
		Week 2	09FEB2016/12:00	0.85	0.6 - 1	No	0
		Week 4	24FEB2016/14:00	0.86	0.6 - 1	No	0
		Week 6	09MAR2016/11:30	0.82	0.6 - 1	No	0
		Week 8	22MAR2016/08:30	0.89	0.6 - 1	No	0
		Week 12	19APR2016/11:32	0.84	0.6 - 1	No	0
		Week 16	17MAY2016/12:55	0.86	0.6 - 1	No	0
		Week 20	20JUN2016/12:12	0.78	0.6 - 1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Magnesium (mmol/L)	Week 24	12JUL2016/11:40	0.81	0.6 - 1	Yes	0
		Week 28	08AUG2016/12:30	0.82	0.6 - 1	No	0
		Week 32	06SEP2016/11:10	0.82	0.6 - 1	No	0
		Week 36	04OCT2016/12:40	0.86	0.6 - 1	No	0
		Week 40	01NOV2016/12:50	0.87	0.6 - 1	No	0
		Week 44	28NOV2016/11:45	0.82	0.6 - 1	No	0
		Week 48	03JAN2017/13:00	0.85	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	07JAN2016/09:30	0.73 L	0.87 - 1.45	Yes	2
		Day 1	27JAN2016/10:00	0.88	0.87 - 1.45	Yes	0
		Week 1	04FEB2016/10:30	0.94	0.87 - 1.45	No	0
		Week 2	09FEB2016/12:00	0.90	0.87 - 1.45	No	0
		Week 4	24FEB2016/14:00	1.03	0.87 - 1.45	No	0
		Week 6	09MAR2016/11:30	0.97	0.87 - 1.45	No	0
		Week 8	22MAR2016/08:30	1.08	0.87 - 1.45	No	0
		Week 12	19APR2016/11:32	0.92	0.87 - 1.45	No	0
		Week 16	17MAY2016/12:55	1.00	0.87 - 1.45	No	0
		Week 20	20JUN2016/12:12	1.17	0.87 - 1.45	No	0
		Week 24	12JUL2016/11:40	1.04	0.87 - 1.45	Yes	0
		Week 28	08AUG2016/12:30	0.69 L	0.87 - 1.45	No	2
		Week 32	06SEP2016/11:10	0.98	0.87 - 1.45	No	0
		Week 36	04OCT2016/12:40	0.97	0.87 - 1.45	No	0
		Week 40	01NOV2016/12:50	0.85 L	0.87 - 1.45	No	1
		Week 44	28NOV2016/11:45	1.00	0.87 - 1.45	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Phosphate (mmol/L)	Week 48	03JAN2017/13:00	0.79 L	0.87 - 1.45	No	2
	Potassium (mmol/L)	Screening	07JAN2016/09:30	4.4	3.5 - 5.1	Yes	0
		Day 1	27JAN2016/10:00	4.2	3.5 - 5.1	Yes	0
		Week 1	04FEB2016/10:30	5.2 H	3.5 - 5.1	No	1
		Week 2	09FEB2016/12:00	5.0	3.5 - 5.1	No	0
		Week 4	24FEB2016/14:00	4.2	3.5 - 5.1	No	0
		Week 6	09MAR2016/11:30	4.5	3.5 - 5.1	No	0
		Week 8	22MAR2016/08:30	4.4	3.5 - 5.1	No	0
		Week 12	19APR2016/11:32	4.3	3.5 - 5.1	No	0
		Week 16	17MAY2016/12:55	4.7	3.5 - 5.1	No	0
		Week 20	20JUN2016/12:12	4.1	3.5 - 5.1	No	0
		Week 24	12JUL2016/11:40	4.2	3.5 - 5.1	Yes	0
		Week 28	08AUG2016/12:30	4.7	3.5 - 5.1	No	0
		Week 32	06SEP2016/11:10	4.5	3.5 - 5.1	No	0
		Week 36	04OCT2016/12:40	4.5	3.5 - 5.1	No	0
		Week 40	01NOV2016/12:50	4.5	3.5 - 5.1	No	0
		Week 44	28NOV2016/11:45	4.5	3.5 - 5.1	No	0
		Week 48	03JAN2017/13:00	4.6	3.5 - 5.1	No	0
	Protein (g/L)	Screening	07JAN2016/09:30	77	63 - 83	Yes	
		Day 1	27JAN2016/10:00	78	63 - 83	Yes	
		Week 1	04FEB2016/10:30	81	63 - 83	No	
		Week 2	09FEB2016/12:00	78	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Protein (g/L)	Week 4	24FEB2016/14:00	78	63 - 83	No	
		Week 6	09MAR2016/11:30	74	63 - 83	No	
		Week 8	22MAR2016/08:30	76	63 - 83	No	
		Week 12	19APR2016/11:32	75	63 - 83	No	
		Week 16	17MAY2016/12:55	75	63 - 83	No	
		Week 20	20JUN2016/12:12	73	63 - 83	No	
		Week 24	12JUL2016/11:40	73	63 - 83	Yes	
		Week 28	08AUG2016/12:30	75	63 - 83	No	
		Week 32	06SEP2016/11:10	82	63 - 83	No	
		Week 36	04OCT2016/12:40	83	63 - 83	No	
		Week 40	01NOV2016/12:50	83	63 - 83	No	
		Week 44	28NOV2016/11:45	78	63 - 83	No	
		Week 48	03JAN2017/13:00	85 H	63 - 83	No	
	Sodium (mmol/L)	Screening	07JAN2016/09:30	139	135 - 145	Yes	0
		Day 1	27JAN2016/10:00	138	135 - 145	Yes	0
		Week 1	04FEB2016/10:30	139	135 - 145	No	0
		Week 2	09FEB2016/12:00	138	135 - 145	No	0
		Week 4	24FEB2016/14:00	139	135 - 145	No	0
		Week 6	09MAR2016/11:30	138	135 - 145	No	0
		Week 8	22MAR2016/08:30	140	135 - 145	No	0
		Week 12	19APR2016/11:32	142	135 - 145	No	0
		Week 16	17MAY2016/12:55	143	135 - 145	No	0
		Week 20	20JUN2016/12:12	142	135 - 145	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Sodium (mmol/L)	Week 24	12JUL2016/11:40	141	135 - 145	Yes	0
		Week 28	08AUG2016/12:30	141	135 - 145	No	0
		Week 32	06SEP2016/11:10	139	135 - 145	No	0
		Week 36	04OCT2016/12:40	141	135 - 145	No	0
		Week 40	01NOV2016/12:50	138	135 - 145	No	0
		Week 44	28NOV2016/11:45	142	135 - 145	No	0
		Week 48	03JAN2017/13:00	139	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	07JAN2016/09:30	1.88	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	07JAN2016/09:30	98	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	07JAN2016/09:30	1.1	0 - 2.2	Yes	0
		Day 1	27JAN2016/10:00	1.0	0 - 2.2	Yes	0
		Week 1	04FEB2016/10:30	0.8	0 - 2.2	No	0
		Week 2	09FEB2016/12:00	0.8	0 - 2.2	No	0
		Week 4	24FEB2016/14:00	1.0	0 - 2.2	No	0
		Week 6	09MAR2016/11:30	0.7	0 - 2.2	No	0
		Week 8	22MAR2016/08:30	0.6	0 - 2.2	No	0
		Week 12	19APR2016/11:32	1.1	0 - 2.2	No	0
		Week 16	17MAY2016/12:55	1.0	0 - 2.2	No	0
		Week 20	20JUN2016/12:12	0.7	0 - 2.2	No	0
		Week 24	12JUL2016/11:40	0.8	0 - 2.2	Yes	0
		Week 28	08AUG2016/12:30	1.5	0 - 2.2	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Triglycerides (mmol/L)	Week 32	06SEP2016/11:10	0.9	0 - 2.2	No	0
		Week 36	04OCT2016/12:40	1.2	0 - 2.2	No	0
		Week 40	01NOV2016/12:50	0.9	0 - 2.2	No	0
		Week 44	28NOV2016/11:45	0.8	0 - 2.2	No	0
		Week 48	03JAN2017/13:00	1.0	0 - 2.2	No	0
	Triiodothyronine (nmol/L)	Screening	07JAN2016/09:30	2.7	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	07JAN2016/09:30	5.8	1.7 - 8.3	Yes	
		Day 1	27JAN2016/10:00	5.3	1.7 - 8.3	Yes	
		Week 1	04FEB2016/10:30	4.3	1.7 - 8.3	No	
		Week 2	09FEB2016/12:00	4.8	1.7 - 8.3	No	
		Week 4	24FEB2016/14:00	4.2	1.7 - 8.3	No	
		Week 6	09MAR2016/11:30	2.9	1.7 - 8.3	No	
		Week 8	22MAR2016/08:30	5.1	1.7 - 8.3	No	
		Week 12	19APR2016/11:32	3.1	1.7 - 8.3	No	
		Week 16	17MAY2016/12:55	3.7	1.7 - 8.3	No	
		Week 20	20JUN2016/12:12	4.3	1.7 - 8.3	No	
		Week 24	12JUL2016/11:40	3.0	1.7 - 8.3	Yes	
		Week 28	08AUG2016/12:30	4.5	1.7 - 8.3	No	
		Week 32	06SEP2016/11:10	3.7	1.7 - 8.3	No	
		Week 36	04OCT2016/12:40	3.9	1.7 - 8.3	No	
		Week 40	01NOV2016/12:50	4.1	1.7 - 8.3	No	
		Week 44	28NOV2016/11:45	4.1	1.7 - 8.3	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Urea (mmol/L)	Week 48	03JAN2017/13:00	4.2	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	07JAN2016/09:30	360	266 - 474	Yes	0
		Day 1	27JAN2016/10:00	353	266 - 474	Yes	0
		Week 1	04FEB2016/10:30	295	266 - 474	No	0
		Week 2	09FEB2016/12:00	317	266 - 474	No	0
		Week 4	24FEB2016/14:00	261 L	266 - 474	No	0
		Week 6	09MAR2016/11:30	236 L	266 - 474	No	0
		Week 8	22MAR2016/08:30	285	266 - 474	No	0
		Week 12	19APR2016/11:32	209 L	266 - 474	No	0
		Week 16	17MAY2016/12:55	218 L	266 - 474	No	0
		Week 20	20JUN2016/12:12	225 L	266 - 474	No	0
		Week 24	12JUL2016/11:40	231 L	266 - 474	Yes	0
		Week 28	08AUG2016/12:30	305	266 - 474	No	0
		Week 32	06SEP2016/11:10	300	266 - 474	No	0
		Week 36	04OCT2016/12:40	325	266 - 474	No	0
		Week 40	01NOV2016/12:50	284	266 - 474	No	0
		Week 44	28NOV2016/11:45	316	266 - 474	No	0
		Week 48	03JAN2017/13:00	350	266 - 474	No	0
301-014	Alanine Aminotransferase (IU/L)	Screening	27JAN2016/11:30	61 H	10 - 50	Yes	1
		Day 1	23FEB2016/13:00	66 H	10 - 50	Yes	1
		Week 1	01MAR2016/11:30	68 H	10 - 50	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Alanine Aminotransferase (IU/L)	Week 2	09MAR2016/10:45	59 H	10 - 50	No	1
		Week 4	22MAR2016/10:15	50	10 - 50	No	0
		Week 6	05APR2016/11:47	46	10 - 50	No	0
		Week 8	20APR2016/09:15	48	10 - 50	Yes	0
		Week 12	19MAY2016/11:55	42	10 - 50	No	0
		Week 16	14JUN2016/11:08	45	10 - 50	No	0
		Week 20	13JUL2016/11:20	47	10 - 50	No	0
		Week 24	10AUG2016/10:50	46	10 - 50	Yes	0
		Week 28	07SEP2016/11:30	47	10 - 50	No	0
		Week 32	05OCT2016/11:00	70 H	10 - 50	No	1
		Week 36	02NOV2016/12:00	80 H	10 - 50	No	1
		Week 40	30NOV2016/10:45	71 H	10 - 50	No	1
		Week 44	22DEC2016/12:00	55 H	10 - 50	No	1
		Week 48	25JAN2017/11:00	62 H	10 - 50	No	1
	Albumin (g/L)	Screening	27JAN2016/11:30	43	34 - 50	Yes	0
		Day 1	23FEB2016/13:00	45	34 - 50	Yes	0
		Week 1	01MAR2016/11:30	45	34 - 50	No	0
		Week 2	09MAR2016/10:45	45	34 - 50	No	0
		Week 4	22MAR2016/10:15	41	34 - 50	No	0
		Week 6	05APR2016/11:47	43	34 - 50	No	0
		Week 8	20APR2016/09:15	44	34 - 50	Yes	0
		Week 12	19MAY2016/11:55	44	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Albumin (g/L)	Week 16	14JUN2016/11:08	44	34 - 50	No	0
		Week 20	13JUL2016/11:20	43	34 - 50	No	0
		Week 24	10AUG2016/10:50	43	34 - 50	Yes	0
		Week 28	07SEP2016/11:30	41	34 - 50	No	0
		Week 32	05OCT2016/11:00	43	34 - 50	No	0
		Week 36	02NOV2016/12:00	43	34 - 50	No	0
		Week 40	30NOV2016/10:45	46	34 - 50	No	0
		Week 44	22DEC2016/12:00	45	34 - 50	No	0
		Week 48	25JAN2017/11:00	45	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	27JAN2016/11:30	81	40 - 129	Yes	0
		Day 1	23FEB2016/13:00	86	40 - 129	Yes	0
		Week 1	01MAR2016/11:30	91	40 - 129	No	0
		Week 2	09MAR2016/10:45	98	40 - 129	No	0
		Week 4	22MAR2016/10:15	104	40 - 129	No	0
		Week 6	05APR2016/11:47	99	40 - 129	No	0
		Week 8	20APR2016/09:15	112	40 - 129	Yes	0
		Week 12	19MAY2016/11:55	113	40 - 129	No	0
		Week 16	14JUN2016/11:08	129	40 - 129	No	0
		Week 20	13JUL2016/11:20	147 H	40 - 129	No	1
		Week 24	10AUG2016/10:50	150 H	40 - 129	Yes	1
		Week 28	07SEP2016/11:30	134 H	40 - 129	No	1
		Week 32	05OCT2016/11:00	118	40 - 129	No	0
		Week 36	02NOV2016/12:00	121	40 - 129	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Alkaline Phosphatase (IU/L)	Week 40	30NOV2016/10:45	111	40 - 129	No	0
		Week 44	22DEC2016/12:00	103	40 - 129	No	0
		Week 48	25JAN2017/11:00	104	40 - 129	No	0
	Amylase (IU/L)	Screening	27JAN2016/11:30	49	28 - 100	Yes	0
		Day 1	23FEB2016/13:00	44	28 - 100	Yes	0
		Week 1	01MAR2016/11:30	41	28 - 100	No	0
		Week 2	09MAR2016/10:45	46	28 - 100	No	0
		Week 4	22MAR2016/10:15	50	28 - 100	No	0
		Week 6	05APR2016/11:47	41	28 - 100	No	0
		Week 8	20APR2016/09:15	49	28 - 100	Yes	0
		Week 12	19MAY2016/11:55	49	28 - 100	No	0
		Week 16	14JUN2016/11:08	54	28 - 100	No	0
		Week 20	13JUL2016/11:20	46	28 - 100	No	0
		Week 24	10AUG2016/10:50	51	28 - 100	Yes	0
		Week 28	07SEP2016/11:30	49	28 - 100	No	0
		Week 32	05OCT2016/11:00	46	28 - 100	No	0
		Week 36	02NOV2016/12:00	53	28 - 100	No	0
		Week 40	30NOV2016/10:45	52	28 - 100	No	0
		Week 44	22DEC2016/12:00	45	28 - 100	No	0
		Week 48	25JAN2017/11:00	44	28 - 100	No	0
	Aspartate Aminotransferase (IU/L)	Screening	27JAN2016/11:30	45 H	0 - 37	Yes	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Aspartate Aminotransferase (IU/L)	Day 1	23FEB2016/13:00	50 H	0 - 37	Yes	1
		Week 1	01MAR2016/11:30	49 H	0 - 37	No	1
		Week 2	09MAR2016/10:45	40 H	0 - 37	No	1
		Week 4	22MAR2016/10:15	40 H	0 - 37	No	1
		Week 6	05APR2016/11:47	38 H	0 - 37	No	1
		Week 8	20APR2016/09:15	44 H	0 - 37	Yes	1
		Week 12	19MAY2016/11:55	40 H	0 - 37	No	1
		Week 16	14JUN2016/11:08	40 H	0 - 37	No	1
		Week 20	13JUL2016/11:20	43 H	0 - 37	No	1
		Week 24	10AUG2016/10:50	45 H	0 - 37	Yes	1
		Week 28	07SEP2016/11:30	40 H	0 - 37	No	1
		Week 32	05OCT2016/11:00	61 H	0 - 37	No	1
		Week 36	02NOV2016/12:00	57 H	0 - 37	No	1
		Week 40	30NOV2016/10:45	54 H	0 - 37	No	1
		Week 44	22DEC2016/12:00	42 H	0 - 37	No	1
		Week 48	25JAN2017/11:00	47 H	0 - 37	No	1
	Bicarbonate (mmol/L)	Screening	27JAN2016/11:30	26	22 - 29	Yes	
		Day 1	23FEB2016/13:00	24	22 - 29	Yes	
		Week 1	01MAR2016/11:30	26	22 - 29	No	
		Week 2	09MAR2016/10:45	25	22 - 29	No	
		Week 4	22MAR2016/10:15	26	22 - 29	No	
		Week 6	05APR2016/11:47	26	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Bicarbonate (mmol/L)	Week 8	20APR2016/09:15	23	22 - 29	Yes	
		Week 12	19MAY2016/11:55	29	22 - 29	No	
		Week 16	14JUN2016/11:08	24	22 - 29	No	
		Week 20	13JUL2016/11:20	28	22 - 29	No	
		Week 24	10AUG2016/10:50	22	22 - 29	Yes	
		Week 28	07SEP2016/11:30	23	22 - 29	No	
		Week 32	05OCT2016/11:00	24	22 - 29	No	
		Week 36	02NOV2016/12:00	27	22 - 29	No	
		Week 40	30NOV2016/10:45	26	22 - 29	No	
		Week 44	22DEC2016/12:00	24	22 - 29	No	
		Week 48	25JAN2017/11:00	21 L	22 - 29	No	
	Bilirubin (umol/L)	Screening	27JAN2016/11:30	7	0 - 20	Yes	0
		Day 1	23FEB2016/13:00	6	0 - 20	Yes	0
		Week 1	01MAR2016/11:30	7	0 - 20	No	0
		Week 2	09MAR2016/10:45	7	0 - 20	No	0
		Week 4	22MAR2016/10:15	5	0 - 20	No	0
		Week 6	05APR2016/11:47	8	0 - 20	No	0
		Week 8	20APR2016/09:15	7	0 - 20	Yes	0
		Week 12	19MAY2016/11:55	6	0 - 20	No	0
		Week 16	14JUN2016/11:08	5	0 - 20	No	0
		Week 20	13JUL2016/11:20	6	0 - 20	No	0
		Week 24	10AUG2016/10:50	6	0 - 20	Yes	0
		Week 28	07SEP2016/11:30	5	0 - 20	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Bilirubin (umol/L)	Week 32	05OCT2016/11:00	6	0 - 20	No	0
		Week 36	02NOV2016/12:00	7	0 - 20	No	0
		Week 40	30NOV2016/10:45	6	0 - 20	No	0
		Week 44	22DEC2016/12:00	8	0 - 20	No	0
		Week 48	25JAN2017/11:00	8	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	27JAN2016/11:30	14.84	4.76 - 23.24	Yes	
		Day 1	23FEB2016/13:00	12.60	4.76 - 23.24	Yes	
		Week 1	01MAR2016/11:30	8.12	4.76 - 23.24	No	
		Week 2	09MAR2016/10:45	13.44	4.76 - 23.24	No	
		Week 4	22MAR2016/10:15	9.52	4.76 - 23.24	No	
		Week 6	05APR2016/11:47	10.92	4.76 - 23.24	No	
		Week 8	20APR2016/09:15	8.68	4.76 - 23.24	Yes	
		Week 12	19MAY2016/11:55	10.08	4.76 - 23.24	No	
		Week 16	14JUN2016/11:08	8.68	4.76 - 23.24	No	
		Week 20	13JUL2016/11:20	8.96	4.76 - 23.24	No	
		Week 24	10AUG2016/10:50	10.36	4.76 - 23.24	Yes	
		Week 28	07SEP2016/11:30	13.16	4.76 - 23.24	No	
		Week 32	05OCT2016/11:00	10.92	4.76 - 23.24	No	
		Week 36	02NOV2016/12:00	15.96	4.76 - 23.24	No	
		Week 40	30NOV2016/10:45	9.24	4.76 - 23.24	No	
		Week 44	22DEC2016/12:00	9.80	4.76 - 23.24	No	
		Week 48	25JAN2017/11:00	11.76	4.76 - 23.24	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Calcium (mmol/L)	Screening	27JAN2016/11:30	2.35	2.2 - 2.6	Yes	0
		Day 1	23FEB2016/13:00	2.37	2.2 - 2.6	Yes	0
		Week 1	01MAR2016/11:30	2.31	2.2 - 2.6	No	0
		Week 2	09MAR2016/10:45	2.24	2.2 - 2.6	No	0
		Week 4	22MAR2016/10:15	2.33	2.2 - 2.6	No	0
		Week 6	05APR2016/11:47	2.32	2.2 - 2.6	No	0
		Week 8	20APR2016/09:15	2.27	2.2 - 2.6	Yes	0
		Week 12	19MAY2016/11:55	2.28	2.2 - 2.6	No	0
		Week 16	14JUN2016/11:08	2.28	2.2 - 2.6	No	0
		Week 20	13JUL2016/11:20	2.32	2.2 - 2.6	No	0
		Week 24	10AUG2016/10:50	2.22	2.2 - 2.6	Yes	0
		Week 28	07SEP2016/11:30	2.20	2.2 - 2.6	No	0
		Week 32	05OCT2016/11:00	2.26	2.2 - 2.6	No	0
		Week 36	02NOV2016/12:00	2.27	2.2 - 2.6	No	0
		Week 40	30NOV2016/10:45	2.31	2.2 - 2.6	No	0
		Week 44	22DEC2016/12:00	2.32	2.2 - 2.6	No	0
		Week 48	25JAN2017/11:00	2.25	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	27JAN2016/11:30	104	98 - 107	Yes	
		Day 1	23FEB2016/13:00	103	98 - 107	Yes	
		Week 1	01MAR2016/11:30	103	98 - 107	No	
		Week 2	09MAR2016/10:45	102	98 - 107	No	
		Week 4	22MAR2016/10:15	101	98 - 107	No	
		Week 6	05APR2016/11:47	97 L	98 - 107	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Chloride (mmol/L)	Week 8	20APR2016/09:15	100	98 - 107	Yes	
		Week 12	19MAY2016/11:55	101	98 - 107	No	
		Week 16	14JUN2016/11:08	99	98 - 107	No	
		Week 20	13JUL2016/11:20	100	98 - 107	No	
		Week 24	10AUG2016/10:50	103	98 - 107	Yes	
		Week 28	07SEP2016/11:30	104	98 - 107	No	
		Week 32	05OCT2016/11:00	101	98 - 107	No	
		Week 36	02NOV2016/12:00	103	98 - 107	No	
		Week 40	30NOV2016/10:45	100	98 - 107	No	
		Week 44	22DEC2016/12:00	98	98 - 107	No	
		Week 48	25JAN2017/11:00	99	98 - 107	No	
	Cholesterol (mmol/L)	Screening	27JAN2016/11:30	4.0	0 - 4.9	Yes	0
		Day 1	23FEB2016/13:00	4.3	0 - 4.9	Yes	0
		Week 1	01MAR2016/11:30	3.0	0 - 4.9	No	0
		Week 2	09MAR2016/10:45	2.6	0 - 4.9	No	0
		Week 4	22MAR2016/10:15	2.8	0 - 4.9	No	0
		Week 6	05APR2016/11:47	2.6	0 - 4.9	No	0
		Week 8	20APR2016/09:15	2.3	0 - 4.9	Yes	0
		Week 12	19MAY2016/11:55	2.4	0 - 4.9	No	0
		Week 16	14JUN2016/11:08	2.4	0 - 4.9	No	0
		Week 20	13JUL2016/11:20	2.3	0 - 4.9	No	0
		Week 24	10AUG2016/10:50	2.5	0 - 4.9	Yes	0
		Week 28	07SEP2016/11:30	3.4	0 - 4.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Cholesterol (mmol/L)	Week 32	05OCT2016/11:00	3.5	0 - 4.9	No	0
		Week 36	02NOV2016/12:00	3.4	0 - 4.9	No	0
		Week 40	30NOV2016/10:45	4.0	0 - 4.9	No	0
		Week 44	22DEC2016/12:00	3.7	0 - 4.9	No	0
		Week 48	25JAN2017/11:00	3.9	0 - 4.9	No	0
	Creatine Kinase (IU/L)	Screening	27JAN2016/11:30	153	38 - 204	Yes	0
		Day 1	23FEB2016/13:00	165	38 - 204	Yes	0
		Week 1	01MAR2016/11:30	203	38 - 204	No	0
		Week 2	09MAR2016/10:45	190	38 - 204	No	0
		Week 4	22MAR2016/10:15	178	38 - 204	No	0
		Week 6	05APR2016/11:47	231 H	38 - 204	No	1
		Week 8	20APR2016/09:15	261 H	38 - 204	Yes	1
		Week 12	19MAY2016/11:55	241 H	38 - 204	No	1
		Week 16	14JUN2016/11:08	154	38 - 204	No	0
		Week 20	13JUL2016/11:20	166	38 - 204	No	0
		Week 24	10AUG2016/10:50	167	38 - 204	Yes	0
		Week 28	07SEP2016/11:30	128	38 - 204	No	0
		Week 32	05OCT2016/11:00	150	38 - 204	No	0
		Week 36	02NOV2016/12:00	194	38 - 204	No	0
		Week 40	30NOV2016/10:45	147	38 - 204	No	0
		Week 44	22DEC2016/12:00	128	38 - 204	No	0
		Week 48	25JAN2017/11:00	168	38 - 204	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Creatinine (umol/L)	Screening	27JAN2016/11:30	75	66 - 112	Yes	0
		Day 1	23FEB2016/13:00	80	66 - 112	Yes	0
		Week 1	01MAR2016/11:30	80	66 - 112	No	0
		Week 2	09MAR2016/10:45	76	66 - 112	No	0
		Week 4	22MAR2016/10:15	74	66 - 112	No	0
		Week 6	05APR2016/11:47	86	66 - 112	No	1
		Week 8	20APR2016/09:15	76	66 - 112	Yes	0
		Week 12	19MAY2016/11:55	76	66 - 112	No	0
		Week 16	14JUN2016/11:08	78	66 - 112	No	0
		Week 20	13JUL2016/11:20	86	66 - 112	No	1
		Week 24	10AUG2016/10:50	80	66 - 112	Yes	0
		Week 28	07SEP2016/11:30	71	66 - 112	No	0
		Week 32	05OCT2016/11:00	80	66 - 112	No	0
		Week 36	02NOV2016/12:00	75	66 - 112	No	0
		Week 40	30NOV2016/10:45	84	66 - 112	No	1
		Week 44	22DEC2016/12:00	89	66 - 112	No	1
		Week 48	25JAN2017/11:00	84	66 - 112	No	1
	Direct Bilirubin (umol/L)	Screening	27JAN2016/11:30	3	0 - 5	Yes	
		Day 1	23FEB2016/13:00	2	0 - 5	Yes	
		Week 1	01MAR2016/11:30	3	0 - 5	No	
		Week 2	09MAR2016/10:45	3	0 - 5	No	
		Week 4	22MAR2016/10:15	2	0 - 5	No	
		Week 6	05APR2016/11:47	3	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Direct Bilirubin (umol/L)	Week 8	20APR2016/09:15	3	0 - 5	Yes	
		Week 12	19MAY2016/11:55	3	0 - 5	No	
		Week 16	14JUN2016/11:08	2	0 - 5	No	
		Week 20	13JUL2016/11:20	3	0 - 5	No	
		Week 24	10AUG2016/10:50	3	0 - 5	Yes	
		Week 28	07SEP2016/11:30	<2	0 - 5	No	
		Week 32	05OCT2016/11:00	3	0 - 5	No	
		Week 36	02NOV2016/12:00	3	0 - 5	No	
		Week 40	30NOV2016/10:45	3	0 - 5	No	
		Week 44	22DEC2016/12:00	3	0 - 5	No	
		Week 48	25JAN2017/11:00	3	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	27JAN2016/11:30	63	10 - 71	Yes	0
		Day 1	23FEB2016/13:00	70	10 - 71	Yes	0
		Week 1	01MAR2016/11:30	80 H	10 - 71	No	1
		Week 2	09MAR2016/10:45	83 H	10 - 71	No	1
		Week 4	22MAR2016/10:15	86 H	10 - 71	No	1
		Week 6	05APR2016/11:47	93 H	10 - 71	No	1
		Week 8	20APR2016/09:15	96 H	10 - 71	Yes	1
		Week 12	19MAY2016/11:55	119 H	10 - 71	No	1
		Week 16	14JUN2016/11:08	117 H	10 - 71	No	1
		Week 20	13JUL2016/11:20	112 H	10 - 71	No	1
		Week 24	10AUG2016/10:50	124 H	10 - 71	Yes	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Gamma Glutamyl Transferase (IU/L)	Week 28	07SEP2016/11:30	82 H	10 - 71	No	1
		Week 32	05OCT2016/11:00	72 H	10 - 71	No	1
		Week 36	02NOV2016/12:00	69	10 - 71	No	0
		Week 40	30NOV2016/10:45	56	10 - 71	No	0
		Week 44	22DEC2016/12:00	56	10 - 71	No	0
		Week 48	25JAN2017/11:00	60	10 - 71	No	0
	Globulin (g/L)	Screening	27JAN2016/11:30	34	19 - 35	Yes	
		Day 1	23FEB2016/13:00	30	19 - 35	Yes	
		Week 1	01MAR2016/11:30	32	19 - 35	No	
		Week 2	09MAR2016/10:45	31	19 - 35	No	
		Week 4	22MAR2016/10:15	33	19 - 35	No	
		Week 6	05APR2016/11:47	32	19 - 35	No	
		Week 8	20APR2016/09:15	33	19 - 35	Yes	
		Week 12	19MAY2016/11:55	30	19 - 35	No	
		Week 16	14JUN2016/11:08	33	19 - 35	No	
		Week 20	13JUL2016/11:20	33	19 - 35	No	
		Week 24	10AUG2016/10:50	33	19 - 35	Yes	
		Week 28	07SEP2016/11:30	31	19 - 35	No	
		Week 32	05OCT2016/11:00	29	19 - 35	No	
		Week 36	02NOV2016/12:00	31	19 - 35	No	
		Week 40	30NOV2016/10:45	30	19 - 35	No	
		Week 44	22DEC2016/12:00	28	19 - 35	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Globulin (g/L)	Week 48	25JAN2017/11:00	32	19 - 35	No	
	Glucose (mmol/L)	Screening	27JAN2016/11:30	4.8	3.9 - 5.8	Yes	0
		Day 1	23FEB2016/13:00	4.8	3.9 - 5.8	Yes	0
		Week 1	01MAR2016/11:30	4.8	3.5 - 7.9	No	0
		Week 2	09MAR2016/10:45	4.5	3.5 - 7.9	No	0
		Week 4	22MAR2016/10:15	5.2	3.5 - 7.9	No	0
		Week 6	05APR2016/11:47	6.2	3.5 - 7.9	No	0
		Week 8	20APR2016/09:15	5.1	3.9 - 5.8	Yes	0
		Week 12	19MAY2016/11:55	4.4	3.5 - 7.9	No	0
		Week 16	14JUN2016/11:08	5.6	3.5 - 7.9	No	0
		Week 20	13JUL2016/11:20	4.8	3.5 - 7.9	No	0
		Week 24	10AUG2016/10:50	4.6	3.9 - 5.8	Yes	0
		Week 28	07SEP2016/11:30	6.4	3.5 - 7.9	No	0
		Week 32	05OCT2016/11:00	5.4	3.5 - 7.9	No	0
		Week 36	02NOV2016/12:00	4.0	3.5 - 7.9	No	0
		Week 40	30NOV2016/10:45	4.3	3.5 - 7.9	No	0
		Week 44	22DEC2016/12:00	8.0 H	3.5 - 7.9	No	1
		Week 48	25JAN2017/11:00	5.0	3.5 - 7.9	No	0
	Indirect Bilirubin (umol/L)	Screening	27JAN2016/11:30	4	0 - 14	Yes	
		Day 1	23FEB2016/13:00	4	0 - 14	Yes	
		Week 1	01MAR2016/11:30	4	0 - 14	No	
		Week 2	09MAR2016/10:45	4	0 - 14	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Indirect Bilirubin (umol/L)	Week 4	22MAR2016/10:15	3	0 - 14	No
		Week 6	05APR2016/11:47	5	0 - 14	No
		Week 8	20APR2016/09:15	4	0 - 14	Yes
		Week 12	19MAY2016/11:55	3	0 - 14	No
		Week 16	14JUN2016/11:08	3	0 - 14	No
		Week 20	13JUL2016/11:20	3	0 - 14	No
		Week 24	10AUG2016/10:50	3	0 - 14	Yes
		Week 28	07SEP2016/11:30		0 - 14	No
		Week 32	05OCT2016/11:00	3	0 - 14	No
		Week 36	02NOV2016/12:00	4	0 - 14	No
		Week 40	30NOV2016/10:45	3	0 - 14	No
		Week 44	22DEC2016/12:00	5	0 - 14	No
		Week 48	25JAN2017/11:00	5	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	27JAN2016/11:30	196	135 - 225	Yes
		Day 1	23FEB2016/13:00	199	135 - 225	Yes
		Week 1	01MAR2016/11:30	178	135 - 225	No
		Week 2	09MAR2016/10:45	182	135 - 225	No
		Week 4	22MAR2016/10:15	178	135 - 225	No
		Week 6	05APR2016/11:47	190	135 - 225	No
		Week 8	20APR2016/09:15	194	135 - 225	Yes
		Week 12	19MAY2016/11:55	188	135 - 225	No
		Week 16	14JUN2016/11:08	208	135 - 225	No
		Week 20	13JUL2016/11:20	210	135 - 225	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Lactate Dehydrogenase (IU/L)	Week 24	10AUG2016/10:50	207	135 - 225	Yes	
		Week 28	07SEP2016/11:30	224	135 - 225	No	
		Week 32	05OCT2016/11:00	219	135 - 225	No	
		Week 36	02NOV2016/12:00	247 H	135 - 225	No	
		Week 40	30NOV2016/10:45	214	135 - 225	No	
		Week 44	22DEC2016/12:00	194	135 - 225	No	
		Week 48	25JAN2017/11:00	202	135 - 225	No	
	Magnesium (mmol/L)	Screening	27JAN2016/11:30	0.88	0.6 - 1	Yes	0
		Day 1	23FEB2016/13:00	0.87	0.6 - 1	Yes	0
		Week 1	01MAR2016/11:30	0.84	0.6 - 1	No	0
		Week 2	09MAR2016/10:45	0.86	0.6 - 1	No	0
		Week 4	22MAR2016/10:15	0.79	0.6 - 1	No	0
		Week 6	05APR2016/11:47	0.82	0.6 - 1	No	0
		Week 8	20APR2016/09:15	0.81	0.6 - 1	Yes	0
		Week 12	19MAY2016/11:55	0.77	0.6 - 1	No	0
		Week 16	14JUN2016/11:08	0.81	0.6 - 1	No	0
		Week 20	13JUL2016/11:20	0.79	0.6 - 1	No	0
		Week 24	10AUG2016/10:50	0.79	0.6 - 1	Yes	0
		Week 28	07SEP2016/11:30	0.81	0.6 - 1	No	0
		Week 32	05OCT2016/11:00	0.87	0.6 - 1	No	0
		Week 36	02NOV2016/12:00	0.84	0.6 - 1	No	0
		Week 40	30NOV2016/10:45	0.88	0.6 - 1	No	0
		Week 44	22DEC2016/12:00	0.83	0.6 - 1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Magnesium (mmol/L)	Week 48	25JAN2017/11:00	0.87	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	27JAN2016/11:30	0.63 L	0.87 - 1.45	Yes	2
		Day 1	23FEB2016/13:00	1.00	0.87 - 1.45	Yes	0
		Week 1	01MAR2016/11:30	0.88	0.87 - 1.45	No	0
		Week 2	09MAR2016/10:45	0.85 L	0.87 - 1.45	No	1
		Week 4	22MAR2016/10:15	1.03	0.87 - 1.45	No	0
		Week 6	05APR2016/11:47	0.78 L	0.87 - 1.45	No	2
		Week 8	20APR2016/09:15	0.78 L	0.87 - 1.45	Yes	2
		Week 12	19MAY2016/11:55	0.86 L	0.87 - 1.45	No	1
		Week 16	14JUN2016/11:08	0.75 L	0.87 - 1.45	No	2
		Week 20	13JUL2016/11:20	0.70 L	0.87 - 1.45	No	2
		Week 24	10AUG2016/10:50	0.80 L	0.87 - 1.45	Yes	1
		Week 28	07SEP2016/11:30	0.73 L	0.87 - 1.45	No	2
		Week 32	05OCT2016/11:00	0.51 L	0.87 - 1.45	No	3
		Week 36	02NOV2016/12:00	0.92	0.87 - 1.45	No	0
		Week 40	30NOV2016/10:45	0.93	0.87 - 1.45	No	0
		Week 44	22DEC2016/12:00	0.74 L	0.87 - 1.45	No	2
		Week 48	25JAN2017/11:00	0.99	0.87 - 1.45	No	0
	Potassium (mmol/L)	Screening	27JAN2016/11:30	4.7	3.5 - 5.1	Yes	0
		Day 1	23FEB2016/13:00	4.8	3.5 - 5.1	Yes	0
		Week 1	01MAR2016/11:30	4.6	3.5 - 5.1	No	0
		Week 2	09MAR2016/10:45	4.2	3.5 - 5.1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Potassium (mmol/L)	Week 4	22MAR2016/10:15	4.3	3.5 - 5.1	No	0
		Week 6	05APR2016/11:47	3.6	3.5 - 5.1	No	0
		Week 8	20APR2016/09:15	3.5	3.5 - 5.1	Yes	0
		Week 12	19MAY2016/11:55	4.2	3.5 - 5.1	No	0
		Week 16	14JUN2016/11:08	3.6	3.5 - 5.1	No	0
		Week 20	13JUL2016/11:20	4.3	3.5 - 5.1	No	0
		Week 24	10AUG2016/10:50	3.9	3.5 - 5.1	Yes	0
		Week 28	07SEP2016/11:30	4.3	3.5 - 5.1	No	0
		Week 32	05OCT2016/11:00	4.5	3.5 - 5.1	No	0
		Week 36	02NOV2016/12:00	4.7	3.5 - 5.1	No	0
		Week 40	30NOV2016/10:45	4.8	3.5 - 5.1	No	0
		Week 44	22DEC2016/12:00	4.5	3.5 - 5.1	No	0
		Week 48	25JAN2017/11:00	4.2	3.5 - 5.1	No	0
	Protein (g/L)	Screening	27JAN2016/11:30	77	63 - 83	Yes	
		Day 1	23FEB2016/13:00	75	63 - 83	Yes	
		Week 1	01MAR2016/11:30	77	63 - 83	No	
		Week 2	09MAR2016/10:45	76	63 - 83	No	
		Week 4	22MAR2016/10:15	74	63 - 83	No	
		Week 6	05APR2016/11:47	75	63 - 83	No	
		Week 8	20APR2016/09:15	77	63 - 83	Yes	
		Week 12	19MAY2016/11:55	74	63 - 83	No	
		Week 16	14JUN2016/11:08	77	63 - 83	No	
		Week 20	13JUL2016/11:20	76	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Protein (g/L)	Week 24	10AUG2016/10:50	76	63 - 83	Yes	
		Week 28	07SEP2016/11:30	72	63 - 83	No	
		Week 32	05OCT2016/11:00	72	63 - 83	No	
		Week 36	02NOV2016/12:00	74	63 - 83	No	
		Week 40	30NOV2016/10:45	76	63 - 83	No	
		Week 44	22DEC2016/12:00	73	63 - 83	No	
		Week 48	25JAN2017/11:00	77	63 - 83	No	
	Sodium (mmol/L)	Screening	27JAN2016/11:30	143	135 - 145	Yes	0
		Day 1	23FEB2016/13:00	142	135 - 145	Yes	0
		Week 1	01MAR2016/11:30	142	135 - 145	No	0
		Week 2	09MAR2016/10:45	141	135 - 145	No	0
		Week 4	22MAR2016/10:15	140	135 - 145	No	0
		Week 6	05APR2016/11:47	138	135 - 145	No	0
		Week 8	20APR2016/09:15	142	135 - 145	Yes	0
		Week 12	19MAY2016/11:55	141	135 - 145	No	0
		Week 16	14JUN2016/11:08	141	135 - 145	No	0
		Week 20	13JUL2016/11:20	142	135 - 145	No	0
		Week 24	10AUG2016/10:50	142	135 - 145	Yes	0
		Week 28	07SEP2016/11:30	141	135 - 145	No	0
		Week 32	05OCT2016/11:00	140	135 - 145	No	0
		Week 36	02NOV2016/12:00	143	135 - 145	No	0
		Week 40	30NOV2016/10:45	142	135 - 145	No	0
		Week 44	22DEC2016/12:00	138	135 - 145	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Sodium (mmol/L)	Week 48	25JAN2017/11:00	140	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	27JAN2016/11:30	2.68	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	27JAN2016/11:30	118	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	27JAN2016/11:30	2.2	0 - 2.2	Yes	1
		Day 1	23FEB2016/13:00	2.9 H	0 - 2.2	Yes	1
		Week 1	01MAR2016/11:30	2.2	0 - 2.2	No	1
		Week 2	09MAR2016/10:45	2.1	0 - 2.2	No	1
		Week 4	22MAR2016/10:15	3.0 H	0 - 2.2	No	1
		Week 6	05APR2016/11:47	2.2	0 - 2.2	No	1
		Week 8	20APR2016/09:15	1.9	0 - 2.2	Yes	1
		Week 12	19MAY2016/11:55	1.8	0 - 2.2	No	1
		Week 16	14JUN2016/11:08	2.0	0 - 2.2	No	1
		Week 20	13JUL2016/11:20	2.2	0 - 2.2	No	1
		Week 24	10AUG2016/10:50	2.6 H	0 - 2.2	Yes	1
		Week 28	07SEP2016/11:30	2.9 H	0 - 2.2	No	1
		Week 32	05OCT2016/11:00	2.7 H	0 - 2.2	No	1
		Week 36	02NOV2016/12:00	2.1	0 - 2.2	No	1
		Week 40	30NOV2016/10:45	2.2	0 - 2.2	No	1
		Week 44	22DEC2016/12:00	1.6	0 - 2.2	No	0
		Week 48	25JAN2017/11:00	2.3 H	0 - 2.2	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Triiodothyronine (nmol/L)	Screening	27JAN2016/11:30	2.3	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	27JAN2016/11:30	5.3	1.7 - 8.3	Yes	
		Day 1	23FEB2016/13:00	4.5	1.7 - 8.3	Yes	
		Week 1	01MAR2016/11:30	2.9	1.7 - 8.3	No	
		Week 2	09MAR2016/10:45	4.8	1.7 - 8.3	No	
		Week 4	22MAR2016/10:15	3.4	1.7 - 8.3	No	
		Week 6	05APR2016/11:47	3.9	1.7 - 8.3	No	
		Week 8	20APR2016/09:15	3.1	1.7 - 8.3	Yes	
		Week 12	19MAY2016/11:55	3.6	1.7 - 8.3	No	
		Week 16	14JUN2016/11:08	3.1	1.7 - 8.3	No	
		Week 20	13JUL2016/11:20	3.2	1.7 - 8.3	No	
		Week 24	10AUG2016/10:50	3.7	1.7 - 8.3	Yes	
		Week 28	07SEP2016/11:30	4.7	1.7 - 8.3	No	
		Week 32	05OCT2016/11:00	3.9	1.7 - 8.3	No	
		Week 36	02NOV2016/12:00	5.7	1.7 - 8.3	No	
		Week 40	30NOV2016/10:45	3.3	1.7 - 8.3	No	
		Week 44	22DEC2016/12:00	3.5	1.7 - 8.3	No	
		Week 48	25JAN2017/11:00	4.2	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	27JAN2016/11:30	342	266 - 474	Yes	0
		Day 1	23FEB2016/13:00	367	266 - 474	Yes	0
		Week 1	01MAR2016/11:30	349	266 - 474	No	0
		Week 2	09MAR2016/10:45	326	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Uric acid (umol/L)	Week 4	22MAR2016/10:15	342	266 - 474	No	0
		Week 6	05APR2016/11:47	394	266 - 474	No	0
		Week 8	20APR2016/09:15	347	266 - 474	Yes	0
		Week 12	19MAY2016/11:55	326	266 - 474	No	0
		Week 16	14JUN2016/11:08	296	266 - 474	No	0
		Week 20	13JUL2016/11:20	329	266 - 474	No	0
		Week 24	10AUG2016/10:50	307	266 - 474	Yes	0
		Week 28	07SEP2016/11:30	328	266 - 474	No	0
		Week 32	05OCT2016/11:00	383	266 - 474	No	0
		Week 36	02NOV2016/12:00	374	266 - 474	No	0
		Week 40	30NOV2016/10:45	336	266 - 474	No	0
		Week 44	22DEC2016/12:00	377	266 - 474	No	0
		Week 48	25JAN2017/11:00	374	266 - 474	No	0
301-016	Alanine Aminotransferase (IU/L)	Screening	03FEB2016/13:00	62 H	10 - 50	Yes	1
		Day 1	25FEB2016/11:50	69 H	10 - 50	No	1
		Week 1	02MAR2016/11:30	56 H	10 - 50	No	1
		Week 2	08MAR2016/11:00	51 H	10 - 50	No	1
		Week 4	24MAR2016/11:35	67 H	10 - 50	No	1
		Week 6	07APR2016/11:10	64 H	10 - 50	No	1
		Week 8	19APR2016/09:00	58 H	10 - 50	Yes	1
		Week 12	24MAY2016/11:56	83 H	10 - 50	No	1
		Week 16	14JUN2016/10:30	85 H	10 - 50	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Alanine Aminotransferase (IU/L)	Week 20	13JUL2016/11:50	69 H	10 - 50	No	1
		Week 24	28JUL2016/11:00	49	10 - 50	Yes	0
		Week 28	06SEP2016/10:10	137 H	10 - 50	No	1
		Week 32	05OCT2016/11:30	116 H	10 - 50	No	1
		Week 36	02NOV2016/11:45	70 H	10 - 50	No	1
		Week 40	29NOV2016/11:00	77 H	10 - 50	No	1
		Week 44	21DEC2016/11:30	66 H	10 - 50	No	1
		Week 48	24JAN2017/12:00	49	10 - 50	No	0
	Albumin (g/L)	Screening	03FEB2016/13:00	47	34 - 50	Yes	0
		Day 1	25FEB2016/11:50	47	34 - 50	No	0
		Week 1	02MAR2016/11:30	47	34 - 50	No	0
		Week 2	08MAR2016/11:00	46	34 - 50	No	0
		Week 4	24MAR2016/11:35	45	34 - 50	No	0
		Week 6	07APR2016/11:10	49	34 - 50	No	0
		Week 8	19APR2016/09:00	43	34 - 50	Yes	0
		Week 12	24MAY2016/11:56	43	34 - 50	No	0
		Week 16	14JUN2016/10:30	43	34 - 50	No	0
		Week 20	13JUL2016/11:50	45	34 - 50	No	0
		Week 24	28JUL2016/11:00	43	34 - 50	Yes	0
		Week 28	06SEP2016/10:10	48	34 - 50	No	0
		Week 32	05OCT2016/11:30	42	34 - 50	No	0
		Week 36	02NOV2016/11:45	45	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Albumin (g/L)	Week 40	29NOV2016/11:00	47	34 - 50	No	0
		Week 44	21DEC2016/11:30	46	34 - 50	No	0
		Week 48	24JAN2017/12:00	44	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	03FEB2016/13:00	89	40 - 129	Yes	0
		Day 1	25FEB2016/11:50	89	40 - 129	No	0
		Week 1	02MAR2016/11:30	86	40 - 129	No	0
		Week 2	08MAR2016/11:00	93	40 - 129	No	0
		Week 4	24MAR2016/11:35	84	40 - 129	No	0
		Week 6	07APR2016/11:10	97	40 - 129	No	0
		Week 8	19APR2016/09:00	80	40 - 129	Yes	0
		Week 12	24MAY2016/11:56	110	40 - 129	No	0
		Week 16	14JUN2016/10:30	99	40 - 129	No	0
		Week 20	13JUL2016/11:50	97	40 - 129	No	0
		Week 24	28JUL2016/11:00	112	40 - 129	Yes	0
		Week 28	06SEP2016/10:10	120	40 - 129	No	0
		Week 32	05OCT2016/11:30	110	40 - 129	No	0
		Week 36	02NOV2016/11:45	111	40 - 129	No	0
		Week 40	29NOV2016/11:00	104	40 - 129	No	0
		Week 44	21DEC2016/11:30	91	40 - 129	No	0
		Week 48	24JAN2017/12:00	90	40 - 129	No	0
	Amylase (IU/L)	Screening	03FEB2016/13:00	84	28 - 100	Yes	0
		Day 1	25FEB2016/11:50	88	28 - 100	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016 Amylase (IU/L)	Week 1	02MAR2016/11:30	87	28 - 100	No	0
	Week 2	08MAR2016/11:00	83	28 - 100	No	0
	Week 4	24MAR2016/11:35	113 H	28 - 100	No	1
	Week 6	07APR2016/11:10	174 H	28 - 100	No	2
	Week 8	19APR2016/09:00	116 H	28 - 100	Yes	1
	Week 12	24MAY2016/11:56	105 H	28 - 100	No	1
	Week 16	14JUN2016/10:30	87	28 - 100	No	0
	Week 20	13JUL2016/11:50	93	28 - 100	No	0
	Week 24	28JUL2016/11:00	79	28 - 100	Yes	0
	Week 28	06SEP2016/10:10	89	28 - 100	No	0
	Week 32	05OCT2016/11:30	80	28 - 100	No	0
	Week 36	02NOV2016/11:45	99	28 - 100	No	0
	Week 40	29NOV2016/11:00	92	28 - 100	No	0
	Week 44	21DEC2016/11:30	76	28 - 100	No	0
	Week 48	24JAN2017/12:00	85	28 - 100	No	0
Aspartate Aminotransferase (IU/L)	Screening	03FEB2016/13:00	33	0 - 37	Yes	0
	Day 1	25FEB2016/11:50	35	0 - 37	No	0
	Week 1	02MAR2016/11:30	34	0 - 37	No	0
	Week 2	08MAR2016/11:00	32	0 - 37	No	0
	Week 4	24MAR2016/11:35	34	0 - 37	No	0
	Week 6	07APR2016/11:10	35	0 - 37	No	0
	Week 8	19APR2016/09:00	30	0 - 37	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Aspartate Aminotransferase (IU/L)	Week 12	24MAY2016/11:56	37	0 - 37	No	0
		Week 16	14JUN2016/10:30	37	0 - 37	No	0
		Week 20	13JUL2016/11:50	32	0 - 37	No	0
		Week 24	28JUL2016/11:00	31	0 - 37	Yes	0
		Week 28	06SEP2016/10:10	68 H	0 - 37	No	1
		Week 32	05OCT2016/11:30	57 H	0 - 37	No	1
		Week 36	02NOV2016/11:45	38 H	0 - 37	No	1
		Week 40	29NOV2016/11:00	40 H	0 - 37	No	1
		Week 44	21DEC2016/11:30	41 H	0 - 37	No	1
		Week 48	24JAN2017/12:00	30	0 - 37	No	0
	Bicarbonate (mmol/L)	Screening	03FEB2016/13:00	23	22 - 29	Yes	
		Day 1	25FEB2016/11:50	24	22 - 29	No	
		Week 1	02MAR2016/11:30	24	22 - 29	No	
		Week 2	08MAR2016/11:00	22	22 - 29	No	
		Week 4	24MAR2016/11:35	25	22 - 29	No	
		Week 6	07APR2016/11:10	23	22 - 29	No	
		Week 8	19APR2016/09:00	21 L	22 - 29	Yes	
		Week 12	24MAY2016/11:56	23	22 - 29	No	
		Week 16	14JUN2016/10:30	22	22 - 29	No	
		Week 20	13JUL2016/11:50	24	22 - 29	No	
		Week 24	28JUL2016/11:00	23	22 - 29	Yes	
		Week 28	06SEP2016/10:10	22	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Bicarbonate (mmol/L)	Week 32	05OCT2016/11:30	23	22 - 29	No	
		Week 36	02NOV2016/11:45	26	22 - 29	No	
		Week 40	29NOV2016/11:00	20 L	22 - 29	No	
		Week 44	21DEC2016/11:30	25	22 - 29	No	
		Week 48	24JAN2017/12:00	22	22 - 29	No	
	Bilirubin (umol/L)	Screening	03FEB2016/13:00	7	0 - 20	Yes	0
		Day 1	25FEB2016/11:50	6	0 - 20	No	0
		Week 1	02MAR2016/11:30	9	0 - 20	No	0
		Week 2	08MAR2016/11:00	7	0 - 20	No	0
		Week 4	24MAR2016/11:35	9	0 - 20	No	0
		Week 6	07APR2016/11:10	7	0 - 20	No	0
		Week 8	19APR2016/09:00	4	0 - 20	Yes	0
		Week 12	24MAY2016/11:56	9	0 - 20	No	0
		Week 16	14JUN2016/10:30	5	0 - 20	No	0
		Week 20	13JUL2016/11:50	8	0 - 20	No	0
		Week 24	28JUL2016/11:00	7	0 - 20	Yes	0
		Week 28	06SEP2016/10:10	6	0 - 20	No	0
		Week 32	05OCT2016/11:30	6	0 - 20	No	0
		Week 36	02NOV2016/11:45	4	0 - 20	No	0
		Week 40	29NOV2016/11:00	13	0 - 20	No	0
		Week 44	21DEC2016/11:30	6	0 - 20	No	0
		Week 48	24JAN2017/12:00	5	0 - 20	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Blood Urea Nitrogen (mg/dL)	Screening	03FEB2016/13:00	13.72	4.76 - 23.24	Yes	
		Day 1	25FEB2016/11:50	12.88	4.76 - 23.24	No	
		Week 1	02MAR2016/11:30	11.76	4.76 - 23.24	No	
		Week 2	08MAR2016/11:00	8.40	4.76 - 23.24	No	
		Week 4	24MAR2016/11:35	11.20	4.76 - 23.24	No	
		Week 6	07APR2016/11:10	9.80	4.76 - 23.24	No	
		Week 8	19APR2016/09:00	10.92	4.76 - 23.24	Yes	
		Week 12	24MAY2016/11:56	7.84	4.76 - 23.24	No	
		Week 16	14JUN2016/10:30	9.80	4.76 - 23.24	No	
		Week 20	13JUL2016/11:50	14.28	4.76 - 23.24	No	
		Week 24	28JUL2016/11:00	7.28	4.76 - 23.24	Yes	
		Week 28	06SEP2016/10:10	10.36	4.76 - 23.24	No	
		Week 32	05OCT2016/11:30	10.92	4.76 - 23.24	No	
		Week 36	02NOV2016/11:45	10.64	4.76 - 23.24	No	
		Week 40	29NOV2016/11:00	12.04	4.76 - 23.24	No	
		Week 44	21DEC2016/11:30	9.52	4.76 - 23.24	No	
		Week 48	24JAN2017/12:00	9.52	4.76 - 23.24	No	
	Calcium (mmol/L)	Screening	03FEB2016/13:00	2.49	2.2 - 2.6	Yes	0
		Day 1	25FEB2016/11:50	2.37	2.2 - 2.6	No	0
		Week 1	02MAR2016/11:30	2.36	2.2 - 2.6	No	0
		Week 2	08MAR2016/11:00	2.38	2.2 - 2.6	No	0
		Week 4	24MAR2016/11:35	2.39	2.2 - 2.6	No	0
		Week 6	07APR2016/11:10	2.38	2.2 - 2.6	No	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Calcium (mmol/L)	Week 8	19APR2016/09:00	2.29	2.2 - 2.6	Yes	0
		Week 12	24MAY2016/11:56	2.38	2.2 - 2.6	No	0
		Week 16	14JUN2016/10:30	2.31	2.2 - 2.6	No	0
		Week 20	13JUL2016/11:50	2.34	2.2 - 2.6	No	0
		Week 24	28JUL2016/11:00	2.43	2.2 - 2.6	Yes	0
		Week 28	06SEP2016/10:10	2.38	2.2 - 2.6	No	0
		Week 32	05OCT2016/11:30	2.30	2.2 - 2.6	No	0
		Week 36	02NOV2016/11:45	2.36	2.2 - 2.6	No	0
		Week 40	29NOV2016/11:00	2.33	2.2 - 2.6	No	0
		Week 44	21DEC2016/11:30	2.31	2.2 - 2.6	No	0
		Week 48	24JAN2017/12:00	2.29	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	03FEB2016/13:00	102	98 - 107	Yes	
		Day 1	25FEB2016/11:50	101	98 - 107	No	
		Week 1	02MAR2016/11:30	100	98 - 107	No	
		Week 2	08MAR2016/11:00	98	98 - 107	No	
		Week 4	24MAR2016/11:35	103	98 - 107	No	
		Week 6	07APR2016/11:10	98	98 - 107	No	
		Week 8	19APR2016/09:00	106	98 - 107	Yes	
		Week 12	24MAY2016/11:56	100	98 - 107	No	
		Week 16	14JUN2016/10:30	100	98 - 107	No	
		Week 20	13JUL2016/11:50	103	98 - 107	No	
		Week 24	28JUL2016/11:00	99	98 - 107	Yes	
		Week 28	06SEP2016/10:10	99	98 - 107	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Chloride (mmol/L)	Week 32	05OCT2016/11:30	102	98 - 107	No	
		Week 36	02NOV2016/11:45	102	98 - 107	No	
		Week 40	29NOV2016/11:00	102	98 - 107	No	
		Week 44	21DEC2016/11:30	102	98 - 107	No	
		Week 48	24JAN2017/12:00	101	98 - 107	No	
	Cholesterol (mmol/L)	Screening	03FEB2016/13:00	6.0 H	0 - 4.9	Yes	1
		Day 1	25FEB2016/11:50	6.6 H	0 - 4.9	No	1
		Week 1	02MAR2016/11:30	4.9	0 - 4.9	No	0
		Week 2	08MAR2016/11:00	5.3 H	0 - 4.9	No	1
		Week 4	24MAR2016/11:35	5.2 H	0 - 4.9	No	1
		Week 6	07APR2016/11:10	4.8	0 - 4.9	No	0
		Week 8	19APR2016/09:00	4.3	0 - 4.9	Yes	0
		Week 12	24MAY2016/11:56	4.5	0 - 4.9	No	0
		Week 16	14JUN2016/10:30	4.5	0 - 4.9	No	0
		Week 20	13JUL2016/11:50	4.2	0 - 4.9	No	0
		Week 24	28JUL2016/11:00	4.7	0 - 4.9	Yes	0
		Week 28	06SEP2016/10:10	6.8 H	0 - 4.9	No	1
		Week 32	05OCT2016/11:30	5.9 H	0 - 4.9	No	1
		Week 36	02NOV2016/11:45	5.7 H	0 - 4.9	No	1
		Week 40	29NOV2016/11:00	6.8 H	0 - 4.9	No	1
		Week 44	21DEC2016/11:30	5.8 H	0 - 4.9	No	1
		Week 48	24JAN2017/12:00	5.6 H	0 - 4.9	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Creatine Kinase (IU/L)	Screening	03FEB2016/13:00	119	38 - 204	Yes	0
		Day 1	25FEB2016/11:50	91	38 - 204	No	0
		Week 1	02MAR2016/11:30	131	38 - 204	No	0
		Week 2	08MAR2016/11:00	138	38 - 204	No	0
		Week 4	24MAR2016/11:35	117	38 - 204	No	0
		Week 6	07APR2016/11:10	110	38 - 204	No	0
		Week 8	19APR2016/09:00	119	38 - 204	Yes	0
		Week 12	24MAY2016/11:56	90	38 - 204	No	0
		Week 16	14JUN2016/10:30	105	38 - 204	No	0
		Week 20	13JUL2016/11:50	87	38 - 204	No	0
		Week 24	28JUL2016/11:00	78	38 - 204	Yes	0
		Week 28	06SEP2016/10:10	115	38 - 204	No	0
		Week 32	05OCT2016/11:30	157	38 - 204	No	0
		Week 36	02NOV2016/11:45	127	38 - 204	No	0
		Week 40	29NOV2016/11:00	131	38 - 204	No	0
		Week 44	21DEC2016/11:30	192	38 - 204	No	0
		Week 48	24JAN2017/12:00	112	38 - 204	No	0
	Creatinine (umol/L)	Screening	03FEB2016/13:00	81	66 - 112	Yes	0
		Day 1	25FEB2016/11:50	83	66 - 112	No	0
		Week 1	02MAR2016/11:30	84	66 - 112	No	1
		Week 2	08MAR2016/11:00	78	66 - 112	No	0
		Week 4	24MAR2016/11:35	72	66 - 112	No	0
		Week 6	07APR2016/11:10	90	66 - 112	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016 Creatinine (umol/L)	Week 8	19APR2016/09:00	69	66 - 112	Yes	0
	Week 12	24MAY2016/11:56	73	66 - 112	No	0
	Week 16	14JUN2016/10:30	83	66 - 112	No	0
	Week 20	13JUL2016/11:50	75	66 - 112	No	0
	Week 24	28JUL2016/11:00	73	66 - 112	Yes	0
	Week 28	06SEP2016/10:10	80	66 - 112	No	0
	Week 32	05OCT2016/11:30	76	66 - 112	No	0
	Week 36	02NOV2016/11:45	68	66 - 112	No	0
	Week 40	29NOV2016/11:00	87	66 - 112	No	1
	Week 44	21DEC2016/11:30	77	66 - 112	No	0
	Week 48	24JAN2017/12:00	80	66 - 112	No	0
Direct Bilirubin (umol/L)	Screening	03FEB2016/13:00	2	0 - 5	Yes	
	Day 1	25FEB2016/11:50	2	0 - 5	No	
	Week 1	02MAR2016/11:30	3	0 - 5	No	
	Week 2	08MAR2016/11:00	2	0 - 5	No	
	Week 4	24MAR2016/11:35	3	0 - 5	No	
	Week 6	07APR2016/11:10	2	0 - 5	No	
	Week 8	19APR2016/09:00	<2	0 - 5	Yes	
	Week 12	24MAY2016/11:56	3	0 - 5	No	
	Week 16	14JUN2016/10:30	2	0 - 5	No	
	Week 20	13JUL2016/11:50	3	0 - 5	No	
	Week 24	28JUL2016/11:00	3	0 - 5	Yes	
	Week 28	06SEP2016/10:10	2	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Direct Bilirubin (umol/L)	Week 32	05OCT2016/11:30	2	0 - 5	No	
		Week 36	02NOV2016/11:45	<2	0 - 5	No	
		Week 40	29NOV2016/11:00	4	0 - 5	No	
		Week 44	21DEC2016/11:30	2	0 - 5	No	
		Week 48	24JAN2017/12:00	2	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	03FEB2016/13:00	57	10 - 71	Yes	0
		Day 1	25FEB2016/11:50	55	10 - 71	No	0
		Week 1	02MAR2016/11:30	53	10 - 71	No	0
		Week 2	08MAR2016/11:00	47	10 - 71	No	0
		Week 4	24MAR2016/11:35	37	10 - 71	No	0
		Week 6	07APR2016/11:10	38	10 - 71	No	0
		Week 8	19APR2016/09:00	30	10 - 71	Yes	0
		Week 12	24MAY2016/11:56	40	10 - 71	No	0
		Week 16	14JUN2016/10:30	30	10 - 71	No	0
		Week 20	13JUL2016/11:50	27	10 - 71	No	0
		Week 24	28JUL2016/11:00	30	10 - 71	Yes	0
		Week 28	06SEP2016/10:10	98 H	10 - 71	No	1
		Week 32	05OCT2016/11:30	73 H	10 - 71	No	1
		Week 36	02NOV2016/11:45	68	10 - 71	No	0
		Week 40	29NOV2016/11:00	63	10 - 71	No	0
		Week 44	21DEC2016/11:30	43	10 - 71	No	0
		Week 48	24JAN2017/12:00	35	10 - 71	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Globulin (g/L)	Screening	03FEB2016/13:00	30	19 - 35	Yes	
		Day 1	25FEB2016/11:50	30	19 - 35	No	
		Week 1	02MAR2016/11:30	29	19 - 35	No	
		Week 2	08MAR2016/11:00	31	19 - 35	No	
		Week 4	24MAR2016/11:35	29	19 - 35	No	
		Week 6	07APR2016/11:10	32	19 - 35	No	
		Week 8	19APR2016/09:00	28	19 - 35	Yes	
		Week 12	24MAY2016/11:56	32	19 - 35	No	
		Week 16	14JUN2016/10:30	30	19 - 35	No	
		Week 20	13JUL2016/11:50	29	19 - 35	No	
		Week 24	28JUL2016/11:00	31	19 - 35	Yes	
		Week 28	06SEP2016/10:10	34	19 - 35	No	
		Week 32	05OCT2016/11:30	29	19 - 35	No	
		Week 36	02NOV2016/11:45	32	19 - 35	No	
		Week 40	29NOV2016/11:00	31	19 - 35	No	
		Week 44	21DEC2016/11:30	27	19 - 35	No	
		Week 48	24JAN2017/12:00	28	19 - 35	No	
	Glucose (mmol/L)	Screening	03FEB2016/13:00	8.3 H	3.9 - 5.8	Yes	1
		Day 1	25FEB2016/11:50	6.1	3.5 - 7.9	No	0
		Week 1	02MAR2016/11:30	6.5	3.5 - 7.9	No	0
		Week 2	08MAR2016/11:00	7.0	3.5 - 7.9	No	0
		Week 4	24MAR2016/11:35	5.5	3.5 - 7.9	No	0
		Week 6	07APR2016/11:10	5.4	3.5 - 7.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016 Glucose (mmol/L)	Week 8	19APR2016/09:00	4.6	3.9 - 5.8	Yes	0
	Week 12	24MAY2016/11:56	5.8	3.5 - 7.9	No	0
	Week 16	14JUN2016/10:30	4.8	3.5 - 7.9	No	0
	Week 20	13JUL2016/11:50	5.4	3.5 - 7.9	No	0
	Week 24	28JUL2016/11:00	5.3	3.9 - 5.8	Yes	0
	Week 28	06SEP2016/10:10	5.3	3.5 - 7.9	No	0
	Week 32	05OCT2016/11:30	5.1	3.5 - 7.9	No	0
	Week 36	02NOV2016/11:45	4.5	3.5 - 7.9	No	0
	Week 40	29NOV2016/11:00	5.2	3.5 - 7.9	No	0
	Week 44	21DEC2016/11:30	5.8	3.5 - 7.9	No	0
	Week 48	24JAN2017/12:00	5.8	3.5 - 7.9	No	0
Indirect Bilirubin (umol/L)	Screening	03FEB2016/13:00	5	0 - 14	Yes	
	Day 1	25FEB2016/11:50	4	0 - 14	No	
	Week 1	02MAR2016/11:30	6	0 - 14	No	
	Week 2	08MAR2016/11:00	5	0 - 14	No	
	Week 4	24MAR2016/11:35	6	0 - 14	No	
	Week 6	07APR2016/11:10	5	0 - 14	No	
	Week 8	19APR2016/09:00		0 - 14	Yes	
	Week 12	24MAY2016/11:56	6	0 - 14	No	
	Week 16	14JUN2016/10:30	3	0 - 14	No	
	Week 20	13JUL2016/11:50	5	0 - 14	No	
	Week 24	28JUL2016/11:00	4	0 - 14	Yes	
	Week 28	06SEP2016/10:10	4	0 - 14	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Indirect Bilirubin (umol/L)	Week 32	05OCT2016/11:30	4	0 - 14	No
		Week 36	02NOV2016/11:45		0 - 14	No
		Week 40	29NOV2016/11:00	9	0 - 14	No
		Week 44	21DEC2016/11:30	4	0 - 14	No
		Week 48	24JAN2017/12:00	3	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	03FEB2016/13:00	194	135 - 225	Yes
		Day 1	25FEB2016/11:50	192	135 - 225	No
		Week 1	02MAR2016/11:30	183	135 - 225	No
		Week 2	08MAR2016/11:00	176	135 - 225	No
		Week 4	24MAR2016/11:35	161	135 - 225	No
		Week 6	07APR2016/11:10	189	135 - 225	No
		Week 8	19APR2016/09:00	177	135 - 225	Yes
		Week 12	24MAY2016/11:56	191	135 - 225	No
		Week 16	14JUN2016/10:30	179	135 - 225	No
		Week 20	13JUL2016/11:50	189	135 - 225	No
		Week 24	28JUL2016/11:00	208	135 - 225	Yes
		Week 28	06SEP2016/10:10	219	135 - 225	No
		Week 32	05OCT2016/11:30	193	135 - 225	No
		Week 36	02NOV2016/11:45	205	135 - 225	No
		Week 40	29NOV2016/11:00	203	135 - 225	No
		Week 44	21DEC2016/11:30	222	135 - 225	No
		Week 48	24JAN2017/12:00	214	135 - 225	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Magnesium (mmol/L)	Screening	03FEB2016/13:00	0.80	0.6 - 1	Yes	0
		Day 1	25FEB2016/11:50	0.94	0.6 - 1	No	0
		Week 1	02MAR2016/11:30	0.84	0.6 - 1	No	0
		Week 2	08MAR2016/11:00	0.82	0.6 - 1	No	0
		Week 4	24MAR2016/11:35	0.85	0.6 - 1	No	0
		Week 6	07APR2016/11:10	0.73	0.6 - 1	No	0
		Week 8	19APR2016/09:00	0.85	0.6 - 1	Yes	0
		Week 12	24MAY2016/11:56	0.81	0.6 - 1	No	0
		Week 16	14JUN2016/10:30	0.84	0.6 - 1	No	0
		Week 20	13JUL2016/11:50	0.87	0.6 - 1	No	0
		Week 24	28JUL2016/11:00	0.83	0.6 - 1	Yes	0
		Week 28	06SEP2016/10:10	0.84	0.6 - 1	No	0
		Week 32	05OCT2016/11:30	0.89	0.6 - 1	No	0
		Week 36	02NOV2016/11:45	0.81	0.6 - 1	No	0
		Week 40	29NOV2016/11:00	0.84	0.6 - 1	No	0
		Week 44	21DEC2016/11:30	0.81	0.6 - 1	No	0
		Week 48	24JAN2017/12:00	0.90	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	03FEB2016/13:00	0.53 L	0.87 - 1.45	Yes	3
		Day 1	25FEB2016/11:50	0.89	0.87 - 1.45	No	0
		Week 1	02MAR2016/11:30	0.81 L	0.87 - 1.45	No	1
		Week 2	08MAR2016/11:00	0.59 L	0.87 - 1.45	No	3
		Week 4	24MAR2016/11:35	0.82 L	0.87 - 1.45	No	1
		Week 6	07APR2016/11:10	1.26	0.87 - 1.45	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Phosphate (mmol/L)	Week 8	19APR2016/09:00	0.93	0.87 - 1.45	Yes	0
		Week 12	24MAY2016/11:56	0.87	0.87 - 1.45	No	0
		Week 16	14JUN2016/10:30	0.78 L	0.87 - 1.45	No	2
		Week 20	13JUL2016/11:50	0.70 L	0.87 - 1.45	No	2
		Week 24	28JUL2016/11:00	1.24	0.87 - 1.45	Yes	0
		Week 28	06SEP2016/10:10	1.13	0.87 - 1.45	No	0
		Week 32	05OCT2016/11:30	0.70 L	0.87 - 1.45	No	2
		Week 36	02NOV2016/11:45	0.56 L	0.87 - 1.45	No	3
		Week 40	29NOV2016/11:00	0.93	0.87 - 1.45	No	0
		Week 44	21DEC2016/11:30	1.04	0.87 - 1.45	No	0
		Week 48	24JAN2017/12:00	0.92	0.87 - 1.45	No	0
	Potassium (mmol/L)	Screening	03FEB2016/13:00	4.2	3.5 - 5.1	Yes	0
		Day 1	25FEB2016/11:50	4.6	3.5 - 5.1	No	0
		Week 1	02MAR2016/11:30	4.3	3.5 - 5.1	No	0
		Week 2	08MAR2016/11:00	4.2	3.5 - 5.1	No	0
		Week 4	24MAR2016/11:35	4.5	3.5 - 5.1	No	0
		Week 6	07APR2016/11:10	4.0	3.5 - 5.1	No	0
		Week 8	19APR2016/09:00	4.6	3.5 - 5.1	Yes	0
		Week 12	24MAY2016/11:56	4.0	3.5 - 5.1	No	0
		Week 16	14JUN2016/10:30	3.5	3.5 - 5.1	No	0
		Week 20	13JUL2016/11:50	4.3	3.5 - 5.1	No	0
		Week 24	28JUL2016/11:00	4.4	3.5 - 5.1	Yes	0
		Week 28	06SEP2016/10:10	3.9	3.5 - 5.1	No	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Potassium (mmol/L)	Week 32	05OCT2016/11:30	4.4	3.5 - 5.1	No	0
		Week 36	02NOV2016/11:45	4.1	3.5 - 5.1	No	0
		Week 40	29NOV2016/11:00	4.9	3.5 - 5.1	No	0
		Week 44	21DEC2016/11:30	4.1	3.5 - 5.1	No	0
		Week 48	24JAN2017/12:00	4.5	3.5 - 5.1	No	0
	Protein (g/L)	Screening	03FEB2016/13:00	77	63 - 83	Yes	
		Day 1	25FEB2016/11:50	77	63 - 83	No	
		Week 1	02MAR2016/11:30	76	63 - 83	No	
		Week 2	08MAR2016/11:00	77	63 - 83	No	
		Week 4	24MAR2016/11:35	74	63 - 83	No	
		Week 6	07APR2016/11:10	81	63 - 83	No	
		Week 8	19APR2016/09:00	71	63 - 83	Yes	
		Week 12	24MAY2016/11:56	75	63 - 83	No	
		Week 16	14JUN2016/10:30	73	63 - 83	No	
		Week 20	13JUL2016/11:50	74	63 - 83	No	
		Week 24	28JUL2016/11:00	74	63 - 83	Yes	
		Week 28	06SEP2016/10:10	82	63 - 83	No	
		Week 32	05OCT2016/11:30	71	63 - 83	No	
		Week 36	02NOV2016/11:45	77	63 - 83	No	
		Week 40	29NOV2016/11:00	78	63 - 83	No	
		Week 44	21DEC2016/11:30	73	63 - 83	No	
		Week 48	24JAN2017/12:00	72	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Sodium (mmol/L)	Screening	03FEB2016/13:00	143	135 - 145	Yes	0
		Day 1	25FEB2016/11:50	141	135 - 145	No	0
		Week 1	02MAR2016/11:30	140	135 - 145	No	0
		Week 2	08MAR2016/11:00	138	135 - 145	No	0
		Week 4	24MAR2016/11:35	143	135 - 145	No	0
		Week 6	07APR2016/11:10	141	135 - 145	No	0
		Week 8	19APR2016/09:00	141	135 - 145	Yes	0
		Week 12	24MAY2016/11:56	141	135 - 145	No	0
		Week 16	14JUN2016/10:30	140	135 - 145	No	0
		Week 20	13JUL2016/11:50	141	135 - 145	No	0
		Week 24	28JUL2016/11:00	139	135 - 145	Yes	0
		Week 28	06SEP2016/10:10	140	135 - 145	No	0
		Week 32	05OCT2016/11:30	141	135 - 145	No	0
		Week 36	02NOV2016/11:45	142	135 - 145	No	0
		Week 40	29NOV2016/11:00	144	135 - 145	No	0
		Week 44	21DEC2016/11:30	142	135 - 145	No	0
		Week 48	24JAN2017/12:00	143	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	03FEB2016/13:00	1.76	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	03FEB2016/13:00	107	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	03FEB2016/13:00	1.9	0 - 2.2	Yes	1
		Day 1	25FEB2016/11:50	1.2	0 - 2.2	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Triglycerides (mmol/L)	Week 1	02MAR2016/11:30	1.1	0 - 2.2	No	0
		Week 2	08MAR2016/11:00	1.5	0 - 2.2	No	0
		Week 4	24MAR2016/11:35	1.2	0 - 2.2	No	0
		Week 6	07APR2016/11:10	1.2	0 - 2.2	No	0
		Week 8	19APR2016/09:00	1.2	0 - 2.2	Yes	0
		Week 12	24MAY2016/11:56	0.8	0 - 2.2	No	0
		Week 16	14JUN2016/10:30	0.9	0 - 2.2	No	0
		Week 20	13JUL2016/11:50	0.8	0 - 2.2	No	0
		Week 24	28JUL2016/11:00	0.8	0 - 2.2	Yes	0
		Week 28	06SEP2016/10:10	1.0	0 - 2.2	No	0
		Week 32	05OCT2016/11:30	0.8	0 - 2.2	No	0
		Week 36	02NOV2016/11:45	0.9	0 - 2.2	No	0
		Week 40	29NOV2016/11:00	0.5	0 - 2.2	No	0
		Week 44	21DEC2016/11:30	1.0	0 - 2.2	No	0
		Week 48	24JAN2017/12:00	0.8	0 - 2.2	No	0
	Triiodothyronine (nmol/L)	Screening	03FEB2016/13:00	2.5	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	03FEB2016/13:00	4.9	1.7 - 8.3	Yes	
		Day 1	25FEB2016/11:50	4.6	1.7 - 8.3	No	
		Week 1	02MAR2016/11:30	4.2	1.7 - 8.3	No	
		Week 2	08MAR2016/11:00	3.0	1.7 - 8.3	No	
		Week 4	24MAR2016/11:35	4.0	1.7 - 8.3	No	
		Week 6	07APR2016/11:10	3.5	1.7 - 8.3	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Urea (mmol/L)	Week 8	19APR2016/09:00	3.9	1.7 - 8.3	Yes	
		Week 12	24MAY2016/11:56	2.8	1.7 - 8.3	No	
		Week 16	14JUN2016/10:30	3.5	1.7 - 8.3	No	
		Week 20	13JUL2016/11:50	5.1	1.7 - 8.3	No	
		Week 24	28JUL2016/11:00	2.6	1.7 - 8.3	Yes	
		Week 28	06SEP2016/10:10	3.7	1.7 - 8.3	No	
		Week 32	05OCT2016/11:30	3.9	1.7 - 8.3	No	
		Week 36	02NOV2016/11:45	3.8	1.7 - 8.3	No	
		Week 40	29NOV2016/11:00	4.3	1.7 - 8.3	No	
		Week 44	21DEC2016/11:30	3.4	1.7 - 8.3	No	
		Week 48	24JAN2017/12:00	3.4	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	03FEB2016/13:00	300	266 - 474	Yes	0
		Day 1	25FEB2016/11:50	347	266 - 474	No	0
		Week 1	02MAR2016/11:30	326	266 - 474	No	0
		Week 2	08MAR2016/11:00	334	266 - 474	No	0
		Week 4	24MAR2016/11:35	298	266 - 474	No	0
		Week 6	07APR2016/11:10	348	266 - 474	No	0
		Week 8	19APR2016/09:00	220 L	266 - 474	Yes	0
		Week 12	24MAY2016/11:56	283	266 - 474	No	0
		Week 16	14JUN2016/10:30	363	266 - 474	No	0
		Week 20	13JUL2016/11:50	290	266 - 474	No	0
		Week 24	28JUL2016/11:00	258 L	266 - 474	Yes	0
		Week 28	06SEP2016/10:10	342	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-016	Uric acid (umol/L)	Week 32	05OCT2016/11:30	352	266 - 474	No	0
		Week 36	02NOV2016/11:45	326	266 - 474	No	0
		Week 40	29NOV2016/11:00	336	266 - 474	No	0
		Week 44	21DEC2016/11:30	352	266 - 474	No	0
		Week 48	24JAN2017/12:00	278	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Alanine Aminotransferase (IU/L)	Screening	02FEB2016/10:50	119 H	10 - 50	Yes	1
		Day 1	23FEB2016/13:40	110 H	10 - 50	Yes	1
		Week 1	03MAR2016/12:00	146 H	10 - 50	No	1
		Week 2	08MAR2016/10:10	126 H	10 - 50	No	1
		Week 4	23MAR2016/11:32	132 H	10 - 50	No	1
		Week 6	06APR2016/11:45	157 H	10 - 50	No	2
		Week 8	20APR2016/09:00	146 H	10 - 50	Yes	1
		Week 12	17MAY2016/11:55	103 H	10 - 50	No	1
		Week 16	16JUN2016/12:50	61 H	10 - 50	No	1
		Week 20	14JUL2016/11:50	48	10 - 50	No	0
		Week 24	10AUG2016/10:20	40	10 - 50	Yes	0
		Week 28	07SEP2016/09:45	128 H	10 - 50	No	1
		Week 40	30NOV2016/09:50	173 H	10 - 50	No	2
		Week 44	28DEC2016/11:00	172 H	10 - 50	No	2
		Week 48	26JAN2017/12:45	103 H	10 - 50	No	1
	Albumin (g/L)	Screening	02FEB2016/10:50	41	34 - 50	Yes	0
		Day 1	23FEB2016/13:40	41	34 - 50	Yes	0
		Week 1	03MAR2016/12:00	40	34 - 50	No	0
		Week 2	08MAR2016/10:10	40	34 - 50	No	0
		Week 4	23MAR2016/11:32	41	34 - 50	No	0
		Week 6	06APR2016/11:45	39	34 - 50	No	0
		Week 8	20APR2016/09:00	41	34 - 50	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Albumin (g/L)	Week 12	17MAY2016/11:55	41	34 - 50	No	0
		Week 16	16JUN2016/12:50	38	34 - 50	No	0
		Week 20	14JUL2016/11:50	40	34 - 50	No	0
		Week 24	10AUG2016/10:20	38	34 - 50	Yes	0
		Week 28	07SEP2016/09:45	40	34 - 50	No	0
		Week 40	30NOV2016/09:50	44	34 - 50	No	0
		Week 44	28DEC2016/11:00	43	34 - 50	No	0
		Week 48	26JAN2017/12:45	44	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	02FEB2016/10:50	159 H	40 - 129	Yes	1
		Day 1	23FEB2016/13:40	143 H	40 - 129	Yes	1
		Week 1	03MAR2016/12:00	131 H	40 - 129	No	1
		Week 2	08MAR2016/10:10	132 H	40 - 129	No	1
		Week 4	23MAR2016/11:32	158 H	40 - 129	No	1
		Week 6	06APR2016/11:45	154 H	40 - 129	No	1
		Week 8	20APR2016/09:00	169 H	40 - 129	Yes	1
		Week 12	17MAY2016/11:55	235 H	40 - 129	No	1
		Week 16	16JUN2016/12:50	223 H	40 - 129	No	1
		Week 20	14JUL2016/11:50	247 H	40 - 129	No	1
		Week 24	10AUG2016/10:20	248 H	40 - 129	Yes	1
		Week 28	07SEP2016/09:45	242 H	40 - 129	No	1
		Week 40	30NOV2016/09:50	216 H	40 - 129	No	1
		Week 44	28DEC2016/11:00	201 H	40 - 129	No	1
		Week 48	26JAN2017/12:45	191 H	40 - 129	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Amylase (IU/L)	Screening	02FEB2016/10:50	91	28 - 100	Yes	0
		Day 1	23FEB2016/13:40	87	28 - 100	Yes	0
		Week 1	03MAR2016/12:00	74	28 - 100	No	0
		Week 2	08MAR2016/10:10	81	28 - 100	No	0
		Week 4	23MAR2016/11:32	115 H	28 - 100	No	1
		Week 6	06APR2016/11:45	86	28 - 100	No	0
		Week 8	20APR2016/09:00	86	28 - 100	Yes	0
		Week 12	17MAY2016/11:55	86	28 - 100	No	0
		Week 16	16JUN2016/12:50	89	28 - 100	No	0
		Week 20	14JUL2016/11:50	96	28 - 100	No	0
		Week 24	10AUG2016/10:20	94	28 - 100	Yes	0
		Week 28	07SEP2016/09:45	112 H	28 - 100	No	1
		Week 40	30NOV2016/09:50	125 H	28 - 100	No	1
		Week 44	28DEC2016/11:00	125 H	28 - 100	No	1
		Week 48	26JAN2017/12:45	134 H	28 - 100	No	1
	Aspartate Aminotransferase (IU/L)	Screening	02FEB2016/10:50	40 H	0 - 37	Yes	1
		Day 1	23FEB2016/13:40	46 H	0 - 37	Yes	1
		Week 1	03MAR2016/12:00	56 H	0 - 37	No	1
		Week 2	08MAR2016/10:10	46 H	0 - 37	No	1
		Week 4	23MAR2016/11:32	50 H	0 - 37	No	1
		Week 6	06APR2016/11:45	58 H	0 - 37	No	1
		Week 8	20APR2016/09:00	62 H	0 - 37	Yes	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Aspartate Aminotransferase (IU/L)	Week 12	17MAY2016/11:55	47 H	0 - 37	No	1
		Week 16	16JUN2016/12:50	37	0 - 37	No	0
		Week 20	14JUL2016/11:50	27	0 - 37	No	0
		Week 24	10AUG2016/10:20	27	0 - 37	Yes	0
		Week 28	07SEP2016/09:45	64 H	0 - 37	No	1
		Week 40	30NOV2016/09:50	68 H	0 - 37	No	1
		Week 44	28DEC2016/11:00	67 H	0 - 37	No	1
		Week 48	26JAN2017/12:45	37	0 - 37	No	0
	Bicarbonate (mmol/L)	Screening	02FEB2016/10:50	27	22 - 29	Yes	
		Day 1	23FEB2016/13:40	25	22 - 29	Yes	
		Week 1	03MAR2016/12:00	27	22 - 29	No	
		Week 2	08MAR2016/10:10	25	22 - 29	No	
		Week 4	23MAR2016/11:32	21 L	22 - 29	No	
		Week 6	06APR2016/11:45	23	22 - 29	No	
		Week 8	20APR2016/09:00	23	22 - 29	Yes	
		Week 12	17MAY2016/11:55	27	22 - 29	No	
		Week 16	16JUN2016/12:50	20 L	22 - 29	No	
		Week 20	14JUL2016/11:50	26	22 - 29	No	
		Week 24	10AUG2016/10:20	26	22 - 29	Yes	
		Week 28	07SEP2016/09:45	26	22 - 29	No	
		Week 40	30NOV2016/09:50	23	22 - 29	No	
		Week 44	28DEC2016/11:00	25	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Bicarbonate (mmol/L)	Week 48	26JAN2017/12:45	26	22 - 29	No	
	Bilirubin (umol/L)	Screening	02FEB2016/10:50	6	0 - 20	Yes	0
		Day 1	23FEB2016/13:40	11	0 - 20	Yes	0
		Week 1	03MAR2016/12:00	10	0 - 20	No	0
		Week 2	08MAR2016/10:10	10	0 - 20	No	0
		Week 4	23MAR2016/11:32	10	0 - 20	No	0
		Week 6	06APR2016/11:45	8	0 - 20	No	0
		Week 8	20APR2016/09:00	10	0 - 20	Yes	0
		Week 12	17MAY2016/11:55	9	0 - 20	No	0
		Week 16	16JUN2016/12:50	8	0 - 20	No	0
		Week 20	14JUL2016/11:50	7	0 - 20	No	0
		Week 24	10AUG2016/10:20	7	0 - 20	Yes	0
		Week 28	07SEP2016/09:45	7	0 - 20	No	0
		Week 40	30NOV2016/09:50	7	0 - 20	No	0
		Week 44	28DEC2016/11:00	11	0 - 20	No	0
		Week 48	26JAN2017/12:45	6	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	02FEB2016/10:50	7.00	4.76 - 23.24	Yes	
		Day 1	23FEB2016/13:40	7.00	4.76 - 23.24	Yes	
		Week 1	03MAR2016/12:00	8.96	4.76 - 23.24	No	
		Week 2	08MAR2016/10:10	10.36	4.76 - 23.24	No	
		Week 4	23MAR2016/11:32	9.24	4.76 - 23.24	No	
		Week 6	06APR2016/11:45	15.40	4.76 - 23.24	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Blood Urea Nitrogen (mg/dL)	Week 8	20APR2016/09:00	20.72	4.76 - 23.24	Yes	
		Week 12	17MAY2016/11:55	16.52	4.76 - 23.24	No	
		Week 16	16JUN2016/12:50	19.04	4.76 - 23.24	No	
		Week 20	14JUL2016/11:50	31.08 H	4.76 - 23.24	No	
		Week 24	10AUG2016/10:20	20.72	4.76 - 23.24	Yes	
		Week 28	07SEP2016/09:45	15.68	4.76 - 23.24	No	
		Week 40	30NOV2016/09:50	24.08 H	4.76 - 23.24	No	
		Week 44	28DEC2016/11:00	17.64	4.76 - 23.24	No	
		Week 48	26JAN2017/12:45	16.52	4.76 - 23.24	No	
	Calcium (mmol/L)	Screening	02FEB2016/10:50	2.24	2.2 - 2.6	Yes	0
		Day 1	23FEB2016/13:40	2.19 L	2.2 - 2.6	Yes	1
		Week 1	03MAR2016/12:00	2.29	2.2 - 2.6	No	0
		Week 2	08MAR2016/10:10	2.22	2.2 - 2.6	No	0
		Week 4	23MAR2016/11:32	2.22	2.2 - 2.6	No	0
		Week 6	06APR2016/11:45	2.17 L	2.2 - 2.6	No	1
		Week 8	20APR2016/09:00	2.23	2.2 - 2.6	Yes	0
		Week 12	17MAY2016/11:55	2.20	2.2 - 2.6	No	0
		Week 16	16JUN2016/12:50	2.15 L	2.2 - 2.6	No	1
		Week 20	14JUL2016/11:50	2.22	2.2 - 2.6	No	0
		Week 24	10AUG2016/10:20	2.13 L	2.2 - 2.6	Yes	1
		Week 28	07SEP2016/09:45	2.19 L	2.2 - 2.6	No	1
		Week 40	30NOV2016/09:50	2.23	2.2 - 2.6	No	0
		Week 44	28DEC2016/11:00	2.20	2.2 - 2.6	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Calcium (mmol/L)	Week 48	26JAN2017/12:45	2.32	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	02FEB2016/10:50	102	98 - 107	Yes	
		Day 1	23FEB2016/13:40	100	98 - 107	Yes	
		Week 1	03MAR2016/12:00	101	98 - 107	No	
		Week 2	08MAR2016/10:10	102	98 - 107	No	
		Week 4	23MAR2016/11:32	104	98 - 107	No	
		Week 6	06APR2016/11:45	105	98 - 107	No	
		Week 8	20APR2016/09:00	101	98 - 107	Yes	
		Week 12	17MAY2016/11:55	101	98 - 107	No	
		Week 16	16JUN2016/12:50	102	98 - 107	No	
		Week 20	14JUL2016/11:50	101	98 - 107	No	
		Week 24	10AUG2016/10:20	104	98 - 107	Yes	
		Week 28	07SEP2016/09:45	103	98 - 107	No	
		Week 40	30NOV2016/09:50	99	98 - 107	No	
		Week 44	28DEC2016/11:00	102	98 - 107	No	
		Week 48	26JAN2017/12:45	104	98 - 107	No	
	Cholesterol (mmol/L)	Screening	02FEB2016/10:50	4.4	0 - 4.9	Yes	0
		Day 1	23FEB2016/13:40	4.2	0 - 4.9	Yes	0
		Week 1	03MAR2016/12:00	2.8	0 - 4.9	No	0
		Week 2	08MAR2016/10:10	2.6	0 - 4.9	No	0
		Week 4	23MAR2016/11:32	2.8	0 - 4.9	No	0
		Week 6	06APR2016/11:45	2.8	0 - 4.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Cholesterol (mmol/L)	Week 8	20APR2016/09:00	2.6	0 - 4.9	Yes	0
		Week 12	17MAY2016/11:55	2.8	0 - 4.9	No	0
		Week 16	16JUN2016/12:50	2.5	0 - 4.9	No	0
		Week 20	14JUL2016/11:50	2.4	0 - 4.9	No	0
		Week 24	10AUG2016/10:20	2.6	0 - 4.9	Yes	0
		Week 28	07SEP2016/09:45	4.0	0 - 4.9	No	0
		Week 40	30NOV2016/09:50	4.2	0 - 4.9	No	0
		Week 44	28DEC2016/11:00	4.6	0 - 4.9	No	0
		Week 48	26JAN2017/12:45	4.5	0 - 4.9	No	0
	Creatine Kinase (IU/L)	Screening	02FEB2016/10:50	87	38 - 204	Yes	0
		Day 1	23FEB2016/13:40	114	38 - 204	Yes	0
		Week 1	03MAR2016/12:00	94	38 - 204	No	0
		Week 2	08MAR2016/10:10	109	38 - 204	No	0
		Week 4	23MAR2016/11:32	115	38 - 204	No	0
		Week 6	06APR2016/11:45	206 H	38 - 204	No	1
		Week 8	20APR2016/09:00	255 H	38 - 204	Yes	1
		Week 12	17MAY2016/11:55	95	38 - 204	No	0
		Week 16	16JUN2016/12:50	87	38 - 204	No	0
		Week 20	14JUL2016/11:50	75	38 - 204	No	0
		Week 24	10AUG2016/10:20	107	38 - 204	Yes	0
		Week 28	07SEP2016/09:45	72	38 - 204	No	0
		Week 40	30NOV2016/09:50	108	38 - 204	No	0
		Week 44	28DEC2016/11:00	84	38 - 204	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Creatine Kinase (IU/L)	Week 48	26JAN2017/12:45	78	38 - 204	No	0
	Creatinine (umol/L)	Screening	02FEB2016/10:50	67	66 - 112	Yes	0
		Day 1	23FEB2016/13:40	70	66 - 112	Yes	0
		Week 1	03MAR2016/12:00	84	66 - 112	No	1
		Week 2	08MAR2016/10:10	72	66 - 112	No	1
		Week 4	23MAR2016/11:32	75	66 - 112	No	1
		Week 6	06APR2016/11:45	73	66 - 112	No	1
		Week 8	20APR2016/09:00	108	66 - 112	Yes	2
		Week 12	17MAY2016/11:55	102	66 - 112	No	1
		Week 16	16JUN2016/12:50	105	66 - 112	No	1
		Week 20	14JUL2016/11:50	159 H	66 - 112	No	2
		Week 24	10AUG2016/10:20	123 H	66 - 112	Yes	2
		Week 28	07SEP2016/09:45	113 H	66 - 112	No	2
		Week 40	30NOV2016/09:50	115 H	66 - 112	No	2
		Week 44	28DEC2016/11:00	116 H	66 - 112	No	2
		Week 48	26JAN2017/12:45	117 H	66 - 112	No	2
	Direct Bilirubin (umol/L)	Screening	02FEB2016/10:50	2	0 - 5	Yes	
		Day 1	23FEB2016/13:40	4	0 - 5	Yes	
		Week 1	03MAR2016/12:00	4	0 - 5	No	
		Week 2	08MAR2016/10:10	5	0 - 5	No	
		Week 4	23MAR2016/11:32	5	0 - 5	No	
		Week 6	06APR2016/11:45	4	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Direct Bilirubin (umol/L)	Week 8	20APR2016/09:00	5	0 - 5	Yes	
		Week 12	17MAY2016/11:55	4	0 - 5	No	
		Week 16	16JUN2016/12:50	4	0 - 5	No	
		Week 20	14JUL2016/11:50	4	0 - 5	No	
		Week 24	10AUG2016/10:20	4	0 - 5	Yes	
		Week 28	07SEP2016/09:45	3	0 - 5	No	
		Week 40	30NOV2016/09:50	3	0 - 5	No	
		Week 44	28DEC2016/11:00	5	0 - 5	No	
		Week 48	26JAN2017/12:45	3	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	02FEB2016/10:50	35	10 - 71	Yes	0
		Day 1	23FEB2016/13:40	33	10 - 71	Yes	0
		Week 1	03MAR2016/12:00	34	10 - 71	No	0
		Week 2	08MAR2016/10:10	29	10 - 71	No	0
		Week 4	23MAR2016/11:32	25	10 - 71	No	0
		Week 6	06APR2016/11:45	22	10 - 71	No	0
		Week 8	20APR2016/09:00	20	10 - 71	Yes	0
		Week 12	17MAY2016/11:55	23	10 - 71	No	0
		Week 16	16JUN2016/12:50	17	10 - 71	No	0
		Week 20	14JUL2016/11:50	17	10 - 71	No	0
		Week 24	10AUG2016/10:20	21	10 - 71	Yes	0
		Week 28	07SEP2016/09:45	25	10 - 71	No	0
		Week 40	30NOV2016/09:50	80 H	10 - 71	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Gamma Glutamyl Transferase (IU/L)	Week 44	28DEC2016/11:00	81 H	10 - 71	No	1
		Week 48	26JAN2017/12:45	54	10 - 71	No	0
	Globulin (g/L)	Screening	02FEB2016/10:50	28	19 - 35	Yes	
		Day 1	23FEB2016/13:40	24	19 - 35	Yes	
		Week 1	03MAR2016/12:00	27	19 - 35	No	
		Week 2	08MAR2016/10:10	26	19 - 35	No	
		Week 4	23MAR2016/11:32	24	19 - 35	No	
		Week 6	06APR2016/11:45	25	19 - 35	No	
		Week 8	20APR2016/09:00	28	19 - 35	Yes	
		Week 12	17MAY2016/11:55	28	19 - 35	No	
		Week 16	16JUN2016/12:50	25	19 - 35	No	
		Week 20	14JUL2016/11:50	25	19 - 35	No	
		Week 24	10AUG2016/10:20	22	19 - 35	Yes	
		Week 28	07SEP2016/09:45	27	19 - 35	No	
		Week 40	30NOV2016/09:50	25	19 - 35	No	
		Week 44	28DEC2016/11:00	24	19 - 35	No	
		Week 48	26JAN2017/12:45	30	19 - 35	No	
	Glucose (mmol/L)	Screening	02FEB2016/10:50	7.8 H	3.9 - 5.8	Yes	1
		Day 1	23FEB2016/13:40	15.8 H	3.9 - 5.8	Yes	3
		Week 1	03MAR2016/12:00	6.2	3.5 - 7.9	No	0
		Week 2	08MAR2016/10:10	5.6	3.5 - 7.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Glucose (mmol/L)	Week 4	23MAR2016/11:32	5.4	3.5 - 7.9	No	0
		Week 6	06APR2016/11:45	5.2	3.5 - 7.9	No	0
		Week 8	20APR2016/09:00	5.4	3.9 - 5.8	Yes	0
		Week 12	17MAY2016/11:55	4.0	3.5 - 7.9	No	0
		Week 16	16JUN2016/12:50	8.0 H	3.5 - 7.9	No	1
		Week 20	14JUL2016/11:50	7.9	3.5 - 7.9	No	0
		Week 24	10AUG2016/10:20	4.1	3.9 - 5.8	Yes	0
		Week 28	07SEP2016/09:45	5.7	3.5 - 7.9	No	0
		Week 40	30NOV2016/09:50	8.2 H	3.5 - 7.9	No	1
		Week 44	28DEC2016/11:00	8.2 H	3.5 - 7.9	No	1
		Week 48	26JAN2017/12:45	7.3	3.5 - 7.9	No	0
	Indirect Bilirubin (umol/L)	Screening	02FEB2016/10:50	4	0 - 14	Yes	
		Day 1	23FEB2016/13:40	7	0 - 14	Yes	
		Week 1	03MAR2016/12:00	6	0 - 14	No	
		Week 2	08MAR2016/10:10	5	0 - 14	No	
		Week 4	23MAR2016/11:32	5	0 - 14	No	
		Week 6	06APR2016/11:45	4	0 - 14	No	
		Week 8	20APR2016/09:00	5	0 - 14	Yes	
		Week 12	17MAY2016/11:55	5	0 - 14	No	
		Week 16	16JUN2016/12:50	4	0 - 14	No	
		Week 20	14JUL2016/11:50	3	0 - 14	No	
		Week 24	10AUG2016/10:20	3	0 - 14	Yes	
		Week 28	07SEP2016/09:45	4	0 - 14	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Indirect Bilirubin (umol/L)	Week 40	30NOV2016/09:50	4	0 - 14	No	
		Week 44	28DEC2016/11:00	6	0 - 14	No	
		Week 48	26JAN2017/12:45	3	0 - 14	No	
	Lactate Dehydrogenase (IU/L)	Screening	02FEB2016/10:50	217	135 - 225	Yes	
		Day 1	23FEB2016/13:40	194	135 - 225	Yes	
		Week 1	03MAR2016/12:00	183	135 - 225	No	
		Week 2	08MAR2016/10:10	175	135 - 225	No	
		Week 4	23MAR2016/11:32	190	135 - 225	No	
		Week 6	06APR2016/11:45	175	135 - 225	No	
		Week 8	20APR2016/09:00	195	135 - 225	Yes	
		Week 12	17MAY2016/11:55	192	135 - 225	No	
		Week 16	16JUN2016/12:50	160	135 - 225	No	
		Week 20	14JUL2016/11:50	148	135 - 225	No	
		Week 24	10AUG2016/10:20	168	135 - 225	Yes	
		Week 28	07SEP2016/09:45	201	135 - 225	No	
		Week 40	30NOV2016/09:50	225	135 - 225	No	
		Week 44	28DEC2016/11:00	203	135 - 225	No	
		Week 48	26JAN2017/12:45	214	135 - 225	No	
	Magnesium (mmol/L)	Screening	02FEB2016/10:50	0.83	0.6 - 1	Yes	0
		Day 1	23FEB2016/13:40	0.85	0.6 - 1	Yes	0
		Week 1	03MAR2016/12:00	0.84	0.6 - 1	No	0
		Week 2	08MAR2016/10:10	0.84	0.6 - 1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Magnesium (mmol/L)	Week 4	23MAR2016/11:32	0.91	0.6 - 1	No	0
		Week 6	06APR2016/11:45	0.94	0.6 - 1	No	0
		Week 8	20APR2016/09:00	0.85	0.6 - 1	Yes	0
		Week 12	17MAY2016/11:55	0.76	0.6 - 1	No	0
		Week 16	16JUN2016/12:50	0.82	0.6 - 1	No	0
		Week 20	14JUL2016/11:50	0.89	0.6 - 1	No	0
		Week 24	10AUG2016/10:20	0.82	0.6 - 1	Yes	0
		Week 28	07SEP2016/09:45	0.89	0.6 - 1	No	0
		Week 40	30NOV2016/09:50	0.84	0.6 - 1	No	0
		Week 44	28DEC2016/11:00	0.83	0.6 - 1	No	0
		Week 48	26JAN2017/12:45	0.84	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	02FEB2016/10:50	0.93	0.87 - 1.45	Yes	0
		Day 1	23FEB2016/13:40	0.63 L	0.87 - 1.45	Yes	2
		Week 1	03MAR2016/12:00	0.60 L	0.87 - 1.45	No	2
		Week 2	08MAR2016/10:10	0.75 L	0.87 - 1.45	No	2
		Week 4	23MAR2016/11:32	0.74 L	0.87 - 1.45	No	2
		Week 6	06APR2016/11:45	0.86 L	0.87 - 1.45	No	1
		Week 8	20APR2016/09:00	0.91	0.87 - 1.45	Yes	0
		Week 12	17MAY2016/11:55	0.88	0.87 - 1.45	No	0
		Week 16	16JUN2016/12:50	0.67 L	0.87 - 1.45	No	2
		Week 20	14JUL2016/11:50	0.86 L	0.87 - 1.45	No	1
		Week 24	10AUG2016/10:20	1.03	0.87 - 1.45	Yes	0
		Week 28	07SEP2016/09:45	1.10	0.87 - 1.45	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Phosphate (mmol/L)	Week 40	30NOV2016/09:50	0.81 L	0.87 - 1.45	No	1
		Week 44	28DEC2016/11:00	0.92	0.87 - 1.45	No	0
		Week 48	26JAN2017/12:45	0.89	0.87 - 1.45	No	0
	Potassium (mmol/L)	Screening	02FEB2016/10:50	4.6	3.5 - 5.1	Yes	0
		Day 1	23FEB2016/13:40	4.0	3.5 - 5.1	Yes	0
		Week 1	03MAR2016/12:00	4.2	3.5 - 5.1	No	0
		Week 2	08MAR2016/10:10	3.8	3.5 - 5.1	No	0
		Week 4	23MAR2016/11:32	4.2	3.5 - 5.1	No	0
		Week 6	06APR2016/11:45	3.8	3.5 - 5.1	No	0
		Week 8	20APR2016/09:00	3.5	3.5 - 5.1	Yes	0
		Week 12	17MAY2016/11:55	3.4 L	3.5 - 5.1	No	1
		Week 16	16JUN2016/12:50	3.7	3.5 - 5.1	No	0
		Week 20	14JUL2016/11:50	3.5	3.5 - 5.1	No	0
		Week 24	10AUG2016/10:20	4.2	3.5 - 5.1	Yes	0
		Week 28	07SEP2016/09:45	4.3	3.5 - 5.1	No	0
		Week 40	30NOV2016/09:50	4.3	3.5 - 5.1	No	0
		Week 44	28DEC2016/11:00	4.2	3.5 - 5.1	No	0
		Week 48	26JAN2017/12:45	4.7	3.5 - 5.1	No	0
	Protein (g/L)	Screening	02FEB2016/10:50	69	63 - 83	Yes	
		Day 1	23FEB2016/13:40	65	63 - 83	Yes	
		Week 1	03MAR2016/12:00	67	63 - 83	No	
		Week 2	08MAR2016/10:10	66	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Protein (g/L)	Week 4	23MAR2016/11:32	65	63 - 83	No	
		Week 6	06APR2016/11:45	64	63 - 83	No	
		Week 8	20APR2016/09:00	69	63 - 83	Yes	
		Week 12	17MAY2016/11:55	69	63 - 83	No	
		Week 16	16JUN2016/12:50	63	63 - 83	No	
		Week 20	14JUL2016/11:50	65	63 - 83	No	
		Week 24	10AUG2016/10:20	60 L	63 - 83	Yes	
		Week 28	07SEP2016/09:45	67	63 - 83	No	
		Week 40	30NOV2016/09:50	69	63 - 83	No	
		Week 44	28DEC2016/11:00	67	63 - 83	No	
		Week 48	26JAN2017/12:45	74	63 - 83	No	
	Sodium (mmol/L)	Screening	02FEB2016/10:50	142	135 - 145	Yes	0
		Day 1	23FEB2016/13:40	139	135 - 145	Yes	0
		Week 1	03MAR2016/12:00	141	135 - 145	No	0
		Week 2	08MAR2016/10:10	142	135 - 145	No	0
		Week 4	23MAR2016/11:32	142	135 - 145	No	0
		Week 6	06APR2016/11:45	141	135 - 145	No	0
		Week 8	20APR2016/09:00	140	135 - 145	Yes	0
		Week 12	17MAY2016/11:55	142	135 - 145	No	0
		Week 16	16JUN2016/12:50	140	135 - 145	No	0
		Week 20	14JUL2016/11:50	140	135 - 145	No	0
		Week 24	10AUG2016/10:20	142	135 - 145	Yes	0
		Week 28	07SEP2016/09:45	143	135 - 145	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Sodium (mmol/L)	Week 40	30NOV2016/09:50	139	135 - 145	No	0
		Week 44	28DEC2016/11:00	142	135 - 145	No	0
		Week 48	26JAN2017/12:45	145	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	02FEB2016/10:50	2.76	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	02FEB2016/10:50	141	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	02FEB2016/10:50	1.7	0 - 2.2	Yes	0
		Day 1	23FEB2016/13:40	1.5	0 - 2.2	Yes	0
		Week 1	03MAR2016/12:00	1.2	0 - 2.2	No	0
		Week 2	08MAR2016/10:10	1.0	0 - 2.2	No	0
		Week 4	23MAR2016/11:32	1.1	0 - 2.2	No	0
		Week 6	06APR2016/11:45	1.0	0 - 2.2	No	0
		Week 8	20APR2016/09:00	0.7	0 - 2.2	Yes	0
		Week 12	17MAY2016/11:55	1.1	0 - 2.2	No	0
		Week 16	16JUN2016/12:50	1.2	0 - 2.2	No	0
		Week 20	14JUL2016/11:50	0.9	0 - 2.2	No	0
		Week 24	10AUG2016/10:20	0.8	0 - 2.2	Yes	0
		Week 28	07SEP2016/09:45	2.0	0 - 2.2	No	1
		Week 40	30NOV2016/09:50	1.2	0 - 2.2	No	0
		Week 44	28DEC2016/11:00	1.7	0 - 2.2	No	0
		Week 48	26JAN2017/12:45	1.6	0 - 2.2	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Triiodothyronine (nmol/L)	Screening	02FEB2016/10:50	2.9	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	02FEB2016/10:50	2.5	1.7 - 8.3	Yes	
		Day 1	23FEB2016/13:40	2.5	1.7 - 8.3	Yes	
		Week 1	03MAR2016/12:00	3.2	1.7 - 8.3	No	
		Week 2	08MAR2016/10:10	3.7	1.7 - 8.3	No	
		Week 4	23MAR2016/11:32	3.3	1.7 - 8.3	No	
		Week 6	06APR2016/11:45	5.5	1.7 - 8.3	No	
		Week 8	20APR2016/09:00	7.4	1.7 - 8.3	Yes	
		Week 12	17MAY2016/11:55	5.9	1.7 - 8.3	No	
		Week 16	16JUN2016/12:50	6.8	1.7 - 8.3	No	
		Week 20	14JUL2016/11:50	11.1 H	1.7 - 8.3	No	
		Week 24	10AUG2016/10:20	7.4	1.7 - 8.3	Yes	
		Week 28	07SEP2016/09:45	5.6	1.7 - 8.3	No	
		Week 40	30NOV2016/09:50	8.6 H	1.7 - 8.3	No	
		Week 44	28DEC2016/11:00	6.3	1.7 - 8.3	No	
		Week 48	26JAN2017/12:45	5.9	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	02FEB2016/10:50	234 L	266 - 474	Yes	0
		Day 1	23FEB2016/13:40	254 L	266 - 474	Yes	0
		Week 1	03MAR2016/12:00	370	266 - 474	No	0
		Week 2	08MAR2016/10:10	303	266 - 474	No	0
		Week 4	23MAR2016/11:32	295	266 - 474	No	0
		Week 6	06APR2016/11:45	367	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Uric acid (umol/L)	Week 8	20APR2016/09:00	550 H	266 - 474	Yes	1
		Week 12	17MAY2016/11:55	397	266 - 474	No	0
		Week 16	16JUN2016/12:50	362	266 - 474	No	0
		Week 20	14JUL2016/11:50	466	266 - 474	No	0
		Week 24	10AUG2016/10:20	335	266 - 474	Yes	0
		Week 28	07SEP2016/09:45	351	266 - 474	No	0
		Week 40	30NOV2016/09:50	371	266 - 474	No	0
		Week 44	28DEC2016/11:00	375	266 - 474	No	0
		Week 48	26JAN2017/12:45	343	266 - 474	No	0
301-018	Alanine Aminotransferase (IU/L)	Screening	17FEB2016/14:45	60 H	10 - 50	Yes	1
		Day 1	09MAR2016/10:15	68 H	10 - 50	Yes	1
		Week 1	16MAR2016/11:05	84 H	10 - 50	No	1
		Week 2	23MAR2016/09:35	85 H	10 - 50	No	1
		Week 4	06APR2016/10:10	80 H	10 - 50	No	1
		Week 6	21APR2016/10:20	128 H	10 - 50	No	1
		Week 8	28APR2016/09:45	139 H	10 - 50	No	1
		Week 12	01JUN2016/08:40	63 H	10 - 50	Yes	1
		Week 16	29JUN2016/09:45	35	10 - 50	No	0
		Week 20	27JUL2016/09:50	45	10 - 50	No	0
		Week 24	23AUG2016/10:00	48	10 - 50	Yes	0
		Week 28	20SEP2016/11:30	135 H	10 - 50	No	1
		Week 32	18OCT2016/11:00	109 H	10 - 50	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Alanine Aminotransferase (IU/L)	Week 36	15NOV2016/12:00	361 H	10 - 50	No	3
		Week 40	14DEC2016/12:00	87 H	10 - 50	No	1
		Week 44	10JAN2017/11:30	91 H	10 - 50	No	1
		Week 48	07FEB2017/10:30	82 H	10 - 50	No	1
	Albumin (g/L)	Screening	17FEB2016/14:45	45	34 - 50	Yes	0
		Day 1	09MAR2016/10:15	42	34 - 50	Yes	0
		Week 1	16MAR2016/11:05	44	34 - 50	No	0
		Week 2	23MAR2016/09:35	45	34 - 50	No	0
		Week 4	06APR2016/10:10	44	34 - 50	No	0
		Week 6	21APR2016/10:20	44	34 - 50	No	0
		Week 8	28APR2016/09:45	45	34 - 50	No	0
		Week 12	01JUN2016/08:40	46	34 - 50	Yes	0
		Week 16	29JUN2016/09:45	43	34 - 50	No	0
		Week 20	27JUL2016/09:50	45	34 - 50	No	0
		Week 24	23AUG2016/10:00	43	34 - 50	Yes	0
		Week 28	20SEP2016/11:30	46	34 - 50	No	0
		Week 32	18OCT2016/11:00	41	34 - 50	No	0
		Week 36	15NOV2016/12:00	44	34 - 50	No	0
		Week 40	14DEC2016/12:00	43	34 - 50	No	0
		Week 44	10JAN2017/11:30	49	34 - 50	No	0
		Week 48	07FEB2017/10:30	47	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Alkaline Phosphatase (IU/L)	Screening	17FEB2016/14:45	85	40 - 129	Yes	0
		Day 1	09MAR2016/10:15	88	40 - 129	Yes	0
		Week 1	16MAR2016/11:05	99	40 - 129	No	0
		Week 2	23MAR2016/09:35	103	40 - 129	No	0
		Week 4	06APR2016/10:10	102	40 - 129	No	0
		Week 6	21APR2016/10:20	117	40 - 129	No	0
		Week 8	28APR2016/09:45	113	40 - 129	No	0
		Week 12	01JUN2016/08:40	98	40 - 129	Yes	0
		Week 16	29JUN2016/09:45	94	40 - 129	No	0
		Week 20	27JUL2016/09:50	96	40 - 129	No	0
		Week 24	23AUG2016/10:00	109	40 - 129	Yes	0
		Week 28	20SEP2016/11:30	110	40 - 129	No	0
		Week 32	18OCT2016/11:00	102	40 - 129	No	0
		Week 36	15NOV2016/12:00	189 H	40 - 129	No	1
		Week 40	14DEC2016/12:00	106	40 - 129	No	0
		Week 44	10JAN2017/11:30	92	40 - 129	No	0
		Week 48	07FEB2017/10:30	104	40 - 129	No	0
	Amylase (IU/L)	Screening	17FEB2016/14:45	94	28 - 100	Yes	0
		Day 1	09MAR2016/10:15	105 H	28 - 100	Yes	1
		Week 1	16MAR2016/11:05	87	28 - 100	No	0
		Week 2	23MAR2016/09:35	95	28 - 100	No	0
		Week 4	06APR2016/10:10	119 H	28 - 100	No	1
		Week 6	21APR2016/10:20	116 H	28 - 100	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Amylase (IU/L)	Week 8	28APR2016/09:45	103 H	28 - 100	No	1
		Week 12	01JUN2016/08:40	95	28 - 100	Yes	0
		Week 16	29JUN2016/09:45	95	28 - 100	No	0
		Week 20	27JUL2016/09:50	105 H	28 - 100	No	1
		Week 24	23AUG2016/10:00	102 H	28 - 100	Yes	1
		Week 28	20SEP2016/11:30	103 H	28 - 100	No	1
		Week 32	18OCT2016/11:00	102 H	28 - 100	No	1
		Week 36	15NOV2016/12:00	79	28 - 100	No	0
		Week 40	14DEC2016/12:00	113 H	28 - 100	No	1
		Week 44	10JAN2017/11:30	101 H	28 - 100	No	1
		Week 48	07FEB2017/10:30	97	28 - 100	No	0
	Aspartate Aminotransferase (IU/L)	Screening	17FEB2016/14:45	33	0 - 37	Yes	0
		Day 1	09MAR2016/10:15	32	0 - 37	Yes	0
		Week 1	16MAR2016/11:05	35	0 - 37	No	0
		Week 2	23MAR2016/09:35	33	0 - 37	No	0
		Week 4	06APR2016/10:10	31	0 - 37	No	0
		Week 6	21APR2016/10:20	38 H	0 - 37	No	1
		Week 8	28APR2016/09:45	45 H	0 - 37	No	1
		Week 12	01JUN2016/08:40	28	0 - 37	Yes	0
		Week 16	29JUN2016/09:45	22	0 - 37	No	0
		Week 20	27JUL2016/09:50	26	0 - 37	No	0
		Week 24	23AUG2016/10:00	25	0 - 37	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Aspartate Aminotransferase (IU/L)	Week 28	20SEP2016/11:30	66 H	0 - 37	No	1
		Week 32	18OCT2016/11:00	55 H	0 - 37	No	1
		Week 36	15NOV2016/12:00	248 H	0 - 37	No	3
		Week 40	14DEC2016/12:00	42 H	0 - 37	No	1
		Week 44	10JAN2017/11:30	53 H	0 - 37	No	1
		Week 48	07FEB2017/10:30	42 H	0 - 37	No	1
	Bicarbonate (mmol/L)	Screening	17FEB2016/14:45	25	22 - 29	Yes	
		Day 1	09MAR2016/10:15	26	22 - 29	Yes	
		Week 1	16MAR2016/11:05	24	22 - 29	No	
		Week 2	23MAR2016/09:35	23	22 - 29	No	
		Week 4	06APR2016/10:10	27	22 - 29	No	
		Week 6	21APR2016/10:20	25	22 - 29	No	
		Week 8	28APR2016/09:45	24	22 - 29	No	
		Week 12	01JUN2016/08:40	25	22 - 29	Yes	
		Week 16	29JUN2016/09:45	26	22 - 29	No	
		Week 20	27JUL2016/09:50	24	22 - 29	No	
		Week 24	23AUG2016/10:00	24	22 - 29	Yes	
		Week 28	20SEP2016/11:30	23	22 - 29	No	
		Week 32	18OCT2016/11:00	26	22 - 29	No	
		Week 36	15NOV2016/12:00	24	22 - 29	No	
		Week 40	14DEC2016/12:00	26	22 - 29	No	
		Week 44	10JAN2017/11:30	21 L	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Bicarbonate (mmol/L)	Week 48	07FEB2017/10:30	23	22 - 29	No	
	Bilirubin (umol/L)	Screening	17FEB2016/14:45	14	0 - 20	Yes	0
		Day 1	09MAR2016/10:15	8	0 - 20	Yes	0
		Week 1	16MAR2016/11:05	5	0 - 20	No	0
		Week 2	23MAR2016/09:35	8	0 - 20	No	0
		Week 4	06APR2016/10:10	6	0 - 20	No	0
		Week 6	21APR2016/10:20	7	0 - 20	No	0
		Week 8	28APR2016/09:45	9	0 - 20	No	0
		Week 12	01JUN2016/08:40	12	0 - 20	Yes	0
		Week 16	29JUN2016/09:45	9	0 - 20	No	0
		Week 20	27JUL2016/09:50	8	0 - 20	No	0
		Week 24	23AUG2016/10:00	10	0 - 20	Yes	0
		Week 28	20SEP2016/11:30	17	0 - 20	No	0
		Week 32	18OCT2016/11:00	12	0 - 20	No	0
		Week 36	15NOV2016/12:00	8	0 - 20	No	0
		Week 40	14DEC2016/12:00	10	0 - 20	No	0
		Week 44	10JAN2017/11:30	17	0 - 20	No	0
		Week 48	07FEB2017/10:30	11	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	17FEB2016/14:45	13.16	4.76 - 23.24	Yes	
		Day 1	09MAR2016/10:15	11.48	4.76 - 23.24	Yes	
		Week 1	16MAR2016/11:05	14.84	4.76 - 23.24	No	
		Week 2	23MAR2016/09:35	15.12	4.76 - 23.24	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Blood Urea Nitrogen (mg/dL)	Week 4	06APR2016/10:10	15.12	4.76 - 23.24	No	
		Week 6	21APR2016/10:20	12.32	4.76 - 23.24	No	
		Week 8	28APR2016/09:45	14.28	4.76 - 23.24	No	
		Week 12	01JUN2016/08:40	11.20	4.76 - 23.24	Yes	
		Week 16	29JUN2016/09:45	20.72	4.76 - 23.24	No	
		Week 20	27JUL2016/09:50	14.00	4.76 - 23.24	No	
		Week 24	23AUG2016/10:00	14.00	4.76 - 23.24	Yes	
		Week 28	20SEP2016/11:30	10.08	4.76 - 23.24	No	
		Week 32	18OCT2016/11:00	15.12	4.76 - 23.24	No	
		Week 36	15NOV2016/12:00	10.36	4.76 - 23.24	No	
		Week 40	14DEC2016/12:00	9.80	4.76 - 23.24	No	
		Week 44	10JAN2017/11:30	16.52	4.76 - 23.24	No	
		Week 48	07FEB2017/10:30	16.24	4.76 - 23.24	No	
	Calcium (mmol/L)	Screening	17FEB2016/14:45	2.38	2.2 - 2.6	Yes	0
		Day 1	09MAR2016/10:15	2.25	2.2 - 2.6	Yes	0
		Week 1	16MAR2016/11:05	2.35	2.2 - 2.6	No	0
		Week 2	23MAR2016/09:35	2.42	2.2 - 2.6	No	0
		Week 4	06APR2016/10:10	2.35	2.2 - 2.6	No	0
		Week 6	21APR2016/10:20	2.28	2.2 - 2.6	No	0
		Week 8	28APR2016/09:45	2.32	2.2 - 2.6	No	0
		Week 12	01JUN2016/08:40	2.46	2.2 - 2.6	Yes	0
		Week 16	29JUN2016/09:45	2.39	2.2 - 2.6	No	0
		Week 20	27JUL2016/09:50	2.28	2.2 - 2.6	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Calcium (mmol/L)	Week 24	23AUG2016/10:00	2.29	2.2 - 2.6	Yes	0
		Week 28	20SEP2016/11:30	2.36	2.2 - 2.6	No	0
		Week 32	18OCT2016/11:00	2.28	2.2 - 2.6	No	0
		Week 36	15NOV2016/12:00	2.40	2.2 - 2.6	No	0
		Week 40	14DEC2016/12:00	2.35	2.2 - 2.6	No	0
		Week 44	10JAN2017/11:30	2.47	2.2 - 2.6	No	0
		Week 48	07FEB2017/10:30	2.36	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	17FEB2016/14:45	103	98 - 107	Yes	
		Day 1	09MAR2016/10:15	102	98 - 107	Yes	
		Week 1	16MAR2016/11:05	104	98 - 107	No	
		Week 2	23MAR2016/09:35	102	98 - 107	No	
		Week 4	06APR2016/10:10	102	98 - 107	No	
		Week 6	21APR2016/10:20	102	98 - 107	No	
		Week 8	28APR2016/09:45	100	98 - 107	No	
		Week 12	01JUN2016/08:40	103	98 - 107	Yes	
		Week 16	29JUN2016/09:45	102	98 - 107	No	
		Week 20	27JUL2016/09:50	105	98 - 107	No	
		Week 24	23AUG2016/10:00	101	98 - 107	Yes	
		Week 28	20SEP2016/11:30	101	98 - 107	No	
		Week 32	18OCT2016/11:00	102	98 - 107	No	
		Week 36	15NOV2016/12:00	102	98 - 107	No	
		Week 40	14DEC2016/12:00	100	98 - 107	No	
		Week 44	10JAN2017/11:30	100	98 - 107	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Chloride (mmol/L)	Week 48	07FEB2017/10:30	102	98 - 107	No	
	Cholesterol (mmol/L)	Screening	17FEB2016/14:45	4.1	0 - 4.9	Yes	0
		Day 1	09MAR2016/10:15	4.0	0 - 4.9	Yes	0
		Week 1	16MAR2016/11:05	3.4	0 - 4.9	No	0
		Week 2	23MAR2016/09:35	3.0	0 - 4.9	No	0
		Week 4	06APR2016/10:10	3.9	0 - 4.9	No	0
		Week 6	21APR2016/10:20	3.0	0 - 4.9	No	0
		Week 8	28APR2016/09:45	2.8	0 - 4.9	No	0
		Week 12	01JUN2016/08:40	4.3	0 - 4.9	Yes	0
		Week 16	29JUN2016/09:45	3.6	0 - 4.9	No	0
		Week 20	27JUL2016/09:50	3.4	0 - 4.9	No	0
		Week 24	23AUG2016/10:00	3.4	0 - 4.9	Yes	0
		Week 28	20SEP2016/11:30	3.3	0 - 4.9	No	0
		Week 32	18OCT2016/11:00	3.5	0 - 4.9	No	0
		Week 36	15NOV2016/12:00	4.2	0 - 4.9	No	0
		Week 40	14DEC2016/12:00	3.6	0 - 4.9	No	0
		Week 44	10JAN2017/11:30	4.4	0 - 4.9	No	0
		Week 48	07FEB2017/10:30	3.7	0 - 4.9	No	0
	Creatine Kinase (IU/L)	Screening	17FEB2016/14:45	91	38 - 204	Yes	0
		Day 1	09MAR2016/10:15	70	38 - 204	Yes	0
		Week 1	16MAR2016/11:05	97	38 - 204	No	0
		Week 2	23MAR2016/09:35	77	38 - 204	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Creatine Kinase (IU/L)	Week 4	06APR2016/10:10	86	38 - 204	No	0
		Week 6	21APR2016/10:20	96	38 - 204	No	0
		Week 8	28APR2016/09:45	82	38 - 204	No	0
		Week 12	01JUN2016/08:40	52	38 - 204	Yes	0
		Week 16	29JUN2016/09:45	96	38 - 204	No	0
		Week 20	27JUL2016/09:50	99	38 - 204	No	0
		Week 24	23AUG2016/10:00	74	38 - 204	Yes	0
		Week 28	20SEP2016/11:30	157	38 - 204	No	0
		Week 32	18OCT2016/11:00	122	38 - 204	No	0
		Week 36	15NOV2016/12:00	74	38 - 204	No	0
		Week 40	14DEC2016/12:00	102	38 - 204	No	0
		Week 44	10JAN2017/11:30	189	38 - 204	No	0
		Week 48	07FEB2017/10:30	207 H	38 - 204	No	1
	Creatinine (umol/L)	Screening	17FEB2016/14:45	71	66 - 112	Yes	0
		Day 1	09MAR2016/10:15	69	66 - 112	Yes	0
		Week 1	16MAR2016/11:05	68	66 - 112	No	0
		Week 2	23MAR2016/09:35	75	66 - 112	No	1
		Week 4	06APR2016/10:10	66	66 - 112	No	0
		Week 6	21APR2016/10:20	71	66 - 112	No	1
		Week 8	28APR2016/09:45	83	66 - 112	No	1
		Week 12	01JUN2016/08:40	76	66 - 112	Yes	1
		Week 16	29JUN2016/09:45	75	66 - 112	No	1
		Week 20	27JUL2016/09:50	80	66 - 112	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Creatinine (umol/L)	Week 24	23AUG2016/10:00	74	66 - 112	Yes	1
		Week 28	20SEP2016/11:30	72	66 - 112	No	1
		Week 32	18OCT2016/11:00	69	66 - 112	No	0
		Week 36	15NOV2016/12:00	60 L	66 - 112	No	0
		Week 40	14DEC2016/12:00	73	66 - 112	No	1
		Week 44	10JAN2017/11:30	73	66 - 112	No	1
		Week 48	07FEB2017/10:30	72	66 - 112	No	1
	Direct Bilirubin (umol/L)	Screening	17FEB2016/14:45	7 H	0 - 5	Yes	
		Day 1	09MAR2016/10:15	4	0 - 5	Yes	
		Week 1	16MAR2016/11:05	2	0 - 5	No	
		Week 2	23MAR2016/09:35	4	0 - 5	No	
		Week 4	06APR2016/10:10	3	0 - 5	No	
		Week 6	21APR2016/10:20	3	0 - 5	No	
		Week 8	28APR2016/09:45	4	0 - 5	No	
		Week 12	01JUN2016/08:40	5	0 - 5	Yes	
		Week 16	29JUN2016/09:45	4	0 - 5	No	
		Week 20	27JUL2016/09:50	4	0 - 5	No	
		Week 24	23AUG2016/10:00	4	0 - 5	Yes	
		Week 28	20SEP2016/11:30	7 H	0 - 5	No	
		Week 32	18OCT2016/11:00	4	0 - 5	No	
		Week 36	15NOV2016/12:00	3	0 - 5	No	
		Week 40	14DEC2016/12:00	4	0 - 5	No	
		Week 44	10JAN2017/11:30	6 H	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Direct Bilirubin (umol/L)	Week 48	07FEB2017/10:30	5	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	17FEB2016/14:45	34	10 - 71	Yes	0
		Day 1	09MAR2016/10:15	25	10 - 71	Yes	0
		Week 1	16MAR2016/11:05	97 H	10 - 71	No	1
		Week 2	23MAR2016/09:35	114 H	10 - 71	No	1
		Week 4	06APR2016/10:10	131 H	10 - 71	No	1
		Week 6	21APR2016/10:20	113 H	10 - 71	No	1
		Week 8	28APR2016/09:45	139 H	10 - 71	No	1
		Week 12	01JUN2016/08:40	71	10 - 71	Yes	0
		Week 16	29JUN2016/09:45	53	10 - 71	No	0
		Week 20	27JUL2016/09:50	51	10 - 71	No	0
		Week 24	23AUG2016/10:00	61	10 - 71	Yes	0
		Week 28	20SEP2016/11:30	32	10 - 71	No	0
		Week 32	18OCT2016/11:00	31	10 - 71	No	0
		Week 36	15NOV2016/12:00	103 H	10 - 71	No	1
		Week 40	14DEC2016/12:00	30	10 - 71	No	0
		Week 44	10JAN2017/11:30	29	10 - 71	No	0
		Week 48	07FEB2017/10:30	24	10 - 71	No	0
	Globulin (g/L)	Screening	17FEB2016/14:45	32	19 - 35	Yes	
		Day 1	09MAR2016/10:15	30	19 - 35	Yes	
		Week 1	16MAR2016/11:05	33	19 - 35	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Globulin (g/L)	Week 2	23MAR2016/09:35	33	19 - 35	No	
		Week 4	06APR2016/10:10	31	19 - 35	No	
		Week 6	21APR2016/10:20	28	19 - 35	No	
		Week 8	28APR2016/09:45	31	19 - 35	No	
		Week 12	01JUN2016/08:40	23	19 - 35	Yes	
		Week 16	29JUN2016/09:45	27	19 - 35	No	
		Week 20	27JUL2016/09:50	27	19 - 35	No	
		Week 24	23AUG2016/10:00	30	19 - 35	Yes	
		Week 28	20SEP2016/11:30	29	19 - 35	No	
		Week 32	18OCT2016/11:00	35	19 - 35	No	
		Week 36	15NOV2016/12:00	35	19 - 35	No	
		Week 40	14DEC2016/12:00	34	19 - 35	No	
		Week 44	10JAN2017/11:30	34	19 - 35	No	
		Week 48	07FEB2017/10:30	31	19 - 35	No	
	Glucose (mmol/L)	Screening	17FEB2016/14:45	5.0	3.9 - 5.8	Yes	0
		Day 1	09MAR2016/10:15	3.6 L	3.9 - 5.8	Yes	1
		Week 1	16MAR2016/11:05	4.4	3.5 - 7.9	No	0
		Week 2	23MAR2016/09:35	4.2	3.5 - 7.9	No	0
		Week 4	06APR2016/10:10	3.5	3.5 - 7.9	No	0
		Week 6	21APR2016/10:20	4.0	3.5 - 7.9	No	0
		Week 8	28APR2016/09:45	4.5	3.5 - 7.9	No	0
		Week 12	01JUN2016/08:40	4.9	3.9 - 5.8	Yes	0
		Week 16	29JUN2016/09:45	4.1	3.5 - 7.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Glucose (mmol/L)	Week 20	27JUL2016/09:50	3.2 L	3.5 - 7.9	No	1
		Week 24	23AUG2016/10:00	3.5 L	3.9 - 5.8	Yes	1
		Week 28	20SEP2016/11:30	3.3 L	3.5 - 7.9	No	1
		Week 32	18OCT2016/11:00	3.9	3.5 - 7.9	No	0
		Week 36	15NOV2016/12:00	5.6	3.5 - 7.9	No	0
		Week 40	14DEC2016/12:00	6.0	3.5 - 7.9	No	0
		Week 44	10JAN2017/11:30	4.4	3.5 - 7.9	No	0
		Week 48	07FEB2017/10:30	4.1	3.5 - 7.9	No	0
	Indirect Bilirubin (umol/L)	Screening	17FEB2016/14:45	7	0 - 14	Yes	
		Day 1	09MAR2016/10:15	4	0 - 14	Yes	
		Week 1	16MAR2016/11:05	3	0 - 14	No	
		Week 2	23MAR2016/09:35	4	0 - 14	No	
		Week 4	06APR2016/10:10	3	0 - 14	No	
		Week 6	21APR2016/10:20	4	0 - 14	No	
		Week 8	28APR2016/09:45	5	0 - 14	No	
		Week 12	01JUN2016/08:40	7	0 - 14	Yes	
		Week 16	29JUN2016/09:45	5	0 - 14	No	
		Week 20	27JUL2016/09:50	4	0 - 14	No	
		Week 24	23AUG2016/10:00	6	0 - 14	Yes	
		Week 28	20SEP2016/11:30	10	0 - 14	No	
		Week 32	18OCT2016/11:00	8	0 - 14	No	
		Week 36	15NOV2016/12:00	5	0 - 14	No	
		Week 40	14DEC2016/12:00	6	0 - 14	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Indirect Bilirubin (umol/L)	Week 44	10JAN2017/11:30	11	0 - 14	No	
		Week 48	07FEB2017/10:30	6	0 - 14	No	
	Lactate Dehydrogenase (IU/L)	Screening	17FEB2016/14:45	169	135 - 225	Yes	
		Day 1	09MAR2016/10:15	220	135 - 225	Yes	
		Week 1	16MAR2016/11:05	170	135 - 225	No	
		Week 2	23MAR2016/09:35	172	135 - 225	No	
		Week 4	06APR2016/10:10	168	135 - 225	No	
		Week 6	21APR2016/10:20	173	135 - 225	No	
		Week 8	28APR2016/09:45	188	135 - 225	No	
		Week 12	01JUN2016/08:40	188	135 - 225	Yes	
		Week 16	29JUN2016/09:45	181	135 - 225	No	
		Week 20	27JUL2016/09:50	177	135 - 225	No	
		Week 24	23AUG2016/10:00	160	135 - 225	Yes	
		Week 28	20SEP2016/11:30	225	135 - 225	No	
		Week 32	18OCT2016/11:00	205	135 - 225	No	
		Week 36	15NOV2016/12:00	253 H	135 - 225	No	
		Week 40	14DEC2016/12:00	204	135 - 225	No	
		Week 44	10JAN2017/11:30	252 H	135 - 225	No	
		Week 48	07FEB2017/10:30	206	135 - 225	No	
	Magnesium (mmol/L)	Screening	17FEB2016/14:45	0.87	0.6 - 1	Yes	0
		Day 1	09MAR2016/10:15	0.86	0.6 - 1	Yes	0
		Week 1	16MAR2016/11:05	0.83	0.6 - 1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Magnesium (mmol/L)	Week 2	23MAR2016/09:35	0.86	0.6 - 1	No	0
		Week 4	06APR2016/10:10	0.85	0.6 - 1	No	0
		Week 6	21APR2016/10:20	0.80	0.6 - 1	No	0
		Week 8	28APR2016/09:45	0.78	0.6 - 1	No	0
		Week 12	01JUN2016/08:40	0.85	0.6 - 1	Yes	0
		Week 16	29JUN2016/09:45	0.85	0.6 - 1	No	0
		Week 20	27JUL2016/09:50	0.86	0.6 - 1	No	0
		Week 24	23AUG2016/10:00	0.83	0.6 - 1	Yes	0
		Week 28	20SEP2016/11:30	0.85	0.6 - 1	No	0
		Week 32	18OCT2016/11:00	0.87	0.6 - 1	No	0
		Week 36	15NOV2016/12:00	0.82	0.6 - 1	No	0
		Week 40	14DEC2016/12:00	0.79	0.6 - 1	No	0
		Week 44	10JAN2017/11:30	0.83	0.6 - 1	No	0
		Week 48	07FEB2017/10:30	0.85	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	17FEB2016/14:45	0.97	0.87 - 1.45	Yes	0
		Day 1	09MAR2016/10:15	0.72 L	0.87 - 1.45	Yes	2
		Week 1	16MAR2016/11:05	0.90	0.87 - 1.45	No	0
		Week 2	23MAR2016/09:35	0.94	0.87 - 1.45	No	0
		Week 4	06APR2016/10:10	1.03	0.87 - 1.45	No	0
		Week 6	21APR2016/10:20	0.91	0.87 - 1.45	No	0
		Week 8	28APR2016/09:45	1.13	0.87 - 1.45	No	0
		Week 12	01JUN2016/08:40	1.17	0.87 - 1.45	Yes	0
		Week 16	29JUN2016/09:45	1.00	0.87 - 1.45	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Phosphate (mmol/L)	Week 20	27JUL2016/09:50	0.80 L	0.87 - 1.45	No	1
		Week 24	23AUG2016/10:00	0.85 L	0.87 - 1.45	Yes	1
		Week 28	20SEP2016/11:30	0.54 L	0.87 - 1.45	No	3
		Week 32	18OCT2016/11:00	0.78 L	0.87 - 1.45	No	2
		Week 36	15NOV2016/12:00	1.27	0.87 - 1.45	No	0
		Week 40	14DEC2016/12:00	0.65 L	0.87 - 1.45	No	2
		Week 44	10JAN2017/11:30	0.85 L	0.87 - 1.45	No	1
		Week 48	07FEB2017/10:30	0.82 L	0.87 - 1.45	No	1
	Potassium (mmol/L)	Screening	17FEB2016/14:45	4.4	3.5 - 5.1	Yes	0
		Day 1	09MAR2016/10:15	4.2	3.5 - 5.1	Yes	0
		Week 1	16MAR2016/11:05	4.4	3.5 - 5.1	No	0
		Week 2	23MAR2016/09:35	4.6	3.5 - 5.1	No	0
		Week 4	06APR2016/10:10	4.3	3.5 - 5.1	No	0
		Week 6	21APR2016/10:20	4.5	3.5 - 5.1	No	0
		Week 8	28APR2016/09:45	4.5	3.5 - 5.1	No	0
		Week 12	01JUN2016/08:40	4.5	3.5 - 5.1	Yes	0
		Week 16	29JUN2016/09:45	4.8	3.5 - 5.1	No	0
		Week 20	27JUL2016/09:50	4.1	3.5 - 5.1	No	0
		Week 24	23AUG2016/10:00	4.0	3.5 - 5.1	Yes	0
		Week 28	20SEP2016/11:30	4.3	3.5 - 5.1	No	0
		Week 32	18OCT2016/11:00	4.7	3.5 - 5.1	No	0
		Week 36	15NOV2016/12:00	4.4	3.5 - 5.1	No	0
		Week 40	14DEC2016/12:00	4.3	3.5 - 5.1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Potassium (mmol/L)	Week 44	10JAN2017/11:30	4.3	3.5 - 5.1	No	0
		Week 48	07FEB2017/10:30	4.2	3.5 - 5.1	No	0
	Protein (g/L)	Screening	17FEB2016/14:45	77	63 - 83	Yes	
		Day 1	09MAR2016/10:15	72	63 - 83	Yes	
		Week 1	16MAR2016/11:05	77	63 - 83	No	
		Week 2	23MAR2016/09:35	78	63 - 83	No	
		Week 4	06APR2016/10:10	75	63 - 83	No	
		Week 6	21APR2016/10:20	72	63 - 83	No	
		Week 8	28APR2016/09:45	76	63 - 83	No	
		Week 12	01JUN2016/08:40	69	63 - 83	Yes	
		Week 16	29JUN2016/09:45	70	63 - 83	No	
		Week 20	27JUL2016/09:50	72	63 - 83	No	
		Week 24	23AUG2016/10:00	73	63 - 83	Yes	
		Week 28	20SEP2016/11:30	75	63 - 83	No	
		Week 32	18OCT2016/11:00	76	63 - 83	No	
		Week 36	15NOV2016/12:00	79	63 - 83	No	
		Week 40	14DEC2016/12:00	77	63 - 83	No	
		Week 44	10JAN2017/11:30	83	63 - 83	No	
		Week 48	07FEB2017/10:30	78	63 - 83	No	
	Sodium (mmol/L)	Screening	17FEB2016/14:45	142	135 - 145	Yes	0
		Day 1	09MAR2016/10:15	141	135 - 145	Yes	0
		Week 1	16MAR2016/11:05	142	135 - 145	No	0

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Sodium (mmol/L)	Week 2	23MAR2016/09:35	142	135 - 145	No	0
		Week 4	06APR2016/10:10	142	135 - 145	No	0
		Week 6	21APR2016/10:20	140	135 - 145	No	0
		Week 8	28APR2016/09:45	139	135 - 145	No	0
		Week 12	01JUN2016/08:40	141	135 - 145	Yes	0
		Week 16	29JUN2016/09:45	141	135 - 145	No	0
		Week 20	27JUL2016/09:50	143	135 - 145	No	0
		Week 24	23AUG2016/10:00	141	135 - 145	Yes	0
		Week 28	20SEP2016/11:30	142	135 - 145	No	0
		Week 32	18OCT2016/11:00	140	135 - 145	No	0
		Week 36	15NOV2016/12:00	143	135 - 145	No	0
		Week 40	14DEC2016/12:00	141	135 - 145	No	0
		Week 44	10JAN2017/11:30	140	135 - 145	No	0
		Week 48	07FEB2017/10:30	142	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	17FEB2016/14:45	1.02	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	17FEB2016/14:45	119	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	17FEB2016/14:45	0.9	0 - 2.2	Yes	0
		Day 1	09MAR2016/10:15	1.7	0 - 2.2	Yes	0
		Week 1	16MAR2016/11:05	1.0	0 - 2.2	No	0
		Week 2	23MAR2016/09:35	1.2	0 - 2.2	No	0
		Week 4	06APR2016/10:10	3.3 H	0 - 2.2	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Triglycerides (mmol/L)	Week 6	21APR2016/10:20	1.6	0 - 2.2	No	0
		Week 8	28APR2016/09:45	1.3	0 - 2.2	No	0
		Week 12	01JUN2016/08:40	1.6	0 - 2.2	Yes	0
		Week 16	29JUN2016/09:45	1.5	0 - 2.2	No	0
		Week 20	27JUL2016/09:50	1.3	0 - 2.2	No	0
		Week 24	23AUG2016/10:00	1.2	0 - 2.2	Yes	0
		Week 28	20SEP2016/11:30	0.9	0 - 2.2	No	0
		Week 32	18OCT2016/11:00	1.3	0 - 2.2	No	0
		Week 36	15NOV2016/12:00	0.9	0 - 2.2	No	0
		Week 40	14DEC2016/12:00	2.7 H	0 - 2.2	No	1
		Week 44	10JAN2017/11:30	1.3	0 - 2.2	No	0
		Week 48	07FEB2017/10:30	0.8	0 - 2.2	No	0
	Triiodothyronine (nmol/L)	Screening	17FEB2016/14:45	2.5	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	17FEB2016/14:45	4.7	1.7 - 8.3	Yes	
		Day 1	09MAR2016/10:15	4.1	1.7 - 8.3	Yes	
		Week 1	16MAR2016/11:05	5.3	1.7 - 8.3	No	
		Week 2	23MAR2016/09:35	5.4	1.7 - 8.3	No	
		Week 4	06APR2016/10:10	5.4	1.7 - 8.3	No	
		Week 6	21APR2016/10:20	4.4	1.7 - 8.3	No	
		Week 8	28APR2016/09:45	5.1	1.7 - 8.3	No	
		Week 12	01JUN2016/08:40	4.0	1.7 - 8.3	Yes	
		Week 16	29JUN2016/09:45	7.4	1.7 - 8.3	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Urea (mmol/L)	Week 20	27JUL2016/09:50	5.0	1.7 - 8.3	No	
		Week 24	23AUG2016/10:00	5.0	1.7 - 8.3	Yes	
		Week 28	20SEP2016/11:30	3.6	1.7 - 8.3	No	
		Week 32	18OCT2016/11:00	5.4	1.7 - 8.3	No	
		Week 36	15NOV2016/12:00	3.7	1.7 - 8.3	No	
		Week 40	14DEC2016/12:00	3.5	1.7 - 8.3	No	
		Week 44	10JAN2017/11:30	5.9	1.7 - 8.3	No	
		Week 48	07FEB2017/10:30	5.8	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	17FEB2016/14:45	344	266 - 474	Yes	0
		Day 1	09MAR2016/10:15	285	266 - 474	Yes	0
		Week 1	16MAR2016/11:05	292	266 - 474	No	0
		Week 2	23MAR2016/09:35	316	266 - 474	No	0
		Week 4	06APR2016/10:10	282	266 - 474	No	0
		Week 6	21APR2016/10:20	245 L	266 - 474	No	0
		Week 8	28APR2016/09:45	262 L	266 - 474	No	0
		Week 12	01JUN2016/08:40	273	266 - 474	Yes	0
		Week 16	29JUN2016/09:45	328	266 - 474	No	0
		Week 20	27JUL2016/09:50	376	266 - 474	No	0
		Week 24	23AUG2016/10:00	273	266 - 474	Yes	0
		Week 28	20SEP2016/11:30	323	266 - 474	No	0
		Week 32	18OCT2016/11:00	348	266 - 474	No	0
		Week 36	15NOV2016/12:00	297	266 - 474	No	0
		Week 40	14DEC2016/12:00	322	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-018	Uric acid (umol/L)	Week 44	10JAN2017/11:30	328	266 - 474	No	0
		Week 48	07FEB2017/10:30	323	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Alanine Aminotransferase (IU/L)	Screening	14JAN2016/13:30	171 H	10 - 50	Yes	2
		Day 1	04FEB2016/09:45	175 H	10 - 50	Yes	2
		Week 1	10FEB2016/13:00	115 H	10 - 50	No	1
		Week 2	16FEB2016/14:00	77 H	10 - 50	No	1
		Week 4	03MAR2016/12:15	53 H	10 - 50	No	1
		Week 6	17MAR2016/11:31	48	10 - 50	No	0
		Week 8	31MAR2016/11:22	53 H	10 - 50	No	1
		Week 12	26APR2016/08:15	77 H	10 - 50	Yes	1
		Week 16	25MAY2016/11:55	55 H	10 - 50	No	1
		Week 20	23JUN2016/12:45	44	10 - 50	No	0
		Week 24	19JUL2016/12:00	67 H	10 - 50	Yes	1
		Week 28	18AUG2016/12:15	600 H	10 - 50	No	3
		Week 32	13SEP2016/11:45	105 H	10 - 50	No	1
		Week 36	13OCT2016/12:10	63 H	10 - 50	No	1
		Week 40	08NOV2016/11:00	77 H	10 - 50	No	1
		Week 44	08DEC2016/11:00	77 H	10 - 50	No	1
		Week 48	03JAN2017/12:00	132 H	10 - 50	No	1
	Albumin (g/L)	Screening	14JAN2016/13:30	46	34 - 50	Yes	0
		Day 1	04FEB2016/09:45	46	34 - 50	Yes	0
		Week 1	10FEB2016/13:00	42	34 - 50	No	0
		Week 2	16FEB2016/14:00	41	34 - 50	No	0
		Week 4	03MAR2016/12:15	40	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Albumin (g/L)	Week 6	17MAR2016/11:31	43	34 - 50	No	0
		Week 8	31MAR2016/11:22	43	34 - 50	No	0
		Week 12	26APR2016/08:15	42	34 - 50	Yes	0
		Week 16	25MAY2016/11:55	43	34 - 50	No	0
		Week 20	23JUN2016/12:45	44	34 - 50	No	0
		Week 24	19JUL2016/12:00	43	34 - 50	Yes	0
		Week 28	18AUG2016/12:15	39	34 - 50	No	0
		Week 32	13SEP2016/11:45	38	34 - 50	No	0
		Week 36	13OCT2016/12:10	42	34 - 50	No	0
		Week 40	08NOV2016/11:00	43	34 - 50	No	0
		Week 44	08DEC2016/11:00	42	34 - 50	No	0
		Week 48	03JAN2017/12:00	44	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	14JAN2016/13:30	77	40 - 129	Yes	0
		Day 1	04FEB2016/09:45	84	40 - 129	Yes	0
		Week 1	10FEB2016/13:00	76	40 - 129	No	0
		Week 2	16FEB2016/14:00	80	40 - 129	No	0
		Week 4	03MAR2016/12:15	86	40 - 129	No	0
		Week 6	17MAR2016/11:31	89	40 - 129	No	0
		Week 8	31MAR2016/11:22	101	40 - 129	No	0
		Week 12	26APR2016/08:15	100	40 - 129	Yes	0
		Week 16	25MAY2016/11:55	105	40 - 129	No	0
		Week 20	23JUN2016/12:45	139 H	40 - 129	No	1
		Week 24	19JUL2016/12:00	162 H	40 - 129	Yes	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Alkaline Phosphatase (IU/L)	Week 28	18AUG2016/12:15	254 H	40 - 129	No	1
		Week 32	13SEP2016/11:45	161 H	40 - 129	No	1
		Week 36	13OCT2016/12:10	145 H	40 - 129	No	1
		Week 40	08NOV2016/11:00	135 H	40 - 129	No	1
		Week 44	08DEC2016/11:00	121	40 - 129	No	0
		Week 48	03JAN2017/12:00	119	40 - 129	No	0
	Amylase (IU/L)	Screening	14JAN2016/13:30	132 H	28 - 100	Yes	1
		Day 1	04FEB2016/09:45	121 H	28 - 100	Yes	1
		Week 1	10FEB2016/13:00	110 H	28 - 100	No	1
		Week 2	16FEB2016/14:00	113 H	28 - 100	No	1
		Week 4	03MAR2016/12:15	124 H	28 - 100	No	1
		Week 6	17MAR2016/11:31	119 H	28 - 100	No	1
		Week 8	31MAR2016/11:22	122 H	28 - 100	No	1
		Week 12	26APR2016/08:15	121 H	28 - 100	Yes	1
		Week 16	25MAY2016/11:55	108 H	28 - 100	No	1
		Week 20	23JUN2016/12:45	112 H	28 - 100	No	1
		Week 24	19JUL2016/12:00	180 H	28 - 100	Yes	2
		Week 28	18AUG2016/12:15	105 H	28 - 100	No	1
		Week 32	13SEP2016/11:45	112 H	28 - 100	No	1
		Week 36	13OCT2016/12:10	122 H	28 - 100	No	1
		Week 40	08NOV2016/11:00	136 H	28 - 100	No	1
		Week 44	08DEC2016/11:00	177 H	28 - 100	No	2
		Week 48	03JAN2017/12:00	133 H	28 - 100	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Aspartate Aminotransferase (IU/L)	Screening	14JAN2016/13:30	81 H	0 - 37	Yes	1
		Day 1	04FEB2016/09:45	88 H	0 - 37	Yes	1
		Week 1	10FEB2016/13:00	56 H	0 - 37	No	1
		Week 2	16FEB2016/14:00	45 H	0 - 37	No	1
		Week 4	03MAR2016/12:15	37	0 - 37	No	0
		Week 6	17MAR2016/11:31	41 H	0 - 37	No	1
		Week 8	31MAR2016/11:22	39 H	0 - 37	No	1
		Week 12	26APR2016/08:15	50 H	0 - 37	Yes	1
		Week 16	25MAY2016/11:55	36	0 - 37	No	0
		Week 20	23JUN2016/12:45	33	0 - 37	No	0
		Week 24	19JUL2016/12:00	46 H	0 - 37	Yes	1
		Week 28	18AUG2016/12:15	432 H	0 - 37	No	3
		Week 32	13SEP2016/11:45	60 H	0 - 37	No	1
		Week 36	13OCT2016/12:10	48 H	0 - 37	No	1
		Week 40	08NOV2016/11:00	49 H	0 - 37	No	1
		Week 44	08DEC2016/11:00	50 H	0 - 37	No	1
		Week 48	03JAN2017/12:00	76 H	0 - 37	No	1
	Bicarbonate (mmol/L)	Screening	14JAN2016/13:30	23	22 - 29	Yes	
		Day 1	04FEB2016/09:45	24	22 - 29	Yes	
		Week 1	10FEB2016/13:00	24	22 - 29	No	
		Week 2	16FEB2016/14:00	26	22 - 29	No	
		Week 4	03MAR2016/12:15	27	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Bicarbonate (mmol/L)	Week 6	17MAR2016/11:31	27	22 - 29	No	
		Week 8	31MAR2016/11:22	24	22 - 29	No	
		Week 12	26APR2016/08:15	25	22 - 29	Yes	
		Week 16	25MAY2016/11:55	27	22 - 29	No	
		Week 20	23JUN2016/12:45	20 L	22 - 29	No	
		Week 24	19JUL2016/12:00	22	22 - 29	Yes	
		Week 28	18AUG2016/12:15	20 L	22 - 29	No	
		Week 32	13SEP2016/11:45	22	22 - 29	No	
		Week 36	13OCT2016/12:10	22	22 - 29	No	
		Week 40	08NOV2016/11:00	20 L	22 - 29	No	
		Week 44	08DEC2016/11:00	19 L	22 - 29	No	
		Week 48	03JAN2017/12:00	25	22 - 29	No	
	Bilirubin (umol/L)	Screening	14JAN2016/13:30	11	0 - 20	Yes	0
		Day 1	04FEB2016/09:45	14	0 - 20	Yes	0
		Week 1	10FEB2016/13:00	13	0 - 20	No	0
		Week 2	16FEB2016/14:00	7	0 - 20	No	0
		Week 4	03MAR2016/12:15	5	0 - 20	No	0
		Week 6	17MAR2016/11:31	7	0 - 20	No	0
		Week 8	31MAR2016/11:22	8	0 - 20	No	0
		Week 12	26APR2016/08:15	12	0 - 20	Yes	0
		Week 16	25MAY2016/11:55	9	0 - 20	No	0
		Week 20	23JUN2016/12:45	7	0 - 20	No	0
		Week 24	19JUL2016/12:00	7	0 - 20	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Bilirubin (umol/L)	Week 28	18AUG2016/12:15	20	0 - 20	No	0
		Week 32	13SEP2016/11:45	9	0 - 20	No	0
		Week 36	13OCT2016/12:10	9	0 - 20	No	0
		Week 40	08NOV2016/11:00	8	0 - 20	No	0
		Week 44	08DEC2016/11:00	7	0 - 20	No	0
		Week 48	03JAN2017/12:00	10	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	14JAN2016/13:30	13.72	4.76 - 23.24	Yes	
		Day 1	04FEB2016/09:45	12.88	4.76 - 23.24	Yes	
		Week 1	10FEB2016/13:00	8.68	4.76 - 23.24	No	
		Week 2	16FEB2016/14:00	11.76	4.76 - 23.24	No	
		Week 4	03MAR2016/12:15	14.00	4.76 - 23.24	No	
		Week 6	17MAR2016/11:31	11.20	4.76 - 23.24	No	
		Week 8	31MAR2016/11:22	11.48	4.76 - 23.24	No	
		Week 12	26APR2016/08:15	11.20	4.76 - 23.24	Yes	
		Week 16	25MAY2016/11:55	12.88	4.76 - 23.24	No	
		Week 20	23JUN2016/12:45	14.28	4.76 - 23.24	No	
		Week 24	19JUL2016/12:00	10.08	4.76 - 23.24	Yes	
		Week 28	18AUG2016/12:15	9.24	4.76 - 23.24	No	
		Week 32	13SEP2016/11:45	9.80	4.76 - 23.24	No	
		Week 36	13OCT2016/12:10	10.92	4.76 - 23.24	No	
		Week 40	08NOV2016/11:00	14.56	4.76 - 23.24	No	
		Week 44	08DEC2016/11:00	8.68	4.76 - 23.24	No	
		Week 48	03JAN2017/12:00	9.80	4.76 - 23.24	No	

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Calcium (mmol/L)	Screening	14JAN2016/13:30	2.40	2.2 - 2.6	Yes	0
		Day 1	04FEB2016/09:45	2.43	2.2 - 2.6	Yes	0
		Week 1	10FEB2016/13:00	2.30	2.2 - 2.6	No	0
		Week 2	16FEB2016/14:00	2.26	2.2 - 2.6	No	0
		Week 4	03MAR2016/12:15	2.34	2.2 - 2.6	No	0
		Week 6	17MAR2016/11:31	2.35	2.2 - 2.6	No	0
		Week 8	31MAR2016/11:22	2.34	2.2 - 2.6	No	0
		Week 12	26APR2016/08:15	2.30	2.2 - 2.6	Yes	0
		Week 16	25MAY2016/11:55	2.40	2.2 - 2.6	No	0
		Week 20	23JUN2016/12:45	2.27	2.2 - 2.6	No	0
		Week 24	19JUL2016/12:00	2.35	2.2 - 2.6	Yes	0
		Week 28	18AUG2016/12:15	2.24	2.2 - 2.6	No	0
		Week 32	13SEP2016/11:45	2.20	2.2 - 2.6	No	0
		Week 36	13OCT2016/12:10	2.26	2.2 - 2.6	No	0
		Week 40	08NOV2016/11:00	2.27	2.2 - 2.6	No	0
		Week 44	08DEC2016/11:00	2.31	2.2 - 2.6	No	0
		Week 48	03JAN2017/12:00	2.35	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	14JAN2016/13:30	100	98 - 107	Yes	
		Day 1	04FEB2016/09:45	99	98 - 107	Yes	
		Week 1	10FEB2016/13:00	98	98 - 107	No	
		Week 2	16FEB2016/14:00	101	98 - 107	No	
		Week 4	03MAR2016/12:15	100	98 - 107	No	
		Week 6	17MAR2016/11:31	100	98 - 107	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Chloride (mmol/L)	Week 8	31MAR2016/11:22	100	98 - 107	No	
		Week 12	26APR2016/08:15	99	98 - 107	Yes	
		Week 16	25MAY2016/11:55	101	98 - 107	No	
		Week 20	23JUN2016/12:45	101	98 - 107	No	
		Week 24	19JUL2016/12:00	99	98 - 107	Yes	
		Week 28	18AUG2016/12:15	101	98 - 107	No	
		Week 32	13SEP2016/11:45	101	98 - 107	No	
		Week 36	13OCT2016/12:10	102	98 - 107	No	
		Week 40	08NOV2016/11:00	101	98 - 107	No	
		Week 44	08DEC2016/11:00	102	98 - 107	No	
		Week 48	03JAN2017/12:00	100	98 - 107	No	
	Cholesterol (mmol/L)	Screening	14JAN2016/13:30	4.7	0 - 4.9	Yes	0
		Day 1	04FEB2016/09:45	5.1 H	0 - 4.9	Yes	1
		Week 1	10FEB2016/13:00	4.2	0 - 4.9	No	0
		Week 2	16FEB2016/14:00	3.9	0 - 4.9	No	0
		Week 4	03MAR2016/12:15	4.1	0 - 4.9	No	0
		Week 6	17MAR2016/11:31	3.9	0 - 4.9	No	0
		Week 8	31MAR2016/11:22	4.1	0 - 4.9	No	0
		Week 12	26APR2016/08:15	3.6	0 - 4.9	Yes	0
		Week 16	25MAY2016/11:55	3.2	0 - 4.9	No	0
		Week 20	23JUN2016/12:45	3.4	0 - 4.9	No	0
		Week 24	19JUL2016/12:00	3.7	0 - 4.9	Yes	0
		Week 28	18AUG2016/12:15	3.4	0 - 4.9	No	0

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Cholesterol (mmol/L)	Week 32	13SEP2016/11:45	5.0 H	0 - 4.9	No	1
		Week 36	13OCT2016/12:10	4.5	0 - 4.9	No	0
		Week 40	08NOV2016/11:00	4.6	0 - 4.9	No	0
		Week 44	08DEC2016/11:00	4.4	0 - 4.9	No	0
		Week 48	03JAN2017/12:00	4.8	0 - 4.9	No	0
	Creatine Kinase (IU/L)	Screening	14JAN2016/13:30	140	38 - 204	Yes	0
		Day 1	04FEB2016/09:45	147	38 - 204	Yes	0
		Week 1	10FEB2016/13:00	162	38 - 204	No	0
		Week 2	16FEB2016/14:00	108	38 - 204	No	0
		Week 4	03MAR2016/12:15	125	38 - 204	No	0
		Week 6	17MAR2016/11:31	183	38 - 204	No	0
		Week 8	31MAR2016/11:22	154	38 - 204	No	0
		Week 12	26APR2016/08:15	123	38 - 204	Yes	0
		Week 16	25MAY2016/11:55	131	38 - 204	No	0
		Week 20	23JUN2016/12:45	98	38 - 204	No	0
		Week 24	19JUL2016/12:00	123	38 - 204	Yes	0
		Week 28	18AUG2016/12:15	120	38 - 204	No	0
		Week 32	13SEP2016/11:45	170	38 - 204	No	0
		Week 36	13OCT2016/12:10	191	38 - 204	No	0
		Week 40	08NOV2016/11:00	125	38 - 204	No	0
		Week 44	08DEC2016/11:00	122	38 - 204	No	0
		Week 48	03JAN2017/12:00	206 H	38 - 204	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006 Creatinine (umol/L)	Screening	14JAN2016/13:30	75	66 - 112	Yes	0
	Day 1	04FEB2016/09:45	75	66 - 112	Yes	0
	Week 1	10FEB2016/13:00	77	66 - 112	No	1
	Week 2	16FEB2016/14:00	71	66 - 112	No	0
	Week 4	03MAR2016/12:15	84	66 - 112	No	1
	Week 6	17MAR2016/11:31	78	66 - 112	No	1
	Week 8	31MAR2016/11:22	77	66 - 112	No	1
	Week 12	26APR2016/08:15	85	66 - 112	Yes	1
	Week 16	25MAY2016/11:55	80	66 - 112	No	1
	Week 20	23JUN2016/12:45	76	66 - 112	No	1
	Week 24	19JUL2016/12:00	96	66 - 112	Yes	1
	Week 28	18AUG2016/12:15	75	66 - 112	No	0
	Week 32	13SEP2016/11:45	70	66 - 112	No	0
	Week 36	13OCT2016/12:10	73	66 - 112	No	0
	Week 40	08NOV2016/11:00	75	66 - 112	No	0
	Week 44	08DEC2016/11:00	80	66 - 112	No	1
	Week 48	03JAN2017/12:00	74	66 - 112	No	0
Direct Bilirubin (umol/L)	Screening	14JAN2016/13:30	5	0 - 5	Yes	
	Day 1	04FEB2016/09:45	5	0 - 5	Yes	
	Week 1	10FEB2016/13:00	5	0 - 5	No	
	Week 2	16FEB2016/14:00	4	0 - 5	No	
	Week 4	03MAR2016/12:15	3	0 - 5	No	
	Week 6	17MAR2016/11:31	4	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Direct Bilirubin (umol/L)	Week 8	31MAR2016/11:22	3	0 - 5	No	
		Week 12	26APR2016/08:15	5	0 - 5	Yes	
		Week 16	25MAY2016/11:55	5	0 - 5	No	
		Week 20	23JUN2016/12:45	4	0 - 5	No	
		Week 24	19JUL2016/12:00	3	0 - 5	Yes	
		Week 28	18AUG2016/12:15	15 H	0 - 5	No	
		Week 32	13SEP2016/11:45	5	0 - 5	No	
		Week 36	13OCT2016/12:10	4	0 - 5	No	
		Week 40	08NOV2016/11:00	4	0 - 5	No	
		Week 44	08DEC2016/11:00	3	0 - 5	No	
		Week 48	03JAN2017/12:00	4	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	14JAN2016/13:30	112 H	10 - 71	Yes	1
		Day 1	04FEB2016/09:45	117 H	10 - 71	Yes	1
		Week 1	10FEB2016/13:00	102 H	10 - 71	No	1
		Week 2	16FEB2016/14:00	89 H	10 - 71	No	1
		Week 4	03MAR2016/12:15	65	10 - 71	No	0
		Week 6	17MAR2016/11:31	54	10 - 71	No	0
		Week 8	31MAR2016/11:22	56	10 - 71	No	0
		Week 12	26APR2016/08:15	43	10 - 71	Yes	0
		Week 16	25MAY2016/11:55	40	10 - 71	No	0
		Week 20	23JUN2016/12:45	48	10 - 71	No	0
		Week 24	19JUL2016/12:00	60	10 - 71	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Gamma Glutamyl Transferase (IU/L)	Week 28	18AUG2016/12:15	246 H	10 - 71	No	2
		Week 32	13SEP2016/11:45	158 H	10 - 71	No	1
		Week 36	13OCT2016/12:10	69	10 - 71	No	0
		Week 40	08NOV2016/11:00	63	10 - 71	No	0
		Week 44	08DEC2016/11:00	51	10 - 71	No	0
		Week 48	03JAN2017/12:00	94 H	10 - 71	No	1
	Globulin (g/L)	Screening	14JAN2016/13:30	34	19 - 35	Yes	
		Day 1	04FEB2016/09:45	40 H	19 - 35	Yes	
		Week 1	10FEB2016/13:00	39 H	19 - 35	No	
		Week 2	16FEB2016/14:00	37 H	19 - 35	No	
		Week 4	03MAR2016/12:15	37 H	19 - 35	No	
		Week 6	17MAR2016/11:31	37 H	19 - 35	No	
		Week 8	31MAR2016/11:22	36 H	19 - 35	No	
		Week 12	26APR2016/08:15	36 H	19 - 35	Yes	
		Week 16	25MAY2016/11:55	32	19 - 35	No	
		Week 20	23JUN2016/12:45	34	19 - 35	No	
		Week 24	19JUL2016/12:00	37 H	19 - 35	Yes	
		Week 28	18AUG2016/12:15	41 H	19 - 35	No	
		Week 32	13SEP2016/11:45	46 H	19 - 35	No	
		Week 36	13OCT2016/12:10	42 H	19 - 35	No	
		Week 40	08NOV2016/11:00	36 H	19 - 35	No	
		Week 44	08DEC2016/11:00	38 H	19 - 35	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Globulin (g/L)	Week 48	03JAN2017/12:00	35	19 - 35	No	
	Glucose (mmol/L)	Screening	14JAN2016/13:30	5.1	3.9 - 5.8	Yes	0
		Day 1	04FEB2016/09:45	4.7	3.9 - 5.8	Yes	0
		Week 1	10FEB2016/13:00	4.8	3.5 - 7.9	No	0
		Week 2	16FEB2016/14:00	4.7	3.5 - 7.9	No	0
		Week 4	03MAR2016/12:15	4.9	3.5 - 7.9	No	0
		Week 6	17MAR2016/11:31	4.7	3.5 - 7.9	No	0
		Week 8	31MAR2016/11:22	5.0	3.5 - 7.9	No	0
		Week 12	26APR2016/08:15	4.9	3.9 - 5.8	Yes	0
		Week 16	25MAY2016/11:55	5.0	3.5 - 7.9	No	0
		Week 20	23JUN2016/12:45	4.7	3.5 - 7.9	No	0
		Week 24	19JUL2016/12:00	4.9	3.9 - 5.8	Yes	0
		Week 28	18AUG2016/12:15	5.4	3.5 - 7.9	No	0
		Week 32	13SEP2016/11:45	4.2	3.5 - 7.9	No	0
		Week 36	13OCT2016/12:10	4.5	3.5 - 7.9	No	0
		Week 40	08NOV2016/11:00	4.6	3.5 - 7.9	No	0
		Week 44	08DEC2016/11:00	4.9	3.5 - 7.9	No	0
		Week 48	03JAN2017/12:00	5.0	3.5 - 7.9	No	0
	Indirect Bilirubin (umol/L)	Screening	14JAN2016/13:30	6	0 - 14	Yes	
		Day 1	04FEB2016/09:45	9	0 - 14	Yes	
		Week 1	10FEB2016/13:00	8	0 - 14	No	
		Week 2	16FEB2016/14:00	3	0 - 14	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Indirect Bilirubin (umol/L)	Week 4	03MAR2016/12:15	2	0 - 14	No
		Week 6	17MAR2016/11:31	3	0 - 14	No
		Week 8	31MAR2016/11:22	5	0 - 14	No
		Week 12	26APR2016/08:15	7	0 - 14	Yes
		Week 16	25MAY2016/11:55	4	0 - 14	No
		Week 20	23JUN2016/12:45	3	0 - 14	No
		Week 24	19JUL2016/12:00	4	0 - 14	Yes
		Week 28	18AUG2016/12:15	5	0 - 14	No
		Week 32	13SEP2016/11:45	4	0 - 14	No
		Week 36	13OCT2016/12:10	5	0 - 14	No
		Week 40	08NOV2016/11:00	4	0 - 14	No
		Week 44	08DEC2016/11:00	4	0 - 14	No
		Week 48	03JAN2017/12:00	6	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	14JAN2016/13:30	205	135 - 225	Yes
		Day 1	04FEB2016/09:45	201	135 - 225	Yes
		Week 1	10FEB2016/13:00	199	135 - 225	No
		Week 2	16FEB2016/14:00	168	135 - 225	No
		Week 4	03MAR2016/12:15	167	135 - 225	No
		Week 6	17MAR2016/11:31	177	135 - 225	No
		Week 8	31MAR2016/11:22	187	135 - 225	No
		Week 12	26APR2016/08:15	167	135 - 225	Yes
		Week 16	25MAY2016/11:55	174	135 - 225	No
		Week 20	23JUN2016/12:45	181	135 - 225	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Lactate Dehydrogenase (IU/L)	Week 24	19JUL2016/12:00	185	135 - 225	Yes	
		Week 28	18AUG2016/12:15	275 H	135 - 225	No	
		Week 32	13SEP2016/11:45	203	135 - 225	No	
		Week 36	13OCT2016/12:10	186	135 - 225	No	
		Week 40	08NOV2016/11:00	195	135 - 225	No	
		Week 44	08DEC2016/11:00	195	135 - 225	No	
		Week 48	03JAN2017/12:00	209	135 - 225	No	
	Magnesium (mmol/L)	Screening	14JAN2016/13:30	0.89	0.6 - 1	Yes	0
		Day 1	04FEB2016/09:45	0.82	0.6 - 1	Yes	0
		Week 1	10FEB2016/13:00	0.87	0.6 - 1	No	0
		Week 2	16FEB2016/14:00	0.85	0.6 - 1	No	0
		Week 4	03MAR2016/12:15	0.81	0.6 - 1	No	0
		Week 6	17MAR2016/11:31	0.78	0.6 - 1	No	0
		Week 8	31MAR2016/11:22	0.80	0.6 - 1	No	0
		Week 12	26APR2016/08:15	0.77	0.6 - 1	Yes	0
		Week 16	25MAY2016/11:55	0.77	0.6 - 1	No	0
		Week 20	23JUN2016/12:45	0.78	0.6 - 1	No	0
		Week 24	19JUL2016/12:00	0.78	0.6 - 1	Yes	0
		Week 28	18AUG2016/12:15	0.88	0.6 - 1	No	0
		Week 32	13SEP2016/11:45	0.85	0.6 - 1	No	0
		Week 36	13OCT2016/12:10	0.86	0.6 - 1	No	0
		Week 40	08NOV2016/11:00	0.87	0.6 - 1	No	0
		Week 44	08DEC2016/11:00	0.85	0.6 - 1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Magnesium (mmol/L)	Week 48	03JAN2017/12:00	0.92	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	14JAN2016/13:30	0.93	0.87 - 1.45	Yes	0
		Day 1	04FEB2016/09:45	1.33	0.87 - 1.45	Yes	0
		Week 1	10FEB2016/13:00	1.07	0.87 - 1.45	No	0
		Week 2	16FEB2016/14:00	0.96	0.87 - 1.45	No	0
		Week 4	03MAR2016/12:15	0.96	0.87 - 1.45	No	0
		Week 6	17MAR2016/11:31	1.05	0.87 - 1.45	No	0
		Week 8	31MAR2016/11:22	1.08	0.87 - 1.45	No	0
		Week 12	26APR2016/08:15	1.17	0.87 - 1.45	Yes	0
		Week 16	25MAY2016/11:55	1.26	0.87 - 1.45	No	0
		Week 20	23JUN2016/12:45	1.05	0.87 - 1.45	No	0
		Week 24	19JUL2016/12:00	1.09	0.87 - 1.45	Yes	0
		Week 28	18AUG2016/12:15	0.86 L	0.87 - 1.45	No	1
		Week 32	13SEP2016/11:45	0.89	0.87 - 1.45	No	0
		Week 36	13OCT2016/12:10	0.73 L	0.87 - 1.45	No	2
		Week 40	08NOV2016/11:00	0.90	0.87 - 1.45	No	0
		Week 44	08DEC2016/11:00	0.96	0.87 - 1.45	No	0
		Week 48	03JAN2017/12:00	1.02	0.87 - 1.45	No	0
	Potassium (mmol/L)	Screening	14JAN2016/13:30	4.4	3.5 - 5.1	Yes	0
		Day 1	04FEB2016/09:45	4.5	3.5 - 5.1	Yes	0
		Week 1	10FEB2016/13:00	4.8	3.5 - 5.1	No	0
		Week 2	16FEB2016/14:00	4.7	3.5 - 5.1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Potassium (mmol/L)	Week 4	03MAR2016/12:15	4.2	3.5 - 5.1	No	0
		Week 6	17MAR2016/11:31	4.2	3.5 - 5.1	No	0
		Week 8	31MAR2016/11:22	4.1	3.5 - 5.1	No	0
		Week 12	26APR2016/08:15	3.6	3.5 - 5.1	Yes	0
		Week 16	25MAY2016/11:55	3.9	3.5 - 5.1	No	0
		Week 20	23JUN2016/12:45	4.0	3.5 - 5.1	No	0
		Week 24	19JUL2016/12:00	3.9	3.5 - 5.1	Yes	0
		Week 28	18AUG2016/12:15	4.3	3.5 - 5.1	No	0
		Week 32	13SEP2016/11:45	4.4	3.5 - 5.1	No	0
		Week 36	13OCT2016/12:10	4.4	3.5 - 5.1	No	0
		Week 40	08NOV2016/11:00	4.7	3.5 - 5.1	No	0
		Week 44	08DEC2016/11:00	4.6	3.5 - 5.1	No	0
		Week 48	03JAN2017/12:00	4.7	3.5 - 5.1	No	0
	Protein (g/L)	Screening	14JAN2016/13:30	80	63 - 83	Yes	
		Day 1	04FEB2016/09:45	86 H	63 - 83	Yes	
		Week 1	10FEB2016/13:00	81	63 - 83	No	
		Week 2	16FEB2016/14:00	78	63 - 83	No	
		Week 4	03MAR2016/12:15	77	63 - 83	No	
		Week 6	17MAR2016/11:31	80	63 - 83	No	
		Week 8	31MAR2016/11:22	79	63 - 83	No	
		Week 12	26APR2016/08:15	78	63 - 83	Yes	
		Week 16	25MAY2016/11:55	75	63 - 83	No	
		Week 20	23JUN2016/12:45	78	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Protein (g/L)	Week 24	19JUL2016/12:00	80	63 - 83	Yes	
		Week 28	18AUG2016/12:15	80	63 - 83	No	
		Week 32	13SEP2016/11:45	84 H	63 - 83	No	
		Week 36	13OCT2016/12:10	84 H	63 - 83	No	
		Week 40	08NOV2016/11:00	79	63 - 83	No	
		Week 44	08DEC2016/11:00	80	63 - 83	No	
		Week 48	03JAN2017/12:00	79	63 - 83	No	
	Sodium (mmol/L)	Screening	14JAN2016/13:30	141	135 - 145	Yes	0
		Day 1	04FEB2016/09:45	140	135 - 145	Yes	0
		Week 1	10FEB2016/13:00	136	135 - 145	No	0
		Week 2	16FEB2016/14:00	138	135 - 145	No	0
		Week 4	03MAR2016/12:15	140	135 - 145	No	0
		Week 6	17MAR2016/11:31	140	135 - 145	No	0
		Week 8	31MAR2016/11:22	140	135 - 145	No	0
		Week 12	26APR2016/08:15	140	135 - 145	Yes	0
		Week 16	25MAY2016/11:55	141	135 - 145	No	0
		Week 20	23JUN2016/12:45	141	135 - 145	No	0
		Week 24	19JUL2016/12:00	140	135 - 145	Yes	0
		Week 28	18AUG2016/12:15	137	135 - 145	No	0
		Week 32	13SEP2016/11:45	139	135 - 145	No	0
		Week 36	13OCT2016/12:10	139	135 - 145	No	0
		Week 40	08NOV2016/11:00	140	135 - 145	No	0
		Week 44	08DEC2016/11:00	142	135 - 145	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Sodium (mmol/L)	Week 48	03JAN2017/12:00	140	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	14JAN2016/13:30	1.48	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	14JAN2016/13:30	119	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	14JAN2016/13:30	0.9	0 - 2.2	Yes	0
		Day 1	04FEB2016/09:45	0.8	0 - 2.2	Yes	0
		Week 1	10FEB2016/13:00	0.9	0 - 2.2	No	0
		Week 2	16FEB2016/14:00	0.8	0 - 2.2	No	0
		Week 4	03MAR2016/12:15	0.8	0 - 2.2	No	0
		Week 6	17MAR2016/11:31	0.8	0 - 2.2	No	0
		Week 8	31MAR2016/11:22	0.9	0 - 2.2	No	0
		Week 12	26APR2016/08:15	0.8	0 - 2.2	Yes	0
		Week 16	25MAY2016/11:55	0.6	0 - 2.2	No	0
		Week 20	23JUN2016/12:45	0.8	0 - 2.2	No	0
		Week 24	19JUL2016/12:00	1.0	0 - 2.2	Yes	0
		Week 28	18AUG2016/12:15	1.0	0 - 2.2	No	0
		Week 32	13SEP2016/11:45	1.3	0 - 2.2	No	0
		Week 36	13OCT2016/12:10	0.9	0 - 2.2	No	0
		Week 40	08NOV2016/11:00	0.7	0 - 2.2	No	0
		Week 44	08DEC2016/11:00	0.9	0 - 2.2	No	0
		Week 48	03JAN2017/12:00	1.2	0 - 2.2	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Triiodothyronine (nmol/L)	Screening	14JAN2016/13:30	2.7	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	14JAN2016/13:30	4.9	1.7 - 8.3	Yes	
		Day 1	04FEB2016/09:45	4.6	1.7 - 8.3	Yes	
		Week 1	10FEB2016/13:00	3.1	1.7 - 8.3	No	
		Week 2	16FEB2016/14:00	4.2	1.7 - 8.3	No	
		Week 4	03MAR2016/12:15	5.0	1.7 - 8.3	No	
		Week 6	17MAR2016/11:31	4.0	1.7 - 8.3	No	
		Week 8	31MAR2016/11:22	4.1	1.7 - 8.3	No	
		Week 12	26APR2016/08:15	4.0	1.7 - 8.3	Yes	
		Week 16	25MAY2016/11:55	4.6	1.7 - 8.3	No	
		Week 20	23JUN2016/12:45	5.1	1.7 - 8.3	No	
		Week 24	19JUL2016/12:00	3.6	1.7 - 8.3	Yes	
		Week 28	18AUG2016/12:15	3.3	1.7 - 8.3	No	
		Week 32	13SEP2016/11:45	3.5	1.7 - 8.3	No	
		Week 36	13OCT2016/12:10	3.9	1.7 - 8.3	No	
		Week 40	08NOV2016/11:00	5.2	1.7 - 8.3	No	
		Week 44	08DEC2016/11:00	3.1	1.7 - 8.3	No	
		Week 48	03JAN2017/12:00	3.5	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	14JAN2016/13:30	356	266 - 474	Yes	0
		Day 1	04FEB2016/09:45	369	266 - 474	Yes	0
		Week 1	10FEB2016/13:00	325	266 - 474	No	0
		Week 2	16FEB2016/14:00	397	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Uric acid (umol/L)	Week 4	03MAR2016/12:15	434	266 - 474	No	0
		Week 6	17MAR2016/11:31	474	266 - 474	No	0
		Week 8	31MAR2016/11:22	415	266 - 474	No	0
		Week 12	26APR2016/08:15	414	266 - 474	Yes	0
		Week 16	25MAY2016/11:55	434	266 - 474	No	0
		Week 20	23JUN2016/12:45	354	266 - 474	No	0
		Week 24	19JUL2016/12:00	403	266 - 474	Yes	0
		Week 28	18AUG2016/12:15	339	266 - 474	No	0
		Week 32	13SEP2016/11:45	445	266 - 474	No	0
		Week 36	13OCT2016/12:10	372	266 - 474	No	0
		Week 40	08NOV2016/11:00	399	266 - 474	No	0
		Week 44	08DEC2016/11:00	345	266 - 474	No	0
		Week 48	03JAN2017/12:00	390	266 - 474	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Alanine Aminotransferase (IU/L)	Screening	17FEB2016/13:00	137 H	10 - 35	Yes	2
		Day 1	08MAR2016/10:50	115 H	10 - 35	No	2
		Week 1	15MAR2016/09:25	104 H	10 - 35	No	1
		Week 2	23MAR2016/09:08	174 H	10 - 35	No	2
		Week 4	05APR2016/10:15	204 H	10 - 35	No	3
		Week 6	19APR2016/09:45	248 H	10 - 35	No	3
		Week 8	28APR2016/10:10	106 H	10 - 35	No	2
		Week 12	01JUN2016/08:30	15	10 - 35	Yes	0
		Week 16	29JUN2016/09:23	20	10 - 35	No	0
		Week 20	26JUL2016/09:45	19	10 - 35	No	0
		Week 24	24AUG2016/09:30	20	10 - 35	Yes	0
		Week 28	20SEP2016/12:00	111 H	10 - 35	No	2
		Week 32	19OCT2016/11:00	98 H	10 - 35	No	1
		Week 36	15NOV2016/11:15	354 H	10 - 35	No	3
		Week 40	14DEC2016/09:30	145 H	10 - 35	No	2
		Week 44	11JAN2017/11:00	146 H	10 - 35	No	2
		Week 48	08FEB2017/11:50	99 H	10 - 35	No	1
	Albumin (g/L)	Screening	17FEB2016/13:00	44	34 - 50	Yes	0
		Day 1	08MAR2016/10:50	42	34 - 50	No	0
		Week 1	15MAR2016/09:25	44	34 - 50	No	0
		Week 2	23MAR2016/09:08	44	34 - 50	No	0
		Week 4	05APR2016/10:15	45	34 - 50	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Albumin (g/L)	Week 6	19APR2016/09:45	46	34 - 50	No	0
		Week 8	28APR2016/10:10	41	34 - 50	No	0
		Week 12	01JUN2016/08:30	43	34 - 50	Yes	0
		Week 16	29JUN2016/09:23	44	34 - 50	No	0
		Week 20	26JUL2016/09:45	44	34 - 50	No	0
		Week 24	24AUG2016/09:30	43	34 - 50	Yes	0
		Week 28	20SEP2016/12:00	45	34 - 50	No	0
		Week 32	19OCT2016/11:00	44	34 - 50	No	0
		Week 36	15NOV2016/11:15	45	34 - 50	No	0
		Week 40	14DEC2016/09:30	43	34 - 50	No	0
		Week 44	11JAN2017/11:00	45	34 - 50	No	0
		Week 48	08FEB2017/11:50	41	34 - 50	No	0
	Alkaline Phosphatase (IU/L)	Screening	17FEB2016/13:00	93	35 - 104	Yes	0
		Day 1	08MAR2016/10:50	96	35 - 104	No	0
		Week 1	15MAR2016/09:25	83	35 - 104	No	0
		Week 2	23MAR2016/09:08	84	35 - 104	No	0
		Week 4	05APR2016/10:15	80	35 - 104	No	0
		Week 6	19APR2016/09:45	81	35 - 104	No	0
		Week 8	28APR2016/10:10	69	35 - 104	No	0
		Week 12	01JUN2016/08:30	88	35 - 104	Yes	0
		Week 16	29JUN2016/09:23	102	35 - 104	No	0
		Week 20	26JUL2016/09:45	103	35 - 104	No	0
		Week 24	24AUG2016/09:30	103	35 - 104	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Alkaline Phosphatase (IU/L)	Week 28	20SEP2016/12:00	121 H	35 - 104	No	1
		Week 32	19OCT2016/11:00	124 H	35 - 104	No	1
		Week 36	15NOV2016/11:15	186 H	35 - 104	No	1
		Week 40	14DEC2016/09:30	147 H	35 - 104	No	1
		Week 44	11JAN2017/11:00	163 H	35 - 104	No	1
		Week 48	08FEB2017/11:50	129 H	35 - 104	No	1
	Amylase (IU/L)	Screening	17FEB2016/13:00	63	28 - 100	Yes	0
		Day 1	08MAR2016/10:50	64	28 - 100	No	0
		Week 1	15MAR2016/09:25	54	28 - 100	No	0
		Week 2	23MAR2016/09:08	52	28 - 100	No	0
		Week 4	05APR2016/10:15	62	28 - 100	No	0
		Week 6	19APR2016/09:45	56	28 - 100	No	0
		Week 8	28APR2016/10:10	66	28 - 100	No	0
		Week 12	01JUN2016/08:30	68	28 - 100	Yes	0
		Week 16	29JUN2016/09:23	73	28 - 100	No	0
		Week 20	26JUL2016/09:45	74	28 - 100	No	0
		Week 24	24AUG2016/09:30	76	28 - 100	Yes	0
		Week 28	20SEP2016/12:00	76	28 - 100	No	0
		Week 32	19OCT2016/11:00	69	28 - 100	No	0
		Week 36	15NOV2016/11:15	79	28 - 100	No	0
		Week 40	14DEC2016/09:30	73	28 - 100	No	0
		Week 44	11JAN2017/11:00	79	28 - 100	No	0
		Week 48	08FEB2017/11:50	70	28 - 100	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Aspartate Aminotransferase (IU/L)	Screening	17FEB2016/13:00	103 H	0 - 31	Yes	2
		Day 1	08MAR2016/10:50	76 H	0 - 31	No	1
		Week 1	15MAR2016/09:25	74 H	0 - 31	No	1
		Week 2	23MAR2016/09:08	93 H	0 - 31	No	1
		Week 4	05APR2016/10:15	91 H	0 - 31	No	1
		Week 6	19APR2016/09:45	110 H	0 - 31	No	2
		Week 8	28APR2016/10:10	39 H	0 - 31	No	1
		Week 12	01JUN2016/08:30	18	0 - 31	Yes	0
		Week 16	29JUN2016/09:23	23	0 - 31	No	0
		Week 20	26JUL2016/09:45	24	0 - 31	No	0
		Week 24	24AUG2016/09:30	24	0 - 31	Yes	0
		Week 28	20SEP2016/12:00	83 H	0 - 31	No	1
		Week 32	19OCT2016/11:00	74 H	0 - 31	No	1
		Week 36	15NOV2016/11:15	242 H	0 - 31	No	3
		Week 40	14DEC2016/09:30	94 H	0 - 31	No	2
		Week 44	11JAN2017/11:00	111 H	0 - 31	No	2
		Week 48	08FEB2017/11:50	89 H	0 - 31	No	1
	Bicarbonate (mmol/L)	Screening	17FEB2016/13:00	25	22 - 29	Yes	
		Day 1	08MAR2016/10:50	24	22 - 29	No	
		Week 1	15MAR2016/09:25	26	22 - 29	No	
		Week 2	23MAR2016/09:08	27	22 - 29	No	
		Week 4	05APR2016/10:15	27	22 - 29	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Bicarbonate (mmol/L)	Week 6	19APR2016/09:45	28	22 - 29	No	
		Week 8	28APR2016/10:10	25	22 - 29	No	
		Week 12	01JUN2016/08:30	24	22 - 29	Yes	
		Week 16	29JUN2016/09:23	26	22 - 29	No	
		Week 20	26JUL2016/09:45	22	22 - 29	No	
		Week 24	24AUG2016/09:30	24	22 - 29	Yes	
		Week 28	20SEP2016/12:00	24	22 - 29	No	
		Week 32	19OCT2016/11:00	25	22 - 29	No	
		Week 36	15NOV2016/11:15	24	22 - 29	No	
		Week 40	14DEC2016/09:30	21 L	22 - 29	No	
		Week 44	11JAN2017/11:00	23	22 - 29	No	
		Week 48	08FEB2017/11:50	25	22 - 29	No	
	Bilirubin (umol/L)	Screening	17FEB2016/13:00	9	0 - 20	Yes	0
		Day 1	08MAR2016/10:50	7	0 - 20	No	0
		Week 1	15MAR2016/09:25	8	0 - 20	No	0
		Week 2	23MAR2016/09:08	7	0 - 20	No	0
		Week 4	05APR2016/10:15	7	0 - 20	No	0
		Week 6	19APR2016/09:45	8	0 - 20	No	0
		Week 8	28APR2016/10:10	5	0 - 20	No	0
		Week 12	01JUN2016/08:30	5	0 - 20	Yes	0
		Week 16	29JUN2016/09:23	3	0 - 20	No	0
		Week 20	26JUL2016/09:45	3	0 - 20	No	0
		Week 24	24AUG2016/09:30	5	0 - 20	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Bilirubin (umol/L)	Week 28	20SEP2016/12:00	7	0 - 20	No	0
		Week 32	19OCT2016/11:00	7	0 - 20	No	0
		Week 36	15NOV2016/11:15	8	0 - 20	No	0
		Week 40	14DEC2016/09:30	6	0 - 20	No	0
		Week 44	11JAN2017/11:00	5	0 - 20	No	0
		Week 48	08FEB2017/11:50	5	0 - 20	No	0
	Blood Urea Nitrogen (mg/dL)	Screening	17FEB2016/13:00	15.96	4.76 - 23.24	Yes	
		Day 1	08MAR2016/10:50	11.20	4.76 - 23.24	No	
		Week 1	15MAR2016/09:25	15.96	4.76 - 23.24	No	
		Week 2	23MAR2016/09:08	15.12	4.76 - 23.24	No	
		Week 4	05APR2016/10:15	12.32	4.76 - 23.24	No	
		Week 6	19APR2016/09:45	11.76	4.76 - 23.24	No	
		Week 8	28APR2016/10:10	10.08	4.76 - 23.24	No	
		Week 12	01JUN2016/08:30	11.76	4.76 - 23.24	Yes	
		Week 16	29JUN2016/09:23	9.52	4.76 - 23.24	No	
		Week 20	26JUL2016/09:45	10.08	4.76 - 23.24	No	
		Week 24	24AUG2016/09:30	13.44	4.76 - 23.24	Yes	
		Week 28	20SEP2016/12:00	10.08	4.76 - 23.24	No	
		Week 32	19OCT2016/11:00	13.44	4.76 - 23.24	No	
		Week 36	15NOV2016/11:15	10.08	4.76 - 23.24	No	
		Week 40	14DEC2016/09:30	13.16	4.76 - 23.24	No	
		Week 44	11JAN2017/11:00	12.32	4.76 - 23.24	No	
		Week 48	08FEB2017/11:50	10.36	4.76 - 23.24	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Calcium (mmol/L)	Screening	17FEB2016/13:00	2.34	2.2 - 2.6	Yes	0
		Day 1	08MAR2016/10:50	2.34	2.2 - 2.6	No	0
		Week 1	15MAR2016/09:25	2.35	2.2 - 2.6	No	0
		Week 2	23MAR2016/09:08	2.38	2.2 - 2.6	No	0
		Week 4	05APR2016/10:15	2.37	2.2 - 2.6	No	0
		Week 6	19APR2016/09:45	2.42	2.2 - 2.6	No	0
		Week 8	28APR2016/10:10	2.31	2.2 - 2.6	No	0
		Week 12	01JUN2016/08:30	2.39	2.2 - 2.6	Yes	0
		Week 16	29JUN2016/09:23	2.48	2.2 - 2.6	No	0
		Week 20	26JUL2016/09:45	2.37	2.2 - 2.6	No	0
		Week 24	24AUG2016/09:30	2.38	2.2 - 2.6	Yes	0
		Week 28	20SEP2016/12:00	2.43	2.2 - 2.6	No	0
		Week 32	19OCT2016/11:00	2.38	2.2 - 2.6	No	0
		Week 36	15NOV2016/11:15	2.42	2.2 - 2.6	No	0
		Week 40	14DEC2016/09:30	2.37	2.2 - 2.6	No	0
		Week 44	11JAN2017/11:00	2.40	2.2 - 2.6	No	0
		Week 48	08FEB2017/11:50	2.29	2.2 - 2.6	No	0
	Chloride (mmol/L)	Screening	17FEB2016/13:00	104	98 - 107	Yes	
		Day 1	08MAR2016/10:50	103	98 - 107	No	
		Week 1	15MAR2016/09:25	101	98 - 107	No	
		Week 2	23MAR2016/09:08	98	98 - 107	No	
		Week 4	05APR2016/10:15	95 L	98 - 107	No	
		Week 6	19APR2016/09:45	95 L	98 - 107	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Chloride (mmol/L)	Week 8	28APR2016/10:10	101	98 - 107	No	
		Week 12	01JUN2016/08:30	103	98 - 107	Yes	
		Week 16	29JUN2016/09:23	101	98 - 107	No	
		Week 20	26JUL2016/09:45	103	98 - 107	No	
		Week 24	24AUG2016/09:30	104	98 - 107	Yes	
		Week 28	20SEP2016/12:00	103	98 - 107	No	
		Week 32	19OCT2016/11:00	105	98 - 107	No	
		Week 36	15NOV2016/11:15	103	98 - 107	No	
		Week 40	14DEC2016/09:30	102	98 - 107	No	
		Week 44	11JAN2017/11:00	102	98 - 107	No	
		Week 48	08FEB2017/11:50	102	98 - 107	No	
	Cholesterol (mmol/L)	Screening	17FEB2016/13:00	4.0	0 - 4.9	Yes	0
		Day 1	08MAR2016/10:50	4.4	0 - 4.9	No	0
		Week 1	15MAR2016/09:25	4.0	0 - 4.9	No	0
		Week 2	23MAR2016/09:08	4.0	0 - 4.9	No	0
		Week 4	05APR2016/10:15	3.9	0 - 4.9	No	0
		Week 6	19APR2016/09:45	4.3	0 - 4.9	No	0
		Week 8	28APR2016/10:10	4.1	0 - 4.9	No	0
		Week 12	01JUN2016/08:30	4.7	0 - 4.9	Yes	0
		Week 16	29JUN2016/09:23	4.5	0 - 4.9	No	0
		Week 20	26JUL2016/09:45	4.6	0 - 4.9	No	0
		Week 24	24AUG2016/09:30	4.3	0 - 4.9	Yes	0
		Week 28	20SEP2016/12:00	4.7	0 - 4.9	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Cholesterol (mmol/L)	Week 32	19OCT2016/11:00	4.2	0 - 4.9	No	0
		Week 36	15NOV2016/11:15	4.1	0 - 4.9	No	0
		Week 40	14DEC2016/09:30	4.4	0 - 4.9	No	0
		Week 44	11JAN2017/11:00	4.4	0 - 4.9	No	0
		Week 48	08FEB2017/11:50	4.0	0 - 4.9	No	0
	Creatine Kinase (IU/L)	Screening	17FEB2016/13:00	72	26 - 140	Yes	0
		Day 1	08MAR2016/10:50	71	26 - 140	No	0
		Week 1	15MAR2016/09:25	88	26 - 140	No	0
		Week 2	23MAR2016/09:08	76	26 - 140	No	0
		Week 4	05APR2016/10:15	73	26 - 140	No	0
		Week 6	19APR2016/09:45	61	26 - 140	No	0
		Week 8	28APR2016/10:10	73	26 - 140	No	0
		Week 12	01JUN2016/08:30	70	26 - 140	Yes	0
		Week 16	29JUN2016/09:23	78	26 - 140	No	0
		Week 20	26JUL2016/09:45	98	26 - 140	No	0
		Week 24	24AUG2016/09:30	88	26 - 140	Yes	0
		Week 28	20SEP2016/12:00	75	26 - 140	No	0
		Week 32	19OCT2016/11:00	77	26 - 140	No	0
		Week 36	15NOV2016/11:15	74	26 - 140	No	0
		Week 40	14DEC2016/09:30	85	26 - 140	No	0
		Week 44	11JAN2017/11:00	77	26 - 140	No	0
		Week 48	08FEB2017/11:50	95	26 - 140	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017 Creatinine (umol/L)	Screening	17FEB2016/13:00	62	49 - 92	Yes	0
	Day 1	08MAR2016/10:50	55	49 - 92	No	0
	Week 1	15MAR2016/09:25	68	49 - 92	No	1
	Week 2	23MAR2016/09:08	77	49 - 92	No	1
	Week 4	05APR2016/10:15	79	49 - 92	No	1
	Week 6	19APR2016/09:45	85	49 - 92	No	2
	Week 8	28APR2016/10:10	64	49 - 92	No	1
	Week 12	01JUN2016/08:30	51	49 - 92	Yes	0
	Week 16	29JUN2016/09:23	59	49 - 92	No	1
	Week 20	26JUL2016/09:45	60	49 - 92	No	1
	Week 24	24AUG2016/09:30	61	49 - 92	Yes	1
	Week 28	20SEP2016/12:00	48 L	49 - 92	No	0
	Week 32	19OCT2016/11:00	59	49 - 92	No	1
	Week 36	15NOV2016/11:15	61	49 - 92	No	1
	Week 40	14DEC2016/09:30	60	49 - 92	No	1
	Week 44	11JAN2017/11:00	51	49 - 92	No	0
	Week 48	08FEB2017/11:50	56	49 - 92	No	1
Direct Bilirubin (umol/L)	Screening	17FEB2016/13:00	4	0 - 5	Yes	
	Day 1	08MAR2016/10:50	3	0 - 5	No	
	Week 1	15MAR2016/09:25	4	0 - 5	No	
	Week 2	23MAR2016/09:08	3	0 - 5	No	
	Week 4	05APR2016/10:15	3	0 - 5	No	
	Week 6	19APR2016/09:45	4	0 - 5	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Direct Bilirubin (umol/L)	Week 8	28APR2016/10:10	3	0 - 5	No	
		Week 12	01JUN2016/08:30	3	0 - 5	Yes	
		Week 16	29JUN2016/09:23	<2	0 - 5	No	
		Week 20	26JUL2016/09:45	<2	0 - 5	No	
		Week 24	24AUG2016/09:30	2	0 - 5	Yes	
		Week 28	20SEP2016/12:00	3	0 - 5	No	
		Week 32	19OCT2016/11:00	3	0 - 5	No	
		Week 36	15NOV2016/11:15	3	0 - 5	No	
		Week 40	14DEC2016/09:30	2	0 - 5	No	
		Week 44	11JAN2017/11:00	2	0 - 5	No	
		Week 48	08FEB2017/11:50	3	0 - 5	No	
	Gamma Glutamyl Transferase (IU/L)	Screening	17FEB2016/13:00	65 H	6 - 42	Yes	1
		Day 1	08MAR2016/10:50	63 H	6 - 42	No	1
		Week 1	15MAR2016/09:25	59 H	6 - 42	No	1
		Week 2	23MAR2016/09:08	54 H	6 - 42	No	1
		Week 4	05APR2016/10:15	51 H	6 - 42	No	1
		Week 6	19APR2016/09:45	60 H	6 - 42	No	1
		Week 8	28APR2016/10:10	47 H	6 - 42	No	1
		Week 12	01JUN2016/08:30	28	6 - 42	Yes	0
		Week 16	29JUN2016/09:23	22	6 - 42	No	0
		Week 20	26JUL2016/09:45	22	6 - 42	No	0
		Week 24	24AUG2016/09:30	21	6 - 42	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Gamma Glutamyl Transferase (IU/L)	Week 28	20SEP2016/12:00	40	6 - 42	No	0
		Week 32	19OCT2016/11:00	55 H	6 - 42	No	1
		Week 36	15NOV2016/11:15	102 H	6 - 42	No	1
		Week 40	14DEC2016/09:30	93 H	6 - 42	No	1
		Week 44	11JAN2017/11:00	94 H	6 - 42	No	1
		Week 48	08FEB2017/11:50	70 H	6 - 42	No	1
	Globulin (g/L)	Screening	17FEB2016/13:00	32	19 - 35	Yes	
		Day 1	08MAR2016/10:50	34	19 - 35	No	
		Week 1	15MAR2016/09:25	34	19 - 35	No	
		Week 2	23MAR2016/09:08	34	19 - 35	No	
		Week 4	05APR2016/10:15	32	19 - 35	No	
		Week 6	19APR2016/09:45	33	19 - 35	No	
		Week 8	28APR2016/10:10	31	19 - 35	No	
		Week 12	01JUN2016/08:30	27	19 - 35	Yes	
		Week 16	29JUN2016/09:23	32	19 - 35	No	
		Week 20	26JUL2016/09:45	31	19 - 35	No	
		Week 24	24AUG2016/09:30	32	19 - 35	Yes	
		Week 28	20SEP2016/12:00	29	19 - 35	No	
		Week 32	19OCT2016/11:00	31	19 - 35	No	
		Week 36	15NOV2016/11:15	34	19 - 35	No	
		Week 40	14DEC2016/09:30	33	19 - 35	No	
		Week 44	11JAN2017/11:00	34	19 - 35	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Globulin (g/L)	Week 48	08FEB2017/11:50	36 H	19 - 35	No	
	Glucose (mmol/L)	Screening	17FEB2016/13:00	4.6	3.9 - 5.8	Yes	0
		Day 1	08MAR2016/10:50	4.4	3.5 - 7.9	No	0
		Week 1	15MAR2016/09:25	4.3	3.5 - 7.9	No	0
		Week 2	23MAR2016/09:08	4.5	3.5 - 7.9	No	0
		Week 4	05APR2016/10:15	4.9	3.5 - 7.9	No	0
		Week 6	19APR2016/09:45	4.5	3.5 - 7.9	No	0
		Week 8	28APR2016/10:10	4.6	3.5 - 7.9	No	0
		Week 12	01JUN2016/08:30	4.7	3.9 - 5.8	Yes	0
		Week 16	29JUN2016/09:23	6.2	3.5 - 7.9	No	0
		Week 20	26JUL2016/09:45	4.1	3.5 - 7.9	No	0
		Week 24	24AUG2016/09:30	4.2	3.9 - 5.8	Yes	0
		Week 28	20SEP2016/12:00	4.6	3.5 - 7.9	No	0
		Week 32	19OCT2016/11:00	5.3	3.5 - 7.9	No	0
		Week 36	15NOV2016/11:15	5.6	3.5 - 7.9	No	0
		Week 40	14DEC2016/09:30	3.9	3.5 - 7.9	No	0
		Week 44	11JAN2017/11:00	3.3 L	3.5 - 7.9	No	1
		Week 48	08FEB2017/11:50	2.8 L	3.5 - 7.9	No	2
	Indirect Bilirubin (umol/L)	Screening	17FEB2016/13:00	5	0 - 14	Yes	
		Day 1	08MAR2016/10:50	4	0 - 14	No	
		Week 1	15MAR2016/09:25	4	0 - 14	No	
		Week 2	23MAR2016/09:08	4	0 - 14	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Indirect Bilirubin (umol/L)	Week 4	05APR2016/10:15	4	0 - 14	No
		Week 6	19APR2016/09:45	4	0 - 14	No
		Week 8	28APR2016/10:10	2	0 - 14	No
		Week 12	01JUN2016/08:30	2	0 - 14	Yes
		Week 16	29JUN2016/09:23		0 - 14	No
		Week 20	26JUL2016/09:45		0 - 14	No
		Week 24	24AUG2016/09:30	3	0 - 14	Yes
		Week 28	20SEP2016/12:00	4	0 - 14	No
		Week 32	19OCT2016/11:00	4	0 - 14	No
		Week 36	15NOV2016/11:15	5	0 - 14	No
		Week 40	14DEC2016/09:30	4	0 - 14	No
		Week 44	11JAN2017/11:00	3	0 - 14	No
		Week 48	08FEB2017/11:50	2	0 - 14	No
	Lactate Dehydrogenase (IU/L)	Screening	17FEB2016/13:00	178	135 - 214	Yes
		Day 1	08MAR2016/10:50	161	135 - 214	No
		Week 1	15MAR2016/09:25	157	135 - 214	No
		Week 2	23MAR2016/09:08	180	135 - 214	No
		Week 4	05APR2016/10:15	185	135 - 214	No
		Week 6	19APR2016/09:45	193	135 - 214	No
		Week 8	28APR2016/10:10	169	135 - 214	No
		Week 12	01JUN2016/08:30	185	135 - 214	Yes
		Week 16	29JUN2016/09:23	199	135 - 214	No
		Week 20	26JUL2016/09:45	199	135 - 214	No

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Lactate Dehydrogenase (IU/L)	Week 24	24AUG2016/09:30	189	135 - 214	Yes	
		Week 28	20SEP2016/12:00	226 H	135 - 214	No	
		Week 32	19OCT2016/11:00	203	135 - 214	No	
		Week 36	15NOV2016/11:15	251 H	135 - 214	No	
		Week 40	14DEC2016/09:30	189	135 - 214	No	
		Week 44	11JAN2017/11:00	204	135 - 214	No	
		Week 48	08FEB2017/11:50	201	135 - 214	No	
	Magnesium (mmol/L)	Screening	17FEB2016/13:00	0.80	0.6 - 1	Yes	0
		Day 1	08MAR2016/10:50	0.85	0.6 - 1	No	0
		Week 1	15MAR2016/09:25	0.84	0.6 - 1	No	0
		Week 2	23MAR2016/09:08	0.77	0.6 - 1	No	0
		Week 4	05APR2016/10:15	0.79	0.6 - 1	No	0
		Week 6	19APR2016/09:45	0.75	0.6 - 1	No	0
		Week 8	28APR2016/10:10	0.85	0.6 - 1	No	0
		Week 12	01JUN2016/08:30	0.81	0.6 - 1	Yes	0
		Week 16	29JUN2016/09:23	0.78	0.6 - 1	No	0
		Week 20	26JUL2016/09:45	0.81	0.6 - 1	No	0
		Week 24	24AUG2016/09:30	0.81	0.6 - 1	Yes	0
		Week 28	20SEP2016/12:00	0.79	0.6 - 1	No	0
		Week 32	19OCT2016/11:00	0.82	0.6 - 1	No	0
		Week 36	15NOV2016/11:15	0.80	0.6 - 1	No	0
		Week 40	14DEC2016/09:30	0.78	0.6 - 1	No	0
		Week 44	11JAN2017/11:00	0.82	0.6 - 1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Magnesium (mmol/L)	Week 48	08FEB2017/11:50	0.80	0.6 - 1	No	0
	Phosphate (mmol/L)	Screening	17FEB2016/13:00	1.30	0.87 - 1.45	Yes	0
		Day 1	08MAR2016/10:50	1.24	0.87 - 1.45	No	0
		Week 1	15MAR2016/09:25	1.15	0.87 - 1.45	No	0
		Week 2	23MAR2016/09:08	1.18	0.87 - 1.45	No	0
		Week 4	05APR2016/10:15	1.13	0.87 - 1.45	No	0
		Week 6	19APR2016/09:45	1.05	0.87 - 1.45	No	0
		Week 8	28APR2016/10:10	1.25	0.87 - 1.45	No	0
		Week 12	01JUN2016/08:30	1.27	0.87 - 1.45	Yes	0
		Week 16	29JUN2016/09:23	1.34	0.87 - 1.45	No	0
		Week 20	26JUL2016/09:45	1.19	0.87 - 1.45	No	0
		Week 24	24AUG2016/09:30	1.35	0.87 - 1.45	Yes	0
		Week 28	20SEP2016/12:00	1.21	0.87 - 1.45	No	0
		Week 32	19OCT2016/11:00	1.24	0.87 - 1.45	No	0
		Week 36	15NOV2016/11:15	1.27	0.87 - 1.45	No	0
		Week 40	14DEC2016/09:30	1.37	0.87 - 1.45	No	0
		Week 44	11JAN2017/11:00	1.27	0.87 - 1.45	No	0
		Week 48	08FEB2017/11:50	1.03	0.87 - 1.45	No	0
	Potassium (mmol/L)	Screening	17FEB2016/13:00	4.8	3.5 - 5.1	Yes	0
		Day 1	08MAR2016/10:50	4.2	3.5 - 5.1	No	0
		Week 1	15MAR2016/09:25	4.1	3.5 - 5.1	No	0
		Week 2	23MAR2016/09:08	4.1	3.5 - 5.1	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Potassium (mmol/L)	Week 4	05APR2016/10:15	3.4 L	3.5 - 5.1	No	1
		Week 6	19APR2016/09:45	3.2 L	3.5 - 5.1	No	1
		Week 8	28APR2016/10:10	3.4 L	3.5 - 5.1	No	1
		Week 12	01JUN2016/08:30	4.0	3.5 - 5.1	Yes	0
		Week 16	29JUN2016/09:23	4.2	3.5 - 5.1	No	0
		Week 20	26JUL2016/09:45	4.1	3.5 - 5.1	No	0
		Week 24	24AUG2016/09:30	4.6	3.5 - 5.1	Yes	0
		Week 28	20SEP2016/12:00	4.3	3.5 - 5.1	No	0
		Week 32	19OCT2016/11:00	4.6	3.5 - 5.1	No	0
		Week 36	15NOV2016/11:15	4.5	3.5 - 5.1	No	0
		Week 40	14DEC2016/09:30	4.0	3.5 - 5.1	No	0
		Week 44	11JAN2017/11:00	4.1	3.5 - 5.1	No	0
		Week 48	08FEB2017/11:50	3.4 L	3.5 - 5.1	No	1
	Protein (g/L)	Screening	17FEB2016/13:00	76	63 - 83	Yes	
		Day 1	08MAR2016/10:50	76	63 - 83	No	
		Week 1	15MAR2016/09:25	78	63 - 83	No	
		Week 2	23MAR2016/09:08	78	63 - 83	No	
		Week 4	05APR2016/10:15	77	63 - 83	No	
		Week 6	19APR2016/09:45	79	63 - 83	No	
		Week 8	28APR2016/10:10	72	63 - 83	No	
		Week 12	01JUN2016/08:30	70	63 - 83	Yes	
		Week 16	29JUN2016/09:23	76	63 - 83	No	
		Week 20	26JUL2016/09:45	75	63 - 83	No	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Protein (g/L)	Week 24	24AUG2016/09:30	75	63 - 83	Yes	
		Week 28	20SEP2016/12:00	74	63 - 83	No	
		Week 32	19OCT2016/11:00	75	63 - 83	No	
		Week 36	15NOV2016/11:15	79	63 - 83	No	
		Week 40	14DEC2016/09:30	76	63 - 83	No	
		Week 44	11JAN2017/11:00	79	63 - 83	No	
		Week 48	08FEB2017/11:50	77	63 - 83	No	
	Sodium (mmol/L)	Screening	17FEB2016/13:00	145	135 - 145	Yes	0
		Day 1	08MAR2016/10:50	142	135 - 145	No	0
		Week 1	15MAR2016/09:25	141	135 - 145	No	0
		Week 2	23MAR2016/09:08	141	135 - 145	No	0
		Week 4	05APR2016/10:15	139	135 - 145	No	0
		Week 6	19APR2016/09:45	140	135 - 145	No	0
		Week 8	28APR2016/10:10	143	135 - 145	No	0
		Week 12	01JUN2016/08:30	142	135 - 145	Yes	0
		Week 16	29JUN2016/09:23	143	135 - 145	No	0
		Week 20	26JUL2016/09:45	143	135 - 145	No	0
		Week 24	24AUG2016/09:30	145	135 - 145	Yes	0
		Week 28	20SEP2016/12:00	144	135 - 145	No	0
		Week 32	19OCT2016/11:00	145	135 - 145	No	0
		Week 36	15NOV2016/11:15	144	135 - 145	No	0
		Week 40	14DEC2016/09:30	142	135 - 145	No	0
		Week 44	11JAN2017/11:00	143	135 - 145	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Sodium (mmol/L)	Week 48	08FEB2017/11:50	145	135 - 145	No	0
	Thyrotropin (mIU/L)	Screening	17FEB2016/13:00	1.47	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	17FEB2016/13:00	149	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	17FEB2016/13:00	0.7	0 - 2.2	Yes	0
		Day 1	08MAR2016/10:50	0.7	0 - 2.2	No	0
		Week 1	15MAR2016/09:25	0.9	0 - 2.2	No	0
		Week 2	23MAR2016/09:08	0.9	0 - 2.2	No	0
		Week 4	05APR2016/10:15	0.9	0 - 2.2	No	0
		Week 6	19APR2016/09:45	1.1	0 - 2.2	No	0
		Week 8	28APR2016/10:10	0.9	0 - 2.2	No	0
		Week 12	01JUN2016/08:30	1.0	0 - 2.2	Yes	0
		Week 16	29JUN2016/09:23	1.1	0 - 2.2	No	0
		Week 20	26JUL2016/09:45	1.1	0 - 2.2	No	0
		Week 24	24AUG2016/09:30	1.0	0 - 2.2	Yes	0
		Week 28	20SEP2016/12:00	1.0	0 - 2.2	No	0
		Week 32	19OCT2016/11:00	0.9	0 - 2.2	No	0
		Week 36	15NOV2016/11:15	0.9	0 - 2.2	No	0
		Week 40	14DEC2016/09:30	1.0	0 - 2.2	No	0
		Week 44	11JAN2017/11:00	1.1	0 - 2.2	No	0
		Week 48	08FEB2017/11:50	0.9	0 - 2.2	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Triiodothyronine (nmol/L)	Screening	17FEB2016/13:00	2.8	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	17FEB2016/13:00	5.7	1.7 - 8.3	Yes	
		Day 1	08MAR2016/10:50	4.0	1.7 - 8.3	No	
		Week 1	15MAR2016/09:25	5.7	1.7 - 8.3	No	
		Week 2	23MAR2016/09:08	5.4	1.7 - 8.3	No	
		Week 4	05APR2016/10:15	4.4	1.7 - 8.3	No	
		Week 6	19APR2016/09:45	4.2	1.7 - 8.3	No	
		Week 8	28APR2016/10:10	3.6	1.7 - 8.3	No	
		Week 12	01JUN2016/08:30	4.2	1.7 - 8.3	Yes	
		Week 16	29JUN2016/09:23	3.4	1.7 - 8.3	No	
		Week 20	26JUL2016/09:45	3.6	1.7 - 8.3	No	
		Week 24	24AUG2016/09:30	4.8	1.7 - 8.3	Yes	
		Week 28	20SEP2016/12:00	3.6	1.7 - 8.3	No	
		Week 32	19OCT2016/11:00	4.8	1.7 - 8.3	No	
		Week 36	15NOV2016/11:15	3.6	1.7 - 8.3	No	
		Week 40	14DEC2016/09:30	4.7	1.7 - 8.3	No	
		Week 44	11JAN2017/11:00	4.4	1.7 - 8.3	No	
		Week 48	08FEB2017/11:50	3.7	1.7 - 8.3	No	
	Uric acid (umol/L)	Screening	17FEB2016/13:00	312	175 - 363	Yes	0
		Day 1	08MAR2016/10:50	284	175 - 363	No	0
		Week 1	15MAR2016/09:25	324	175 - 363	No	0
		Week 2	23MAR2016/09:08	393 H	175 - 363	No	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Uric acid (umol/L)	Week 4	05APR2016/10:15	420 H	175 - 363	No	1
		Week 6	19APR2016/09:45	420 H	175 - 363	No	1
		Week 8	28APR2016/10:10	329	175 - 363	No	0
		Week 12	01JUN2016/08:30	269	175 - 363	Yes	0
		Week 16	29JUN2016/09:23	290	175 - 363	No	0
		Week 20	26JUL2016/09:45	244	175 - 363	No	0
		Week 24	24AUG2016/09:30	285	175 - 363	Yes	0
		Week 28	20SEP2016/12:00	281	175 - 363	No	0
		Week 32	19OCT2016/11:00	309	175 - 363	No	0
		Week 36	15NOV2016/11:15	298	175 - 363	No	0
		Week 40	14DEC2016/09:30	282	175 - 363	No	0
		Week 44	11JAN2017/11:00	284	175 - 363	No	0
		Week 48	08FEB2017/11:50	282	175 - 363	No	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-004	Alanine Aminotransferase (IU/L)	Screening	16DEC2015/11:50	260 H	10 - 35	Yes	3
	Albumin (g/L)	Screening	16DEC2015/11:50	45	34 - 50	Yes	0
	Alkaline Phosphatase (IU/L)	Screening	16DEC2015/11:50	62	35 - 104	Yes	0
	Amylase (IU/L)	Screening	16DEC2015/11:50	143 H	28 - 100	Yes	1
	Aspartate Aminotransferase (IU/L)	Screening	16DEC2015/11:50	148 H	0 - 31	Yes	2
	Bicarbonate (mmol/L)	Screening	16DEC2015/11:50	28	22 - 29	Yes	
	Bilirubin (umol/L)	Screening	16DEC2015/11:50	4	0 - 20	Yes	0
	Blood Urea Nitrogen (mg/dL)	Screening	16DEC2015/11:50	10.08	4.76 - 23.24	Yes	
	Calcium (mmol/L)	Screening	16DEC2015/11:50	2.64 H	2.2 - 2.6	Yes	1
	Chloride (mmol/L)	Screening	16DEC2015/11:50	103	98 - 107	Yes	
	Cholesterol (mmol/L)	Screening	16DEC2015/11:50	5.6 H	0 - 4.9	Yes	1

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-004	Creatine Kinase (IU/L)	Screening	16DEC2015/11:50	164 H	26 - 140	Yes	1
	Creatinine (umol/L)	Screening	16DEC2015/11:50	69	49 - 92	Yes	0
	Direct Bilirubin (umol/L)	Screening	16DEC2015/11:50	2	0 - 5	Yes	
	Gamma Glutamyl Transferase (IU/L)	Screening	16DEC2015/11:50	28	6 - 42	Yes	0
	Globulin (g/L)	Screening	16DEC2015/11:50	44 H	19 - 35	Yes	
	Glucose (mmol/L)	Screening	16DEC2015/11:50	5.4	3.9 - 5.8	Yes	0
	Indirect Bilirubin (umol/L)	Screening	16DEC2015/11:50	2	0 - 14	Yes	
	Lactate Dehydrogenase (IU/L)	Screening	16DEC2015/11:50	216 H	135 - 214	Yes	
	Magnesium (mmol/L)	Screening	16DEC2015/11:50	0.87	0.6 - 1	Yes	0
	Phosphate (mmol/L)	Screening	16DEC2015/11:50	1.22	0.87 - 1.45	Yes	0
	Potassium (mmol/L)	Screening	16DEC2015/11:50	4.0	3.5 - 5.1	Yes	0
	Protein (g/L)	Screening	16DEC2015/11:50	89 H	63 - 83	Yes	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-004	Sodium (mmol/L)	Screening	16DEC2015/11:50	144	135 - 145	Yes	0
	Thyrotropin (mIU/L)	Screening	16DEC2015/11:50	0.58	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	16DEC2015/11:50	115	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	16DEC2015/11:50	1.2	0 - 2.2	Yes	0
	Triiodothyronine (nmol/L)	Screening	16DEC2015/11:50	2.3	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	16DEC2015/11:50	3.6	1.7 - 8.3	Yes	
	Uric acid (umol/L)	Screening	16DEC2015/11:50	314	175 - 363	Yes	0
301-012	Alanine Aminotransferase (IU/L)	Screening	26JAN2016/13:00	136 H	10 - 50	Yes	1
	Albumin (g/L)	Screening	26JAN2016/13:00	42	34 - 50	Yes	0
	Alkaline Phosphatase (IU/L)	Screening	26JAN2016/13:00	95	40 - 129	Yes	0
	Amylase (IU/L)	Screening	26JAN2016/13:00	56	28 - 100	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-012	Aspartate Aminotransferase (IU/L)	Screening	26JAN2016/13:00	64 H	0 - 37	Yes	1
	Bicarbonate (mmol/L)	Screening	26JAN2016/13:00	24	22 - 29	Yes	
	Bilirubin (umol/L)	Screening	26JAN2016/13:00	9	0 - 20	Yes	0
	Blood Urea Nitrogen (mg/dL)	Screening	26JAN2016/13:00	11.20	4.76 - 23.24	Yes	
	Calcium (mmol/L)	Screening	26JAN2016/13:00	2.30	2.2 - 2.6	Yes	0
	Chloride (mmol/L)	Screening	26JAN2016/13:00	102	98 - 107	Yes	
	Cholesterol (mmol/L)	Screening	26JAN2016/13:00	5.0 H	0 - 4.9	Yes	1
	Creatine Kinase (IU/L)	Screening	26JAN2016/13:00	205 H	38 - 204	Yes	1
	Creatinine (umol/L)	Screening	26JAN2016/13:00	95	66 - 112	Yes	0
	Direct Bilirubin (umol/L)	Screening	26JAN2016/13:00	4	0 - 5	Yes	
	Gamma Glutamyl Transferase (IU/L)	Screening	26JAN2016/13:00	56	10 - 71	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-012	Globulin (g/L)	Screening	26JAN2016/13:00	31	19 - 35	Yes	
	Glucose (mmol/L)	Screening	26JAN2016/13:00	4.7	3.9 - 5.8	Yes	0
	Indirect Bilirubin (umol/L)	Screening	26JAN2016/13:00	5	0 - 14	Yes	
	Lactate Dehydrogenase (IU/L)	Screening	26JAN2016/13:00	172	135 - 225	Yes	
	Magnesium (mmol/L)	Screening	26JAN2016/13:00	0.86	0.6 - 1	Yes	0
	Phosphate (mmol/L)	Screening	26JAN2016/13:00	0.98	0.87 - 1.45	Yes	0
	Potassium (mmol/L)	Screening	26JAN2016/13:00	4.4	3.5 - 5.1	Yes	0
	Protein (g/L)	Screening	26JAN2016/13:00	73	63 - 83	Yes	
	Sodium (mmol/L)	Screening	26JAN2016/13:00	140	135 - 145	Yes	0
	Thyrotropin (mIU/L)	Screening	26JAN2016/13:00	1.96	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	26JAN2016/13:00	114	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	26JAN2016/13:00	1.4	0 - 2.2	Yes	0

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-012	Triiodothyronine (nmol/L)	Screening	26JAN2016/13:00	2.3	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	26JAN2016/13:00	4.0	1.7 - 8.3	Yes	
	Uric acid (umol/L)	Screening	26JAN2016/13:00	344	266 - 474	Yes	0
301-013	Alanine Aminotransferase (IU/L)	Screening	26JAN2016/13:00	64 H	10 - 50	Yes	1
	Albumin (g/L)	Screening	26JAN2016/13:00	44	34 - 50	Yes	0
	Alkaline Phosphatase (IU/L)	Screening	26JAN2016/13:00	94	40 - 129	Yes	0
	Amylase (IU/L)	Screening	26JAN2016/13:00	121 H	28 - 100	Yes	1
	Aspartate Aminotransferase (IU/L)	Screening	26JAN2016/13:00	32	0 - 37	Yes	0
	Bicarbonate (mmol/L)	Screening	26JAN2016/13:00	25	22 - 29	Yes	
	Bilirubin (umol/L)	Screening	26JAN2016/13:00	5	0 - 20	Yes	0
	Blood Urea Nitrogen (mg/dL)	Screening	26JAN2016/13:00	17.08	4.76 - 23.24	Yes	

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-013	Calcium (mmol/L)	Screening	26JAN2016/13:00	2.31	2.2 - 2.6	Yes	0
	Chloride (mmol/L)	Screening	26JAN2016/13:00	101	98 - 107	Yes	
	Cholesterol (mmol/L)	Screening	26JAN2016/13:00	3.8	0 - 4.9	Yes	0
	Creatine Kinase (IU/L)	Screening	26JAN2016/13:00	157	38 - 204	Yes	0
	Creatinine (umol/L)	Screening	26JAN2016/13:00	126 H	66 - 112	Yes	1
	Direct Bilirubin (umol/L)	Screening	26JAN2016/13:00	3	0 - 5	Yes	
	Gamma Glutamyl Transferase (IU/L)	Screening	26JAN2016/13:00	27	10 - 71	Yes	0
	Globulin (g/L)	Screening	26JAN2016/13:00	29	19 - 35	Yes	
	Glucose (mmol/L)	Screening	26JAN2016/13:00	4.8	3.9 - 5.8	Yes	0
	Indirect Bilirubin (umol/L)	Screening	26JAN2016/13:00	2	0 - 14	Yes	
	Lactate Dehydrogenase (IU/L)	Screening	26JAN2016/13:00	146	135 - 225	Yes	
	Magnesium (mmol/L)	Screening	26JAN2016/13:00	0.96	0.6 - 1	Yes	0

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.2  
Laboratory Results - Clinical Chemistry  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-013	Phosphate (mmol/L)	Screening	26JAN2016/13:00	1.17	0.87 - 1.45	Yes	0
	Potassium (mmol/L)	Screening	26JAN2016/13:00	4.3	3.5 - 5.1	Yes	0
	Protein (g/L)	Screening	26JAN2016/13:00	73	63 - 83	Yes	
	Sodium (mmol/L)	Screening	26JAN2016/13:00	141	135 - 145	Yes	0
	Thyrotropin (mIU/L)	Screening	26JAN2016/13:00	1.45	0.27 - 4.2	Yes	
	Thyroxine (nmol/L)	Screening	26JAN2016/13:00	80	59 - 154	Yes	
	Triglycerides (mmol/L)	Screening	26JAN2016/13:00	1.0	0 - 2.2	Yes	0
	Triiodothyronine (nmol/L)	Screening	26JAN2016/13:00	1.5	1.3 - 3.1	Yes	
	Urea (mmol/L)	Screening	26JAN2016/13:00	6.1	1.7 - 8.3	Yes	
	Uric acid (umol/L)	Screening	26JAN2016/13:00	179 L	266 - 474	Yes	0

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-007	Prothrombin Intl. Normalized Ratio	Screening	05JAN2016/11:00	1.18	0.9 - 1.2	Yes	0
		Early Term	21APR2016/08:00	1.11	0.9 - 1.2	Yes	0
		Week 28	19MAY2016/12:20	1.19	0.9 - 1.2	No	0
		Week 32	16JUN2016/10:25	1.19	0.9 - 1.2	No	0
		Week 40	11AUG2016/12:00	1.13	0.9 - 1.2	No	0
		Week 44	08SEP2016/12:10	1.24 H	0.9 - 1.2	No	1
		Week 48	06OCT2016/12:30	1.21 H	0.9 - 1.2	No	1
	Prothrombin Time (sec)	Screening	05JAN2016/11:00	13 H	10 - 12	Yes	
		Early Term	21APR2016/08:00	12	10 - 12	Yes	
		Week 28	19MAY2016/12:20	13 H	10 - 12	No	
		Week 32	16JUN2016/10:25	13 H	10 - 12	No	
		Week 40	11AUG2016/12:00	12	10 - 12	No	
		Week 44	08SEP2016/12:10	14 H	10 - 12	No	
		Week 48	06OCT2016/12:30	13 H	10 - 12	No	
301-011	Prothrombin Intl. Normalized Ratio	Screening	07JAN2016/12:00	1.04	0.9 - 1.2	Yes	0
		Week 4	26FEB2016/10:20	1.07	0.9 - 1.2	No	0
		Week 24	12JUL2016/10:00	1.28 H	0.9 - 1.2	Yes	1
		Week 28	09AUG2016/09:50	1.22 H	0.9 - 1.2	No	1
		Week 32	06SEP2016/09:00	1.09	0.9 - 1.2	No	0
		Week 36	06OCT2016/09:50	1.10	0.9 - 1.2	No	0

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-011	Prothrombin Intl. Normalized Ratio	Week 40	03NOV2016/11:00	1.15	0.9 - 1.2	No	0
		Week 44	06DEC2016/10:30	1.10	0.9 - 1.2	No	0
		Week 48	03JAN2017/10:45	1.22 H	0.9 - 1.2	No	1
	Prothrombin Time (sec)	Screening	07JAN2016/12:00	12	10 - 12	Yes	
		Week 4	26FEB2016/10:20	12	10 - 12	No	
		Week 24	12JUL2016/10:00	14 H	10 - 12	Yes	
		Week 28	09AUG2016/09:50	13 H	10 - 12	No	
		Week 32	06SEP2016/09:00	12	10 - 12	No	
		Week 36	06OCT2016/09:50	12	10 - 12	No	
		Week 40	03NOV2016/11:00	13 H	10 - 12	No	
		Week 44	06DEC2016/10:30	12	10 - 12	No	
		Week 48	03JAN2017/10:45	13 H	10 - 12	No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-001	Prothrombin Intl. Normalized Ratio	Screening	06JAN2016/11:00	1.08	0.9 - 1.2	Yes	0
		Week 4	01MAR2016/10:30	1.04	0.9 - 1.2	No	0
		Week 24	20JUL2016/09:30	1.28 H	0.9 - 1.2	Yes	1
		Week 28	18AUG2016/10:45	1.13	0.9 - 1.2	No	0
		Week 32	15SEP2016/10:00	1.08	0.9 - 1.2	No	0
		Week 36	13OCT2016/12:30	1.13	0.9 - 1.2	No	0
		Week 40	10NOV2016/10:15	1.14	0.9 - 1.2	No	0
		Week 44	06DEC2016/11:00	1.18	0.9 - 1.2	No	0
		Week 48	03JAN2017/12:00	1.18	0.9 - 1.2	No	0
	Prothrombin Time (sec)	Screening	06JAN2016/11:00	12	10 - 12	Yes	
		Week 4	01MAR2016/10:30	12	10 - 12	No	
		Week 24	20JUL2016/09:30	14 H	10 - 12	Yes	
		Week 28	18AUG2016/10:45	12	10 - 12	No	
		Week 32	15SEP2016/10:00	12	10 - 12	No	
		Week 36	13OCT2016/12:30	12	10 - 12	No	
		Week 40	10NOV2016/10:15	13 H	10 - 12	No	
		Week 44	06DEC2016/11:00	13 H	10 - 12	No	
		Week 48	03JAN2017/12:00	13 H	10 - 12	No	
301-002	Prothrombin Intl. Normalized Ratio	Screening	15DEC2015/09:00	1.12	0.9 - 1.2	Yes	0
		Week 24	21JUN2016/11:30	1.23 H	0.9 - 1.2	No	1

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Prothrombin Intl. Normalized Ratio	Week 28	20JUL2016/11:45	1.19	0.9 - 1.2	No	0
		Week 32	18AUG2016/10:30	1.20	0.9 - 1.2	No	0
		Week 36	13SEP2016/11:00	1.13	0.9 - 1.2	No	0
		Week 40	11OCT2016/12:05	1.10	0.9 - 1.2	No	0
		Week 44	09NOV2016/12:30	1.23 H	0.9 - 1.2	No	1
		Week 48	06DEC2016/13:00	1.23 H	0.9 - 1.2	No	1
	Prothrombin Time (sec)	Screening	15DEC2015/09:00	12	10 - 12	Yes	
		Week 24	21JUN2016/11:30	14 H	10 - 12	No	
		Week 28	20JUL2016/11:45	13 H	10 - 12	No	
		Week 32	18AUG2016/10:30	13 H	10 - 12	No	
		Week 36	13SEP2016/11:00	12	10 - 12	No	
		Week 40	11OCT2016/12:05	12	10 - 12	No	
		Week 44	09NOV2016/12:30	14 H	10 - 12	No	
		Week 48	06DEC2016/13:00	14 H	10 - 12	No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Prothrombin Intl. Normalized Ratio	Screening	15DEC2015/12:00	0.99	0.9 - 1.2	Yes	0
		Week 24	22JUN2016/12:30	1.06	0.9 - 1.2	No	0
		Week 28	19JUL2016/10:10	1.16	0.9 - 1.2	No	0
		Week 32	16AUG2016/12:10	1.03	0.9 - 1.2	No	0
		Week 36	15SEP2016/12:35	0.93	0.9 - 1.2	No	0
		Week 40	12OCT2016/11:20	1.02	0.9 - 1.2	Yes	0
		Week 44	09NOV2016/12:00	1.05	0.9 - 1.2	No	0
		Week 48	14DEC2016/12:00	0.99	0.9 - 1.2	No	0
	Prothrombin Time (sec)	Screening	15DEC2015/12:00	11	10 - 12	Yes	
		Week 24	22JUN2016/12:30	12	10 - 12	No	
		Week 28	19JUL2016/10:10	13 H	10 - 12	No	
		Week 32	16AUG2016/12:10	11	10 - 12	No	
		Week 36	15SEP2016/12:35	10	10 - 12	No	
		Week 40	12OCT2016/11:20	11	10 - 12	Yes	
		Week 44	09NOV2016/12:00	12	10 - 12	No	
		Week 48	14DEC2016/12:00	11	10 - 12	No	
301-005	Prothrombin Intl. Normalized Ratio	Screening	16DEC2015/08:45	1.30 H	0.9 - 1.2	Yes	1
		Unscheduled Visit	07JAN2016/10:00	1.12	0.9 - 1.2	Yes	0
		Week 24	23JUN2016/11:45	1.02	0.9 - 1.2	No	0

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-005	Prothrombin Intl. Normalized Ratio	Week 28	26JUL2016/09:15	1.12	0.9 - 1.2	No	0
		Week 32	16AUG2016/10:45	1.37 H	0.9 - 1.2	No	1
		Week 36	14SEP2016/12:00	1.37 H	0.9 - 1.2	No	1
		Week 40	12OCT2016/12:10	1.34 H	0.9 - 1.2	No	1
		Week 44	10NOV2016/11:00	1.24 H	0.9 - 1.2	No	1
		Week 48	07DEC2016/12:00	1.54 H	0.9 - 1.2	No	1
	Prothrombin Time (sec)	Screening	16DEC2015/08:45	14 H	10 - 12	Yes	
		Unscheduled Visit	07JAN2016/10:00	12	10 - 12	Yes	
		Week 24	23JUN2016/11:45	11	10 - 12	No	
		Week 28	26JUL2016/09:15	12	10 - 12	No	
		Week 32	16AUG2016/10:45	15 H	10 - 12	No	
		Week 36	14SEP2016/12:00	15 H	10 - 12	No	
		Week 40	12OCT2016/12:10	15 H	10 - 12	No	
		Week 44	10NOV2016/11:00	14 H	10 - 12	No	
		Week 48	07DEC2016/12:00	17 H	10 - 12	No	
301-008	Prothrombin Intl. Normalized Ratio	Screening	19JAN2016/12:00	1.22 H	0.9 - 1.2	Yes	1
		Week 28	17MAY2016/08:30	1.17	0.9 - 1.2	No	0
		Week 32	09JUN2016/08:30	1.18	0.9 - 1.2	No	0
		Week 36	06JUL2016/08:25	1.24 H	0.9 - 1.2	No	1

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-008	Prothrombin Intl. Normalized Ratio	Week 40	03AUG2016/08:45	1.19	0.9 - 1.2	No	0
		Week 44	07SEP2016/07:55	1.13	0.9 - 1.2	No	0
		Week 48	19OCT2016/07:20	1.19	0.9 - 1.2	No	0
	Prothrombin Time (sec)	Screening	19JAN2016/12:00	14 H	10 - 12	Yes	
		Week 28	17MAY2016/08:30	13 H	10 - 12	No	
		Week 32	09JUN2016/08:30	13 H	10 - 12	No	
		Week 36	06JUL2016/08:25	14 H	10 - 12	No	
		Week 40	03AUG2016/08:45	13 H	10 - 12	No	
		Week 44	07SEP2016/07:55	12	10 - 12	No	
		Week 48	19OCT2016/07:20	13 H	10 - 12	No	
301-009	Prothrombin Intl. Normalized Ratio	Screening	06JAN2016/11:00	1.13	0.9 - 1.2	Yes	0
		Day 1	27JAN2016/11:00	1.27 H	0.9 - 1.2	No	1
		Week 24	20JUL2016/13:50	1.34 H	0.9 - 1.2	Yes	1
		Week 28	09AUG2016/12:10	1.40 H	0.9 - 1.2	No	1
		Week 32	06SEP2016/13:10	1.39 H	0.9 - 1.2	No	1
		Week 36	04OCT2016/12:30	1.41 H	0.9 - 1.2	No	1
		Week 40	01NOV2016/12:30	1.39 H	0.9 - 1.2	No	1
		Week 44	29NOV2016/13:15	1.52 H	0.9 - 1.2	No	1
		Week 48	02JAN2017/12:00	1.39 H	0.9 - 1.2	No	1

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-009	Prothrombin Time (sec)	Screening	06JAN2016/11:00	13 H	10 - 12	Yes	
		Day 1	27JAN2016/11:00	14 H	10 - 12	No	
		Week 24	20JUL2016/13:50	15 H	10 - 12	Yes	
		Week 28	09AUG2016/12:10	15 H	10 - 12	No	
		Week 32	06SEP2016/13:10	15 H	10 - 12	No	
		Week 36	04OCT2016/12:30	15 H	10 - 12	No	
		Week 40	01NOV2016/12:30	15 H	10 - 12	No	
		Week 44	29NOV2016/13:15	17 H	10 - 12	No	
		Week 48	02JAN2017/12:00	15 H	10 - 12	No	
301-010	Prothrombin Intl. Normalized Ratio	Screening	07JAN2016/09:30	1.08	0.9 - 1.2	Yes	0
		Day 1	27JAN2016/10:00	1.14	0.9 - 1.2	Yes	0
		Week 24	12JUL2016/11:40	1.20	0.9 - 1.2	Yes	0
		Week 28	08AUG2016/12:30	1.32 H	0.9 - 1.2	No	1
		Week 32	06SEP2016/11:10	1.17	0.9 - 1.2	No	0
		Week 36	04OCT2016/12:40	1.09	0.9 - 1.2	No	0
		Week 40	01NOV2016/12:50	1.19	0.9 - 1.2	No	0
		Week 44	28NOV2016/11:45	1.28 H	0.9 - 1.2	No	1
		Week 48	03JAN2017/13:00	1.36 H	0.9 - 1.2	No	1
	Prothrombin Time (sec)	Screening	07JAN2016/09:30	12	10 - 12	Yes	
		Day 1	27JAN2016/10:00	13 H	10 - 12	Yes	
		Week 24	12JUL2016/11:40	13 H	10 - 12	Yes	

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-010	Prothrombin Time (sec)	Week 28	08AUG2016/12:30	14 H	10 - 12	No	
		Week 32	06SEP2016/11:10	13 H	10 - 12	No	
		Week 36	04OCT2016/12:40	12	10 - 12	No	
		Week 40	01NOV2016/12:50	13 H	10 - 12	No	
		Week 44	28NOV2016/11:45	14 H	10 - 12	No	
		Week 48	03JAN2017/13:00	15 H	10 - 12	No	
301-014	Prothrombin Intl. Normalized Ratio	Screening	27JAN2016/11:30	1.12	0.9 - 1.2	Yes	0
		Week 24	10AUG2016/10:50	1.33 H	0.9 - 1.2	Yes	1
		Week 28	07SEP2016/11:30	1.23 H	0.9 - 1.2	No	1
		Week 32	05OCT2016/11:00	1.25 H	0.9 - 1.2	No	1
		Week 36	02NOV2016/12:00	1.28 H	0.9 - 1.2	No	1
		Week 40	30NOV2016/10:45	1.16	0.9 - 1.2	No	0
		Week 44	22DEC2016/12:00		0.9 - 1.2	No	
		Week 48	25JAN2017/11:00	1.23 H	0.9 - 1.2	No	1
	Prothrombin Time (sec)	Screening	27JAN2016/11:30	12	10 - 12	Yes	
		Week 24	10AUG2016/10:50	15 H	10 - 12	Yes	
		Week 28	07SEP2016/11:30	14 H	10 - 12	No	
		Week 32	05OCT2016/11:00	14 H	10 - 12	No	
		Week 36	02NOV2016/12:00	14 H	10 - 12	No	
		Week 40	30NOV2016/10:45	13 H	10 - 12	No	
		Week 44	22DEC2016/12:00		10 - 12	No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-014	Prothrombin Time (sec)	Week 48	25JAN2017/11:00	14 H	10 - 12	No	
301-016	Prothrombin Intl. Normalized Ratio	Screening	03FEB2016/13:00	1.15	0.9 - 1.2	Yes	0
		Week 24	28JUL2016/11:00	1.13	0.9 - 1.2	Yes	0
		Week 28	06SEP2016/10:10	1.26 H	0.9 - 1.2	No	1
		Week 32	05OCT2016/11:30	1.19	0.9 - 1.2	No	0
		Week 36	02NOV2016/11:45	1.04	0.9 - 1.2	No	0
		Week 40	29NOV2016/11:00	1.08	0.9 - 1.2	No	0
		Week 44	21DEC2016/11:30	1.18	0.9 - 1.2	No	0
		Week 48	24JAN2017/12:00	1.17	0.9 - 1.2	No	0
	Prothrombin Time (sec)	Screening	03FEB2016/13:00	13 H	10 - 12	Yes	
		Week 24	28JUL2016/11:00	12	10 - 12	Yes	
		Week 28	06SEP2016/10:10	14 H	10 - 12	No	
		Week 32	05OCT2016/11:30	13 H	10 - 12	No	
		Week 36	02NOV2016/11:45	11	10 - 12	No	
		Week 40	29NOV2016/11:00	12	10 - 12	No	
		Week 44	21DEC2016/11:30	13 H	10 - 12	No	
		Week 48	24JAN2017/12:00	13 H	10 - 12	No	

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Prothrombin Intl. Normalized Ratio	Screening	02FEB2016/10:50	1.20	0.9 - 1.2	Yes	0
		Week 24	10AUG2016/10:20	1.22 H	0.9 - 1.2	Yes	1
		Week 28	07SEP2016/09:45	1.16	0.9 - 1.2	No	0
		Week 40	30NOV2016/09:50	1.27 H	0.9 - 1.2	No	1
		Week 44	28DEC2016/11:00	1.23 H	0.9 - 1.2	No	1
		Week 48	26JAN2017/12:45	1.07	0.9 - 1.2	No	0
	Prothrombin Time (sec)	Screening	02FEB2016/10:50	13 H	10 - 12	Yes	
		Week 24	10AUG2016/10:20	13 H	10 - 12	Yes	
		Week 28	07SEP2016/09:45	13 H	10 - 12	No	
		Week 40	30NOV2016/09:50	14 H	10 - 12	No	
		Week 44	28DEC2016/11:00	13 H	10 - 12	No	
		Week 48	26JAN2017/12:45	12	10 - 12	No	
301-018	Prothrombin Intl. Normalized Ratio	Screening	17FEB2016/14:45	1.26 H	0.9 - 1.2	Yes	1
		Week 24	23AUG2016/10:00	1.32 H	0.9 - 1.2	Yes	1
		Week 28	20SEP2016/11:30	1.38 H	0.9 - 1.2	No	1
		Week 32	18OCT2016/11:00	1.23 H	0.9 - 1.2	No	1
		Week 36	15NOV2016/12:00	1.24 H	0.9 - 1.2	No	1
		Week 40	14DEC2016/12:00	1.27 H	0.9 - 1.2	No	1
		Week 44	10JAN2017/11:30	1.48 H	0.9 - 1.2	No	1
		Week 48	07FEB2017/10:30	1.28 H	0.9 - 1.2	No	1

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Prothrombin Time (sec)	Screening	17FEB2016/14:45	14 H	10 - 12	Yes
		Week 24	23AUG2016/10:00	14 H	10 - 12	Yes
		Week 28	20SEP2016/11:30	15 H	10 - 12	No
		Week 32	18OCT2016/11:00	13 H	10 - 12	No
		Week 36	15NOV2016/12:00	14 H	10 - 12	No
		Week 40	14DEC2016/12:00	14 H	10 - 12	No
		Week 44	10JAN2017/11:30	16 H	10 - 12	No
		Week 48	07FEB2017/10:30	14 H	10 - 12	No

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Prothrombin Intl. Normalized Ratio	Screening	14JAN2016/13:30	1.18	0.9 - 1.2	Yes	0
		Week 24	19JUL2016/12:00	1.14	0.9 - 1.2	Yes	0
		Week 28	18AUG2016/12:15	1.13	0.9 - 1.2	No	0
		Week 32	13SEP2016/11:45	1.27 H	0.9 - 1.2	No	1
		Week 36	13OCT2016/12:10	1.20	0.9 - 1.2	No	0
		Week 40	08NOV2016/11:00	1.16	0.9 - 1.2	No	0
		Week 44	08DEC2016/11:00	1.22 H	0.9 - 1.2	No	1
		Week 48	03JAN2017/12:00	1.27 H	0.9 - 1.2	No	1
	Prothrombin Time (sec)	Screening	14JAN2016/13:30	13 H	10 - 12	Yes	
		Week 24	19JUL2016/12:00	13 H	10 - 12	Yes	
		Week 28	18AUG2016/12:15	12	10 - 12	No	
		Week 32	13SEP2016/11:45	14 H	10 - 12	No	
		Week 36	13OCT2016/12:10	13 H	10 - 12	No	
		Week 40	08NOV2016/11:00	13 H	10 - 12	No	
		Week 44	08DEC2016/11:00	13 H	10 - 12	No	
		Week 48	03JAN2017/12:00	14 H	10 - 12	No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Prothrombin Intl. Normalized Ratio	Screening	17FEB2016/13:00	1.12	0.9 - 1.2	Yes	0
		Week 24	24AUG2016/09:30	1.11	0.9 - 1.2	Yes	0
		Week 28	20SEP2016/12:00	1.17	0.9 - 1.2	No	0
		Week 32	19OCT2016/11:00	1.07	0.9 - 1.2	No	0
		Week 36	15NOV2016/11:15	1.08	0.9 - 1.2	No	0
		Week 40	14DEC2016/09:30	1.14	0.9 - 1.2	No	0
		Week 44	11JAN2017/11:00	1.13	0.9 - 1.2	No	0
		Week 48	08FEB2017/11:50	1.13	0.9 - 1.2	No	0
	Prothrombin Time (sec)	Screening	17FEB2016/13:00	12	10 - 12	Yes	
		Week 24	24AUG2016/09:30	12	10 - 12	Yes	
		Week 28	20SEP2016/12:00	13 H	10 - 12	No	
		Week 32	19OCT2016/11:00	12	10 - 12	No	
		Week 36	15NOV2016/11:15	12	10 - 12	No	
		Week 40	14DEC2016/09:30	13 H	10 - 12	No	
		Week 44	11JAN2017/11:00	12	10 - 12	No	
		Week 48	08FEB2017/11:50	12	10 - 12	No	

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Listing 16.2.7.3  
Laboratory Results - Coagulation  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-004	Prothrombin Intl. Normalized Ratio	Screening	16DEC2015/11:50	1.12	0.9 - 1.2	Yes	0
	Prothrombin Time (sec)	Screening	16DEC2015/11:50	12	10 - 12	Yes	
301-012	Prothrombin Intl. Normalized Ratio	Screening	26JAN2016/13:00	1.17	0.9 - 1.2	Yes	0
	Prothrombin Time (sec)	Screening	26JAN2016/13:00	13 H	10 - 12	Yes	
301-013	Prothrombin Intl. Normalized Ratio	Screening	26JAN2016/13:00	1.15	0.9 - 1.2	Yes	0
	Prothrombin Time (sec)	Screening	26JAN2016/13:00	13 H	10 - 12	Yes	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007 Urine Bilirubin	Screening	05JAN2016/11:00	NEGATIVE		Yes
	Day 1	26JAN2016/10:00	NEGATIVE		No
	Week 2	11FEB2016/12:15	NEGATIVE		No
	Week 4	24FEB2016/13:10	NEGATIVE		No
	Week 6	08MAR2016/11:35	NEGATIVE		No
	Week 8	24MAR2016/10:55	NEGATIVE		No
	Early Term	21APR2016/08:05	NEGATIVE		Yes
	Week 28	19MAY2016/12:25	NEGATIVE		No
	Week 32	16JUN2016/10:30	NEGATIVE		No
	Week 40	11AUG2016/12:10	NEGATIVE		No
	Week 44	08SEP2016/12:15	NEGATIVE		No
	Week 48	06OCT2016/12:35	NEGATIVE		No
Urine Blood	Screening	05JAN2016/11:00	NEGATIVE		Yes
	Day 1	26JAN2016/10:00	NEGATIVE		No
	Week 2	11FEB2016/12:15	NEGATIVE		No
	Week 4	24FEB2016/13:10	NEGATIVE		No
	Week 6	08MAR2016/11:35	NEGATIVE		No
	Week 8	24MAR2016/10:55	NEGATIVE		No
	Early Term	21APR2016/08:05	NEGATIVE		Yes
	Week 28	19MAY2016/12:25	NEGATIVE		No
	Week 32	16JUN2016/10:30	NEGATIVE		No
	Week 40	11AUG2016/12:10	NEGATIVE		No
	Week 44	08SEP2016/12:15	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Urine Blood	Week 48	06OCT2016/12:35	NEGATIVE		No
	Urine Cellular Casts	Screening	05JAN2016/11:00	NOT SEEN		Yes
		Day 1	26JAN2016/10:00	NOT SEEN		No
		Week 2	11FEB2016/12:15	NOT SEEN		No
		Week 4	24FEB2016/13:10	NOT SEEN		No
		Week 6	08MAR2016/11:35	NOT SEEN		No
		Week 8	24MAR2016/10:55	NOT SEEN		No
		Early Term	21APR2016/08:05	NOT SEEN		Yes
		Week 28	19MAY2016/12:25	NOT SEEN		No
		Week 32	16JUN2016/10:30	NOT SEEN		No
		Week 40	11AUG2016/12:10	NOT SEEN		No
		Week 44	08SEP2016/12:15	NOT SEEN		No
		Week 48	06OCT2016/12:35	NOT SEEN		No
	Urine Crystals	Screening	05JAN2016/11:00	NOT SEEN		Yes
		Day 1	26JAN2016/10:00	NOT SEEN		No
		Week 2	11FEB2016/12:15	NOT SEEN		No
		Week 4	24FEB2016/13:10	NOT SEEN		No
		Week 6	08MAR2016/11:35	NOT SEEN		No
		Week 8	24MAR2016/10:55	NOT SEEN		No
		Early Term	21APR2016/08:05	NOT SEEN		Yes
		Week 28	19MAY2016/12:25	NOT SEEN		No
		Week 32	16JUN2016/10:30	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Urine Crystals	Week 40	11AUG2016/12:10	NOT SEEN		No
		Week 44	08SEP2016/12:15	NOT SEEN		No
		Week 48	06OCT2016/12:35	NOT SEEN		No
	Urine Epithelial Cells	Screening	05JAN2016/11:00	NOT SEEN		Yes
		Day 1	26JAN2016/10:00	NOT SEEN		No
		Week 2	11FEB2016/12:15	NOT SEEN		No
		Week 4	24FEB2016/13:10	NOT SEEN		No
		Week 6	08MAR2016/11:35	NOT SEEN		No
		Week 8	24MAR2016/10:55	NOT SEEN		No
		Early Term	21APR2016/08:05	NOT SEEN		Yes
		Week 28	19MAY2016/12:25	NOT SEEN		No
		Week 32	16JUN2016/10:30	NOT SEEN		No
		Week 40	11AUG2016/12:10	NOT SEEN		No
		Week 44	08SEP2016/12:15	NOT SEEN		No
		Week 48	06OCT2016/12:35	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	05JAN2016/11:00	NOT SEEN		Yes
		Day 1	26JAN2016/10:00	NOT SEEN		No
		Week 2	11FEB2016/12:15	NOT SEEN		No
		Week 4	24FEB2016/13:10	NOT SEEN		No
		Week 6	08MAR2016/11:35	1 - 9 /HPF		No
		Week 8	24MAR2016/10:55	NOT SEEN		No
		Early Term	21APR2016/08:05	1 - 9 /HPF		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Urine Erythrocytes (/HPF)	Week 28	19MAY2016/12:25	NOT SEEN		No
		Week 32	16JUN2016/10:30	NOT SEEN		No
		Week 40	11AUG2016/12:10	NOT SEEN		No
		Week 44	08SEP2016/12:15	NOT SEEN		No
		Week 48	06OCT2016/12:35	NOT SEEN		No
	Urine Granular Casts	Screening	05JAN2016/11:00	NOT SEEN		Yes
		Day 1	26JAN2016/10:00	NOT SEEN		No
		Week 2	11FEB2016/12:15	NOT SEEN		No
		Week 4	24FEB2016/13:10	NOT SEEN		No
		Week 6	08MAR2016/11:35	NOT SEEN		No
		Week 8	24MAR2016/10:55	NOT SEEN		No
		Early Term	21APR2016/08:05	NOT SEEN		Yes
		Week 28	19MAY2016/12:25	NOT SEEN		No
		Week 32	16JUN2016/10:30	NOT SEEN		No
		Week 40	11AUG2016/12:10	NOT SEEN		No
		Week 44	08SEP2016/12:15	NOT SEEN		No
		Week 48	06OCT2016/12:35	NOT SEEN		No
	Urine Hyaline Casts	Screening	05JAN2016/11:00	NOT SEEN		Yes
		Day 1	26JAN2016/10:00	NOT SEEN		No
		Week 2	11FEB2016/12:15	NOT SEEN		No
		Week 4	24FEB2016/13:10	NOT SEEN		No
		Week 6	08MAR2016/11:35	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Urine Hyaline Casts	Week 8	24MAR2016/10:55	NOT SEEN		No
		Early Term	21APR2016/08:05	NOT SEEN		Yes
		Week 28	19MAY2016/12:25	NOT SEEN		No
		Week 32	16JUN2016/10:30	NOT SEEN		No
		Week 40	11AUG2016/12:10	NOT SEEN		No
		Week 44	08SEP2016/12:15	NOT SEEN		No
		Week 48	06OCT2016/12:35	NOT SEEN		No
	Urine Ketones	Screening	05JAN2016/11:00	NEGATIVE		Yes
		Day 1	26JAN2016/10:00	NEGATIVE		No
		Week 2	11FEB2016/12:15	NEGATIVE		No
		Week 4	24FEB2016/13:10	NEGATIVE		No
		Week 6	08MAR2016/11:35	NEGATIVE		No
		Week 8	24MAR2016/10:55	NEGATIVE		No
		Early Term	21APR2016/08:05	NEGATIVE		Yes
		Week 28	19MAY2016/12:25	NEGATIVE		No
		Week 32	16JUN2016/10:30	NEGATIVE		No
		Week 40	11AUG2016/12:10	NEGATIVE		No
		Week 44	08SEP2016/12:15	NEGATIVE		No
		Week 48	06OCT2016/12:35	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	05JAN2016/11:00	NOT SEEN		Yes
		Day 1	26JAN2016/10:00	NOT SEEN		No
		Week 2	11FEB2016/12:15	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Urine Leukocytes (/HPF)	Week 4	24FEB2016/13:10	NOT SEEN		No
		Week 6	08MAR2016/11:35	NOT SEEN		No
		Week 8	24MAR2016/10:55	NOT SEEN		No
		Early Term	21APR2016/08:05	NOT SEEN		Yes
		Week 28	19MAY2016/12:25	NOT SEEN		No
		Week 32	16JUN2016/10:30	NOT SEEN		No
		Week 40	11AUG2016/12:10	NOT SEEN		No
		Week 44	08SEP2016/12:15	NOT SEEN		No
		Week 48	06OCT2016/12:35	NOT SEEN		No
	Urine Nitrite	Screening	05JAN2016/11:00	NEGATIVE		Yes
		Day 1	26JAN2016/10:00	NEGATIVE		No
		Week 2	11FEB2016/12:15	NEGATIVE		No
		Week 4	24FEB2016/13:10	NEGATIVE		No
		Week 6	08MAR2016/11:35	NEGATIVE		No
		Week 8	24MAR2016/10:55	NEGATIVE		No
		Early Term	21APR2016/08:05	NEGATIVE		Yes
		Week 28	19MAY2016/12:25	NEGATIVE		No
		Week 32	16JUN2016/10:30	NEGATIVE		No
		Week 40	11AUG2016/12:10	NEGATIVE		No
		Week 44	08SEP2016/12:15	NEGATIVE		No
		Week 48	06OCT2016/12:35	NEGATIVE		No
	Urine Organisms	Screening	05JAN2016/11:00	NOT SEEN		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007 Urine Organisms	Day 1	26JAN2016/10:00	NOT SEEN		No
	Week 2	11FEB2016/12:15	NOT SEEN		No
	Week 4	24FEB2016/13:10	NOT SEEN		No
	Week 6	08MAR2016/11:35	NOT SEEN		No
	Week 8	24MAR2016/10:55	NOT SEEN		No
	Early Term	21APR2016/08:05	NOT SEEN		Yes
	Week 28	19MAY2016/12:25	NOT SEEN		No
	Week 32	16JUN2016/10:30	NOT SEEN		No
	Week 40	11AUG2016/12:10	NOT SEEN		No
	Week 44	08SEP2016/12:15	NOT SEEN		No
	Week 48	06OCT2016/12:35	NOT SEEN		No
	Screening	05JAN2016/11:00	NEGATIVE		Yes
	Day 1	26JAN2016/10:00	NEGATIVE		No
	Week 2	11FEB2016/12:15	NEGATIVE		No
	Week 4	24FEB2016/13:10	NEGATIVE		No
	Week 6	08MAR2016/11:35	NEGATIVE		No
	Week 8	24MAR2016/10:55	NEGATIVE		No
	Early Term	21APR2016/08:05	NEGATIVE		Yes
	Week 28	19MAY2016/12:25	NEGATIVE		No
	Week 32	16JUN2016/10:30	NEGATIVE		No
	Week 40	11AUG2016/12:10	NEGATIVE		No
	Week 44	08SEP2016/12:15	NEGATIVE		No
	Week 48	06OCT2016/12:35	TRACE		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Urine Specific Gravity	Screening	05JAN2016/11:00	1.005	1 - 1.03	Yes
		Day 1	26JAN2016/10:00	1.005	1 - 1.03	No
		Week 2	11FEB2016/12:15	1.009	1 - 1.03	No
		Week 4	24FEB2016/13:10	1.008	1 - 1.03	No
		Week 6	08MAR2016/11:35	1.007	1 - 1.03	No
		Week 8	24MAR2016/10:55	1.007	1 - 1.03	No
		Early Term	21APR2016/08:05	1.006	1 - 1.03	Yes
		Week 28	19MAY2016/12:25	1.006	1 - 1.03	No
		Week 32	16JUN2016/10:30	1.004	1 - 1.03	No
		Week 40	11AUG2016/12:10	1.007	1 - 1.03	No
		Week 44	08SEP2016/12:15	1.005	1 - 1.03	No
		Week 48	06OCT2016/12:35	1.015	1 - 1.03	No
	Urine Urobilinogen	Screening	05JAN2016/11:00	NORMAL		Yes
		Day 1	26JAN2016/10:00	NORMAL		No
		Week 2	11FEB2016/12:15	NORMAL		No
		Week 4	24FEB2016/13:10	NORMAL		No
		Week 6	08MAR2016/11:35	NORMAL		No
		Week 8	24MAR2016/10:55	NORMAL		No
		Early Term	21APR2016/08:05	NORMAL		Yes
		Week 28	19MAY2016/12:25	NORMAL		No
		Week 32	16JUN2016/10:30	NORMAL		No
		Week 40	11AUG2016/12:10	NORMAL		No
		Week 44	08SEP2016/12:15	NORMAL		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-007	Urine Urobilinogen	Week 48	06OCT2016/12:35	NORMAL		No
301-011	Urine Bilirubin	Screening	07JAN2016/12:10	NEGATIVE		Yes
		Day 1	27JAN2016/08:50	NEGATIVE		Yes
		Week 2	11FEB2016/11:45	NEGATIVE		Yes
		Week 4	26FEB2016/10:30	NEGATIVE		No
		Week 6	10MAR2016/10:50	NEGATIVE		No
		Week 8	24MAR2016/09:34	NEGATIVE		No
		Week 12	19APR2016/09:22	NEGATIVE		Yes
		Week 16	18MAY2016/10:15	NEGATIVE		No
		Week 20	21JUN2016/10:40	NEGATIVE		No
		Week 24	12JUL2016/10:05	NEGATIVE		Yes
		Week 28	09AUG2016/09:55	NEGATIVE		No
		Week 32	06SEP2016/09:00	NEGATIVE		No
		Week 36	06OCT2016/09:55	NEGATIVE		No
		Week 40	03NOV2016/11:10	NEGATIVE		No
		Week 44	06DEC2016/10:35	NEGATIVE		No
		Week 48	03JAN2017/11:00	NEGATIVE		No
	Urine Blood	Screening	07JAN2016/12:10	NEGATIVE		Yes
		Day 1	27JAN2016/08:50	NEGATIVE		Yes
		Week 2	11FEB2016/11:45	NEGATIVE		Yes
		Week 4	26FEB2016/10:30	NEGATIVE		No
		Week 6	10MAR2016/10:50	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Urine Blood	Week 8	24MAR2016/09:34	NEGATIVE		No
		Week 12	19APR2016/09:22	NEGATIVE		Yes
		Week 16	18MAY2016/10:15	NEGATIVE		No
		Week 20	21JUN2016/10:40	NEGATIVE		No
		Week 24	12JUL2016/10:05	NEGATIVE		Yes
		Week 28	09AUG2016/09:55	NEGATIVE		No
		Week 32	06SEP2016/09:00	NEGATIVE		No
		Week 36	06OCT2016/09:55	NEGATIVE		No
		Week 40	03NOV2016/11:10	NEGATIVE		No
		Week 44	06DEC2016/10:35	NEGATIVE		No
		Week 48	03JAN2017/11:00	NEGATIVE		No
	Urine Cellular Casts	Screening	07JAN2016/12:10	NOT SEEN		Yes
		Day 1	27JAN2016/08:50	NOT SEEN		Yes
		Week 2	11FEB2016/11:45	NOT SEEN		Yes
		Week 4	26FEB2016/10:30	NOT SEEN		No
		Week 6	10MAR2016/10:50	NOT SEEN		No
		Week 8	24MAR2016/09:34	NOT SEEN		No
		Week 12	19APR2016/09:22	NOT SEEN		Yes
		Week 16	18MAY2016/10:15	NOT SEEN		No
		Week 20	21JUN2016/10:40	NOT SEEN		No
		Week 24	12JUL2016/10:05	NOT SEEN		Yes
		Week 28	09AUG2016/09:55	NOT SEEN		No
		Week 32	06SEP2016/09:00	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Urine Cellular Casts	Week 36	06OCT2016/09:55	NOT SEEN		No
		Week 40	03NOV2016/11:10	NOT SEEN		No
		Week 44	06DEC2016/10:35	NOT SEEN		No
		Week 48	03JAN2017/11:00	NOT SEEN		No
	Urine Crystals	Screening	07JAN2016/12:10	NOT SEEN		Yes
		Day 1	27JAN2016/08:50	NOT SEEN		Yes
		Week 2	11FEB2016/11:45	NOT SEEN		Yes
		Week 4	26FEB2016/10:30	NOT SEEN		No
		Week 6	10MAR2016/10:50	NOT SEEN		No
		Week 8	24MAR2016/09:34	NOT SEEN		No
		Week 12	19APR2016/09:22	NOT SEEN		Yes
		Week 16	18MAY2016/10:15	NOT SEEN		No
		Week 20	21JUN2016/10:40	NOT SEEN		No
		Week 24	12JUL2016/10:05	NOT SEEN		Yes
		Week 28	09AUG2016/09:55	NOT SEEN		No
		Week 32	06SEP2016/09:00	NOT SEEN		No
		Week 36	06OCT2016/09:55	NOT SEEN		No
		Week 40	03NOV2016/11:10	NOT SEEN		No
		Week 44	06DEC2016/10:35	NOT SEEN		No
		Week 48	03JAN2017/11:00	NOT SEEN		No
	Urine Epithelial Cells	Screening	07JAN2016/12:10	NOT SEEN		Yes
		Day 1	27JAN2016/08:50	NOT SEEN		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Urine Epithelial Cells	Week 2	11FEB2016/11:45	NOT SEEN		Yes
		Week 4	26FEB2016/10:30	NOT SEEN		No
		Week 6	10MAR2016/10:50	SCANTY		No
		Week 8	24MAR2016/09:34	NOT SEEN		No
		Week 12	19APR2016/09:22	NOT SEEN		Yes
		Week 16	18MAY2016/10:15	SCANTY		No
		Week 20	21JUN2016/10:40	NOT SEEN		No
		Week 24	12JUL2016/10:05	NOT SEEN		Yes
		Week 28	09AUG2016/09:55	NOT SEEN		No
		Week 32	06SEP2016/09:00	NOT SEEN		No
		Week 36	06OCT2016/09:55	NOT SEEN		No
		Week 40	03NOV2016/11:10	NOT SEEN		No
		Week 44	06DEC2016/10:35	NOT SEEN		No
		Week 48	03JAN2017/11:00	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	07JAN2016/12:10	NOT SEEN		Yes
		Day 1	27JAN2016/08:50	NOT SEEN		Yes
		Week 2	11FEB2016/11:45	NOT SEEN		Yes
		Week 4	26FEB2016/10:30	NOT SEEN		No
		Week 6	10MAR2016/10:50	NOT SEEN		No
		Week 8	24MAR2016/09:34	1 - 9 /HPF		No
		Week 12	19APR2016/09:22	NOT SEEN		Yes
		Week 16	18MAY2016/10:15	1 - 9 /HPF		No
		Week 20	21JUN2016/10:40	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Urine Erythrocytes (/HPF)	Week 24	12JUL2016/10:05	NOT SEEN		Yes
		Week 28	09AUG2016/09:55	NOT SEEN		No
		Week 32	06SEP2016/09:00	NOT SEEN		No
		Week 36	06OCT2016/09:55	NOT SEEN		No
		Week 40	03NOV2016/11:10	NOT SEEN		No
		Week 44	06DEC2016/10:35	1 - 9 /HPF		No
		Week 48	03JAN2017/11:00	NOT SEEN		No
	Urine Granular Casts	Screening	07JAN2016/12:10	NOT SEEN		Yes
		Day 1	27JAN2016/08:50	NOT SEEN		Yes
		Week 2	11FEB2016/11:45	NOT SEEN		Yes
		Week 4	26FEB2016/10:30	NOT SEEN		No
		Week 6	10MAR2016/10:50	NOT SEEN		No
		Week 8	24MAR2016/09:34	NOT SEEN		No
		Week 12	19APR2016/09:22	NOT SEEN		Yes
		Week 16	18MAY2016/10:15	NOT SEEN		No
		Week 20	21JUN2016/10:40	NOT SEEN		No
		Week 24	12JUL2016/10:05	NOT SEEN		Yes
		Week 28	09AUG2016/09:55	NOT SEEN		No
		Week 32	06SEP2016/09:00	NOT SEEN		No
		Week 36	06OCT2016/09:55	NOT SEEN		No
		Week 40	03NOV2016/11:10	NOT SEEN		No
		Week 44	06DEC2016/10:35	NOT SEEN		No
		Week 48	03JAN2017/11:00	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011 Urine Hyaline Casts	Screening	07JAN2016/12:10	NOT SEEN		Yes
	Day 1	27JAN2016/08:50	NOT SEEN		Yes
	Week 2	11FEB2016/11:45	NOT SEEN		Yes
	Week 4	26FEB2016/10:30	NOT SEEN		No
	Week 6	10MAR2016/10:50	NOT SEEN		No
	Week 8	24MAR2016/09:34	NOT SEEN		No
	Week 12	19APR2016/09:22	NOT SEEN		Yes
	Week 16	18MAY2016/10:15	SCANTY		No
	Week 20	21JUN2016/10:40	NOT SEEN		No
	Week 24	12JUL2016/10:05	NOT SEEN		Yes
	Week 28	09AUG2016/09:55	NOT SEEN		No
	Week 32	06SEP2016/09:00	NOT SEEN		No
	Week 36	06OCT2016/09:55	NOT SEEN		No
	Week 40	03NOV2016/11:10	NOT SEEN		No
	Week 44	06DEC2016/10:35	NOT SEEN		No
	Week 48	03JAN2017/11:00	NOT SEEN		No
Urine Ketones	Screening	07JAN2016/12:10	NEGATIVE		Yes
	Day 1	27JAN2016/08:50	NEGATIVE		Yes
	Week 2	11FEB2016/11:45	NEGATIVE		Yes
	Week 4	26FEB2016/10:30	NEGATIVE		No
	Week 6	10MAR2016/10:50	NEGATIVE		No
	Week 8	24MAR2016/09:34	NEGATIVE		No
	Week 12	19APR2016/09:22	NEGATIVE		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011 Urine Ketones	Week 16	18MAY2016/10:15	NEGATIVE		No
	Week 20	21JUN2016/10:40	NEGATIVE		No
	Week 24	12JUL2016/10:05	NEGATIVE		Yes
	Week 28	09AUG2016/09:55	NEGATIVE		No
	Week 32	06SEP2016/09:00	NEGATIVE		No
	Week 36	06OCT2016/09:55	NEGATIVE		No
	Week 40	03NOV2016/11:10	NEGATIVE		No
	Week 44	06DEC2016/10:35	NEGATIVE		No
	Week 48	03JAN2017/11:00	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	07JAN2016/12:10	1 - 9 /HPF	Yes
		Day 1	27JAN2016/08:50	NOT SEEN	Yes
		Week 2	11FEB2016/11:45	1 - 9 /HPF	Yes
		Week 4	26FEB2016/10:30	1 - 9 /HPF	No
		Week 6	10MAR2016/10:50	1 - 9 /HPF	No
		Week 8	24MAR2016/09:34	NOT SEEN	No
		Week 12	19APR2016/09:22	1 - 9 /HPF	Yes
		Week 16	18MAY2016/10:15	1 - 9 /HPF	No
		Week 20	21JUN2016/10:40	1 - 9 /HPF	No
		Week 24	12JUL2016/10:05	1 - 9 /HPF	Yes
		Week 28	09AUG2016/09:55	1 - 9 /HPF	No
		Week 32	06SEP2016/09:00	NOT SEEN	No
		Week 36	06OCT2016/09:55	1 - 9 /HPF	No
		Week 40	03NOV2016/11:10	1 - 9 /HPF	No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Urine Leukocytes (/HPF)	Week 44	06DEC2016/10:35	1 - 9 /HPF		No
		Week 48	03JAN2017/11:00	NOT SEEN		No
	Urine Nitrite	Screening	07JAN2016/12:10	NEGATIVE		Yes
		Day 1	27JAN2016/08:50	NEGATIVE		Yes
		Week 2	11FEB2016/11:45	NEGATIVE		Yes
		Week 4	26FEB2016/10:30	NEGATIVE		No
		Week 6	10MAR2016/10:50	NEGATIVE		No
		Week 8	24MAR2016/09:34	NEGATIVE		No
		Week 12	19APR2016/09:22	NEGATIVE		Yes
		Week 16	18MAY2016/10:15	NEGATIVE		No
		Week 20	21JUN2016/10:40	NEGATIVE		No
		Week 24	12JUL2016/10:05	NEGATIVE		Yes
		Week 28	09AUG2016/09:55	NEGATIVE		No
		Week 32	06SEP2016/09:00	NEGATIVE		No
		Week 36	06OCT2016/09:55	NEGATIVE		No
		Week 40	03NOV2016/11:10	NEGATIVE		No
		Week 44	06DEC2016/10:35	NEGATIVE		No
		Week 48	03JAN2017/11:00	NEGATIVE		No
	Urine Organisms	Screening	07JAN2016/12:10	NOT SEEN		Yes
		Day 1	27JAN2016/08:50	NOT SEEN		Yes
		Week 2	11FEB2016/11:45	NOT SEEN		Yes
		Week 4	26FEB2016/10:30	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011 Urine Organisms	Week 6	10MAR2016/10:50	NOT SEEN		No
	Week 8	24MAR2016/09:34	NOT SEEN		No
	Week 12	19APR2016/09:22	NOT SEEN		Yes
	Week 16	18MAY2016/10:15	NOT SEEN		No
	Week 20	21JUN2016/10:40	NOT SEEN		No
	Week 24	12JUL2016/10:05	NOT SEEN		Yes
	Week 28	09AUG2016/09:55	NOT SEEN		No
	Week 32	06SEP2016/09:00	+		No
	Week 36	06OCT2016/09:55	NOT SEEN		No
	Week 40	03NOV2016/11:10	NOT SEEN		No
	Week 44	06DEC2016/10:35	NOT SEEN		No
	Week 48	03JAN2017/11:00	NOT SEEN		No
Urine Protein	Screening	07JAN2016/12:10	NEGATIVE		Yes
	Day 1	27JAN2016/08:50	NEGATIVE		Yes
	Week 2	11FEB2016/11:45	TRACE		Yes
	Week 4	26FEB2016/10:30	NEGATIVE		No
	Week 6	10MAR2016/10:50	NEGATIVE		No
	Week 8	24MAR2016/09:34	NEGATIVE		No
	Week 12	19APR2016/09:22	NEGATIVE		Yes
	Week 16	18MAY2016/10:15	NEGATIVE		No
	Week 20	21JUN2016/10:40	NEGATIVE		No
	Week 24	12JUL2016/10:05	NEGATIVE		Yes
	Week 28	09AUG2016/09:55	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Urine Protein	Week 32	06SEP2016/09:00	NEGATIVE		No
		Week 36	06OCT2016/09:55	NEGATIVE		No
		Week 40	03NOV2016/11:10	NEGATIVE		No
		Week 44	06DEC2016/10:35	NEGATIVE		No
		Week 48	03JAN2017/11:00	NEGATIVE		No
	Urine Specific Gravity	Screening	07JAN2016/12:10	1.017	1 - 1.03	Yes
		Day 1	27JAN2016/08:50	1.010	1 - 1.03	Yes
		Week 2	11FEB2016/11:45	1.021	1 - 1.03	Yes
		Week 4	26FEB2016/10:30	1.015	1 - 1.03	No
		Week 6	10MAR2016/10:50	1.009	1 - 1.03	No
		Week 8	24MAR2016/09:34	1.017	1 - 1.03	No
		Week 12	19APR2016/09:22	1.015	1 - 1.03	Yes
		Week 16	18MAY2016/10:15	1.014	1 - 1.03	No
		Week 20	21JUN2016/10:40	1.017	1 - 1.03	No
		Week 24	12JUL2016/10:05	1.015	1 - 1.03	Yes
		Week 28	09AUG2016/09:55	1.015	1 - 1.03	No
		Week 32	06SEP2016/09:00	1.016	1 - 1.03	No
		Week 36	06OCT2016/09:55	1.018	1 - 1.03	No
		Week 40	03NOV2016/11:10	1.014	1 - 1.03	No
		Week 44	06DEC2016/10:35	1.016	1 - 1.03	No
		Week 48	03JAN2017/11:00	1.010	1 - 1.03	No
	Urine Urobilinogen	Screening	07JAN2016/12:10	NORMAL		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-011	Urine Urobilinogen	Day 1	27JAN2016/08:50	NORMAL		Yes
		Week 2	11FEB2016/11:45	NORMAL		Yes
		Week 4	26FEB2016/10:30	NORMAL		No
		Week 6	10MAR2016/10:50	NORMAL		No
		Week 8	24MAR2016/09:34	NORMAL		No
		Week 12	19APR2016/09:22	NORMAL		Yes
		Week 16	18MAY2016/10:15	NORMAL		No
		Week 20	21JUN2016/10:40	NORMAL		No
		Week 24	12JUL2016/10:05	NORMAL		Yes
		Week 28	09AUG2016/09:55	NORMAL		No
		Week 32	06SEP2016/09:00	NORMAL		No
		Week 36	06OCT2016/09:55	NORMAL		No
		Week 40	03NOV2016/11:10	NORMAL		No
		Week 44	06DEC2016/10:35	NORMAL		No
		Week 48	03JAN2017/11:00	NORMAL		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Bilirubin	Screening	06JAN2016/10:50	NEGATIVE		Yes
		Day 1	02FEB2016/11:15	NEGATIVE		Yes
		Week 2	16FEB2016/11:10	NEGATIVE		No
		Week 4	01MAR2016/10:35	NEGATIVE		No
		Week 6	16MAR2016/11:50	NEGATIVE		No
		Week 8	31MAR2016/09:55	NEGATIVE		No
		Week 12	28APR2016/08:20	NEGATIVE		Yes
		Week 16	26MAY2016/12:15	NEGATIVE		No
		Week 20	22JUN2016/10:00	NEGATIVE		No
		Week 24	20JUL2016/09:35	NEGATIVE		Yes
		Week 28	18AUG2016/10:50	NEGATIVE		No
		Week 32	15SEP2016/10:05	NEGATIVE		No
		Week 36	13OCT2016/12:35	NEGATIVE		No
		Week 40	10NOV2016/10:20	NEGATIVE		No
		Week 44	06DEC2016/11:10	NEGATIVE		No
		Week 48	03JAN2017/12:05	NEGATIVE		No
	Urine Blood	Screening	06JAN2016/10:50	TRACE		Yes
		Day 1	02FEB2016/11:15	NEGATIVE		Yes
		Week 2	16FEB2016/11:10	+		No
		Week 4	01MAR2016/10:35	+		No
		Week 6	16MAR2016/11:50	NEGATIVE		No
		Week 8	31MAR2016/09:55	+		No
		Week 12	28APR2016/08:20	+		Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Blood	Week 16	26MAY2016/12:15	NEGATIVE		No
		Week 20	22JUN2016/10:00	NEGATIVE		No
		Week 24	20JUL2016/09:35	NEGATIVE		Yes
		Week 28	18AUG2016/10:50	NEGATIVE		No
		Week 32	15SEP2016/10:05	NEGATIVE		No
		Week 36	13OCT2016/12:35	+		No
		Week 40	10NOV2016/10:20	+		No
		Week 44	06DEC2016/11:10	+		No
		Week 48	03JAN2017/12:05	NEGATIVE		No
	Urine Cellular Casts	Screening	06JAN2016/10:50	NOT SEEN		Yes
		Day 1	02FEB2016/11:15	NOT SEEN		Yes
		Week 2	16FEB2016/11:10	NOT SEEN		No
		Week 4	01MAR2016/10:35	NOT SEEN		No
		Week 6	16MAR2016/11:50	NOT SEEN		No
		Week 8	31MAR2016/09:55	NOT SEEN		No
		Week 12	28APR2016/08:20	NOT SEEN		Yes
		Week 16	26MAY2016/12:15	NOT SEEN		No
		Week 20	22JUN2016/10:00	NOT SEEN		No
		Week 24	20JUL2016/09:35	NOT SEEN		Yes
		Week 28	18AUG2016/10:50	NOT SEEN		No
		Week 32	15SEP2016/10:05	NOT SEEN		No
		Week 36	13OCT2016/12:35	NOT SEEN		No
		Week 40	10NOV2016/10:20	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Cellular Casts	Week 44	06DEC2016/11:10	NOT SEEN		No
		Week 48	03JAN2017/12:05	NOT SEEN		No
	Urine Crystals	Screening	06JAN2016/10:50	+++		Yes
		Day 1	02FEB2016/11:15	NOT SEEN		Yes
		Week 2	16FEB2016/11:10	NOT SEEN		No
		Week 4	01MAR2016/10:35	NOT SEEN		No
		Week 6	16MAR2016/11:50	+		No
		Week 8	31MAR2016/09:55	NOT SEEN		No
		Week 12	28APR2016/08:20	NOT SEEN		Yes
		Week 16	26MAY2016/12:15	NOT SEEN		No
		Week 20	22JUN2016/10:00	NOT SEEN		No
		Week 24	20JUL2016/09:35	NOT SEEN		Yes
		Week 28	18AUG2016/10:50	NOT SEEN		No
		Week 32	15SEP2016/10:05	NOT SEEN		No
		Week 36	13OCT2016/12:35	NOT SEEN		No
		Week 40	10NOV2016/10:20	NOT SEEN		No
		Week 44	06DEC2016/11:10	NOT SEEN		No
		Week 48	03JAN2017/12:05	NOT SEEN		No
	Urine Epithelial Cells	Screening	06JAN2016/10:50	NOT SEEN		Yes
		Day 1	02FEB2016/11:15	NOT SEEN		Yes
		Week 2	16FEB2016/11:10	NOT SEEN		No
		Week 4	01MAR2016/10:35	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Epithelial Cells	Week 6	16MAR2016/11:50	NOT SEEN		No
		Week 8	31MAR2016/09:55	NOT SEEN		No
		Week 12	28APR2016/08:20	NOT SEEN		Yes
		Week 16	26MAY2016/12:15	NOT SEEN		No
		Week 20	22JUN2016/10:00	NOT SEEN		No
		Week 24	20JUL2016/09:35	NOT SEEN		Yes
		Week 28	18AUG2016/10:50	NOT SEEN		No
		Week 32	15SEP2016/10:05	NOT SEEN		No
		Week 36	13OCT2016/12:35	NOT SEEN		No
		Week 40	10NOV2016/10:20	NOT SEEN		No
		Week 44	06DEC2016/11:10	NOT SEEN		No
		Week 48	03JAN2017/12:05	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	06JAN2016/10:50	1 - 9 /HPF		Yes
		Day 1	02FEB2016/11:15	1 - 9 /HPF		Yes
		Week 2	16FEB2016/11:10	NOT SEEN		No
		Week 4	01MAR2016/10:35	1 - 9 /HPF		No
		Week 6	16MAR2016/11:50	10 - 50 /HPF		No
		Week 8	31MAR2016/09:55	NOT SEEN		No
		Week 12	28APR2016/08:20	1 - 9 /HPF		Yes
		Week 16	26MAY2016/12:15	1 - 9 /HPF		No
		Week 20	22JUN2016/10:00	1 - 9 /HPF		No
		Week 24	20JUL2016/09:35	1 - 9 /HPF		Yes
		Week 28	18AUG2016/10:50	1 - 9 /HPF		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Erythrocytes (/HPF)	Week 32	15SEP2016/10:05	1 - 9 /HPF		No
		Week 36	13OCT2016/12:35	1 - 9 /HPF		No
		Week 40	10NOV2016/10:20	1 - 9 /HPF		No
		Week 44	06DEC2016/11:10	NOT SEEN		No
		Week 48	03JAN2017/12:05	NOT SEEN		No
	Urine Granular Casts	Screening	06JAN2016/10:50	NOT SEEN		Yes
		Day 1	02FEB2016/11:15	NOT SEEN		Yes
		Week 2	16FEB2016/11:10	NOT SEEN		No
		Week 4	01MAR2016/10:35	NOT SEEN		No
		Week 6	16MAR2016/11:50	NOT SEEN		No
		Week 8	31MAR2016/09:55	NOT SEEN		No
		Week 12	28APR2016/08:20	NOT SEEN		Yes
		Week 16	26MAY2016/12:15	NOT SEEN		No
		Week 20	22JUN2016/10:00	NOT SEEN		No
		Week 24	20JUL2016/09:35	NOT SEEN		Yes
		Week 28	18AUG2016/10:50	NOT SEEN		No
		Week 32	15SEP2016/10:05	NOT SEEN		No
		Week 36	13OCT2016/12:35	NOT SEEN		No
		Week 40	10NOV2016/10:20	NOT SEEN		No
		Week 44	06DEC2016/11:10	NOT SEEN		No
		Week 48	03JAN2017/12:05	NOT SEEN		No
	Urine Hyaline Casts	Screening	06JAN2016/10:50	NOT SEEN		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Hyaline Casts	Day 1	02FEB2016/11:15	NOT SEEN		Yes
		Week 2	16FEB2016/11:10	NOT SEEN		No
		Week 4	01MAR2016/10:35	NOT SEEN		No
		Week 6	16MAR2016/11:50	NOT SEEN		No
		Week 8	31MAR2016/09:55	NOT SEEN		No
		Week 12	28APR2016/08:20	NOT SEEN		Yes
		Week 16	26MAY2016/12:15	NOT SEEN		No
		Week 20	22JUN2016/10:00	NOT SEEN		No
		Week 24	20JUL2016/09:35	NOT SEEN		Yes
		Week 28	18AUG2016/10:50	NOT SEEN		No
		Week 32	15SEP2016/10:05	NOT SEEN		No
		Week 36	13OCT2016/12:35	NOT SEEN		No
		Week 40	10NOV2016/10:20	NOT SEEN		No
		Week 44	06DEC2016/11:10	NOT SEEN		No
		Week 48	03JAN2017/12:05	NOT SEEN		No
	Urine Ketones	Screening	06JAN2016/10:50	NEGATIVE		Yes
		Day 1	02FEB2016/11:15	NEGATIVE		Yes
		Week 2	16FEB2016/11:10	NEGATIVE		No
		Week 4	01MAR2016/10:35	NEGATIVE		No
		Week 6	16MAR2016/11:50	NEGATIVE		No
		Week 8	31MAR2016/09:55	NEGATIVE		No
		Week 12	28APR2016/08:20	NEGATIVE		Yes
		Week 16	26MAY2016/12:15	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Ketones	Week 20	22JUN2016/10:00	NEGATIVE		No
		Week 24	20JUL2016/09:35	NEGATIVE		Yes
		Week 28	18AUG2016/10:50	NEGATIVE		No
		Week 32	15SEP2016/10:05	NEGATIVE		No
		Week 36	13OCT2016/12:35	NEGATIVE		No
		Week 40	10NOV2016/10:20	NEGATIVE		No
		Week 44	06DEC2016/11:10	NEGATIVE		No
		Week 48	03JAN2017/12:05	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	06JAN2016/10:50	NOT SEEN		Yes
		Day 1	02FEB2016/11:15	50 - 100 /HPF		Yes
		Week 2	16FEB2016/11:10	NOT SEEN		No
		Week 4	01MAR2016/10:35	NOT SEEN		No
		Week 6	16MAR2016/11:50	NOT SEEN		No
		Week 8	31MAR2016/09:55	NOT SEEN		No
		Week 12	28APR2016/08:20	1 - 9 /HPF		Yes
		Week 16	26MAY2016/12:15	NOT SEEN		No
		Week 20	22JUN2016/10:00	NOT SEEN		No
		Week 24	20JUL2016/09:35	NOT SEEN		Yes
		Week 28	18AUG2016/10:50	NOT SEEN		No
		Week 32	15SEP2016/10:05	NOT SEEN		No
		Week 36	13OCT2016/12:35	NOT SEEN		No
		Week 40	10NOV2016/10:20	NOT SEEN		No
		Week 44	06DEC2016/11:10	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Leukocytes (/HPF)	Week 48	03JAN2017/12:05	NOT SEEN		No
	Urine Nitrite	Screening	06JAN2016/10:50	NEGATIVE		Yes
		Day 1	02FEB2016/11:15	NEGATIVE		Yes
		Week 2	16FEB2016/11:10	NEGATIVE		No
		Week 4	01MAR2016/10:35	NEGATIVE		No
		Week 6	16MAR2016/11:50	NEGATIVE		No
		Week 8	31MAR2016/09:55	NEGATIVE		No
		Week 12	28APR2016/08:20	NEGATIVE		Yes
		Week 16	26MAY2016/12:15	NEGATIVE		No
		Week 20	22JUN2016/10:00	NEGATIVE		No
		Week 24	20JUL2016/09:35	NEGATIVE		Yes
		Week 28	18AUG2016/10:50	NEGATIVE		No
		Week 32	15SEP2016/10:05	NEGATIVE		No
		Week 36	13OCT2016/12:35	NEGATIVE		No
		Week 40	10NOV2016/10:20	NEGATIVE		No
		Week 44	06DEC2016/11:10	NEGATIVE		No
		Week 48	03JAN2017/12:05	NEGATIVE		No
	Urine Organisms	Screening	06JAN2016/10:50	NOT SEEN		Yes
		Day 1	02FEB2016/11:15	NOT SEEN		Yes
		Week 2	16FEB2016/11:10	NOT SEEN		No
		Week 4	01MAR2016/10:35	NOT SEEN		No
		Week 6	16MAR2016/11:50	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Organisms	Week 8	31MAR2016/09:55	NOT SEEN		No
		Week 12	28APR2016/08:20	NOT SEEN		Yes
		Week 16	26MAY2016/12:15	NOT SEEN		No
		Week 20	22JUN2016/10:00	NOT SEEN		No
		Week 24	20JUL2016/09:35	+++		Yes
		Week 28	18AUG2016/10:50	NOT SEEN		No
		Week 32	15SEP2016/10:05	NOT SEEN		No
		Week 36	13OCT2016/12:35	NOT SEEN		No
		Week 40	10NOV2016/10:20	NOT SEEN		No
		Week 44	06DEC2016/11:10	NOT SEEN		No
		Week 48	03JAN2017/12:05	NOT SEEN		No
	Urine Protein	Screening	06JAN2016/10:50	TRACE		Yes
		Day 1	02FEB2016/11:15	TRACE		Yes
		Week 2	16FEB2016/11:10	NEGATIVE		No
		Week 4	01MAR2016/10:35	NEGATIVE		No
		Week 6	16MAR2016/11:50	NEGATIVE		No
		Week 8	31MAR2016/09:55	NEGATIVE		No
		Week 12	28APR2016/08:20	NEGATIVE		Yes
		Week 16	26MAY2016/12:15	NEGATIVE		No
		Week 20	22JUN2016/10:00	NEGATIVE		No
		Week 24	20JUL2016/09:35	TRACE		Yes
		Week 28	18AUG2016/10:50	NEGATIVE		No
		Week 32	15SEP2016/10:05	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Protein	Week 36	13OCT2016/12:35	NEGATIVE		No
		Week 40	10NOV2016/10:20	NEGATIVE		No
		Week 44	06DEC2016/11:10	NEGATIVE		No
		Week 48	03JAN2017/12:05	TRACE		No
	Urine Specific Gravity	Screening	06JAN2016/10:50	1.030	1 - 1.03	Yes
		Day 1	02FEB2016/11:15	1.024	1 - 1.03	Yes
		Week 2	16FEB2016/11:10	1.019	1 - 1.03	No
		Week 4	01MAR2016/10:35	1.022	1 - 1.03	No
		Week 6	16MAR2016/11:50	1.018	1 - 1.03	No
		Week 8	31MAR2016/09:55	1.021	1 - 1.03	No
		Week 12	28APR2016/08:20	1.027	1 - 1.03	Yes
		Week 16	26MAY2016/12:15	1.015	1 - 1.03	No
		Week 20	22JUN2016/10:00	1.024	1 - 1.03	No
		Week 24	20JUL2016/09:35	1.021	1 - 1.03	Yes
		Week 28	18AUG2016/10:50	1.020	1 - 1.03	No
		Week 32	15SEP2016/10:05	1.028	1 - 1.03	No
		Week 36	13OCT2016/12:35	1.024	1 - 1.03	No
		Week 40	10NOV2016/10:20	1.020	1 - 1.03	No
		Week 44	06DEC2016/11:10	1.022	1 - 1.03	No
		Week 48	03JAN2017/12:05	1.027	1 - 1.03	No
	Urine Urobilinogen	Screening	06JAN2016/10:50	NORMAL		Yes
		Day 1	02FEB2016/11:15	NORMAL		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-001	Urine Urobilinogen	Week 2	16FEB2016/11:10	NORMAL		No
		Week 4	01MAR2016/10:35	NORMAL		No
		Week 6	16MAR2016/11:50	NORMAL		No
		Week 8	31MAR2016/09:55	NORMAL		No
		Week 12	28APR2016/08:20	NORMAL		Yes
		Week 16	26MAY2016/12:15	NORMAL		No
		Week 20	22JUN2016/10:00	NORMAL		No
		Week 24	20JUL2016/09:35	NORMAL		Yes
		Week 28	18AUG2016/10:50	NORMAL		No
		Week 32	15SEP2016/10:05	NORMAL		No
		Week 36	13OCT2016/12:35	NORMAL		No
		Week 40	10NOV2016/10:20	NORMAL		No
		Week 44	06DEC2016/11:10	NORMAL		No
		Week 48	03JAN2017/12:05	NORMAL		No
301-002	Urine Bilirubin	Screening	15DEC2015/09:05	NEGATIVE		Yes
		Day 1	05JAN2016/09:10	NEGATIVE		Yes
		Week 2	20JAN2016/10:00	NEGATIVE		No
		Week 4	03FEB2016/09:55	NEGATIVE		No
		Week 6	17FEB2016/13:10	NEGATIVE		No
		Week 8	01MAR2016/09:00	NEGATIVE		No
		Week 12	30MAR2016/09:55	NEGATIVE		No
		Week 16	26APR2016/10:27	NEGATIVE		No
		Week 20	24MAY2016/11:45	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Urine Bilirubin	Week 24	21JUN2016/11:35	NEGATIVE		No
		Week 28	20JUL2016/11:50	NEGATIVE		No
		Week 32	18AUG2016/10:35	NEGATIVE		No
		Week 36	13SEP2016/11:05	NEGATIVE		No
		Week 40	11OCT2016/12:10	NEGATIVE		No
		Week 44	09NOV2016/12:35	NEGATIVE		No
		Week 48	07DEC2016/13:05	NEGATIVE		No
	Urine Blood	Screening	15DEC2015/09:05	NEGATIVE		Yes
		Day 1	05JAN2016/09:10	NEGATIVE		Yes
		Week 2	20JAN2016/10:00	NEGATIVE		No
		Week 4	03FEB2016/09:55	NEGATIVE		No
		Week 6	17FEB2016/13:10	NEGATIVE		No
		Week 8	01MAR2016/09:00	NEGATIVE		No
		Week 12	30MAR2016/09:55	NEGATIVE		No
		Week 16	26APR2016/10:27	NEGATIVE		No
		Week 20	24MAY2016/11:45	NEGATIVE		No
		Week 24	21JUN2016/11:35	NEGATIVE		No
		Week 28	20JUL2016/11:50	NEGATIVE		No
		Week 32	18AUG2016/10:35	NEGATIVE		No
		Week 36	13SEP2016/11:05	NEGATIVE		No
		Week 40	11OCT2016/12:10	NEGATIVE		No
		Week 44	09NOV2016/12:35	NEGATIVE		No
		Week 48	07DEC2016/13:05	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Urine Cellular Casts	Screening	15DEC2015/09:05	NOT SEEN		Yes
		Day 1	05JAN2016/09:10	NOT SEEN		Yes
		Week 2	20JAN2016/10:00	NOT SEEN		No
		Week 4	03FEB2016/09:55	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	01MAR2016/09:00	NOT SEEN		No
		Week 12	30MAR2016/09:55	NOT SEEN		No
		Week 16	26APR2016/10:27	NOT SEEN		No
		Week 20	24MAY2016/11:45	NOT SEEN		No
		Week 24	21JUN2016/11:35	NOT SEEN		No
		Week 28	20JUL2016/11:50	NOT SEEN		No
		Week 32	18AUG2016/10:35	NOT SEEN		No
		Week 36	13SEP2016/11:05	NOT SEEN		No
		Week 40	11OCT2016/12:10	NOT SEEN		No
		Week 44	09NOV2016/12:35	NOT SEEN		No
		Week 48	07DEC2016/13:05	NOT SEEN		No
	Urine Crystals	Screening	15DEC2015/09:05	NOT SEEN		Yes
		Day 1	05JAN2016/09:10	++		Yes
		Week 2	20JAN2016/10:00	NOT SEEN		No
		Week 4	03FEB2016/09:55	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	01MAR2016/09:00	NOT SEEN		No
		Week 12	30MAR2016/09:55	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Urine Crystals	Week 16	26APR2016/10:27	NOT SEEN		No
		Week 20	24MAY2016/11:45	NOT SEEN		No
		Week 24	21JUN2016/11:35	NOT SEEN		No
		Week 28	20JUL2016/11:50	NOT SEEN		No
		Week 32	18AUG2016/10:35	NOT SEEN		No
		Week 36	13SEP2016/11:05	NOT SEEN		No
		Week 40	11OCT2016/12:10	NOT SEEN		No
		Week 44	09NOV2016/12:35	NOT SEEN		No
		Week 48	07DEC2016/13:05	NOT SEEN		No
	Urine Epithelial Cells	Screening	15DEC2015/09:05	NOT SEEN		Yes
		Day 1	05JAN2016/09:10	NOT SEEN		Yes
		Week 2	20JAN2016/10:00	NOT SEEN		No
		Week 4	03FEB2016/09:55	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	01MAR2016/09:00	NOT SEEN		No
		Week 12	30MAR2016/09:55	NOT SEEN		No
		Week 16	26APR2016/10:27	NOT SEEN		No
		Week 20	24MAY2016/11:45	NOT SEEN		No
		Week 24	21JUN2016/11:35	NOT SEEN		No
		Week 28	20JUL2016/11:50	NOT SEEN		No
		Week 32	18AUG2016/10:35	NOT SEEN		No
		Week 36	13SEP2016/11:05	NOT SEEN		No
		Week 40	11OCT2016/12:10	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Urine Epithelial Cells	Week 44	09NOV2016/12:35	NOT SEEN		No
		Week 48	07DEC2016/13:05	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	15DEC2015/09:05	NOT SEEN		Yes
		Day 1	05JAN2016/09:10	NOT SEEN		Yes
		Week 2	20JAN2016/10:00	NOT SEEN		No
		Week 4	03FEB2016/09:55	1 - 9 /HPF		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	01MAR2016/09:00	NOT SEEN		No
		Week 12	30MAR2016/09:55	1 - 9 /HPF		No
		Week 16	26APR2016/10:27	NOT SEEN		No
		Week 20	24MAY2016/11:45	NOT SEEN		No
		Week 24	21JUN2016/11:35	NOT SEEN		No
		Week 28	20JUL2016/11:50	NOT SEEN		No
		Week 32	18AUG2016/10:35	NOT SEEN		No
		Week 36	13SEP2016/11:05	NOT SEEN		No
		Week 40	11OCT2016/12:10	NOT SEEN		No
		Week 44	09NOV2016/12:35	NOT SEEN		No
		Week 48	07DEC2016/13:05	NOT SEEN		No
	Urine Granular Casts	Screening	15DEC2015/09:05	NOT SEEN		Yes
		Day 1	05JAN2016/09:10	NOT SEEN		Yes
		Week 2	20JAN2016/10:00	NOT SEEN		No
		Week 4	03FEB2016/09:55	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Urine Granular Casts	Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	01MAR2016/09:00	NOT SEEN		No
		Week 12	30MAR2016/09:55	NOT SEEN		No
		Week 16	26APR2016/10:27	NOT SEEN		No
		Week 20	24MAY2016/11:45	NOT SEEN		No
		Week 24	21JUN2016/11:35	NOT SEEN		No
		Week 28	20JUL2016/11:50	NOT SEEN		No
		Week 32	18AUG2016/10:35	NOT SEEN		No
		Week 36	13SEP2016/11:05	NOT SEEN		No
		Week 40	11OCT2016/12:10	NOT SEEN		No
		Week 44	09NOV2016/12:35	NOT SEEN		No
		Week 48	07DEC2016/13:05	NOT SEEN		No
	Urine Hyaline Casts	Screening	15DEC2015/09:05	NOT SEEN		Yes
		Day 1	05JAN2016/09:10	NOT SEEN		Yes
		Week 2	20JAN2016/10:00	NOT SEEN		No
		Week 4	03FEB2016/09:55	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	01MAR2016/09:00	NOT SEEN		No
		Week 12	30MAR2016/09:55	NOT SEEN		No
		Week 16	26APR2016/10:27	NOT SEEN		No
		Week 20	24MAY2016/11:45	NOT SEEN		No
		Week 24	21JUN2016/11:35	NOT SEEN		No
		Week 28	20JUL2016/11:50	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Urine Hyaline Casts	Week 32	18AUG2016/10:35	NOT SEEN		No
		Week 36	13SEP2016/11:05	NOT SEEN		No
		Week 40	11OCT2016/12:10	NOT SEEN		No
		Week 44	09NOV2016/12:35	NOT SEEN		No
		Week 48	07DEC2016/13:05	NOT SEEN		No
	Urine Ketones	Screening	15DEC2015/09:05	NEGATIVE		Yes
		Day 1	05JAN2016/09:10	NEGATIVE		Yes
		Week 2	20JAN2016/10:00	NEGATIVE		No
		Week 4	03FEB2016/09:55	NEGATIVE		No
		Week 6	17FEB2016/13:10	NEGATIVE		No
		Week 8	01MAR2016/09:00	NEGATIVE		No
		Week 12	30MAR2016/09:55	NEGATIVE		No
		Week 16	26APR2016/10:27	NEGATIVE		No
		Week 20	24MAY2016/11:45	NEGATIVE		No
		Week 24	21JUN2016/11:35	NEGATIVE		No
		Week 28	20JUL2016/11:50	NEGATIVE		No
		Week 32	18AUG2016/10:35	NEGATIVE		No
		Week 36	13SEP2016/11:05	NEGATIVE		No
		Week 40	11OCT2016/12:10	NEGATIVE		No
		Week 44	09NOV2016/12:35	NEGATIVE		No
		Week 48	07DEC2016/13:05	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	15DEC2015/09:05	NOT SEEN		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Urine Leukocytes (/HPF)	Day 1	05JAN2016/09:10	NOT SEEN		Yes
		Week 2	20JAN2016/10:00	1 - 9 /HPF		No
		Week 4	03FEB2016/09:55	1 - 9 /HPF		No
		Week 6	17FEB2016/13:10	1 - 9 /HPF		No
		Week 8	01MAR2016/09:00	1 - 9 /HPF		No
		Week 12	30MAR2016/09:55	1 - 9 /HPF		No
		Week 16	26APR2016/10:27	NOT SEEN		No
		Week 20	24MAY2016/11:45	NOT SEEN		No
		Week 24	21JUN2016/11:35	1 - 9 /HPF		No
		Week 28	20JUL2016/11:50	NOT SEEN		No
		Week 32	18AUG2016/10:35	NOT SEEN		No
		Week 36	13SEP2016/11:05	NOT SEEN		No
		Week 40	11OCT2016/12:10	NOT SEEN		No
		Week 44	09NOV2016/12:35	NOT SEEN		No
		Week 48	07DEC2016/13:05	NOT SEEN		No
	Urine Nitrite	Screening	15DEC2015/09:05	NEGATIVE		Yes
		Day 1	05JAN2016/09:10	NEGATIVE		Yes
		Week 2	20JAN2016/10:00	NEGATIVE		No
		Week 4	03FEB2016/09:55	NEGATIVE		No
		Week 6	17FEB2016/13:10	NEGATIVE		No
		Week 8	01MAR2016/09:00	NEGATIVE		No
		Week 12	30MAR2016/09:55	NEGATIVE		No
		Week 16	26APR2016/10:27	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Urine Nitrite	Week 20	24MAY2016/11:45	NEGATIVE		No
		Week 24	21JUN2016/11:35	NEGATIVE		No
		Week 28	20JUL2016/11:50	NEGATIVE		No
		Week 32	18AUG2016/10:35	NEGATIVE		No
		Week 36	13SEP2016/11:05	NEGATIVE		No
		Week 40	11OCT2016/12:10	NEGATIVE		No
		Week 44	09NOV2016/12:35	NEGATIVE		No
		Week 48	07DEC2016/13:05	NEGATIVE		No
	Urine Organisms	Screening	15DEC2015/09:05	NOT SEEN		Yes
		Day 1	05JAN2016/09:10	NOT SEEN		Yes
		Week 2	20JAN2016/10:00	NOT SEEN		No
		Week 4	03FEB2016/09:55	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	01MAR2016/09:00	NOT SEEN		No
		Week 12	30MAR2016/09:55	NOT SEEN		No
		Week 16	26APR2016/10:27	NOT SEEN		No
		Week 20	24MAY2016/11:45	NOT SEEN		No
		Week 24	21JUN2016/11:35	NOT SEEN		No
		Week 28	20JUL2016/11:50	++		No
		Week 32	18AUG2016/10:35	NOT SEEN		No
		Week 36	13SEP2016/11:05	NOT SEEN		No
		Week 40	11OCT2016/12:10	NOT SEEN		No
		Week 44	09NOV2016/12:35	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Urine Organisms	Week 48	07DEC2016/13:05	NOT SEEN		No
	Urine Protein	Screening	15DEC2015/09:05	TRACE		Yes
		Day 1	05JAN2016/09:10	TRACE		Yes
		Week 2	20JAN2016/10:00	TRACE		No
		Week 4	03FEB2016/09:55	TRACE		No
		Week 6	17FEB2016/13:10	TRACE		No
		Week 8	01MAR2016/09:00	NEGATIVE		No
		Week 12	30MAR2016/09:55	TRACE		No
		Week 16	26APR2016/10:27	NEGATIVE		No
		Week 20	24MAY2016/11:45	TRACE		No
		Week 24	21JUN2016/11:35	NEGATIVE		No
		Week 28	20JUL2016/11:50	TRACE		No
		Week 32	18AUG2016/10:35	TRACE		No
		Week 36	13SEP2016/11:05	TRACE		No
		Week 40	11OCT2016/12:10	NEGATIVE		No
		Week 44	09NOV2016/12:35	NEGATIVE		No
		Week 48	07DEC2016/13:05	TRACE		No
	Urine Specific Gravity	Screening	15DEC2015/09:05	1.029	1 - 1.03	Yes
		Day 1	05JAN2016/09:10	1.030	1 - 1.03	Yes
		Week 2	20JAN2016/10:00	1.027	1 - 1.03	No
		Week 4	03FEB2016/09:55	1.017	1 - 1.03	No
		Week 6	17FEB2016/13:10	1.021	1 - 1.03	No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-002	Urine Specific Gravity	Week 8	01MAR2016/09:00	1.013	1 - 1.03	No
		Week 12	30MAR2016/09:55	1.023	1 - 1.03	No
		Week 16	26APR2016/10:27	1.019	1 - 1.03	No
		Week 20	24MAY2016/11:45	1.023	1 - 1.03	No
		Week 24	21JUN2016/11:35	1.012	1 - 1.03	No
		Week 28	20JUL2016/11:50	1.026	1 - 1.03	No
		Week 32	18AUG2016/10:35	1.030	1 - 1.03	No
		Week 36	13SEP2016/11:05	1.032 H	1 - 1.03	No
		Week 40	11OCT2016/12:10	1.024	1 - 1.03	No
		Week 44	09NOV2016/12:35	1.022	1 - 1.03	No
		Week 48	07DEC2016/13:05	1.034 H	1 - 1.03	No
	Urine Urobilinogen	Screening	15DEC2015/09:05	+ (41.3 UMOL/L)		Yes
		Day 1	05JAN2016/09:10	NORMAL		Yes
		Week 2	20JAN2016/10:00	+++ (165 UMOL/L)		No
		Week 4	03FEB2016/09:55	+ (41.3 UMOL/L)		No
		Week 6	17FEB2016/13:10	NORMAL		No
		Week 8	01MAR2016/09:00	+ (41.3 UMOL/L)		No
		Week 12	30MAR2016/09:55	NORMAL		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-002	Urine Urobilinogen	Week 16	26APR2016/10:27	++ (82.5 UMOL/L)		No	
		Week 20	24MAY2016/11:45	++ (82.5 UMOL/L)		No	
		Week 24	21JUN2016/11:35	NORMAL		No	
		Week 28	20JUL2016/11:50	NORMAL		No	
		Week 32	18AUG2016/10:35	+ (41.3 UMOL/L)		No	
		Week 36	13SEP2016/11:05	NORMAL		No	
		Week 40	11OCT2016/12:10	NORMAL		No	
		Week 44	09NOV2016/12:35	+ (41.3 UMOL/L)		No	
		Week 48	07DEC2016/13:05	+ (41.3 UMOL/L)		No	

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Bilirubin	Screening	15DEC2015/12:15	NEGATIVE		Yes
		Day 1	06JAN2016/11:10	NEGATIVE		Yes
		Week 2	20JAN2016/11:10	NEGATIVE		No
		Week 4	03FEB2016/12:10	NEGATIVE		No
		Week 6	18FEB2016/13:35	NEGATIVE		No
		Week 8	08MAR2016/08:37	NEGATIVE		No
		Week 12	29MAR2016/09:20	NEGATIVE		No
		Week 16	25APR2016/08:55	NEGATIVE		No
		Week 20	26MAY2016/12:55	NEGATIVE		No
		Week 24	22JUN2016/12:35	NEGATIVE		No
		Week 28	19JUL2016/10:15	NEGATIVE		No
		Week 32	16AUG2016/12:20	NEGATIVE		No
		Week 36	15SEP2016/12:40	NEGATIVE		No
		Week 40	12OCT2016/11:25	NEGATIVE		Yes
		Week 44	09NOV2016/12:05	NEGATIVE		No
		Week 48	14DEC2016/12:05	NEGATIVE		No
	Urine Blood	Screening	15DEC2015/12:15	+++		Yes
		Day 1	06JAN2016/11:10	NEGATIVE		Yes
		Week 2	20JAN2016/11:10	+++		No
		Week 4	03FEB2016/12:10	NEGATIVE		No
		Week 6	18FEB2016/13:35	NEGATIVE		No
		Week 8	08MAR2016/08:37	NEGATIVE		No
		Week 12	29MAR2016/09:20	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Blood	Week 16	25APR2016/08:55	NEGATIVE		No
		Week 20	26MAY2016/12:55	NEGATIVE		No
		Week 24	22JUN2016/12:35	NEGATIVE		No
		Week 28	19JUL2016/10:15	NEGATIVE		No
		Week 32	16AUG2016/12:20	++		No
		Week 36	15SEP2016/12:40	NEGATIVE		No
		Week 40	12OCT2016/11:25	NEGATIVE		Yes
		Week 44	09NOV2016/12:05	NEGATIVE		No
		Week 48	14DEC2016/12:05	TRACE		No
	Urine Cellular Casts	Screening	15DEC2015/12:15	NOT SEEN		Yes
		Day 1	06JAN2016/11:10	NOT SEEN		Yes
		Week 2	20JAN2016/11:10	NOT SEEN		No
		Week 4	03FEB2016/12:10	NOT SEEN		No
		Week 6	18FEB2016/13:35	NOT SEEN		No
		Week 8	08MAR2016/08:37	NOT SEEN		No
		Week 12	29MAR2016/09:20	NOT SEEN		No
		Week 16	25APR2016/08:55	NOT SEEN		No
		Week 20	26MAY2016/12:55	NOT SEEN		No
		Week 24	22JUN2016/12:35	NOT SEEN		No
		Week 28	19JUL2016/10:15	NOT SEEN		No
		Week 32	16AUG2016/12:20	NOT SEEN		No
		Week 36	15SEP2016/12:40	NOT SEEN		No
		Week 40	12OCT2016/11:25	NOT SEEN		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Cellular Casts	Week 44	09NOV2016/12:05	NOT SEEN		No
		Week 48	14DEC2016/12:05	NOT SEEN		No
301-003	Urine Choriogonadotropin Beta	Day 1	06JAN2016/00:00	Negative		
		Week 4	03FEB2016/00:00	Negative		
		Week 6	18FEB2016/00:00	Negative		
		Week 8	08MAR2016/00:00	Negative		
		Week 12	29MAR2016/00:00	Negative		
		Week 16	25APR2016/00:00	Negative		
		Week 20	26MAY2016/00:00	Negative		
		Week 24	22JUN2016/00:00	Negative		
		Week 28	19JUL2016/00:00	Negative		
		Week 32	16AUG2016/00:00	Negative		
		Week 36	15SEP2016/00:00	Negative		
		Week 40	12OCT2016/00:00	Negative		
		Week 44	09NOV2016/00:00	Negative		
		Week 48	14DEC2016/00:00	Negative		
301-003	Urine Crystals	Screening	15DEC2015/12:15	NOT SEEN		Yes
		Day 1	06JAN2016/11:10	NOT SEEN		Yes
		Week 2	20JAN2016/11:10	NOT SEEN		No
		Week 4	03FEB2016/12:10	NOT SEEN		No
		Week 6	18FEB2016/13:35	NOT SEEN		No
		Week 8	08MAR2016/08:37	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Crystals	Week 12	29MAR2016/09:20	NOT SEEN		No
		Week 16	25APR2016/08:55	NOT SEEN		No
		Week 20	26MAY2016/12:55	NOT SEEN		No
		Week 24	22JUN2016/12:35	NOT SEEN		No
		Week 28	19JUL2016/10:15	NOT SEEN		No
		Week 32	16AUG2016/12:20	NOT SEEN		No
		Week 36	15SEP2016/12:40	NOT SEEN		No
		Week 40	12OCT2016/11:25	NOT SEEN		Yes
		Week 44	09NOV2016/12:05	NOT SEEN		No
		Week 48	14DEC2016/12:05	NOT SEEN		No
	Urine Epithelial Cells	Screening	15DEC2015/12:15	NOT SEEN		Yes
		Day 1	06JAN2016/11:10	NOT SEEN		Yes
		Week 2	20JAN2016/11:10	NOT SEEN		No
		Week 4	03FEB2016/12:10	SCANTY		No
		Week 6	18FEB2016/13:35	SCANTY		No
		Week 8	08MAR2016/08:37	NOT SEEN		No
		Week 12	29MAR2016/09:20	SCANTY		No
		Week 16	25APR2016/08:55	+		No
		Week 20	26MAY2016/12:55	NOT SEEN		No
		Week 24	22JUN2016/12:35	NOT SEEN		No
		Week 28	19JUL2016/10:15	NOT SEEN		No
		Week 32	16AUG2016/12:20	NOT SEEN		No
		Week 36	15SEP2016/12:40	+		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Epithelial Cells	Week 40	12OCT2016/11:25	+		Yes
		Week 44	09NOV2016/12:05	+		No
		Week 48	14DEC2016/12:05	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	15DEC2015/12:15	10 - 50 /HPF		Yes
		Day 1	06JAN2016/11:10	NOT SEEN		Yes
		Week 2	20JAN2016/11:10	1 - 9 /HPF		No
		Week 4	03FEB2016/12:10	1 - 9 /HPF		No
		Week 6	18FEB2016/13:35	NOT SEEN		No
		Week 8	08MAR2016/08:37	1 - 9 /HPF		No
		Week 12	29MAR2016/09:20	1 - 9 /HPF		No
		Week 16	25APR2016/08:55	NOT SEEN		No
		Week 20	26MAY2016/12:55	NOT SEEN		No
		Week 24	22JUN2016/12:35	NOT SEEN		No
		Week 28	19JUL2016/10:15	NOT SEEN		No
		Week 32	16AUG2016/12:20	NOT SEEN		No
		Week 36	15SEP2016/12:40	10 - 50 /HPF		No
		Week 40	12OCT2016/11:25	NOT SEEN		Yes
		Week 44	09NOV2016/12:05	1 - 9 /HPF		No
		Week 48	14DEC2016/12:05	NOT SEEN		No
	Urine Granular Casts	Screening	15DEC2015/12:15	NOT SEEN		Yes
		Day 1	06JAN2016/11:10	NOT SEEN		Yes
		Week 2	20JAN2016/11:10	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Granular Casts	Week 4	03FEB2016/12:10	NOT SEEN		No
		Week 6	18FEB2016/13:35	NOT SEEN		No
		Week 8	08MAR2016/08:37	NOT SEEN		No
		Week 12	29MAR2016/09:20	NOT SEEN		No
		Week 16	25APR2016/08:55	NOT SEEN		No
		Week 20	26MAY2016/12:55	NOT SEEN		No
		Week 24	22JUN2016/12:35	NOT SEEN		No
		Week 28	19JUL2016/10:15	NOT SEEN		No
		Week 32	16AUG2016/12:20	NOT SEEN		No
		Week 36	15SEP2016/12:40	NOT SEEN		No
		Week 40	12OCT2016/11:25	NOT SEEN		Yes
		Week 44	09NOV2016/12:05	NOT SEEN		No
		Week 48	14DEC2016/12:05	NOT SEEN		No
	Urine Hyaline Casts	Screening	15DEC2015/12:15	NOT SEEN		Yes
		Day 1	06JAN2016/11:10	NOT SEEN		Yes
		Week 2	20JAN2016/11:10	NOT SEEN		No
		Week 4	03FEB2016/12:10	NOT SEEN		No
		Week 6	18FEB2016/13:35	NOT SEEN		No
		Week 8	08MAR2016/08:37	NOT SEEN		No
		Week 12	29MAR2016/09:20	NOT SEEN		No
		Week 16	25APR2016/08:55	NOT SEEN		No
		Week 20	26MAY2016/12:55	NOT SEEN		No
		Week 24	22JUN2016/12:35	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Hyaline Casts	Week 28	19JUL2016/10:15	NOT SEEN		No
		Week 32	16AUG2016/12:20	NOT SEEN		No
		Week 36	15SEP2016/12:40	NOT SEEN		No
		Week 40	12OCT2016/11:25	NOT SEEN		Yes
		Week 44	09NOV2016/12:05	NOT SEEN		No
		Week 48	14DEC2016/12:05	NOT SEEN		No
	Urine Ketones	Screening	15DEC2015/12:15	NEGATIVE		Yes
		Day 1	06JAN2016/11:10	NEGATIVE		Yes
		Week 2	20JAN2016/11:10	NEGATIVE		No
		Week 4	03FEB2016/12:10	NEGATIVE		No
		Week 6	18FEB2016/13:35	NEGATIVE		No
		Week 8	08MAR2016/08:37	NEGATIVE		No
		Week 12	29MAR2016/09:20	NEGATIVE		No
		Week 16	25APR2016/08:55	NEGATIVE		No
		Week 20	26MAY2016/12:55	NEGATIVE		No
		Week 24	22JUN2016/12:35	NEGATIVE		No
		Week 28	19JUL2016/10:15	NEGATIVE		No
		Week 32	16AUG2016/12:20	NEGATIVE		No
		Week 36	15SEP2016/12:40	NEGATIVE		No
		Week 40	12OCT2016/11:25	NEGATIVE		Yes
		Week 44	09NOV2016/12:05	NEGATIVE		No
		Week 48	14DEC2016/12:05	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-003	Urine Leukocytes (/HPF)	Screening	15DEC2015/12:15	1 - 9 /HPF		Yes	
		Day 1	06JAN2016/11:10	NOT SEEN		Yes	
		Week 2	20JAN2016/11:10	1 - 9 /HPF		No	
		Week 4	03FEB2016/12:10	1 - 9 /HPF		No	
		Week 6	18FEB2016/13:35	NOT SEEN		No	
		Week 8	08MAR2016/08:37	NOT SEEN		No	
		Week 12	29MAR2016/09:20	1 - 9 /HPF		No	
		Week 16	25APR2016/08:55	1 - 9 /HPF		No	
		Week 20	26MAY2016/12:55	NOT SEEN		No	
		Week 24	22JUN2016/12:35	1 - 9 /HPF		No	
		Week 28	19JUL2016/10:15	1 - 9 /HPF		No	
		Week 32	16AUG2016/12:20	NOT SEEN		No	
		Week 36	15SEP2016/12:40	10 - 50 /HPF		No	
		Week 40	12OCT2016/11:25	10 - 50 /HPF		Yes	
		Week 44	09NOV2016/12:05	1 - 9 /HPF		No	
		Week 48	14DEC2016/12:05	1 - 9 /HPF		No	
	Urine Nitrite	Screening	15DEC2015/12:15	NEGATIVE		Yes	
		Day 1	06JAN2016/11:10	NEGATIVE		Yes	
		Week 2	20JAN2016/11:10	NEGATIVE		No	
		Week 4	03FEB2016/12:10	NEGATIVE		No	
		Week 6	18FEB2016/13:35	NEGATIVE		No	
		Week 8	08MAR2016/08:37	NEGATIVE		No	
		Week 12	29MAR2016/09:20	NEGATIVE		No	

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Nitrite	Week 16	25APR2016/08:55	NEGATIVE		No
		Week 20	26MAY2016/12:55	NEGATIVE		No
		Week 24	22JUN2016/12:35	NEGATIVE		No
		Week 28	19JUL2016/10:15	NEGATIVE		No
		Week 32	16AUG2016/12:20	NEGATIVE		No
		Week 36	15SEP2016/12:40	NEGATIVE		No
		Week 40	12OCT2016/11:25	NEGATIVE		Yes
		Week 44	09NOV2016/12:05	NEGATIVE		No
		Week 48	14DEC2016/12:05	NEGATIVE		No
	Urine Organisms	Screening	15DEC2015/12:15	NOT SEEN		Yes
		Day 1	06JAN2016/11:10	NOT SEEN		Yes
		Week 2	20JAN2016/11:10	NOT SEEN		No
		Week 4	03FEB2016/12:10	NOT SEEN		No
		Week 6	18FEB2016/13:35	NOT SEEN		No
		Week 8	08MAR2016/08:37	NOT SEEN		No
		Week 12	29MAR2016/09:20	NOT SEEN		No
		Week 16	25APR2016/08:55	NOT SEEN		No
		Week 20	26MAY2016/12:55	NOT SEEN		No
		Week 24	22JUN2016/12:35	+		No
		Week 28	19JUL2016/10:15	+		No
		Week 32	16AUG2016/12:20	NOT SEEN		No
		Week 36	15SEP2016/12:40	NOT SEEN		No
		Week 40	12OCT2016/11:25	NOT SEEN		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Organisms	Week 44	09NOV2016/12:05	NOT SEEN		No
		Week 48	14DEC2016/12:05	NOT SEEN		No
	Urine Protein	Screening	15DEC2015/12:15	NEGATIVE		Yes
		Day 1	06JAN2016/11:10	NEGATIVE		Yes
		Week 2	20JAN2016/11:10	NEGATIVE		No
		Week 4	03FEB2016/12:10	NEGATIVE		No
		Week 6	18FEB2016/13:35	NEGATIVE		No
		Week 8	08MAR2016/08:37	NEGATIVE		No
		Week 12	29MAR2016/09:20	NEGATIVE		No
		Week 16	25APR2016/08:55	NEGATIVE		No
		Week 20	26MAY2016/12:55	NEGATIVE		No
		Week 24	22JUN2016/12:35	NEGATIVE		No
		Week 28	19JUL2016/10:15	NEGATIVE		No
		Week 32	16AUG2016/12:20	TRACE		No
		Week 36	15SEP2016/12:40	NEGATIVE		No
		Week 40	12OCT2016/11:25	TRACE		Yes
		Week 44	09NOV2016/12:05	NEGATIVE		No
		Week 48	14DEC2016/12:05	NEGATIVE		No
	Urine Specific Gravity	Screening	15DEC2015/12:15	1.006	1 - 1.03	Yes
		Day 1	06JAN2016/11:10	1.006	1 - 1.03	Yes
		Week 2	20JAN2016/11:10	1.015	1 - 1.03	No
		Week 4	03FEB2016/12:10	1.009	1 - 1.03	No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Specific Gravity	Week 6	18FEB2016/13:35	1.007	1 - 1.03	No
		Week 8	08MAR2016/08:37	1.009	1 - 1.03	No
		Week 12	29MAR2016/09:20	1.009	1 - 1.03	No
		Week 16	25APR2016/08:55	1.005	1 - 1.03	No
		Week 20	26MAY2016/12:55	1.010	1 - 1.03	No
		Week 24	22JUN2016/12:35	1.009	1 - 1.03	No
		Week 28	19JUL2016/10:15	1.018	1 - 1.03	No
		Week 32	16AUG2016/12:20	1.013	1 - 1.03	No
		Week 36	15SEP2016/12:40	1.017	1 - 1.03	No
		Week 40	12OCT2016/11:25	1.023	1 - 1.03	Yes
		Week 44	09NOV2016/12:05	1.012	1 - 1.03	No
		Week 48	14DEC2016/12:05	1.015	1 - 1.03	No
	Urine Urobilinogen	Screening	15DEC2015/12:15	NORMAL		Yes
		Day 1	06JAN2016/11:10	NORMAL		Yes
		Week 2	20JAN2016/11:10	NORMAL		No
		Week 4	03FEB2016/12:10	NORMAL		No
		Week 6	18FEB2016/13:35	NORMAL		No
		Week 8	08MAR2016/08:37	NORMAL		No
		Week 12	29MAR2016/09:20	NORMAL		No
		Week 16	25APR2016/08:55	NORMAL		No
		Week 20	26MAY2016/12:55	NORMAL		No
		Week 24	22JUN2016/12:35	NORMAL		No
		Week 28	19JUL2016/10:15	NORMAL		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-003	Urine Urobilinogen	Week 32	16AUG2016/12:20	NORMAL		No
		Week 36	15SEP2016/12:40	NORMAL		No
		Week 40	12OCT2016/11:25	NORMAL		Yes
		Week 44	09NOV2016/12:05	NORMAL		No
		Week 48	14DEC2016/12:05	NORMAL		No
301-005	Urine Bilirubin	Screening	16DEC2015/08:55	NEGATIVE		Yes
		Day 1	07JAN2016/10:10	NEGATIVE		Yes
		Week 2	21JAN2016/10:00	NEGATIVE		No
		Week 4	02FEB2016/09:10	NEGATIVE		No
		Week 6	17FEB2016/13:10	NEGATIVE		No
		Week 8	02MAR2016/09:30	NEGATIVE		No
		Week 12	31MAR2016/10:20	NEGATIVE		No
		Week 16	26APR2016/10:05	NEGATIVE		No
		Week 20	26MAY2016/12:35	NEGATIVE		No
		Week 24	23JUN2016/11:50	NEGATIVE		No
		Week 28	26JUL2016/09:25	NEGATIVE		No
		Week 32	16AUG2016/10:50	NEGATIVE		No
		Week 36	14SEP2016/12:05	NEGATIVE		No
		Week 40	12OCT2016/12:15	NEGATIVE		No
		Week 44	10NOV2016/11:05	NEGATIVE		No
		Week 48	07DEC2016/12:05	NEGATIVE		No
	Urine Blood	Screening	16DEC2015/08:55	NEGATIVE		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Urine Blood	Day 1	07JAN2016/10:10	NEGATIVE		Yes
		Week 2	21JAN2016/10:00	NEGATIVE		No
		Week 4	02FEB2016/09:10	NEGATIVE		No
		Week 6	17FEB2016/13:10	NEGATIVE		No
		Week 8	02MAR2016/09:30	NEGATIVE		No
		Week 12	31MAR2016/10:20	NEGATIVE		No
		Week 16	26APR2016/10:05	NEGATIVE		No
		Week 20	26MAY2016/12:35	NEGATIVE		No
		Week 24	23JUN2016/11:50	NEGATIVE		No
		Week 28	26JUL2016/09:25	NEGATIVE		No
		Week 32	16AUG2016/10:50	NEGATIVE		No
		Week 36	14SEP2016/12:05	NEGATIVE		No
		Week 40	12OCT2016/12:15	NEGATIVE		No
		Week 44	10NOV2016/11:05	NEGATIVE		No
		Week 48	07DEC2016/12:05	NEGATIVE		No
	Urine Cellular Casts	Screening	16DEC2015/08:55	NOT SEEN		Yes
		Day 1	07JAN2016/10:10	NOT SEEN		Yes
		Week 2	21JAN2016/10:00	NOT SEEN		No
		Week 4	02FEB2016/09:10	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	02MAR2016/09:30	NOT SEEN		No
		Week 12	31MAR2016/10:20	NOT SEEN		No
		Week 16	26APR2016/10:05	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Urine Cellular Casts	Week 20	26MAY2016/12:35	NOT SEEN		No
		Week 24	23JUN2016/11:50	NOT SEEN		No
		Week 28	26JUL2016/09:25	NOT SEEN		No
		Week 32	16AUG2016/10:50	NOT SEEN		No
		Week 36	14SEP2016/12:05	NOT SEEN		No
		Week 40	12OCT2016/12:15	NOT SEEN		No
		Week 44	10NOV2016/11:05	NOT SEEN		No
		Week 48	07DEC2016/12:05	NOT SEEN		No
	Urine Crystals	Screening	16DEC2015/08:55	NOT SEEN		Yes
		Day 1	07JAN2016/10:10	NOT SEEN		Yes
		Week 2	21JAN2016/10:00	NOT SEEN		No
		Week 4	02FEB2016/09:10	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	02MAR2016/09:30	NOT SEEN		No
		Week 12	31MAR2016/10:20	NOT SEEN		No
		Week 16	26APR2016/10:05	NOT SEEN		No
		Week 20	26MAY2016/12:35	NOT SEEN		No
		Week 24	23JUN2016/11:50	NOT SEEN		No
		Week 28	26JUL2016/09:25	NOT SEEN		No
		Week 32	16AUG2016/10:50	NOT SEEN		No
		Week 36	14SEP2016/12:05	NOT SEEN		No
		Week 40	12OCT2016/12:15	NOT SEEN		No
		Week 44	10NOV2016/11:05	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Urine Crystals	Week 48	07DEC2016/12:05	NOT SEEN		No
	Urine Epithelial Cells	Screening	16DEC2015/08:55	NOT SEEN		Yes
		Day 1	07JAN2016/10:10	NOT SEEN		Yes
		Week 2	21JAN2016/10:00	NOT SEEN		No
		Week 4	02FEB2016/09:10	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	02MAR2016/09:30	NOT SEEN		No
		Week 12	31MAR2016/10:20	NOT SEEN		No
		Week 16	26APR2016/10:05	NOT SEEN		No
		Week 20	26MAY2016/12:35	NOT SEEN		No
		Week 24	23JUN2016/11:50	NOT SEEN		No
		Week 28	26JUL2016/09:25	NOT SEEN		No
		Week 32	16AUG2016/10:50	NOT SEEN		No
		Week 36	14SEP2016/12:05	NOT SEEN		No
		Week 40	12OCT2016/12:15	NOT SEEN		No
		Week 44	10NOV2016/11:05	NOT SEEN		No
		Week 48	07DEC2016/12:05	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	16DEC2015/08:55	NOT SEEN		Yes
		Day 1	07JAN2016/10:10	NOT SEEN		Yes
		Week 2	21JAN2016/10:00	NOT SEEN		No
		Week 4	02FEB2016/09:10	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Urine Erythrocytes (/HPF)	Week 8	02MAR2016/09:30	NOT SEEN		No
		Week 12	31MAR2016/10:20	NOT SEEN		No
		Week 16	26APR2016/10:05	NOT SEEN		No
		Week 20	26MAY2016/12:35	NOT SEEN		No
		Week 24	23JUN2016/11:50	NOT SEEN		No
		Week 28	26JUL2016/09:25	1 - 9 /HPF		No
		Week 32	16AUG2016/10:50	NOT SEEN		No
		Week 36	14SEP2016/12:05	NOT SEEN		No
		Week 40	12OCT2016/12:15	NOT SEEN		No
		Week 44	10NOV2016/11:05	NOT SEEN		No
		Week 48	07DEC2016/12:05	NOT SEEN		No
	Urine Granular Casts	Screening	16DEC2015/08:55	NOT SEEN		Yes
		Day 1	07JAN2016/10:10	NOT SEEN		Yes
		Week 2	21JAN2016/10:00	NOT SEEN		No
		Week 4	02FEB2016/09:10	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	02MAR2016/09:30	NOT SEEN		No
		Week 12	31MAR2016/10:20	NOT SEEN		No
		Week 16	26APR2016/10:05	NOT SEEN		No
		Week 20	26MAY2016/12:35	NOT SEEN		No
		Week 24	23JUN2016/11:50	NOT SEEN		No
		Week 28	26JUL2016/09:25	NOT SEEN		No
		Week 32	16AUG2016/10:50	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Urine Granular Casts	Week 36	14SEP2016/12:05	NOT SEEN		No
		Week 40	12OCT2016/12:15	NOT SEEN		No
		Week 44	10NOV2016/11:05	NOT SEEN		No
		Week 48	07DEC2016/12:05	NOT SEEN		No
	Urine Hyaline Casts	Screening	16DEC2015/08:55	NOT SEEN		Yes
		Day 1	07JAN2016/10:10	NOT SEEN		Yes
		Week 2	21JAN2016/10:00	NOT SEEN		No
		Week 4	02FEB2016/09:10	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	02MAR2016/09:30	NOT SEEN		No
		Week 12	31MAR2016/10:20	SCANTY		No
		Week 16	26APR2016/10:05	NOT SEEN		No
		Week 20	26MAY2016/12:35	NOT SEEN		No
		Week 24	23JUN2016/11:50	NOT SEEN		No
		Week 28	26JUL2016/09:25	NOT SEEN		No
		Week 32	16AUG2016/10:50	NOT SEEN		No
		Week 36	14SEP2016/12:05	NOT SEEN		No
		Week 40	12OCT2016/12:15	NOT SEEN		No
		Week 44	10NOV2016/11:05	NOT SEEN		No
		Week 48	07DEC2016/12:05	NOT SEEN		No
	Urine Ketones	Screening	16DEC2015/08:55	NEGATIVE		Yes
		Day 1	07JAN2016/10:10	NEGATIVE		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Urine Ketones	Week 2	21JAN2016/10:00	NEGATIVE		No
		Week 4	02FEB2016/09:10	NEGATIVE		No
		Week 6	17FEB2016/13:10	NEGATIVE		No
		Week 8	02MAR2016/09:30	NEGATIVE		No
		Week 12	31MAR2016/10:20	NEGATIVE		No
		Week 16	26APR2016/10:05	NEGATIVE		No
		Week 20	26MAY2016/12:35	NEGATIVE		No
		Week 24	23JUN2016/11:50	NEGATIVE		No
		Week 28	26JUL2016/09:25	NEGATIVE		No
		Week 32	16AUG2016/10:50	NEGATIVE		No
		Week 36	14SEP2016/12:05	NEGATIVE		No
		Week 40	12OCT2016/12:15	NEGATIVE		No
		Week 44	10NOV2016/11:05	NEGATIVE		No
		Week 48	07DEC2016/12:05	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	16DEC2015/08:55	NOT SEEN		Yes
		Day 1	07JAN2016/10:10	NOT SEEN		Yes
		Week 2	21JAN2016/10:00	NOT SEEN		No
		Week 4	02FEB2016/09:10	NOT SEEN		No
		Week 6	17FEB2016/13:10	NOT SEEN		No
		Week 8	02MAR2016/09:30	1 - 9 /HPF		No
		Week 12	31MAR2016/10:20	NOT SEEN		No
		Week 16	26APR2016/10:05	NOT SEEN		No
		Week 20	26MAY2016/12:35	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Urine Leukocytes (/HPF)	Week 24	23JUN2016/11:50	NOT SEEN		No
		Week 28	26JUL2016/09:25	NOT SEEN		No
		Week 32	16AUG2016/10:50	NOT SEEN		No
		Week 36	14SEP2016/12:05	NOT SEEN		No
		Week 40	12OCT2016/12:15	NOT SEEN		No
		Week 44	10NOV2016/11:05	NOT SEEN		No
		Week 48	07DEC2016/12:05	NOT SEEN		No
	Urine Nitrite	Screening	16DEC2015/08:55	NEGATIVE		Yes
		Day 1	07JAN2016/10:10	NEGATIVE		Yes
		Week 2	21JAN2016/10:00	NEGATIVE		No
		Week 4	02FEB2016/09:10	NEGATIVE		No
		Week 6	17FEB2016/13:10	NEGATIVE		No
		Week 8	02MAR2016/09:30	NEGATIVE		No
		Week 12	31MAR2016/10:20	NEGATIVE		No
		Week 16	26APR2016/10:05	NEGATIVE		No
		Week 20	26MAY2016/12:35	NEGATIVE		No
		Week 24	23JUN2016/11:50	NEGATIVE		No
		Week 28	26JUL2016/09:25	NEGATIVE		No
		Week 32	16AUG2016/10:50	NEGATIVE		No
		Week 36	14SEP2016/12:05	NEGATIVE		No
		Week 40	12OCT2016/12:15	NEGATIVE		No
		Week 44	10NOV2016/11:05	NEGATIVE		No
		Week 48	07DEC2016/12:05	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005 Urine Organisms	Screening	16DEC2015/08:55	NOT SEEN		Yes
	Day 1	07JAN2016/10:10	NOT SEEN		Yes
	Week 2	21JAN2016/10:00	NOT SEEN		No
	Week 4	02FEB2016/09:10	NOT SEEN		No
	Week 6	17FEB2016/13:10	NOT SEEN		No
	Week 8	02MAR2016/09:30	NOT SEEN		No
	Week 12	31MAR2016/10:20	NOT SEEN		No
	Week 16	26APR2016/10:05	NOT SEEN		No
	Week 20	26MAY2016/12:35	NOT SEEN		No
	Week 24	23JUN2016/11:50	NOT SEEN		No
	Week 28	26JUL2016/09:25	NOT SEEN		No
	Week 32	16AUG2016/10:50	NOT SEEN		No
	Week 36	14SEP2016/12:05	NOT SEEN		No
	Week 40	12OCT2016/12:15	NOT SEEN		No
	Week 44	10NOV2016/11:05	NOT SEEN		No
	Week 48	07DEC2016/12:05	NOT SEEN		No
Urine Protein	Screening	16DEC2015/08:55	NEGATIVE		Yes
	Day 1	07JAN2016/10:10	NEGATIVE		Yes
	Week 2	21JAN2016/10:00	NEGATIVE		No
	Week 4	02FEB2016/09:10	NEGATIVE		No
	Week 6	17FEB2016/13:10	NEGATIVE		No
	Week 8	02MAR2016/09:30	NEGATIVE		No
	Week 12	31MAR2016/10:20	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Urine Protein	Week 16	26APR2016/10:05	NEGATIVE		No
		Week 20	26MAY2016/12:35	NEGATIVE		No
		Week 24	23JUN2016/11:50	NEGATIVE		No
		Week 28	26JUL2016/09:25	NEGATIVE		No
		Week 32	16AUG2016/10:50	NEGATIVE		No
		Week 36	14SEP2016/12:05	NEGATIVE		No
		Week 40	12OCT2016/12:15	NEGATIVE		No
		Week 44	10NOV2016/11:05	NEGATIVE		No
		Week 48	07DEC2016/12:05	NEGATIVE		No
	Urine Specific Gravity	Screening	16DEC2015/08:55	1.007	1 - 1.03	Yes
		Day 1	07JAN2016/10:10	1.016	1 - 1.03	Yes
		Week 2	21JAN2016/10:00	1.013	1 - 1.03	No
		Week 4	02FEB2016/09:10	1.004	1 - 1.03	No
		Week 6	17FEB2016/13:10	1.014	1 - 1.03	No
		Week 8	02MAR2016/09:30	1.013	1 - 1.03	No
		Week 12	31MAR2016/10:20	1.018	1 - 1.03	No
		Week 16	26APR2016/10:05	1.012	1 - 1.03	No
		Week 20	26MAY2016/12:35	1.003	1 - 1.03	No
		Week 24	23JUN2016/11:50	1.009	1 - 1.03	No
		Week 28	26JUL2016/09:25	1.010	1 - 1.03	No
		Week 32	16AUG2016/10:50	1.007	1 - 1.03	No
		Week 36	14SEP2016/12:05	1.014	1 - 1.03	No
		Week 40	12OCT2016/12:15	1.014	1 - 1.03	No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-005	Urine Specific Gravity	Week 44	10NOV2016/11:05	1.012	1 - 1.03	No
		Week 48	07DEC2016/12:05	1.007	1 - 1.03	No
301-005	Urine Urobilinogen	Screening	16DEC2015/08:55	NORMAL		Yes
		Day 1	07JAN2016/10:10	+ (41.3 UMOL/L)		Yes
		Week 2	21JAN2016/10:00	NORMAL		No
		Week 4	02FEB2016/09:10	NORMAL		No
		Week 6	17FEB2016/13:10	NORMAL		No
		Week 8	02MAR2016/09:30	NORMAL		No
		Week 12	31MAR2016/10:20	NORMAL		No
		Week 16	26APR2016/10:05	NORMAL		No
		Week 20	26MAY2016/12:35	NORMAL		No
		Week 24	23JUN2016/11:50	NORMAL		No
		Week 28	26JUL2016/09:25	NORMAL		No
		Week 32	16AUG2016/10:50	NORMAL		No
		Week 36	14SEP2016/12:05	NORMAL		No
		Week 40	12OCT2016/12:15	NORMAL		No
		Week 44	10NOV2016/11:05	NORMAL		No
		Week 48	07DEC2016/12:05	NORMAL		No
301-008	Urine Bilirubin	Screening	19JAN2016/12:00	NEGATIVE		Yes
		Day 1	11FEB2016/09:05	NEGATIVE		No
		Week 2	24FEB2016/08:38	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Urine Bilirubin	Week 4	10MAR2016/08:03	NEGATIVE		No
		Week 6	24MAR2016/08:04	NEGATIVE		No
		Week 8	07APR2016/08:35	NEGATIVE		Yes
		Early Term	13APR2016/12:40	NEGATIVE		Yes
		Week 28	17MAY2016/08:35	NEGATIVE		No
		Week 32	09JUN2016/08:35	NEGATIVE		No
		Week 36	06JUL2016/08:30	NEGATIVE		No
		Week 40	03AUG2016/08:50	NEGATIVE		No
		Week 44	07SEP2016/08:00	NEGATIVE		No
		Week 48	19OCT2016/07:25	NEGATIVE		No
	Urine Blood	Screening	19JAN2016/12:00	NEGATIVE		Yes
		Day 1	11FEB2016/09:05	NEGATIVE		No
		Week 2	24FEB2016/08:38	NEGATIVE		No
		Week 4	10MAR2016/08:03	NEGATIVE		No
		Week 6	24MAR2016/08:04	NEGATIVE		No
		Week 8	07APR2016/08:35	NEGATIVE		Yes
		Early Term	13APR2016/12:40	NEGATIVE		Yes
		Week 28	17MAY2016/08:35	NEGATIVE		No
		Week 32	09JUN2016/08:35	NEGATIVE		No
		Week 36	06JUL2016/08:30	NEGATIVE		No
		Week 40	03AUG2016/08:50	NEGATIVE		No
		Week 44	07SEP2016/08:00	NEGATIVE		No
		Week 48	19OCT2016/07:25	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Urine Cellular Casts	Screening	19JAN2016/12:00	NOT SEEN		Yes
		Day 1	11FEB2016/09:05	NOT SEEN		No
		Week 2	24FEB2016/08:38	NOT SEEN		No
		Week 4	10MAR2016/08:03	NOT SEEN		No
		Week 6	24MAR2016/08:04	NOT SEEN		No
		Week 8	07APR2016/08:35	NOT SEEN		Yes
		Early Term	13APR2016/12:40	NOT SEEN		Yes
		Week 28	17MAY2016/08:35	NOT SEEN		No
		Week 32	09JUN2016/08:35	NOT SEEN		No
		Week 36	06JUL2016/08:30	NOT SEEN		No
		Week 40	03AUG2016/08:50	NOT SEEN		No
		Week 44	07SEP2016/08:00	NOT SEEN		No
		Week 48	19OCT2016/07:25	NOT SEEN		No
	Urine Crystals	Screening	19JAN2016/12:00	NOT SEEN		Yes
		Day 1	11FEB2016/09:05	NOT SEEN		No
		Week 2	24FEB2016/08:38	NOT SEEN		No
		Week 4	10MAR2016/08:03	NOT SEEN		No
		Week 6	24MAR2016/08:04	NOT SEEN		No
		Week 8	07APR2016/08:35	NOT SEEN		Yes
		Early Term	13APR2016/12:40	NOT SEEN		Yes
		Week 28	17MAY2016/08:35	NOT SEEN		No
		Week 32	09JUN2016/08:35	NOT SEEN		No
		Week 36	06JUL2016/08:30	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Urine Crystals	Week 40	03AUG2016/08:50	NOT SEEN		No
		Week 44	07SEP2016/08:00	NOT SEEN		No
		Week 48	19OCT2016/07:25	NOT SEEN		No
	Urine Epithelial Cells	Screening	19JAN2016/12:00	NOT SEEN		Yes
		Day 1	11FEB2016/09:05	NOT SEEN		No
		Week 2	24FEB2016/08:38	NOT SEEN		No
		Week 4	10MAR2016/08:03	NOT SEEN		No
		Week 6	24MAR2016/08:04	NOT SEEN		No
		Week 8	07APR2016/08:35	NOT SEEN		Yes
		Early Term	13APR2016/12:40	NOT SEEN		Yes
		Week 28	17MAY2016/08:35	NOT SEEN		No
		Week 32	09JUN2016/08:35	NOT SEEN		No
		Week 36	06JUL2016/08:30	NOT SEEN		No
		Week 40	03AUG2016/08:50	NOT SEEN		No
		Week 44	07SEP2016/08:00	NOT SEEN		No
		Week 48	19OCT2016/07:25	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	19JAN2016/12:00	NOT SEEN		Yes
		Day 1	11FEB2016/09:05	NOT SEEN		No
		Week 2	24FEB2016/08:38	NOT SEEN		No
		Week 4	10MAR2016/08:03	NOT SEEN		No
		Week 6	24MAR2016/08:04	NOT SEEN		No
		Week 8	07APR2016/08:35	NOT SEEN		Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Urine Erythrocytes (/HPF)	Early Term	13APR2016/12:40	1 - 9 /HPF		Yes
		Week 28	17MAY2016/08:35	NOT SEEN		No
		Week 32	09JUN2016/08:35	NOT SEEN		No
		Week 36	06JUL2016/08:30	NOT SEEN		No
		Week 40	03AUG2016/08:50	NOT SEEN		No
		Week 44	07SEP2016/08:00	NOT SEEN		No
		Week 48	19OCT2016/07:25	NOT SEEN		No
	Urine Granular Casts	Screening	19JAN2016/12:00	NOT SEEN		Yes
		Day 1	11FEB2016/09:05	NOT SEEN		No
		Week 2	24FEB2016/08:38	NOT SEEN		No
		Week 4	10MAR2016/08:03	NOT SEEN		No
		Week 6	24MAR2016/08:04	NOT SEEN		No
		Week 8	07APR2016/08:35	NOT SEEN		Yes
		Early Term	13APR2016/12:40	NOT SEEN		Yes
		Week 28	17MAY2016/08:35	NOT SEEN		No
		Week 32	09JUN2016/08:35	NOT SEEN		No
		Week 36	06JUL2016/08:30	NOT SEEN		No
		Week 40	03AUG2016/08:50	NOT SEEN		No
		Week 44	07SEP2016/08:00	NOT SEEN		No
		Week 48	19OCT2016/07:25	NOT SEEN		No
	Urine Hyaline Casts	Screening	19JAN2016/12:00	NOT SEEN		Yes
		Day 1	11FEB2016/09:05	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Urine Hyaline Casts	Week 2	24FEB2016/08:38	NOT SEEN		No
		Week 4	10MAR2016/08:03	NOT SEEN		No
		Week 6	24MAR2016/08:04	NOT SEEN		No
		Week 8	07APR2016/08:35	NOT SEEN		Yes
		Early Term	13APR2016/12:40	NOT SEEN		Yes
		Week 28	17MAY2016/08:35	NOT SEEN		No
		Week 32	09JUN2016/08:35	NOT SEEN		No
		Week 36	06JUL2016/08:30	NOT SEEN		No
		Week 40	03AUG2016/08:50	NOT SEEN		No
		Week 44	07SEP2016/08:00	NOT SEEN		No
		Week 48	19OCT2016/07:25	NOT SEEN		No
	Urine Ketones	Screening	19JAN2016/12:00	NEGATIVE		Yes
		Day 1	11FEB2016/09:05	NEGATIVE		No
		Week 2	24FEB2016/08:38	+ (1.5 MMOL/L)		No
		Week 4	10MAR2016/08:03	NEGATIVE		No
		Week 6	24MAR2016/08:04	NEGATIVE		No
		Week 8	07APR2016/08:35	NEGATIVE		Yes
		Early Term	13APR2016/12:40	NEGATIVE		Yes
		Week 28	17MAY2016/08:35	NEGATIVE		No
		Week 32	09JUN2016/08:35	NEGATIVE		No
		Week 36	06JUL2016/08:30	NEGATIVE		No
		Week 40	03AUG2016/08:50	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Urine Ketones	Week 44	07SEP2016/08:00	NEGATIVE		No
		Week 48	19OCT2016/07:25	NEGATIVE		No
301-008	Urine Leukocytes (/HPF)	Screening	19JAN2016/12:00	1 - 9 /HPF		Yes
		Day 1	11FEB2016/09:05	NOT SEEN		No
		Week 2	24FEB2016/08:38	NOT SEEN		No
		Week 4	10MAR2016/08:03	1 - 9 /HPF		No
		Week 6	24MAR2016/08:04	1 - 9 /HPF		No
		Week 8	07APR2016/08:35	NOT SEEN		Yes
		Early Term	13APR2016/12:40	1 - 9 /HPF		Yes
		Week 28	17MAY2016/08:35	NOT SEEN		No
		Week 32	09JUN2016/08:35	NOT SEEN		No
		Week 36	06JUL2016/08:30	NOT SEEN		No
		Week 40	03AUG2016/08:50	NOT SEEN		No
		Week 44	07SEP2016/08:00	NOT SEEN		No
		Week 48	19OCT2016/07:25	NOT SEEN		No
301-008	Urine Nitrite	Screening	19JAN2016/12:00	NEGATIVE		Yes
		Day 1	11FEB2016/09:05	NEGATIVE		No
		Week 2	24FEB2016/08:38	NEGATIVE		No
		Week 4	10MAR2016/08:03	NEGATIVE		No
		Week 6	24MAR2016/08:04	NEGATIVE		No
		Week 8	07APR2016/08:35	NEGATIVE		Yes
		Early Term	13APR2016/12:40	NEGATIVE		Yes

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Urine Nitrite	Week 28	17MAY2016/08:35	NEGATIVE		No
		Week 32	09JUN2016/08:35	NEGATIVE		No
		Week 36	06JUL2016/08:30	NEGATIVE		No
		Week 40	03AUG2016/08:50	NEGATIVE		No
		Week 44	07SEP2016/08:00	NEGATIVE		No
		Week 48	19OCT2016/07:25	NEGATIVE		No
	Urine Organisms	Screening	19JAN2016/12:00	NOT SEEN		Yes
		Day 1	11FEB2016/09:05	NOT SEEN		No
		Week 2	24FEB2016/08:38	NOT SEEN		No
		Week 4	10MAR2016/08:03	NOT SEEN		No
		Week 6	24MAR2016/08:04	NOT SEEN		No
		Week 8	07APR2016/08:35	NOT SEEN		Yes
		Early Term	13APR2016/12:40	NOT SEEN		Yes
		Week 28	17MAY2016/08:35	NOT SEEN		No
		Week 32	09JUN2016/08:35	NOT SEEN		No
		Week 36	06JUL2016/08:30	NOT SEEN		No
		Week 40	03AUG2016/08:50	NOT SEEN		No
		Week 44	07SEP2016/08:00	NOT SEEN		No
		Week 48	19OCT2016/07:25	NOT SEEN		No
	Urine Protein	Screening	19JAN2016/12:00	NEGATIVE		Yes
		Day 1	11FEB2016/09:05	NEGATIVE		No
		Week 2	24FEB2016/08:38	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Urine Protein	Week 4	10MAR2016/08:03	NEGATIVE		No
		Week 6	24MAR2016/08:04	NEGATIVE		No
		Week 8	07APR2016/08:35	NEGATIVE		Yes
		Early Term	13APR2016/12:40	TRACE		Yes
		Week 28	17MAY2016/08:35	NEGATIVE		No
		Week 32	09JUN2016/08:35	NEGATIVE		No
		Week 36	06JUL2016/08:30	NEGATIVE		No
		Week 40	03AUG2016/08:50	NEGATIVE		No
		Week 44	07SEP2016/08:00	NEGATIVE		No
		Week 48	19OCT2016/07:25	NEGATIVE		No
	Urine Specific Gravity	Screening	19JAN2016/12:00	1.025	1 - 1.03	Yes
		Day 1	11FEB2016/09:05	1.012	1 - 1.03	No
		Week 2	24FEB2016/08:38	1.017	1 - 1.03	No
		Week 4	10MAR2016/08:03	1.016	1 - 1.03	No
		Week 6	24MAR2016/08:04	1.017	1 - 1.03	No
		Week 8	07APR2016/08:35	1.012	1 - 1.03	Yes
		Early Term	13APR2016/12:40	1.022	1 - 1.03	Yes
		Week 28	17MAY2016/08:35	1.020	1 - 1.03	No
		Week 32	09JUN2016/08:35	1.007	1 - 1.03	No
		Week 36	06JUL2016/08:30	1.017	1 - 1.03	No
		Week 40	03AUG2016/08:50	1.007	1 - 1.03	No
		Week 44	07SEP2016/08:00	1.012	1 - 1.03	No
		Week 48	19OCT2016/07:25	1.009	1 - 1.03	No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-008	Urine Urobilinogen	Screening	19JAN2016/12:00	NORMAL		Yes
		Day 1	11FEB2016/09:05	NORMAL		No
		Week 2	24FEB2016/08:38	NORMAL		No
		Week 4	10MAR2016/08:03	NORMAL		No
		Week 6	24MAR2016/08:04	NORMAL		No
		Week 8	07APR2016/08:35	NORMAL		Yes
		Early Term	13APR2016/12:40	NORMAL		Yes
		Week 28	17MAY2016/08:35	NORMAL		No
		Week 32	09JUN2016/08:35	NORMAL		No
		Week 36	06JUL2016/08:30	NORMAL		No
		Week 40	03AUG2016/08:50	NORMAL		No
		Week 44	07SEP2016/08:00	NORMAL		No
		Week 48	19OCT2016/07:25	NORMAL		No
301-009	Urine Bilirubin	Screening	06JAN2016/11:10	NEGATIVE		Yes
		Day 1	27JAN2016/11:10	NEGATIVE		No
		Week 2	10FEB2016/12:50	NEGATIVE		No
		Week 4	25FEB2016/11:35	NEGATIVE		No
		Week 6	09MAR2016/12:05	NEGATIVE		No
		Week 8	22MAR2016/08:22	NEGATIVE		No
		Week 12	19APR2016/11:22	NEGATIVE		No
		Week 16	18MAY2016/12:25	NEGATIVE		No
		Week 20	15JUN2016/12:20	NEGATIVE		No
		Week 24	20JUL2016/13:55	NEGATIVE		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Bilirubin	Week 28	09AUG2016/12:15	NEGATIVE		No
		Week 32	06SEP2016/13:20	NEGATIVE		No
		Week 36	04OCT2016/12:35	NEGATIVE		No
		Week 40	01NOV2016/12:35	NEGATIVE		No
		Week 44	29NOV2016/13:20	NEGATIVE		No
		Week 48	02JAN2017/12:00	NEGATIVE		No
	Urine Blood	Screening	06JAN2016/11:10	NEGATIVE		Yes
		Day 1	27JAN2016/11:10	NEGATIVE		No
		Week 2	10FEB2016/12:50	NEGATIVE		No
		Week 4	25FEB2016/11:35	NEGATIVE		No
		Week 6	09MAR2016/12:05	NEGATIVE		No
		Week 8	22MAR2016/08:22	NEGATIVE		No
		Week 12	19APR2016/11:22	NEGATIVE		No
		Week 16	18MAY2016/12:25	NEGATIVE		No
		Week 20	15JUN2016/12:20	NEGATIVE		No
		Week 24	20JUL2016/13:55	NEGATIVE		Yes
		Week 28	09AUG2016/12:15	NEGATIVE		No
		Week 32	06SEP2016/13:20	NEGATIVE		No
		Week 36	04OCT2016/12:35	NEGATIVE		No
		Week 40	01NOV2016/12:35	NEGATIVE		No
		Week 44	29NOV2016/13:20	NEGATIVE		No
		Week 48	02JAN2017/12:00	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Cellular Casts	Screening	06JAN2016/11:10	NOT SEEN		Yes
		Day 1	27JAN2016/11:10	NOT SEEN		No
		Week 2	10FEB2016/12:50	NOT SEEN		No
		Week 4	25FEB2016/11:35	NOT SEEN		No
		Week 6	09MAR2016/12:05	NOT SEEN		No
		Week 8	22MAR2016/08:22	NOT SEEN		No
		Week 12	19APR2016/11:22	NOT SEEN		No
		Week 16	18MAY2016/12:25	NOT SEEN		No
		Week 20	15JUN2016/12:20	NOT SEEN		No
		Week 24	20JUL2016/13:55	NOT SEEN		Yes
		Week 28	09AUG2016/12:15	NOT SEEN		No
		Week 32	06SEP2016/13:20	NOT SEEN		No
		Week 36	04OCT2016/12:35	NOT SEEN		No
		Week 40	01NOV2016/12:35	NOT SEEN		No
		Week 44	29NOV2016/13:20	NOT SEEN		No
		Week 48	02JAN2017/12:00	NOT SEEN		No
	Urine Crystals	Screening	06JAN2016/11:10	NOT SEEN		Yes
		Day 1	27JAN2016/11:10	NOT SEEN		No
		Week 2	10FEB2016/12:50	NOT SEEN		No
		Week 4	25FEB2016/11:35	NOT SEEN		No
		Week 6	09MAR2016/12:05	NOT SEEN		No
		Week 8	22MAR2016/08:22	NOT SEEN		No
		Week 12	19APR2016/11:22	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Crystals	Week 16	18MAY2016/12:25	NOT SEEN		No
		Week 20	15JUN2016/12:20	NOT SEEN		No
		Week 24	20JUL2016/13:55	NOT SEEN		Yes
		Week 28	09AUG2016/12:15	NOT SEEN		No
		Week 32	06SEP2016/13:20	NOT SEEN		No
		Week 36	04OCT2016/12:35	NOT SEEN		No
		Week 40	01NOV2016/12:35	NOT SEEN		No
		Week 44	29NOV2016/13:20	NOT SEEN		No
		Week 48	02JAN2017/12:00	NOT SEEN		No
	Urine Epithelial Cells	Screening	06JAN2016/11:10	NOT SEEN		Yes
		Day 1	27JAN2016/11:10	NOT SEEN		No
		Week 2	10FEB2016/12:50	NOT SEEN		No
		Week 4	25FEB2016/11:35	NOT SEEN		No
		Week 6	09MAR2016/12:05	NOT SEEN		No
		Week 8	22MAR2016/08:22	NOT SEEN		No
		Week 12	19APR2016/11:22	NOT SEEN		No
		Week 16	18MAY2016/12:25	NOT SEEN		No
		Week 20	15JUN2016/12:20	NOT SEEN		No
		Week 24	20JUL2016/13:55	NOT SEEN		Yes
		Week 28	09AUG2016/12:15	NOT SEEN		No
		Week 32	06SEP2016/13:20	NOT SEEN		No
		Week 36	04OCT2016/12:35	NOT SEEN		No
		Week 40	01NOV2016/12:35	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Epithelial Cells	Week 44	29NOV2016/13:20	NOT SEEN		No
		Week 48	02JAN2017/12:00	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	06JAN2016/11:10	NOT SEEN		Yes
		Day 1	27JAN2016/11:10	1 - 9 /HPF		No
		Week 2	10FEB2016/12:50	NOT SEEN		No
		Week 4	25FEB2016/11:35	NOT SEEN		No
		Week 6	09MAR2016/12:05	NOT SEEN		No
		Week 8	22MAR2016/08:22	1 - 9 /HPF		No
		Week 12	19APR2016/11:22	NOT SEEN		No
		Week 16	18MAY2016/12:25	NOT SEEN		No
		Week 20	15JUN2016/12:20	NOT SEEN		No
		Week 24	20JUL2016/13:55	NOT SEEN		Yes
		Week 28	09AUG2016/12:15	NOT SEEN		No
		Week 32	06SEP2016/13:20	NOT SEEN		No
		Week 36	04OCT2016/12:35	NOT SEEN		No
		Week 40	01NOV2016/12:35	NOT SEEN		No
		Week 44	29NOV2016/13:20	NOT SEEN		No
		Week 48	02JAN2017/12:00	NOT SEEN		No
	Urine Granular Casts	Screening	06JAN2016/11:10	NOT SEEN		Yes
		Day 1	27JAN2016/11:10	NOT SEEN		No
		Week 2	10FEB2016/12:50	NOT SEEN		No
		Week 4	25FEB2016/11:35	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Granular Casts	Week 6	09MAR2016/12:05	NOT SEEN		No
		Week 8	22MAR2016/08:22	NOT SEEN		No
		Week 12	19APR2016/11:22	NOT SEEN		No
		Week 16	18MAY2016/12:25	NOT SEEN		No
		Week 20	15JUN2016/12:20	NOT SEEN		No
		Week 24	20JUL2016/13:55	NOT SEEN		Yes
		Week 28	09AUG2016/12:15	NOT SEEN		No
		Week 32	06SEP2016/13:20	NOT SEEN		No
		Week 36	04OCT2016/12:35	NOT SEEN		No
		Week 40	01NOV2016/12:35	NOT SEEN		No
		Week 44	29NOV2016/13:20	NOT SEEN		No
		Week 48	02JAN2017/12:00	NOT SEEN		No
	Urine Hyaline Casts	Screening	06JAN2016/11:10	NOT SEEN		Yes
		Day 1	27JAN2016/11:10	NOT SEEN		No
		Week 2	10FEB2016/12:50	NOT SEEN		No
		Week 4	25FEB2016/11:35	NOT SEEN		No
		Week 6	09MAR2016/12:05	NOT SEEN		No
		Week 8	22MAR2016/08:22	NOT SEEN		No
		Week 12	19APR2016/11:22	NOT SEEN		No
		Week 16	18MAY2016/12:25	NOT SEEN		No
		Week 20	15JUN2016/12:20	NOT SEEN		No
		Week 24	20JUL2016/13:55	NOT SEEN		Yes
		Week 28	09AUG2016/12:15	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Hyaline Casts	Week 32	06SEP2016/13:20	NOT SEEN		No
		Week 36	04OCT2016/12:35	NOT SEEN		No
		Week 40	01NOV2016/12:35	NOT SEEN		No
		Week 44	29NOV2016/13:20	NOT SEEN		No
		Week 48	02JAN2017/12:00	NOT SEEN		No
	Urine Ketones	Screening	06JAN2016/11:10	NEGATIVE		Yes
		Day 1	27JAN2016/11:10	NEGATIVE		No
		Week 2	10FEB2016/12:50	NEGATIVE		No
		Week 4	25FEB2016/11:35	NEGATIVE		No
		Week 6	09MAR2016/12:05	NEGATIVE		No
		Week 8	22MAR2016/08:22	NEGATIVE		No
		Week 12	19APR2016/11:22	NEGATIVE		No
		Week 16	18MAY2016/12:25	NEGATIVE		No
		Week 20	15JUN2016/12:20	NEGATIVE		No
		Week 24	20JUL2016/13:55	NEGATIVE		Yes
		Week 28	09AUG2016/12:15	NEGATIVE		No
		Week 32	06SEP2016/13:20	NEGATIVE		No
		Week 36	04OCT2016/12:35	NEGATIVE		No
		Week 40	01NOV2016/12:35	NEGATIVE		No
		Week 44	29NOV2016/13:20	NEGATIVE		No
		Week 48	02JAN2017/12:00	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	06JAN2016/11:10	1 - 9 /HPF		Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Leukocytes (/HPF)	Day 1	27JAN2016/11:10	1 - 9 /HPF		No
		Week 2	10FEB2016/12:50	NOT SEEN		No
		Week 4	25FEB2016/11:35	NOT SEEN		No
		Week 6	09MAR2016/12:05	NOT SEEN		No
		Week 8	22MAR2016/08:22	1 - 9 /HPF		No
		Week 12	19APR2016/11:22	1 - 9 /HPF		No
		Week 16	18MAY2016/12:25	NOT SEEN		No
		Week 20	15JUN2016/12:20	1 - 9 /HPF		No
		Week 24	20JUL2016/13:55	1 - 9 /HPF		Yes
		Week 28	09AUG2016/12:15	NOT SEEN		No
		Week 32	06SEP2016/13:20	NOT SEEN		No
		Week 36	04OCT2016/12:35	1 - 9 /HPF		No
		Week 40	01NOV2016/12:35	1 - 9 /HPF		No
		Week 44	29NOV2016/13:20	1 - 9 /HPF		No
		Week 48	02JAN2017/12:00	1 - 9 /HPF		No
	Urine Nitrite	Screening	06JAN2016/11:10	NEGATIVE		Yes
		Day 1	27JAN2016/11:10	NEGATIVE		No
		Week 2	10FEB2016/12:50	NEGATIVE		No
		Week 4	25FEB2016/11:35	NEGATIVE		No
		Week 6	09MAR2016/12:05	NEGATIVE		No
		Week 8	22MAR2016/08:22	NEGATIVE		No
		Week 12	19APR2016/11:22	NEGATIVE		No
		Week 16	18MAY2016/12:25	NEGATIVE		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Nitrite	Week 20	15JUN2016/12:20	NEGATIVE		No
		Week 24	20JUL2016/13:55	NEGATIVE		Yes
		Week 28	09AUG2016/12:15	NEGATIVE		No
		Week 32	06SEP2016/13:20	NEGATIVE		No
		Week 36	04OCT2016/12:35	NEGATIVE		No
		Week 40	01NOV2016/12:35	NEGATIVE		No
		Week 44	29NOV2016/13:20	NEGATIVE		No
		Week 48	02JAN2017/12:00	NEGATIVE		No
	Urine Organisms	Screening	06JAN2016/11:10	NOT SEEN		Yes
		Day 1	27JAN2016/11:10	NOT SEEN		No
		Week 2	10FEB2016/12:50	NOT SEEN		No
		Week 4	25FEB2016/11:35	NOT SEEN		No
		Week 6	09MAR2016/12:05	NOT SEEN		No
		Week 8	22MAR2016/08:22	NOT SEEN		No
		Week 12	19APR2016/11:22	NOT SEEN		No
		Week 16	18MAY2016/12:25	NOT SEEN		No
		Week 20	15JUN2016/12:20	NOT SEEN		No
		Week 24	20JUL2016/13:55	NOT SEEN		Yes
		Week 28	09AUG2016/12:15	NOT SEEN		No
		Week 32	06SEP2016/13:20	NOT SEEN		No
		Week 36	04OCT2016/12:35	NOT SEEN		No
		Week 40	01NOV2016/12:35	NOT SEEN		No
		Week 44	29NOV2016/13:20	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Organisms	Week 48	02JAN2017/12:00	NOT SEEN		No
	Urine Protein	Screening	06JAN2016/11:10	NEGATIVE		Yes
		Day 1	27JAN2016/11:10	NEGATIVE		No
		Week 2	10FEB2016/12:50	NEGATIVE		No
		Week 4	25FEB2016/11:35	NEGATIVE		No
		Week 6	09MAR2016/12:05	NEGATIVE		No
		Week 8	22MAR2016/08:22	NEGATIVE		No
		Week 12	19APR2016/11:22	NEGATIVE		No
		Week 16	18MAY2016/12:25	NEGATIVE		No
		Week 20	15JUN2016/12:20	NEGATIVE		No
		Week 24	20JUL2016/13:55	TRACE		Yes
		Week 28	09AUG2016/12:15	NEGATIVE		No
		Week 32	06SEP2016/13:20	NEGATIVE		No
		Week 36	04OCT2016/12:35	NEGATIVE		No
		Week 40	01NOV2016/12:35	NEGATIVE		No
		Week 44	29NOV2016/13:20	NEGATIVE		No
		Week 48	02JAN2017/12:00	NEGATIVE		No
	Urine Specific Gravity	Screening	06JAN2016/11:10	1.013	1 - 1.03	Yes
		Day 1	27JAN2016/11:10	1.011	1 - 1.03	No
		Week 2	10FEB2016/12:50	1.006	1 - 1.03	No
		Week 4	25FEB2016/11:35	1.011	1 - 1.03	No
		Week 6	09MAR2016/12:05	1.005	1 - 1.03	No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Specific Gravity	Week 8	22MAR2016/08:22	1.019	1 - 1.03	No
		Week 12	19APR2016/11:22	1.017	1 - 1.03	No
		Week 16	18MAY2016/12:25	1.007	1 - 1.03	No
		Week 20	15JUN2016/12:20	1.016	1 - 1.03	No
		Week 24	20JUL2016/13:55	1.023	1 - 1.03	Yes
		Week 28	09AUG2016/12:15	1.009	1 - 1.03	No
		Week 32	06SEP2016/13:20	1.010	1 - 1.03	No
		Week 36	04OCT2016/12:35	1.017	1 - 1.03	No
		Week 40	01NOV2016/12:35	1.014	1 - 1.03	No
		Week 44	29NOV2016/13:20	1.007	1 - 1.03	No
		Week 48	02JAN2017/12:00	1.012	1 - 1.03	No
	Urine Urobilinogen	Screening	06JAN2016/11:10	NORMAL		Yes
		Day 1	27JAN2016/11:10	NORMAL		No
		Week 2	10FEB2016/12:50	NORMAL		No
		Week 4	25FEB2016/11:35	NORMAL		No
		Week 6	09MAR2016/12:05	NORMAL		No
		Week 8	22MAR2016/08:22	NORMAL		No
		Week 12	19APR2016/11:22	+ (41.3 UMOL/L)		No
		Week 16	18MAY2016/12:25	NORMAL		No
		Week 20	15JUN2016/12:20	NORMAL		No
		Week 24	20JUL2016/13:55	NORMAL		Yes
		Week 28	09AUG2016/12:15	NORMAL		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-009	Urine Urobilinogen	Week 32	06SEP2016/13:20	NORMAL		No
		Week 36	04OCT2016/12:35	NORMAL		No
		Week 40	01NOV2016/12:35	NORMAL		No
		Week 44	29NOV2016/13:20	NORMAL		No
		Week 48	02JAN2017/12:00	NORMAL		No
301-010	Urine Bilirubin	Screening	07JAN2016/09:45	NEGATIVE		Yes
		Day 1	27JAN2016/10:10	NEGATIVE		Yes
		Week 2	09FEB2016/12:10	NEGATIVE		No
		Week 4	24FEB2016/14:10	NEGATIVE		No
		Week 6	09MAR2016/11:35	NEGATIVE		No
		Week 8	22MAR2016/08:35	NEGATIVE		No
		Week 12	19APR2016/11:34	NEGATIVE		No
		Week 16	17MAY2016/13:00	NEGATIVE		No
		Week 20	20JUN2016/12:15	NEGATIVE		No
		Week 24	12JUL2016/11:45	NEGATIVE		Yes
		Week 28	08AUG2016/12:35	NEGATIVE		No
		Week 32	07SEP2016/11:20	NEGATIVE		No
		Week 36	04OCT2016/12:45	NEGATIVE		No
		Week 40	01NOV2016/12:55	NEGATIVE		No
		Week 44	28NOV2016/11:50	NEGATIVE		No
		Week 48	03JAN2017/11:50	NEGATIVE		No
	Urine Blood	Screening	07JAN2016/09:45	NEGATIVE		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Urine Blood	Day 1	27JAN2016/10:10	NEGATIVE		Yes
		Week 2	09FEB2016/12:10	NEGATIVE		No
		Week 4	24FEB2016/14:10	NEGATIVE		No
		Week 6	09MAR2016/11:35	NEGATIVE		No
		Week 8	22MAR2016/08:35	NEGATIVE		No
		Week 12	19APR2016/11:34	NEGATIVE		No
		Week 16	17MAY2016/13:00	NEGATIVE		No
		Week 20	20JUN2016/12:15	NEGATIVE		No
		Week 24	12JUL2016/11:45	NEGATIVE		Yes
		Week 28	08AUG2016/12:35	NEGATIVE		No
		Week 32	07SEP2016/11:20	NEGATIVE		No
		Week 36	04OCT2016/12:45	NEGATIVE		No
		Week 40	01NOV2016/12:55	NEGATIVE		No
		Week 44	28NOV2016/11:50	NEGATIVE		No
		Week 48	03JAN2017/11:50	NEGATIVE		No
	Urine Cellular Casts	Screening	07JAN2016/09:45	NOT SEEN		Yes
		Day 1	27JAN2016/10:10	NOT SEEN		Yes
		Week 2	09FEB2016/12:10	NOT SEEN		No
		Week 4	24FEB2016/14:10	NOT SEEN		No
		Week 6	09MAR2016/11:35	NOT SEEN		No
		Week 8	22MAR2016/08:35	NOT SEEN		No
		Week 12	19APR2016/11:34	NOT SEEN		No
		Week 16	17MAY2016/13:00	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Urine Cellular Casts	Week 20	20JUN2016/12:15	NOT SEEN		No
		Week 24	12JUL2016/11:45	NOT SEEN		Yes
		Week 28	08AUG2016/12:35	NOT SEEN		No
		Week 32	07SEP2016/11:20	NOT SEEN		No
		Week 36	04OCT2016/12:45	NOT SEEN		No
		Week 40	01NOV2016/12:55	NOT SEEN		No
		Week 44	28NOV2016/11:50	NOT SEEN		No
		Week 48	03JAN2017/11:50	NOT SEEN		No
	Urine Crystals	Screening	07JAN2016/09:45	NOT SEEN		Yes
		Day 1	27JAN2016/10:10	NOT SEEN		Yes
		Week 2	09FEB2016/12:10	NOT SEEN		No
		Week 4	24FEB2016/14:10	NOT SEEN		No
		Week 6	09MAR2016/11:35	NOT SEEN		No
		Week 8	22MAR2016/08:35	+		No
		Week 12	19APR2016/11:34	NOT SEEN		No
		Week 16	17MAY2016/13:00	NOT SEEN		No
		Week 20	20JUN2016/12:15	NOT SEEN		No
		Week 24	12JUL2016/11:45	NOT SEEN		Yes
		Week 28	08AUG2016/12:35	NOT SEEN		No
		Week 32	07SEP2016/11:20	NOT SEEN		No
		Week 36	04OCT2016/12:45	NOT SEEN		No
		Week 40	01NOV2016/12:55	NOT SEEN		No
		Week 44	28NOV2016/11:50	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Urine Crystals	Week 48	03JAN2017/11:50	NOT SEEN		No
	Urine Epithelial Cells	Screening	07JAN2016/09:45	NOT SEEN		Yes
		Day 1	27JAN2016/10:10	NOT SEEN		Yes
		Week 2	09FEB2016/12:10	NOT SEEN		No
		Week 4	24FEB2016/14:10	NOT SEEN		No
		Week 6	09MAR2016/11:35	NOT SEEN		No
		Week 8	22MAR2016/08:35	NOT SEEN		No
		Week 12	19APR2016/11:34	NOT SEEN		No
		Week 16	17MAY2016/13:00	NOT SEEN		No
		Week 20	20JUN2016/12:15	NOT SEEN		No
		Week 24	12JUL2016/11:45	NOT SEEN		Yes
		Week 28	08AUG2016/12:35	NOT SEEN		No
		Week 32	07SEP2016/11:20	NOT SEEN		No
		Week 36	04OCT2016/12:45	NOT SEEN		No
		Week 40	01NOV2016/12:55	NOT SEEN		No
		Week 44	28NOV2016/11:50	NOT SEEN		No
		Week 48	03JAN2017/11:50	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	07JAN2016/09:45	NOT SEEN		Yes
		Day 1	27JAN2016/10:10	NOT SEEN		Yes
		Week 2	09FEB2016/12:10	NOT SEEN		No
		Week 4	24FEB2016/14:10	NOT SEEN		No
		Week 6	09MAR2016/11:35	1 - 9 /HPF		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Urine Erythrocytes (/HPF)	Week 8	22MAR2016/08:35	NOT SEEN		No
		Week 12	19APR2016/11:34	NOT SEEN		No
		Week 16	17MAY2016/13:00	1 - 9 /HPF		No
		Week 20	20JUN2016/12:15	NOT SEEN		No
		Week 24	12JUL2016/11:45	1 - 9 /HPF		Yes
		Week 28	08AUG2016/12:35	NOT SEEN		No
		Week 32	07SEP2016/11:20	NOT SEEN		No
		Week 36	04OCT2016/12:45	NOT SEEN		No
		Week 40	01NOV2016/12:55	1 - 9 /HPF		No
		Week 44	28NOV2016/11:50	NOT SEEN		No
		Week 48	03JAN2017/11:50	NOT SEEN		No
	Urine Granular Casts	Screening	07JAN2016/09:45	NOT SEEN		Yes
		Day 1	27JAN2016/10:10	NOT SEEN		Yes
		Week 2	09FEB2016/12:10	NOT SEEN		No
		Week 4	24FEB2016/14:10	NOT SEEN		No
		Week 6	09MAR2016/11:35	NOT SEEN		No
		Week 8	22MAR2016/08:35	NOT SEEN		No
		Week 12	19APR2016/11:34	NOT SEEN		No
		Week 16	17MAY2016/13:00	NOT SEEN		No
		Week 20	20JUN2016/12:15	NOT SEEN		No
		Week 24	12JUL2016/11:45	NOT SEEN		Yes
		Week 28	08AUG2016/12:35	NOT SEEN		No
		Week 32	07SEP2016/11:20	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Urine Granular Casts	Week 36	04OCT2016/12:45	NOT SEEN		No
		Week 40	01NOV2016/12:55	NOT SEEN		No
		Week 44	28NOV2016/11:50	NOT SEEN		No
		Week 48	03JAN2017/11:50	NOT SEEN		No
	Urine Hyaline Casts	Screening	07JAN2016/09:45	NOT SEEN		Yes
		Day 1	27JAN2016/10:10	NOT SEEN		Yes
		Week 2	09FEB2016/12:10	NOT SEEN		No
		Week 4	24FEB2016/14:10	NOT SEEN		No
		Week 6	09MAR2016/11:35	NOT SEEN		No
		Week 8	22MAR2016/08:35	NOT SEEN		No
		Week 12	19APR2016/11:34	NOT SEEN		No
		Week 16	17MAY2016/13:00	NOT SEEN		No
		Week 20	20JUN2016/12:15	NOT SEEN		No
		Week 24	12JUL2016/11:45	NOT SEEN		Yes
		Week 28	08AUG2016/12:35	NOT SEEN		No
		Week 32	07SEP2016/11:20	NOT SEEN		No
		Week 36	04OCT2016/12:45	NOT SEEN		No
		Week 40	01NOV2016/12:55	NOT SEEN		No
		Week 44	28NOV2016/11:50	NOT SEEN		No
		Week 48	03JAN2017/11:50	NOT SEEN		No
	Urine Ketones	Screening	07JAN2016/09:45	NEGATIVE		Yes
		Day 1	27JAN2016/10:10	NEGATIVE		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Urine Ketones	Week 2	09FEB2016/12:10	NEGATIVE		No
		Week 4	24FEB2016/14:10	NEGATIVE		No
		Week 6	09MAR2016/11:35	NEGATIVE		No
		Week 8	22MAR2016/08:35	NEGATIVE		No
		Week 12	19APR2016/11:34	NEGATIVE		No
		Week 16	17MAY2016/13:00	NEGATIVE		No
		Week 20	20JUN2016/12:15	NEGATIVE		No
		Week 24	12JUL2016/11:45	NEGATIVE		Yes
		Week 28	08AUG2016/12:35	NEGATIVE		No
		Week 32	07SEP2016/11:20	NEGATIVE		No
		Week 36	04OCT2016/12:45	NEGATIVE		No
		Week 40	01NOV2016/12:55	NEGATIVE		No
		Week 44	28NOV2016/11:50	NEGATIVE		No
		Week 48	03JAN2017/11:50	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	07JAN2016/09:45	NOT SEEN		Yes
		Day 1	27JAN2016/10:10	1 - 9 /HPF		Yes
		Week 2	09FEB2016/12:10	NOT SEEN		No
		Week 4	24FEB2016/14:10	NOT SEEN		No
		Week 6	09MAR2016/11:35	NOT SEEN		No
		Week 8	22MAR2016/08:35	1 - 9 /HPF		No
		Week 12	19APR2016/11:34	NOT SEEN		No
		Week 16	17MAY2016/13:00	NOT SEEN		No
		Week 20	20JUN2016/12:15	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Urine Leukocytes (/HPF)	Week 24	12JUL2016/11:45	NOT SEEN		Yes
		Week 28	08AUG2016/12:35	NOT SEEN		No
		Week 32	07SEP2016/11:20	NOT SEEN		No
		Week 36	04OCT2016/12:45	NOT SEEN		No
		Week 40	01NOV2016/12:55	10 - 50 /HPF		No
		Week 44	28NOV2016/11:50	NOT SEEN		No
		Week 48	03JAN2017/11:50	NOT SEEN		No
	Urine Nitrite	Screening	07JAN2016/09:45	NEGATIVE		Yes
		Day 1	27JAN2016/10:10	NEGATIVE		Yes
		Week 2	09FEB2016/12:10	NEGATIVE		No
		Week 4	24FEB2016/14:10	NEGATIVE		No
		Week 6	09MAR2016/11:35	NEGATIVE		No
		Week 8	22MAR2016/08:35	NEGATIVE		No
		Week 12	19APR2016/11:34	NEGATIVE		No
		Week 16	17MAY2016/13:00	NEGATIVE		No
		Week 20	20JUN2016/12:15	NEGATIVE		No
		Week 24	12JUL2016/11:45	NEGATIVE		Yes
		Week 28	08AUG2016/12:35	NEGATIVE		No
		Week 32	07SEP2016/11:20	NEGATIVE		No
		Week 36	04OCT2016/12:45	NEGATIVE		No
		Week 40	01NOV2016/12:55	NEGATIVE		No
		Week 44	28NOV2016/11:50	NEGATIVE		No
		Week 48	03JAN2017/11:50	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010 Urine Organisms	Screening	07JAN2016/09:45	NOT SEEN		Yes
	Day 1	27JAN2016/10:10	NOT SEEN		Yes
	Week 2	09FEB2016/12:10	NOT SEEN		No
	Week 4	24FEB2016/14:10	NOT SEEN		No
	Week 6	09MAR2016/11:35	NOT SEEN		No
	Week 8	22MAR2016/08:35	NOT SEEN		No
	Week 12	19APR2016/11:34	NOT SEEN		No
	Week 16	17MAY2016/13:00	NOT SEEN		No
	Week 20	20JUN2016/12:15	NOT SEEN		No
	Week 24	12JUL2016/11:45	NOT SEEN		Yes
	Week 28	08AUG2016/12:35	NOT SEEN		No
	Week 32	07SEP2016/11:20	NOT SEEN		No
	Week 36	04OCT2016/12:45	NOT SEEN		No
	Week 40	01NOV2016/12:55	NOT SEEN		No
	Week 44	28NOV2016/11:50	NOT SEEN		No
	Week 48	03JAN2017/11:50	NOT SEEN		No
Urine Protein	Screening	07JAN2016/09:45	NEGATIVE		Yes
	Day 1	27JAN2016/10:10	NEGATIVE		Yes
	Week 2	09FEB2016/12:10	NEGATIVE		No
	Week 4	24FEB2016/14:10	NEGATIVE		No
	Week 6	09MAR2016/11:35	NEGATIVE		No
	Week 8	22MAR2016/08:35	NEGATIVE		No
	Week 12	19APR2016/11:34	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Urine Protein	Week 16	17MAY2016/13:00	NEGATIVE		No
		Week 20	20JUN2016/12:15	NEGATIVE		No
		Week 24	12JUL2016/11:45	NEGATIVE		Yes
		Week 28	08AUG2016/12:35	NEGATIVE		No
		Week 32	07SEP2016/11:20	NEGATIVE		No
		Week 36	04OCT2016/12:45	NEGATIVE		No
		Week 40	01NOV2016/12:55	NEGATIVE		No
		Week 44	28NOV2016/11:50	NEGATIVE		No
		Week 48	03JAN2017/11:50	NEGATIVE		No
	Urine Specific Gravity	Screening	07JAN2016/09:45	1.016	1 - 1.03	Yes
		Day 1	27JAN2016/10:10	1.012	1 - 1.03	Yes
		Week 2	09FEB2016/12:10	1.012	1 - 1.03	No
		Week 4	24FEB2016/14:10	1.008	1 - 1.03	No
		Week 6	09MAR2016/11:35	1.010	1 - 1.03	No
		Week 8	22MAR2016/08:35	1.007	1 - 1.03	No
		Week 12	19APR2016/11:34	1.012	1 - 1.03	No
		Week 16	17MAY2016/13:00	1.011	1 - 1.03	No
		Week 20	20JUN2016/12:15	1.012	1 - 1.03	No
		Week 24	12JUL2016/11:45	1.008	1 - 1.03	Yes
		Week 28	08AUG2016/12:35	1.011	1 - 1.03	No
		Week 32	07SEP2016/11:20	1.014	1 - 1.03	No
		Week 36	04OCT2016/12:45	1.007	1 - 1.03	No
		Week 40	01NOV2016/12:55	1.011	1 - 1.03	No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-010	Urine Specific Gravity	Week 44	28NOV2016/11:50	1.011	1 - 1.03	No
		Week 48	03JAN2017/11:50	1.012	1 - 1.03	No
301-010	Urine Urobilinogen	Screening	07JAN2016/09:45	NORMAL		Yes
		Day 1	27JAN2016/10:10	NORMAL		Yes
		Week 2	09FEB2016/12:10	NORMAL		No
		Week 4	24FEB2016/14:10	NORMAL		No
		Week 6	09MAR2016/11:35	NORMAL		No
		Week 8	22MAR2016/08:35	NORMAL		No
		Week 12	19APR2016/11:34	NORMAL		No
		Week 16	17MAY2016/13:00	NORMAL		No
		Week 20	20JUN2016/12:15	NORMAL		No
		Week 24	12JUL2016/11:45	NORMAL		Yes
		Week 28	08AUG2016/12:35	NORMAL		No
		Week 32	07SEP2016/11:20	NORMAL		No
		Week 36	04OCT2016/12:45	NORMAL		No
		Week 40	01NOV2016/12:55	NORMAL		No
		Week 44	28NOV2016/11:50	NORMAL		No
		Week 48	03JAN2017/11:50	NORMAL		No
301-014	Urine Bilirubin	Screening	27JAN2016/11:40	NEGATIVE		Yes
		Day 1	23FEB2016/13:10	NEGATIVE		Yes
		Week 2	09MAR2016/10:50	NEGATIVE		No
		Week 4	22MAR2016/10:18	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Bilirubin	Week 6	05APR2016/11:49	NEGATIVE		No
		Week 8	20APR2016/09:20	NEGATIVE		Yes
		Week 12	19MAY2016/11:58	NEGATIVE		No
		Week 16	14JUN2016/11:10	NEGATIVE		No
		Week 20	13JUL2016/11:25	NEGATIVE		No
		Week 24	10AUG2016/10:55	NEGATIVE		Yes
		Week 28	07SEP2016/11:35	NEGATIVE		No
		Week 32	05OCT2016/11:10	NEGATIVE		No
		Week 36	02NOV2016/12:05	NEGATIVE		No
		Week 40	30NOV2016/11:00	NEGATIVE		No
		Week 44	22DEC2016/12:05	NEGATIVE		No
		Week 48	25JAN2017/11:05	NEGATIVE		No
	Urine Blood	Screening	27JAN2016/11:40	NEGATIVE		Yes
		Day 1	23FEB2016/13:10	NEGATIVE		Yes
		Week 2	09MAR2016/10:50	NEGATIVE		No
		Week 4	22MAR2016/10:18	NEGATIVE		No
		Week 6	05APR2016/11:49	NEGATIVE		No
		Week 8	20APR2016/09:20	NEGATIVE		Yes
		Week 12	19MAY2016/11:58	NEGATIVE		No
		Week 16	14JUN2016/11:10	NEGATIVE		No
		Week 20	13JUL2016/11:25	NEGATIVE		No
		Week 24	10AUG2016/10:55	NEGATIVE		Yes
		Week 28	07SEP2016/11:35	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Blood	Week 32	05OCT2016/11:10	NEGATIVE		No
		Week 36	02NOV2016/12:05	NEGATIVE		No
		Week 40	30NOV2016/11:00	NEGATIVE		No
		Week 44	22DEC2016/12:05	NEGATIVE		No
		Week 48	25JAN2017/11:05	NEGATIVE		No
	Urine Cellular Casts	Screening	27JAN2016/11:40	NOT SEEN		Yes
		Day 1	23FEB2016/13:10	NOT SEEN		Yes
		Week 2	09MAR2016/10:50	NOT SEEN		No
		Week 4	22MAR2016/10:18	NOT SEEN		No
		Week 6	05APR2016/11:49	NOT SEEN		No
		Week 8	20APR2016/09:20	NOT SEEN		Yes
		Week 12	19MAY2016/11:58	NOT SEEN		No
		Week 16	14JUN2016/11:10	NOT SEEN		No
		Week 20	13JUL2016/11:25	NOT SEEN		No
		Week 24	10AUG2016/10:55	NOT SEEN		Yes
		Week 28	07SEP2016/11:35	NOT SEEN		No
		Week 32	05OCT2016/11:10	NOT SEEN		No
		Week 36	02NOV2016/12:05	NOT SEEN		No
		Week 40	30NOV2016/11:00	NOT SEEN		No
		Week 44	22DEC2016/12:05	NOT SEEN		No
		Week 48	25JAN2017/11:05	NOT SEEN		No
	Urine Crystals	Screening	27JAN2016/11:40	NOT SEEN		Yes

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Crystals	Day 1	23FEB2016/13:10	NOT SEEN		Yes
		Week 2	09MAR2016/10:50	NOT SEEN		No
		Week 4	22MAR2016/10:18	NOT SEEN		No
		Week 6	05APR2016/11:49	NOT SEEN		No
		Week 8	20APR2016/09:20	NOT SEEN		Yes
		Week 12	19MAY2016/11:58	NOT SEEN		No
		Week 16	14JUN2016/11:10	NOT SEEN		No
		Week 20	13JUL2016/11:25	NOT SEEN		No
		Week 24	10AUG2016/10:55	NOT SEEN		Yes
		Week 28	07SEP2016/11:35	NOT SEEN		No
		Week 32	05OCT2016/11:10	NOT SEEN		No
		Week 36	02NOV2016/12:05	NOT SEEN		No
		Week 40	30NOV2016/11:00	NOT SEEN		No
		Week 44	22DEC2016/12:05	NOT SEEN		No
		Week 48	25JAN2017/11:05	NOT SEEN		No
	Urine Epithelial Cells	Screening	27JAN2016/11:40	NOT SEEN		Yes
		Day 1	23FEB2016/13:10	NOT SEEN		Yes
		Week 2	09MAR2016/10:50	NOT SEEN		No
		Week 4	22MAR2016/10:18	NOT SEEN		No
		Week 6	05APR2016/11:49	NOT SEEN		No
		Week 8	20APR2016/09:20	NOT SEEN		Yes
		Week 12	19MAY2016/11:58	NOT SEEN		No
		Week 16	14JUN2016/11:10	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Epithelial Cells	Week 20	13JUL2016/11:25	NOT SEEN		No
		Week 24	10AUG2016/10:55	NOT SEEN		Yes
		Week 28	07SEP2016/11:35	NOT SEEN		No
		Week 32	05OCT2016/11:10	NOT SEEN		No
		Week 36	02NOV2016/12:05	NOT SEEN		No
		Week 40	30NOV2016/11:00	NOT SEEN		No
		Week 44	22DEC2016/12:05	NOT SEEN		No
		Week 48	25JAN2017/11:05	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	27JAN2016/11:40	NOT SEEN		Yes
		Day 1	23FEB2016/13:10	NOT SEEN		Yes
		Week 2	09MAR2016/10:50	NOT SEEN		No
		Week 4	22MAR2016/10:18	NOT SEEN		No
		Week 6	05APR2016/11:49	NOT SEEN		No
		Week 8	20APR2016/09:20	NOT SEEN		Yes
		Week 12	19MAY2016/11:58	NOT SEEN		No
		Week 16	14JUN2016/11:10	NOT SEEN		No
		Week 20	13JUL2016/11:25	NOT SEEN		No
		Week 24	10AUG2016/10:55	NOT SEEN		Yes
		Week 28	07SEP2016/11:35	NOT SEEN		No
		Week 32	05OCT2016/11:10	NOT SEEN		No
		Week 36	02NOV2016/12:05	NOT SEEN		No
		Week 40	30NOV2016/11:00	NOT SEEN		No
		Week 44	22DEC2016/12:05	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Erythrocytes (/HPF)	Week 48	25JAN2017/11:05	NOT SEEN		No
	Urine Granular Casts	Screening	27JAN2016/11:40	NOT SEEN		Yes
		Day 1	23FEB2016/13:10	NOT SEEN		Yes
		Week 2	09MAR2016/10:50	NOT SEEN		No
		Week 4	22MAR2016/10:18	NOT SEEN		No
		Week 6	05APR2016/11:49	NOT SEEN		No
		Week 8	20APR2016/09:20	NOT SEEN		Yes
		Week 12	19MAY2016/11:58	NOT SEEN		No
		Week 16	14JUN2016/11:10	NOT SEEN		No
		Week 20	13JUL2016/11:25	NOT SEEN		No
		Week 24	10AUG2016/10:55	NOT SEEN		Yes
		Week 28	07SEP2016/11:35	NOT SEEN		No
		Week 32	05OCT2016/11:10	NOT SEEN		No
		Week 36	02NOV2016/12:05	NOT SEEN		No
		Week 40	30NOV2016/11:00	NOT SEEN		No
		Week 44	22DEC2016/12:05	NOT SEEN		No
		Week 48	25JAN2017/11:05	NOT SEEN		No
	Urine Hyaline Casts	Screening	27JAN2016/11:40	NOT SEEN		Yes
		Day 1	23FEB2016/13:10	NOT SEEN		Yes
		Week 2	09MAR2016/10:50	NOT SEEN		No
		Week 4	22MAR2016/10:18	NOT SEEN		No
		Week 6	05APR2016/11:49	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Hyaline Casts	Week 8	20APR2016/09:20	NOT SEEN		Yes
		Week 12	19MAY2016/11:58	NOT SEEN		No
		Week 16	14JUN2016/11:10	NOT SEEN		No
		Week 20	13JUL2016/11:25	NOT SEEN		No
		Week 24	10AUG2016/10:55	NOT SEEN		Yes
		Week 28	07SEP2016/11:35	NOT SEEN		No
		Week 32	05OCT2016/11:10	NOT SEEN		No
		Week 36	02NOV2016/12:05	NOT SEEN		No
		Week 40	30NOV2016/11:00	NOT SEEN		No
		Week 44	22DEC2016/12:05	NOT SEEN		No
		Week 48	25JAN2017/11:05	NOT SEEN		No
	Urine Ketones	Screening	27JAN2016/11:40	NEGATIVE		Yes
		Day 1	23FEB2016/13:10	NEGATIVE		Yes
		Week 2	09MAR2016/10:50	NEGATIVE		No
		Week 4	22MAR2016/10:18	NEGATIVE		No
		Week 6	05APR2016/11:49	NEGATIVE		No
		Week 8	20APR2016/09:20	NEGATIVE		Yes
		Week 12	19MAY2016/11:58	NEGATIVE		No
		Week 16	14JUN2016/11:10	NEGATIVE		No
		Week 20	13JUL2016/11:25	NEGATIVE		No
		Week 24	10AUG2016/10:55	NEGATIVE		Yes
		Week 28	07SEP2016/11:35	NEGATIVE		No
		Week 32	05OCT2016/11:10	NEGATIVE		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Ketones	Week 36	02NOV2016/12:05	NEGATIVE		No
		Week 40	30NOV2016/11:00	NEGATIVE		No
		Week 44	22DEC2016/12:05	NEGATIVE		No
		Week 48	25JAN2017/11:05	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	27JAN2016/11:40	NOT SEEN		Yes
		Day 1	23FEB2016/13:10	NOT SEEN		Yes
		Week 2	09MAR2016/10:50	NOT SEEN		No
		Week 4	22MAR2016/10:18	NOT SEEN		No
		Week 6	05APR2016/11:49	NOT SEEN		No
		Week 8	20APR2016/09:20	NOT SEEN		Yes
		Week 12	19MAY2016/11:58	1 - 9 /HPF		No
		Week 16	14JUN2016/11:10	NOT SEEN		No
		Week 20	13JUL2016/11:25	NOT SEEN		No
		Week 24	10AUG2016/10:55	NOT SEEN		Yes
		Week 28	07SEP2016/11:35	NOT SEEN		No
		Week 32	05OCT2016/11:10	NOT SEEN		No
		Week 36	02NOV2016/12:05	NOT SEEN		No
		Week 40	30NOV2016/11:00	NOT SEEN		No
		Week 44	22DEC2016/12:05	NOT SEEN		No
		Week 48	25JAN2017/11:05	NOT SEEN		No
	Urine Nitrite	Screening	27JAN2016/11:40	NEGATIVE		Yes
		Day 1	23FEB2016/13:10	NEGATIVE		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Nitrite	Week 2	09MAR2016/10:50	NEGATIVE		No
		Week 4	22MAR2016/10:18	NEGATIVE		No
		Week 6	05APR2016/11:49	NEGATIVE		No
		Week 8	20APR2016/09:20	NEGATIVE		Yes
		Week 12	19MAY2016/11:58	NEGATIVE		No
		Week 16	14JUN2016/11:10	NEGATIVE		No
		Week 20	13JUL2016/11:25	NEGATIVE		No
		Week 24	10AUG2016/10:55	NEGATIVE		Yes
		Week 28	07SEP2016/11:35	NEGATIVE		No
		Week 32	05OCT2016/11:10	NEGATIVE		No
		Week 36	02NOV2016/12:05	NEGATIVE		No
		Week 40	30NOV2016/11:00	NEGATIVE		No
		Week 44	22DEC2016/12:05	NEGATIVE		No
		Week 48	25JAN2017/11:05	NEGATIVE		No
	Urine Organisms	Screening	27JAN2016/11:40	NOT SEEN		Yes
		Day 1	23FEB2016/13:10	NOT SEEN		Yes
		Week 2	09MAR2016/10:50	NOT SEEN		No
		Week 4	22MAR2016/10:18	NOT SEEN		No
		Week 6	05APR2016/11:49	NOT SEEN		No
		Week 8	20APR2016/09:20	NOT SEEN		Yes
		Week 12	19MAY2016/11:58	NOT SEEN		No
		Week 16	14JUN2016/11:10	NOT SEEN		No
		Week 20	13JUL2016/11:25	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Organisms	Week 24	10AUG2016/10:55	NOT SEEN		Yes
		Week 28	07SEP2016/11:35	NOT SEEN		No
		Week 32	05OCT2016/11:10	NOT SEEN		No
		Week 36	02NOV2016/12:05	NOT SEEN		No
		Week 40	30NOV2016/11:00	NOT SEEN		No
		Week 44	22DEC2016/12:05	NOT SEEN		No
		Week 48	25JAN2017/11:05	NOT SEEN		No
	Urine Protein	Screening	27JAN2016/11:40	NEGATIVE		Yes
		Day 1	23FEB2016/13:10	NEGATIVE		Yes
		Week 2	09MAR2016/10:50	NEGATIVE		No
		Week 4	22MAR2016/10:18	NEGATIVE		No
		Week 6	05APR2016/11:49	NEGATIVE		No
		Week 8	20APR2016/09:20	NEGATIVE		Yes
		Week 12	19MAY2016/11:58	NEGATIVE		No
		Week 16	14JUN2016/11:10	NEGATIVE		No
		Week 20	13JUL2016/11:25	NEGATIVE		No
		Week 24	10AUG2016/10:55	NEGATIVE		Yes
		Week 28	07SEP2016/11:35	TRACE		No
		Week 32	05OCT2016/11:10	NEGATIVE		No
		Week 36	02NOV2016/12:05	NEGATIVE		No
		Week 40	30NOV2016/11:00	NEGATIVE		No
		Week 44	22DEC2016/12:05	NEGATIVE		No
		Week 48	25JAN2017/11:05	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Specific Gravity	Screening	27JAN2016/11:40	1.008	1 - 1.03	Yes
		Day 1	23FEB2016/13:10	1.006	1 - 1.03	Yes
		Week 2	09MAR2016/10:50	1.004	1 - 1.03	No
		Week 4	22MAR2016/10:18	1.010	1 - 1.03	No
		Week 6	05APR2016/11:49	1.010	1 - 1.03	No
		Week 8	20APR2016/09:20	1.009	1 - 1.03	Yes
		Week 12	19MAY2016/11:58	1.012	1 - 1.03	No
		Week 16	14JUN2016/11:10	1.006	1 - 1.03	No
		Week 20	13JUL2016/11:25	1.012	1 - 1.03	No
		Week 24	10AUG2016/10:55	1.008	1 - 1.03	Yes
		Week 28	07SEP2016/11:35	1.021	1 - 1.03	No
		Week 32	05OCT2016/11:10	1.007	1 - 1.03	No
		Week 36	02NOV2016/12:05	1.015	1 - 1.03	No
		Week 40	30NOV2016/11:00	1.004	1 - 1.03	No
		Week 44	22DEC2016/12:05	1.009	1 - 1.03	No
		Week 48	25JAN2017/11:05	1.009	1 - 1.03	No
	Urine Urobilinogen	Screening	27JAN2016/11:40	NORMAL		Yes
		Day 1	23FEB2016/13:10	NORMAL		Yes
		Week 2	09MAR2016/10:50	NORMAL		No
		Week 4	22MAR2016/10:18	NORMAL		No
		Week 6	05APR2016/11:49	NORMAL		No
		Week 8	20APR2016/09:20	NORMAL		Yes
		Week 12	19MAY2016/11:58	NORMAL		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-014	Urine Urobilinogen	Week 16	14JUN2016/11:10	NORMAL		No
		Week 20	13JUL2016/11:25	NORMAL		No
		Week 24	10AUG2016/10:55	NORMAL		Yes
		Week 28	07SEP2016/11:35	NORMAL		No
		Week 32	05OCT2016/11:10	NORMAL		No
		Week 36	02NOV2016/12:05	NORMAL		No
		Week 40	30NOV2016/11:00	NORMAL		No
		Week 44	22DEC2016/12:05	NORMAL		No
		Week 48	25JAN2017/11:05	NORMAL		No
301-016	Urine Bilirubin	Screening	03FEB2016/13:00	NEGATIVE		Yes
		Day 1	25FEB2016/11:55	NEGATIVE		Yes
		Week 2	08MAR2016/11:02	NEGATIVE		No
		Week 4	24MAR2016/11:38	NEGATIVE		No
		Week 6	07APR2016/11:15	NEGATIVE		No
		Week 8	19APR2016/09:02	NEGATIVE		Yes
		Week 12	24MAY2016/12:00	NEGATIVE		No
		Week 16	14JUN2016/10:35	NEGATIVE		No
		Week 20	13JUL2016/11:55	NEGATIVE		No
		Week 24	28JUL2016/11:05	NEGATIVE		Yes
		Week 28	06SEP2016/10:15	NEGATIVE		No
		Week 32	05OCT2016/11:35	NEGATIVE		No
		Week 36	02NOV2016/11:50	NEGATIVE		No
		Week 40	29NOV2016/11:05	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Urine Bilirubin	Week 44	21DEC2016/11:40	NEGATIVE		No
		Week 48	24JAN2017/12:10	NEGATIVE		No
	Urine Blood	Screening	03FEB2016/13:00	NEGATIVE		Yes
		Day 1	25FEB2016/11:55	NEGATIVE		Yes
		Week 2	08MAR2016/11:02	NEGATIVE		No
		Week 4	24MAR2016/11:38	NEGATIVE		No
		Week 6	07APR2016/11:15	NEGATIVE		No
		Week 8	19APR2016/09:02	NEGATIVE		Yes
		Week 12	24MAY2016/12:00	NEGATIVE		No
		Week 16	14JUN2016/10:35	NEGATIVE		No
		Week 20	13JUL2016/11:55	NEGATIVE		No
		Week 24	28JUL2016/11:05	NEGATIVE		Yes
		Week 28	06SEP2016/10:15	NEGATIVE		No
		Week 32	05OCT2016/11:35	NEGATIVE		No
		Week 36	02NOV2016/11:50	NEGATIVE		No
		Week 40	29NOV2016/11:05	NEGATIVE		No
		Week 44	21DEC2016/11:40	NEGATIVE		No
		Week 48	24JAN2017/12:10	NEGATIVE		No
	Urine Cellular Casts	Screening	03FEB2016/13:00	NOT SEEN		Yes
		Day 1	25FEB2016/11:55	NOT SEEN		Yes
		Week 2	08MAR2016/11:02	NOT SEEN		No
		Week 4	24MAR2016/11:38	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Urine Cellular Casts	Week 6	07APR2016/11:15	NOT SEEN		No
		Week 8	19APR2016/09:02	NOT SEEN		Yes
		Week 12	24MAY2016/12:00	NOT SEEN		No
		Week 16	14JUN2016/10:35	NOT SEEN		No
		Week 20	13JUL2016/11:55	NOT SEEN		No
		Week 24	28JUL2016/11:05	NOT SEEN		Yes
		Week 28	06SEP2016/10:15	NOT SEEN		No
		Week 32	05OCT2016/11:35	NOT SEEN		No
		Week 36	02NOV2016/11:50	NOT SEEN		No
		Week 40	29NOV2016/11:05	NOT SEEN		No
		Week 44	21DEC2016/11:40	NOT SEEN		No
		Week 48	24JAN2017/12:10	NOT SEEN		No
	Urine Crystals	Screening	03FEB2016/13:00	NOT SEEN		Yes
		Day 1	25FEB2016/11:55	+++		Yes
		Week 2	08MAR2016/11:02	+		No
		Week 4	24MAR2016/11:38	NOT SEEN		No
		Week 6	07APR2016/11:15	NOT SEEN		No
		Week 8	19APR2016/09:02	NOT SEEN		Yes
		Week 12	24MAY2016/12:00	NOT SEEN		No
		Week 16	14JUN2016/10:35	NOT SEEN		No
		Week 20	13JUL2016/11:55	NOT SEEN		No
		Week 24	28JUL2016/11:05	NOT SEEN		Yes
		Week 28	06SEP2016/10:15	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Urine Crystals	Week 32	05OCT2016/11:35	NOT SEEN		No
		Week 36	02NOV2016/11:50	NOT SEEN		No
		Week 40	29NOV2016/11:05	NOT SEEN		No
		Week 44	21DEC2016/11:40	NOT SEEN		No
		Week 48	24JAN2017/12:10	NOT SEEN		No
	Urine Epithelial Cells	Screening	03FEB2016/13:00	NOT SEEN		Yes
		Day 1	25FEB2016/11:55	NOT SEEN		Yes
		Week 2	08MAR2016/11:02	NOT SEEN		No
		Week 4	24MAR2016/11:38	NOT SEEN		No
		Week 6	07APR2016/11:15	NOT SEEN		No
		Week 8	19APR2016/09:02	NOT SEEN		Yes
		Week 12	24MAY2016/12:00	NOT SEEN		No
		Week 16	14JUN2016/10:35	NOT SEEN		No
		Week 20	13JUL2016/11:55	NOT SEEN		No
		Week 24	28JUL2016/11:05	NOT SEEN		Yes
		Week 28	06SEP2016/10:15	NOT SEEN		No
		Week 32	05OCT2016/11:35	NOT SEEN		No
		Week 36	02NOV2016/11:50	NOT SEEN		No
		Week 40	29NOV2016/11:05	NOT SEEN		No
		Week 44	21DEC2016/11:40	NOT SEEN		No
		Week 48	24JAN2017/12:10	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	03FEB2016/13:00	NOT SEEN		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Urine Erythrocytes (/HPF)	Day 1	25FEB2016/11:55	1 - 9 /HPF		Yes
		Week 2	08MAR2016/11:02	NOT SEEN		No
		Week 4	24MAR2016/11:38	NOT SEEN		No
		Week 6	07APR2016/11:15	1 - 9 /HPF		No
		Week 8	19APR2016/09:02	NOT SEEN		Yes
		Week 12	24MAY2016/12:00	NOT SEEN		No
		Week 16	14JUN2016/10:35	NOT SEEN		No
		Week 20	13JUL2016/11:55	NOT SEEN		No
		Week 24	28JUL2016/11:05	1 - 9 /HPF		Yes
		Week 28	06SEP2016/10:15	NOT SEEN		No
		Week 32	05OCT2016/11:35	NOT SEEN		No
		Week 36	02NOV2016/11:50	NOT SEEN		No
		Week 40	29NOV2016/11:05	NOT SEEN		No
		Week 44	21DEC2016/11:40	NOT SEEN		No
		Week 48	24JAN2017/12:10	NOT SEEN		No
	Urine Granular Casts	Screening	03FEB2016/13:00	NOT SEEN		Yes
		Day 1	25FEB2016/11:55	NOT SEEN		Yes
		Week 2	08MAR2016/11:02	NOT SEEN		No
		Week 4	24MAR2016/11:38	NOT SEEN		No
		Week 6	07APR2016/11:15	NOT SEEN		No
		Week 8	19APR2016/09:02	NOT SEEN		Yes
		Week 12	24MAY2016/12:00	NOT SEEN		No
		Week 16	14JUN2016/10:35	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Urine Granular Casts	Week 20	13JUL2016/11:55	NOT SEEN		No
		Week 24	28JUL2016/11:05	NOT SEEN		Yes
		Week 28	06SEP2016/10:15	NOT SEEN		No
		Week 32	05OCT2016/11:35	NOT SEEN		No
		Week 36	02NOV2016/11:50	NOT SEEN		No
		Week 40	29NOV2016/11:05	NOT SEEN		No
		Week 44	21DEC2016/11:40	NOT SEEN		No
		Week 48	24JAN2017/12:10	NOT SEEN		No
	Urine Hyaline Casts	Screening	03FEB2016/13:00	NOT SEEN		Yes
		Day 1	25FEB2016/11:55	NOT SEEN		Yes
		Week 2	08MAR2016/11:02	NOT SEEN		No
		Week 4	24MAR2016/11:38	NOT SEEN		No
		Week 6	07APR2016/11:15	NOT SEEN		No
		Week 8	19APR2016/09:02	NOT SEEN		Yes
		Week 12	24MAY2016/12:00	NOT SEEN		No
		Week 16	14JUN2016/10:35	NOT SEEN		No
		Week 20	13JUL2016/11:55	NOT SEEN		No
		Week 24	28JUL2016/11:05	NOT SEEN		Yes
		Week 28	06SEP2016/10:15	NOT SEEN		No
		Week 32	05OCT2016/11:35	NOT SEEN		No
		Week 36	02NOV2016/11:50	NOT SEEN		No
		Week 40	29NOV2016/11:05	NOT SEEN		No
		Week 44	21DEC2016/11:40	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Urine Hyaline Casts	Week 48	24JAN2017/12:10	NOT SEEN		No
	Urine Ketones	Screening	03FEB2016/13:00	NEGATIVE		Yes
		Day 1	25FEB2016/11:55	NEGATIVE		Yes
		Week 2	08MAR2016/11:02	NEGATIVE		No
		Week 4	24MAR2016/11:38	NEGATIVE		No
		Week 6	07APR2016/11:15	NEGATIVE		No
		Week 8	19APR2016/09:02	NEGATIVE		Yes
		Week 12	24MAY2016/12:00	NEGATIVE		No
		Week 16	14JUN2016/10:35	NEGATIVE		No
		Week 20	13JUL2016/11:55	NEGATIVE		No
		Week 24	28JUL2016/11:05	NEGATIVE		Yes
		Week 28	06SEP2016/10:15	NEGATIVE		No
		Week 32	05OCT2016/11:35	NEGATIVE		No
		Week 36	02NOV2016/11:50	NEGATIVE		No
		Week 40	29NOV2016/11:05	NEGATIVE		No
		Week 44	21DEC2016/11:40	NEGATIVE		No
		Week 48	24JAN2017/12:10	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	03FEB2016/13:00	NOT SEEN		Yes
		Day 1	25FEB2016/11:55	10 - 50 /HPF		Yes
		Week 2	08MAR2016/11:02	NOT SEEN		No
		Week 4	24MAR2016/11:38	NOT SEEN		No
		Week 6	07APR2016/11:15	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Urine Leukocytes (/HPF)	Week 8	19APR2016/09:02	NOT SEEN		Yes
		Week 12	24MAY2016/12:00	1 - 9 /HPF		No
		Week 16	14JUN2016/10:35	NOT SEEN		No
		Week 20	13JUL2016/11:55	NOT SEEN		No
		Week 24	28JUL2016/11:05	1 - 9 /HPF		Yes
		Week 28	06SEP2016/10:15	NOT SEEN		No
		Week 32	05OCT2016/11:35	NOT SEEN		No
		Week 36	02NOV2016/11:50	NOT SEEN		No
		Week 40	29NOV2016/11:05	NOT SEEN		No
		Week 44	21DEC2016/11:40	1 - 9 /HPF		No
		Week 48	24JAN2017/12:10	NOT SEEN		No
	Urine Nitrite	Screening	03FEB2016/13:00	NEGATIVE		Yes
		Day 1	25FEB2016/11:55	NEGATIVE		Yes
		Week 2	08MAR2016/11:02	NEGATIVE		No
		Week 4	24MAR2016/11:38	NEGATIVE		No
		Week 6	07APR2016/11:15	NEGATIVE		No
		Week 8	19APR2016/09:02	NEGATIVE		Yes
		Week 12	24MAY2016/12:00	NEGATIVE		No
		Week 16	14JUN2016/10:35	NEGATIVE		No
		Week 20	13JUL2016/11:55	NEGATIVE		No
		Week 24	28JUL2016/11:05	NEGATIVE		Yes
		Week 28	06SEP2016/10:15	NEGATIVE		No
		Week 32	05OCT2016/11:35	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Urine Nitrite	Week 36	02NOV2016/11:50	NEGATIVE		No
		Week 40	29NOV2016/11:05	NEGATIVE		No
		Week 44	21DEC2016/11:40	NEGATIVE		No
		Week 48	24JAN2017/12:10	NEGATIVE		No
	Urine Organisms	Screening	03FEB2016/13:00	NOT SEEN		Yes
		Day 1	25FEB2016/11:55	NOT SEEN		Yes
		Week 2	08MAR2016/11:02	NOT SEEN		No
		Week 4	24MAR2016/11:38	NOT SEEN		No
		Week 6	07APR2016/11:15	NOT SEEN		No
		Week 8	19APR2016/09:02	NOT SEEN		Yes
		Week 12	24MAY2016/12:00	NOT SEEN		No
		Week 16	14JUN2016/10:35	NOT SEEN		No
		Week 20	13JUL2016/11:55	NOT SEEN		No
		Week 24	28JUL2016/11:05	NOT SEEN		Yes
		Week 28	06SEP2016/10:15	NOT SEEN		No
		Week 32	05OCT2016/11:35	NOT SEEN		No
		Week 36	02NOV2016/11:50	NOT SEEN		No
		Week 40	29NOV2016/11:05	NOT SEEN		No
		Week 44	21DEC2016/11:40	NOT SEEN		No
		Week 48	24JAN2017/12:10	++		No
	Urine Protein	Screening	03FEB2016/13:00	NEGATIVE		Yes
		Day 1	25FEB2016/11:55	NEGATIVE		Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016 Urine Protein	Week 2	08MAR2016/11:02	NEGATIVE		No
	Week 4	24MAR2016/11:38	NEGATIVE		No
	Week 6	07APR2016/11:15	NEGATIVE		No
	Week 8	19APR2016/09:02	NEGATIVE		Yes
	Week 12	24MAY2016/12:00	NEGATIVE		No
	Week 16	14JUN2016/10:35	TRACE		No
	Week 20	13JUL2016/11:55	TRACE		No
	Week 24	28JUL2016/11:05	NEGATIVE		Yes
	Week 28	06SEP2016/10:15	NEGATIVE		No
	Week 32	05OCT2016/11:35	NEGATIVE		No
	Week 36	02NOV2016/11:50	NEGATIVE		No
	Week 40	29NOV2016/11:05	NEGATIVE		No
	Week 44	21DEC2016/11:40	NEGATIVE		No
	Week 48	24JAN2017/12:10	NEGATIVE		No
Urine Specific Gravity	Screening	03FEB2016/13:00	1.018	1 - 1.03	Yes
	Day 1	25FEB2016/11:55	1.017	1 - 1.03	Yes
	Week 2	08MAR2016/11:02	1.014	1 - 1.03	No
	Week 4	24MAR2016/11:38	1.008	1 - 1.03	No
	Week 6	07APR2016/11:15	1.013	1 - 1.03	No
	Week 8	19APR2016/09:02	1.010	1 - 1.03	Yes
	Week 12	24MAY2016/12:00	1.016	1 - 1.03	No
	Week 16	14JUN2016/10:35	1.022	1 - 1.03	No
	Week 20	13JUL2016/11:55	1.022	1 - 1.03	No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-016	Urine Specific Gravity	Week 24	28JUL2016/11:05	1.015	1 - 1.03	Yes
		Week 28	06SEP2016/10:15	1.014	1 - 1.03	No
		Week 32	05OCT2016/11:35	1.017	1 - 1.03	No
		Week 36	02NOV2016/11:50	1.011	1 - 1.03	No
		Week 40	29NOV2016/11:05	1.014	1 - 1.03	No
		Week 44	21DEC2016/11:40	1.018	1 - 1.03	No
		Week 48	24JAN2017/12:10	1.018	1 - 1.03	No
	Urine Urobilinogen	Screening	03FEB2016/13:00	NORMAL		Yes
		Day 1	25FEB2016/11:55	NORMAL		Yes
		Week 2	08MAR2016/11:02	NORMAL		No
		Week 4	24MAR2016/11:38	NORMAL		No
		Week 6	07APR2016/11:15	NORMAL		No
		Week 8	19APR2016/09:02	NORMAL		Yes
		Week 12	24MAY2016/12:00	NORMAL		No
		Week 16	14JUN2016/10:35	NORMAL		No
		Week 20	13JUL2016/11:55	NORMAL		No
		Week 24	28JUL2016/11:05	NORMAL		Yes
		Week 28	06SEP2016/10:15	NORMAL		No
		Week 32	05OCT2016/11:35	NORMAL		No
		Week 36	02NOV2016/11:50	NORMAL		No
		Week 40	29NOV2016/11:05	NORMAL		No
		Week 44	21DEC2016/11:40	NORMAL		No
		Week 48	24JAN2017/12:10	NORMAL		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Urine Bilirubin	Screening	02FEB2016/11:00	NEGATIVE		Yes
		Day 1	23FEB2016/13:50	NEGATIVE		Yes
		Week 2	08MAR2016/10:12	NEGATIVE		No
		Week 4	23MAR2016/11:34	NEGATIVE		No
		Week 6	06APR2016/11:50	NEGATIVE		No
		Week 8	20APR2016/09:05	NEGATIVE		Yes
		Week 12	17MAY2016/12:00	NEGATIVE		No
		Week 16	16JUN2016/12:55	NEGATIVE		No
		Week 20	14JUL2016/11:55	NEGATIVE		No
		Week 24	10AUG2016/10:25	NEGATIVE		Yes
		Week 28	07SEP2016/09:50	NEGATIVE		No
		Week 40	30NOV2016/10:00	NEGATIVE		No
		Week 44	28DEC2016/11:15	NEGATIVE		No
		Week 48	26JAN2017/12:50	NEGATIVE		No
	Urine Blood	Screening	02FEB2016/11:00	NEGATIVE		Yes
		Day 1	23FEB2016/13:50	NEGATIVE		Yes
		Week 2	08MAR2016/10:12	NEGATIVE		No
		Week 4	23MAR2016/11:34	NEGATIVE		No
		Week 6	06APR2016/11:50	NEGATIVE		No
		Week 8	20APR2016/09:05	NEGATIVE		Yes
		Week 12	17MAY2016/12:00	NEGATIVE		No
		Week 16	16JUN2016/12:55	NEGATIVE		No
		Week 20	14JUL2016/11:55	NEGATIVE		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Urine Blood	Week 24	10AUG2016/10:25	NEGATIVE		Yes
		Week 28	07SEP2016/09:50	NEGATIVE		No
		Week 40	30NOV2016/10:00	NEGATIVE		No
		Week 44	28DEC2016/11:15	NEGATIVE		No
		Week 48	26JAN2017/12:50	NEGATIVE		No
	Urine Cellular Casts	Screening	02FEB2016/11:00	NOT SEEN		Yes
		Day 1	23FEB2016/13:50	NOT SEEN		Yes
		Week 2	08MAR2016/10:12	NOT SEEN		No
		Week 4	23MAR2016/11:34	NOT SEEN		No
		Week 6	06APR2016/11:50	NOT SEEN		No
		Week 8	20APR2016/09:05	NOT SEEN		Yes
		Week 12	17MAY2016/12:00	NOT SEEN		No
		Week 16	16JUN2016/12:55	NOT SEEN		No
		Week 20	14JUL2016/11:55	NOT SEEN		No
		Week 24	10AUG2016/10:25	NOT SEEN		Yes
		Week 28	07SEP2016/09:50	NOT SEEN		No
		Week 40	30NOV2016/10:00	NOT SEEN		No
		Week 44	28DEC2016/11:15	NOT SEEN		No
		Week 48	26JAN2017/12:50	NOT SEEN		No
	Urine Crystals	Screening	02FEB2016/11:00	NOT SEEN		Yes
		Day 1	23FEB2016/13:50	NOT SEEN		Yes
		Week 2	08MAR2016/10:12	++		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Urine Crystals	Week 4	23MAR2016/11:34	NOT SEEN		No
		Week 6	06APR2016/11:50	+		No
		Week 8	20APR2016/09:05	+		Yes
		Week 12	17MAY2016/12:00	NOT SEEN		No
		Week 16	16JUN2016/12:55	NOT SEEN		No
		Week 20	14JUL2016/11:55	NOT SEEN		No
		Week 24	10AUG2016/10:25	NOT SEEN		Yes
		Week 28	07SEP2016/09:50	NOT SEEN		No
		Week 40	30NOV2016/10:00	NOT SEEN		No
		Week 44	28DEC2016/11:15	NOT SEEN		No
		Week 48	26JAN2017/12:50	NOT SEEN		No
	Urine Epithelial Cells	Screening	02FEB2016/11:00	NOT SEEN		Yes
		Day 1	23FEB2016/13:50	NOT SEEN		Yes
		Week 2	08MAR2016/10:12	NOT SEEN		No
		Week 4	23MAR2016/11:34	NOT SEEN		No
		Week 6	06APR2016/11:50	NOT SEEN		No
		Week 8	20APR2016/09:05	NOT SEEN		Yes
		Week 12	17MAY2016/12:00	NOT SEEN		No
		Week 16	16JUN2016/12:55	NOT SEEN		No
		Week 20	14JUL2016/11:55	NOT SEEN		No
		Week 24	10AUG2016/10:25	NOT SEEN		Yes
		Week 28	07SEP2016/09:50	NOT SEEN		No
		Week 40	30NOV2016/10:00	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Urine Epithelial Cells	Week 44	28DEC2016/11:15	NOT SEEN		No
		Week 48	26JAN2017/12:50	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	02FEB2016/11:00	NOT SEEN		Yes
		Day 1	23FEB2016/13:50	NOT SEEN		Yes
		Week 2	08MAR2016/10:12	NOT SEEN		No
		Week 4	23MAR2016/11:34	1 - 9 /HPF		No
		Week 6	06APR2016/11:50	> 100 /HPF		No
		Week 8	20APR2016/09:05	10 - 50 /HPF		Yes
		Week 12	17MAY2016/12:00	1 - 9 /HPF		No
		Week 16	16JUN2016/12:55	NOT SEEN		No
		Week 20	14JUL2016/11:55	NOT SEEN		No
		Week 24	10AUG2016/10:25	1 - 9 /HPF		Yes
		Week 28	07SEP2016/09:50	NOT SEEN		No
		Week 40	30NOV2016/10:00	NOT SEEN		No
		Week 44	28DEC2016/11:15	NOT SEEN		No
		Week 48	26JAN2017/12:50	NOT SEEN		No
	Urine Granular Casts	Screening	02FEB2016/11:00	NOT SEEN		Yes
		Day 1	23FEB2016/13:50	NOT SEEN		Yes
		Week 2	08MAR2016/10:12	NOT SEEN		No
		Week 4	23MAR2016/11:34	NOT SEEN		No
		Week 6	06APR2016/11:50	NOT SEEN		No
		Week 8	20APR2016/09:05	NOT SEEN		Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Urine Granular Casts	Week 12	17MAY2016/12:00	NOT SEEN		No
		Week 16	16JUN2016/12:55	NOT SEEN		No
		Week 20	14JUL2016/11:55	NOT SEEN		No
		Week 24	10AUG2016/10:25	NOT SEEN		Yes
		Week 28	07SEP2016/09:50	NOT SEEN		No
		Week 40	30NOV2016/10:00	NOT SEEN		No
		Week 44	28DEC2016/11:15	NOT SEEN		No
		Week 48	26JAN2017/12:50	NOT SEEN		No
	Urine Hyaline Casts	Screening	02FEB2016/11:00	NOT SEEN		Yes
		Day 1	23FEB2016/13:50	NOT SEEN		Yes
		Week 2	08MAR2016/10:12	NOT SEEN		No
		Week 4	23MAR2016/11:34	NOT SEEN		No
		Week 6	06APR2016/11:50	NOT SEEN		No
		Week 8	20APR2016/09:05	NOT SEEN		Yes
		Week 12	17MAY2016/12:00	NOT SEEN		No
		Week 16	16JUN2016/12:55	NOT SEEN		No
		Week 20	14JUL2016/11:55	NOT SEEN		No
		Week 24	10AUG2016/10:25	NOT SEEN		Yes
		Week 28	07SEP2016/09:50	NOT SEEN		No
		Week 40	30NOV2016/10:00	NOT SEEN		No
		Week 44	28DEC2016/11:15	NOT SEEN		No
		Week 48	26JAN2017/12:50	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015 Urine Ketones	Screening	02FEB2016/11:00	NEGATIVE		Yes
	Day 1	23FEB2016/13:50	NEGATIVE		Yes
	Week 2	08MAR2016/10:12	NEGATIVE		No
	Week 4	23MAR2016/11:34	NEGATIVE		No
	Week 6	06APR2016/11:50	NEGATIVE		No
	Week 8	20APR2016/09:05	NEGATIVE		Yes
	Week 12	17MAY2016/12:00	NEGATIVE		No
	Week 16	16JUN2016/12:55	NEGATIVE		No
	Week 20	14JUL2016/11:55	NEGATIVE		No
	Week 24	10AUG2016/10:25	NEGATIVE		Yes
	Week 28	07SEP2016/09:50	NEGATIVE		No
	Week 40	30NOV2016/10:00	NEGATIVE		No
	Week 44	28DEC2016/11:15	NEGATIVE		No
	Week 48	26JAN2017/12:50	NEGATIVE		No
Urine Leukocytes (/HPF)	Screening	02FEB2016/11:00	1 - 9 /HPF		Yes
	Day 1	23FEB2016/13:50	1 - 9 /HPF		Yes
	Week 2	08MAR2016/10:12	NOT SEEN		No
	Week 4	23MAR2016/11:34	1 - 9 /HPF		No
	Week 6	06APR2016/11:50	10 - 50 /HPF		No
	Week 8	20APR2016/09:05	1 - 9 /HPF		Yes
	Week 12	17MAY2016/12:00	NOT SEEN		No
	Week 16	16JUN2016/12:55	1 - 9 /HPF		No
	Week 20	14JUL2016/11:55	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Urine Leukocytes (/HPF)	Week 24	10AUG2016/10:25	1 - 9 /HPF		Yes
		Week 28	07SEP2016/09:50	NOT SEEN		No
		Week 40	30NOV2016/10:00	NOT SEEN		No
		Week 44	28DEC2016/11:15	NOT SEEN		No
		Week 48	26JAN2017/12:50	NOT SEEN		No
	Urine Nitrite	Screening	02FEB2016/11:00	NEGATIVE		Yes
		Day 1	23FEB2016/13:50	NEGATIVE		Yes
		Week 2	08MAR2016/10:12	NEGATIVE		No
		Week 4	23MAR2016/11:34	NEGATIVE		No
		Week 6	06APR2016/11:50	NEGATIVE		No
		Week 8	20APR2016/09:05	NEGATIVE		Yes
		Week 12	17MAY2016/12:00	NEGATIVE		No
		Week 16	16JUN2016/12:55	NEGATIVE		No
		Week 20	14JUL2016/11:55	NEGATIVE		No
		Week 24	10AUG2016/10:25	NEGATIVE		Yes
		Week 28	07SEP2016/09:50	NEGATIVE		No
		Week 40	30NOV2016/10:00	NEGATIVE		No
		Week 44	28DEC2016/11:15	NEGATIVE		No
		Week 48	26JAN2017/12:50	NEGATIVE		No
	Urine Organisms	Screening	02FEB2016/11:00	NOT SEEN		Yes
		Day 1	23FEB2016/13:50	NOT SEEN		Yes
		Week 2	08MAR2016/10:12	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Urine Organisms	Week 4	23MAR2016/11:34	NOT SEEN		No
		Week 6	06APR2016/11:50	NOT SEEN		No
		Week 8	20APR2016/09:05	NOT SEEN		Yes
		Week 12	17MAY2016/12:00	NOT SEEN		No
		Week 16	16JUN2016/12:55	NOT SEEN		No
		Week 20	14JUL2016/11:55	NOT SEEN		No
		Week 24	10AUG2016/10:25	NOT SEEN		Yes
		Week 28	07SEP2016/09:50	NOT SEEN		No
		Week 40	30NOV2016/10:00	NOT SEEN		No
		Week 44	28DEC2016/11:15	NOT SEEN		No
		Week 48	26JAN2017/12:50	NOT SEEN		No
	Urine Protein	Screening	02FEB2016/11:00	NEGATIVE		Yes
		Day 1	23FEB2016/13:50	NEGATIVE		Yes
		Week 2	08MAR2016/10:12	NEGATIVE		No
		Week 4	23MAR2016/11:34	NEGATIVE		No
		Week 6	06APR2016/11:50	NEGATIVE		No
		Week 8	20APR2016/09:05	NEGATIVE		Yes
		Week 12	17MAY2016/12:00	TRACE		No
		Week 16	16JUN2016/12:55	TRACE		No
		Week 20	14JUL2016/11:55	NEGATIVE		No
		Week 24	10AUG2016/10:25	NEGATIVE		Yes
		Week 28	07SEP2016/09:50	NEGATIVE		No
		Week 40	30NOV2016/10:00	NEGATIVE		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-015	Urine Protein	Week 44	28DEC2016/11:15	NEGATIVE		No
		Week 48	26JAN2017/12:50	NEGATIVE		No
	Urine Specific Gravity	Screening	02FEB2016/11:00	1.010	1 - 1.03	Yes
		Day 1	23FEB2016/13:50	1.013	1 - 1.03	Yes
		Week 2	08MAR2016/10:12	1.020	1 - 1.03	No
		Week 4	23MAR2016/11:34	1.016	1 - 1.03	No
		Week 6	06APR2016/11:50	1.021	1 - 1.03	No
		Week 8	20APR2016/09:05	1.019	1 - 1.03	Yes
		Week 12	17MAY2016/12:00	1.021	1 - 1.03	No
		Week 16	16JUN2016/12:55	1.020	1 - 1.03	No
		Week 20	14JUL2016/11:55	1.014	1 - 1.03	No
		Week 24	10AUG2016/10:25	1.017	1 - 1.03	Yes
		Week 28	07SEP2016/09:50	1.011	1 - 1.03	No
		Week 40	30NOV2016/10:00	1.011	1 - 1.03	No
		Week 44	28DEC2016/11:15	1.013	1 - 1.03	No
		Week 48	26JAN2017/12:50	1.006	1 - 1.03	No
	Urine Urobilinogen	Screening	02FEB2016/11:00	NORMAL		Yes
		Day 1	23FEB2016/13:50	NORMAL		Yes
		Week 2	08MAR2016/10:12	++ (82.5 UMOL/L)		No
		Week 4	23MAR2016/11:34	NORMAL		No
		Week 6	06APR2016/11:50	NORMAL		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-015	Urine Urobilinogen	Week 8	20APR2016/09:05	NORMAL		Yes	
		Week 12	17MAY2016/12:00	NORMAL		No	
		Week 16	16JUN2016/12:55	+ (41.3 UMOL/L)		No	
		Week 20	14JUL2016/11:55	NORMAL		No	
		Week 24	10AUG2016/10:25	NORMAL		Yes	
		Week 28	07SEP2016/09:50	NORMAL		No	
		Week 40	30NOV2016/10:00	NORMAL		No	
		Week 44	28DEC2016/11:15	NORMAL		No	
		Week 48	26JAN2017/12:50	NORMAL		No	
301-018	Urine Bilirubin	Screening	17FEB2016/14:50	NEGATIVE		Yes	
		Day 1	09MAR2016/10:20	NEGATIVE		Yes	
		Week 2	23MAR2016/09:37	NEGATIVE		No	
		Week 4	06APR2016/10:12	NEGATIVE		No	
		Week 6	21APR2016/10:22	NEGATIVE		No	
		Week 8	28APR2016/09:50	NEGATIVE		No	
		Week 12	01JUN2016/08:42	NEGATIVE		Yes	
		Week 16	29JUN2016/09:50	NEGATIVE		No	
		Week 20	27JUL2016/09:55	NEGATIVE		No	
		Week 24	23AUG2016/10:05	NEGATIVE		Yes	
		Week 28	20SEP2016/11:35	NEGATIVE		No	
		Week 32	18OCT2016/11:05	NEGATIVE		No	
		Week 36	15NOV2016/12:05	NEGATIVE		No	

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Bilirubin	Week 40	14DEC2016/12:05	NEGATIVE		No
		Week 44	10JAN2017/11:40	NEGATIVE		No
		Week 48	07FEB2017/10:35	NEGATIVE		No
	Urine Blood	Screening	17FEB2016/14:50	NEGATIVE		Yes
		Day 1	09MAR2016/10:20	NEGATIVE		Yes
		Week 2	23MAR2016/09:37	NEGATIVE		No
		Week 4	06APR2016/10:12	NEGATIVE		No
		Week 6	21APR2016/10:22	NEGATIVE		No
		Week 8	28APR2016/09:50	NEGATIVE		No
		Week 12	01JUN2016/08:42	NEGATIVE		Yes
		Week 16	29JUN2016/09:50	NEGATIVE		No
		Week 20	27JUL2016/09:55	NEGATIVE		No
		Week 24	23AUG2016/10:05	NEGATIVE		Yes
		Week 28	20SEP2016/11:35	NEGATIVE		No
		Week 32	18OCT2016/11:05	NEGATIVE		No
		Week 36	15NOV2016/12:05	NEGATIVE		No
		Week 40	14DEC2016/12:05	NEGATIVE		No
		Week 44	10JAN2017/11:40	NEGATIVE		No
		Week 48	07FEB2017/10:35	NEGATIVE		No
	Urine Cellular Casts	Screening	17FEB2016/14:50	NOT SEEN		Yes
		Day 1	09MAR2016/10:20	NOT SEEN		Yes
		Week 2	23MAR2016/09:37	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Cellular Casts	Week 4	06APR2016/10:12	NOT SEEN		No
		Week 6	21APR2016/10:22	NOT SEEN		No
		Week 8	28APR2016/09:50	NOT SEEN		No
		Week 12	01JUN2016/08:42	NOT SEEN		Yes
		Week 16	29JUN2016/09:50	NOT SEEN		No
		Week 20	27JUL2016/09:55	NOT SEEN		No
		Week 24	23AUG2016/10:05	NOT SEEN		Yes
		Week 28	20SEP2016/11:35	NOT SEEN		No
		Week 32	18OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/12:05	NOT SEEN		No
		Week 40	14DEC2016/12:05	NOT SEEN		No
		Week 44	10JAN2017/11:40	NOT SEEN		No
		Week 48	07FEB2017/10:35	NOT SEEN		No
	Urine Crystals	Screening	17FEB2016/14:50	NOT SEEN		Yes
		Day 1	09MAR2016/10:20	NOT SEEN		Yes
		Week 2	23MAR2016/09:37	NOT SEEN		No
		Week 4	06APR2016/10:12	NOT SEEN		No
		Week 6	21APR2016/10:22	NOT SEEN		No
		Week 8	28APR2016/09:50	NOT SEEN		No
		Week 12	01JUN2016/08:42	NOT SEEN		Yes
		Week 16	29JUN2016/09:50	NOT SEEN		No
		Week 20	27JUL2016/09:55	NOT SEEN		No
		Week 24	23AUG2016/10:05	NOT SEEN		Yes

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Crystals	Week 28	20SEP2016/11:35	NOT SEEN		No
		Week 32	18OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/12:05	NOT SEEN		No
		Week 40	14DEC2016/12:05	NOT SEEN		No
		Week 44	10JAN2017/11:40	NOT SEEN		No
		Week 48	07FEB2017/10:35	NOT SEEN		No
	Urine Epithelial Cells	Screening	17FEB2016/14:50	NOT SEEN		Yes
		Day 1	09MAR2016/10:20	NOT SEEN		Yes
		Week 2	23MAR2016/09:37	NOT SEEN		No
		Week 4	06APR2016/10:12	NOT SEEN		No
		Week 6	21APR2016/10:22	NOT SEEN		No
		Week 8	28APR2016/09:50	NOT SEEN		No
		Week 12	01JUN2016/08:42	NOT SEEN		Yes
		Week 16	29JUN2016/09:50	NOT SEEN		No
		Week 20	27JUL2016/09:55	NOT SEEN		No
		Week 24	23AUG2016/10:05	NOT SEEN		Yes
		Week 28	20SEP2016/11:35	NOT SEEN		No
		Week 32	18OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/12:05	NOT SEEN		No
		Week 40	14DEC2016/12:05	NOT SEEN		No
		Week 44	10JAN2017/11:40	NOT SEEN		No
		Week 48	07FEB2017/10:35	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Erythrocytes (/HPF)	Screening	17FEB2016/14:50	NOT SEEN		Yes
		Day 1	09MAR2016/10:20	NOT SEEN		Yes
		Week 2	23MAR2016/09:37	1 - 9 /HPF		No
		Week 4	06APR2016/10:12	NOT SEEN		No
		Week 6	21APR2016/10:22	1 - 9 /HPF		No
		Week 8	28APR2016/09:50	1 - 9 /HPF		No
		Week 12	01JUN2016/08:42	NOT SEEN		Yes
		Week 16	29JUN2016/09:50	NOT SEEN		No
		Week 20	27JUL2016/09:55	> 100 /HPF		No
		Week 24	23AUG2016/10:05	NOT SEEN		Yes
		Week 28	20SEP2016/11:35	NOT SEEN		No
		Week 32	18OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/12:05	NOT SEEN		No
		Week 40	14DEC2016/12:05	NOT SEEN		No
		Week 44	10JAN2017/11:40	NOT SEEN		No
		Week 48	07FEB2017/10:35	10 - 50 /HPF		No
	Urine Granular Casts	Screening	17FEB2016/14:50	NOT SEEN		Yes
		Day 1	09MAR2016/10:20	NOT SEEN		Yes
		Week 2	23MAR2016/09:37	NOT SEEN		No
		Week 4	06APR2016/10:12	NOT SEEN		No
		Week 6	21APR2016/10:22	NOT SEEN		No
		Week 8	28APR2016/09:50	NOT SEEN		No
		Week 12	01JUN2016/08:42	NOT SEEN		Yes

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Granular Casts	Week 16	29JUN2016/09:50	NOT SEEN		No
		Week 20	27JUL2016/09:55	NOT SEEN		No
		Week 24	23AUG2016/10:05	NOT SEEN		Yes
		Week 28	20SEP2016/11:35	NOT SEEN		No
		Week 32	18OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/12:05	NOT SEEN		No
		Week 40	14DEC2016/12:05	NOT SEEN		No
		Week 44	10JAN2017/11:40	NOT SEEN		No
		Week 48	07FEB2017/10:35	NOT SEEN		No
	Urine Hyaline Casts	Screening	17FEB2016/14:50	NOT SEEN		Yes
		Day 1	09MAR2016/10:20	NOT SEEN		Yes
		Week 2	23MAR2016/09:37	NOT SEEN		No
		Week 4	06APR2016/10:12	NOT SEEN		No
		Week 6	21APR2016/10:22	NOT SEEN		No
		Week 8	28APR2016/09:50	NOT SEEN		No
		Week 12	01JUN2016/08:42	NOT SEEN		Yes
		Week 16	29JUN2016/09:50	NOT SEEN		No
		Week 20	27JUL2016/09:55	NOT SEEN		No
		Week 24	23AUG2016/10:05	NOT SEEN		Yes
		Week 28	20SEP2016/11:35	NOT SEEN		No
		Week 32	18OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/12:05	NOT SEEN		No
		Week 40	14DEC2016/12:05	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Hyaline Casts	Week 44	10JAN2017/11:40	NOT SEEN		No
		Week 48	07FEB2017/10:35	NOT SEEN		No
	Urine Ketones	Screening	17FEB2016/14:50	NEGATIVE		Yes
		Day 1	09MAR2016/10:20	NEGATIVE		Yes
		Week 2	23MAR2016/09:37	NEGATIVE		No
		Week 4	06APR2016/10:12	NEGATIVE		No
		Week 6	21APR2016/10:22	NEGATIVE		No
		Week 8	28APR2016/09:50	NEGATIVE		No
		Week 12	01JUN2016/08:42	NEGATIVE		Yes
		Week 16	29JUN2016/09:50	NEGATIVE		No
		Week 20	27JUL2016/09:55	NEGATIVE		No
		Week 24	23AUG2016/10:05	NEGATIVE		Yes
		Week 28	20SEP2016/11:35	NEGATIVE		No
		Week 32	18OCT2016/11:05	NEGATIVE		No
		Week 36	15NOV2016/12:05	NEGATIVE		No
		Week 40	14DEC2016/12:05	NEGATIVE		No
		Week 44	10JAN2017/11:40	NEGATIVE		No
		Week 48	07FEB2017/10:35	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	17FEB2016/14:50	NOT SEEN		Yes
		Day 1	09MAR2016/10:20	NOT SEEN		Yes
		Week 2	23MAR2016/09:37	NOT SEEN		No
		Week 4	06APR2016/10:12	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Leukocytes (/HPF)	Week 6	21APR2016/10:22	1 - 9 /HPF		No
		Week 8	28APR2016/09:50	NOT SEEN		No
		Week 12	01JUN2016/08:42	NOT SEEN		Yes
		Week 16	29JUN2016/09:50	NOT SEEN		No
		Week 20	27JUL2016/09:55	1 - 9 /HPF		No
		Week 24	23AUG2016/10:05	NOT SEEN		Yes
		Week 28	20SEP2016/11:35	NOT SEEN		No
		Week 32	18OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/12:05	NOT SEEN		No
		Week 40	14DEC2016/12:05	NOT SEEN		No
		Week 44	10JAN2017/11:40	NOT SEEN		No
		Week 48	07FEB2017/10:35	NOT SEEN		No
	Urine Nitrite	Screening	17FEB2016/14:50	NEGATIVE		Yes
		Day 1	09MAR2016/10:20	NEGATIVE		Yes
		Week 2	23MAR2016/09:37	NEGATIVE		No
		Week 4	06APR2016/10:12	NEGATIVE		No
		Week 6	21APR2016/10:22	NEGATIVE		No
		Week 8	28APR2016/09:50	NEGATIVE		No
		Week 12	01JUN2016/08:42	NEGATIVE		Yes
		Week 16	29JUN2016/09:50	NEGATIVE		No
		Week 20	27JUL2016/09:55	NEGATIVE		No
		Week 24	23AUG2016/10:05	NEGATIVE		Yes
		Week 28	20SEP2016/11:35	NEGATIVE		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Nitrite	Week 32	18OCT2016/11:05	NEGATIVE		No
		Week 36	15NOV2016/12:05	NEGATIVE		No
		Week 40	14DEC2016/12:05	NEGATIVE		No
		Week 44	10JAN2017/11:40	NEGATIVE		No
		Week 48	07FEB2017/10:35	NEGATIVE		No
	Urine Organisms	Screening	17FEB2016/14:50	NOT SEEN		Yes
		Day 1	09MAR2016/10:20	NOT SEEN		Yes
		Week 2	23MAR2016/09:37	NOT SEEN		No
		Week 4	06APR2016/10:12	NOT SEEN		No
		Week 6	21APR2016/10:22	NOT SEEN		No
		Week 8	28APR2016/09:50	NOT SEEN		No
		Week 12	01JUN2016/08:42	NOT SEEN		Yes
		Week 16	29JUN2016/09:50	NOT SEEN		No
		Week 20	27JUL2016/09:55	NOT SEEN		No
		Week 24	23AUG2016/10:05	NOT SEEN		Yes
		Week 28	20SEP2016/11:35	NOT SEEN		No
		Week 32	18OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/12:05	NOT SEEN		No
		Week 40	14DEC2016/12:05	NOT SEEN		No
		Week 44	10JAN2017/11:40	NOT SEEN		No
		Week 48	07FEB2017/10:35	NOT SEEN		No
	Urine Protein	Screening	17FEB2016/14:50	NEGATIVE		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Protein	Day 1	09MAR2016/10:20	NEGATIVE		Yes
		Week 2	23MAR2016/09:37	NEGATIVE		No
		Week 4	06APR2016/10:12	NEGATIVE		No
		Week 6	21APR2016/10:22	NEGATIVE		No
		Week 8	28APR2016/09:50	NEGATIVE		No
		Week 12	01JUN2016/08:42	NEGATIVE		Yes
		Week 16	29JUN2016/09:50	NEGATIVE		No
		Week 20	27JUL2016/09:55	NEGATIVE		No
		Week 24	23AUG2016/10:05	NEGATIVE		Yes
		Week 28	20SEP2016/11:35	NEGATIVE		No
		Week 32	18OCT2016/11:05	NEGATIVE		No
		Week 36	15NOV2016/12:05	NEGATIVE		No
		Week 40	14DEC2016/12:05	NEGATIVE		No
		Week 44	10JAN2017/11:40	NEGATIVE		No
		Week 48	07FEB2017/10:35	NEGATIVE		No
	Urine Specific Gravity	Screening	17FEB2016/14:50	1.011	1 - 1.03	Yes
		Day 1	09MAR2016/10:20	1.016	1 - 1.03	Yes
		Week 2	23MAR2016/09:37	1.021	1 - 1.03	No
		Week 4	06APR2016/10:12	1.021	1 - 1.03	No
		Week 6	21APR2016/10:22	1.019	1 - 1.03	No
		Week 8	28APR2016/09:50	1.007	1 - 1.03	No
		Week 12	01JUN2016/08:42	1.005	1 - 1.03	Yes
		Week 16	29JUN2016/09:50	1.018	1 - 1.03	No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Specific Gravity	Week 20	27JUL2016/09:55	1.017	1 - 1.03	No
		Week 24	23AUG2016/10:05	1.017	1 - 1.03	Yes
		Week 28	20SEP2016/11:35	1.007	1 - 1.03	No
		Week 32	18OCT2016/11:05	1.020	1 - 1.03	No
		Week 36	15NOV2016/12:05	1.008	1 - 1.03	No
		Week 40	14DEC2016/12:05	1.010	1 - 1.03	No
		Week 44	10JAN2017/11:40	1.009	1 - 1.03	No
		Week 48	07FEB2017/10:35	1.024	1 - 1.03	No
	Urine Urobilinogen	Screening	17FEB2016/14:50	NORMAL		Yes
		Day 1	09MAR2016/10:20	NORMAL		Yes
		Week 2	23MAR2016/09:37	NORMAL		No
		Week 4	06APR2016/10:12	NORMAL		No
		Week 6	21APR2016/10:22	NORMAL		No
		Week 8	28APR2016/09:50	NORMAL		No
		Week 12	01JUN2016/08:42	NORMAL		Yes
		Week 16	29JUN2016/09:50	NORMAL		No
		Week 20	27JUL2016/09:55	NORMAL		No
		Week 24	23AUG2016/10:05	NORMAL		Yes
		Week 28	20SEP2016/11:35	NORMAL		No
		Week 32	18OCT2016/11:05	NORMAL		No
		Week 36	15NOV2016/12:05	NORMAL		No
		Week 40	14DEC2016/12:05	NORMAL		No
		Week 44	10JAN2017/11:40	NORMAL		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-018	Urine Urobilinogen	Week 48	07FEB2017/10:35	NORMAL		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Urine Bilirubin	Screening	14JAN2016/13:30	NEGATIVE		No
		Day 1	04FEB2016/09:50	NEGATIVE		Yes
		Week 2	16FEB2016/14:10	NEGATIVE		No
		Week 4	03MAR2016/12:20	NEGATIVE		No
		Week 6	17MAR2016/11:32	NEGATIVE		No
		Week 8	31MAR2016/11:25	NEGATIVE		No
		Week 12	26APR2016/08:20	NEGATIVE		Yes
		Week 16	25MAY2016/11:58	NEGATIVE		No
		Week 20	23JUN2016/12:50	NEGATIVE		No
		Week 24	19JUL2016/12:05	NEGATIVE		Yes
		Week 28	18AUG2016/12:20	NEGATIVE		No
		Week 32	13SEP2016/11:50	NEGATIVE		No
		Week 36	13OCT2016/12:15	NEGATIVE		No
		Week 40	08NOV2016/11:10	NEGATIVE		No
		Week 44	08DEC2016/11:05	NEGATIVE		No
		Week 48	04JAN2017/12:05	NEGATIVE		No
	Urine Blood	Screening	14JAN2016/13:30	NEGATIVE		No
		Day 1	04FEB2016/09:50	NEGATIVE		Yes
		Week 2	16FEB2016/14:10	NEGATIVE		No
		Week 4	03MAR2016/12:20	NEGATIVE		No
		Week 6	17MAR2016/11:32	NEGATIVE		No
		Week 8	31MAR2016/11:25	NEGATIVE		No
		Week 12	26APR2016/08:20	NEGATIVE		Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Urine Blood	Week 16	25MAY2016/11:58	NEGATIVE		No
		Week 20	23JUN2016/12:50	NEGATIVE		No
		Week 24	19JUL2016/12:05	NEGATIVE		Yes
		Week 28	18AUG2016/12:20	NEGATIVE		No
		Week 32	13SEP2016/11:50	NEGATIVE		No
		Week 36	13OCT2016/12:15	NEGATIVE		No
		Week 40	08NOV2016/11:10	NEGATIVE		No
		Week 44	08DEC2016/11:05	NEGATIVE		No
		Week 48	04JAN2017/12:05	NEGATIVE		No
	Urine Cellular Casts	Screening	14JAN2016/13:30	NOT SEEN		No
		Day 1	04FEB2016/09:50	NOT SEEN		Yes
		Week 2	16FEB2016/14:10	NOT SEEN		No
		Week 4	03MAR2016/12:20	NOT SEEN		No
		Week 6	17MAR2016/11:32	NOT SEEN		No
		Week 8	31MAR2016/11:25	NOT SEEN		No
		Week 12	26APR2016/08:20	NOT SEEN		Yes
		Week 16	25MAY2016/11:58	NOT SEEN		No
		Week 20	23JUN2016/12:50	NOT SEEN		No
		Week 24	19JUL2016/12:05	NOT SEEN		Yes
		Week 28	18AUG2016/12:20	NOT SEEN		No
		Week 32	13SEP2016/11:50	NOT SEEN		No
		Week 36	13OCT2016/12:15	NOT SEEN		No
		Week 40	08NOV2016/11:10	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Urine Cellular Casts	Week 44	08DEC2016/11:05	NOT SEEN		No
		Week 48	04JAN2017/12:05	NOT SEEN		No
	Urine Crystals	Screening	14JAN2016/13:30	NOT SEEN		No
		Day 1	04FEB2016/09:50	NOT SEEN		Yes
		Week 2	16FEB2016/14:10	NOT SEEN		No
		Week 4	03MAR2016/12:20	NOT SEEN		No
		Week 6	17MAR2016/11:32	NOT SEEN		No
		Week 8	31MAR2016/11:25	NOT SEEN		No
		Week 12	26APR2016/08:20	SCANTY		Yes
		Week 16	25MAY2016/11:58	NOT SEEN		No
		Week 20	23JUN2016/12:50	NOT SEEN		No
		Week 24	19JUL2016/12:05	NOT SEEN		Yes
		Week 28	18AUG2016/12:20	NOT SEEN		No
		Week 32	13SEP2016/11:50	NOT SEEN		No
		Week 36	13OCT2016/12:15	NOT SEEN		No
		Week 40	08NOV2016/11:10	NOT SEEN		No
		Week 44	08DEC2016/11:05	NOT SEEN		No
		Week 48	04JAN2017/12:05	NOT SEEN		No
	Urine Epithelial Cells	Screening	14JAN2016/13:30	NOT SEEN		No
		Day 1	04FEB2016/09:50	NOT SEEN		Yes
		Week 2	16FEB2016/14:10	NOT SEEN		No
		Week 4	03MAR2016/12:20	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Urine Epithelial Cells	Week 6	17MAR2016/11:32	NOT SEEN		No
		Week 8	31MAR2016/11:25	NOT SEEN		No
		Week 12	26APR2016/08:20	NOT SEEN		Yes
		Week 16	25MAY2016/11:58	NOT SEEN		No
		Week 20	23JUN2016/12:50	NOT SEEN		No
		Week 24	19JUL2016/12:05	NOT SEEN		Yes
		Week 28	18AUG2016/12:20	NOT SEEN		No
		Week 32	13SEP2016/11:50	NOT SEEN		No
		Week 36	13OCT2016/12:15	NOT SEEN		No
		Week 40	08NOV2016/11:10	NOT SEEN		No
		Week 44	08DEC2016/11:05	NOT SEEN		No
		Week 48	04JAN2017/12:05	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	14JAN2016/13:30	NOT SEEN		No
		Day 1	04FEB2016/09:50	NOT SEEN		Yes
		Week 2	16FEB2016/14:10	NOT SEEN		No
		Week 4	03MAR2016/12:20	1 - 9 /HPF		No
		Week 6	17MAR2016/11:32	NOT SEEN		No
		Week 8	31MAR2016/11:25	NOT SEEN		No
		Week 12	26APR2016/08:20	1 - 9 /HPF		Yes
		Week 16	25MAY2016/11:58	NOT SEEN		No
		Week 20	23JUN2016/12:50	1 - 9 /HPF		No
		Week 24	19JUL2016/12:05	NOT SEEN		Yes
		Week 28	18AUG2016/12:20	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Urine Erythrocytes (/HPF)	Week 32	13SEP2016/11:50	NOT SEEN		No
		Week 36	13OCT2016/12:15	1 - 9 /HPF		No
		Week 40	08NOV2016/11:10	NOT SEEN		No
		Week 44	08DEC2016/11:05	NOT SEEN		No
		Week 48	04JAN2017/12:05	1 - 9 /HPF		No
	Urine Granular Casts	Screening	14JAN2016/13:30	NOT SEEN		No
		Day 1	04FEB2016/09:50	NOT SEEN		Yes
		Week 2	16FEB2016/14:10	NOT SEEN		No
		Week 4	03MAR2016/12:20	NOT SEEN		No
		Week 6	17MAR2016/11:32	NOT SEEN		No
		Week 8	31MAR2016/11:25	NOT SEEN		No
		Week 12	26APR2016/08:20	NOT SEEN		Yes
		Week 16	25MAY2016/11:58	NOT SEEN		No
		Week 20	23JUN2016/12:50	NOT SEEN		No
		Week 24	19JUL2016/12:05	NOT SEEN		Yes
		Week 28	18AUG2016/12:20	NOT SEEN		No
		Week 32	13SEP2016/11:50	NOT SEEN		No
		Week 36	13OCT2016/12:15	NOT SEEN		No
		Week 40	08NOV2016/11:10	NOT SEEN		No
		Week 44	08DEC2016/11:05	NOT SEEN		No
		Week 48	04JAN2017/12:05	NOT SEEN		No
	Urine Hyaline Casts	Screening	14JAN2016/13:30	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Urine Hyaline Casts	Day 1	04FEB2016/09:50	NOT SEEN		Yes
		Week 2	16FEB2016/14:10	NOT SEEN		No
		Week 4	03MAR2016/12:20	NOT SEEN		No
		Week 6	17MAR2016/11:32	NOT SEEN		No
		Week 8	31MAR2016/11:25	NOT SEEN		No
		Week 12	26APR2016/08:20	NOT SEEN		Yes
		Week 16	25MAY2016/11:58	NOT SEEN		No
		Week 20	23JUN2016/12:50	NOT SEEN		No
		Week 24	19JUL2016/12:05	NOT SEEN		Yes
		Week 28	18AUG2016/12:20	NOT SEEN		No
		Week 32	13SEP2016/11:50	NOT SEEN		No
		Week 36	13OCT2016/12:15	NOT SEEN		No
		Week 40	08NOV2016/11:10	NOT SEEN		No
		Week 44	08DEC2016/11:05	NOT SEEN		No
		Week 48	04JAN2017/12:05	NOT SEEN		No
	Urine Ketones	Screening	14JAN2016/13:30	NEGATIVE		No
		Day 1	04FEB2016/09:50	NEGATIVE		Yes
		Week 2	16FEB2016/14:10	NEGATIVE		No
		Week 4	03MAR2016/12:20	NEGATIVE		No
		Week 6	17MAR2016/11:32	NEGATIVE		No
		Week 8	31MAR2016/11:25	NEGATIVE		No
		Week 12	26APR2016/08:20	NEGATIVE		Yes
		Week 16	25MAY2016/11:58	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Urine Ketones	Week 20	23JUN2016/12:50	NEGATIVE		No
		Week 24	19JUL2016/12:05	NEGATIVE		Yes
		Week 28	18AUG2016/12:20	NEGATIVE		No
		Week 32	13SEP2016/11:50	NEGATIVE		No
		Week 36	13OCT2016/12:15	NEGATIVE		No
		Week 40	08NOV2016/11:10	NEGATIVE		No
		Week 44	08DEC2016/11:05	NEGATIVE		No
		Week 48	04JAN2017/12:05	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	14JAN2016/13:30	NOT SEEN		No
		Day 1	04FEB2016/09:50	NOT SEEN		Yes
		Week 2	16FEB2016/14:10	NOT SEEN		No
		Week 4	03MAR2016/12:20	1 - 9 /HPF		No
		Week 6	17MAR2016/11:32	NOT SEEN		No
		Week 8	31MAR2016/11:25	1 - 9 /HPF		No
		Week 12	26APR2016/08:20	NOT SEEN		Yes
		Week 16	25MAY2016/11:58	NOT SEEN		No
		Week 20	23JUN2016/12:50	1 - 9 /HPF		No
		Week 24	19JUL2016/12:05	NOT SEEN		Yes
		Week 28	18AUG2016/12:20	1 - 9 /HPF		No
		Week 32	13SEP2016/11:50	1 - 9 /HPF		No
		Week 36	13OCT2016/12:15	NOT SEEN		No
		Week 40	08NOV2016/11:10	1 - 9 /HPF		No
		Week 44	08DEC2016/11:05	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Urine Leukocytes (/HPF)	Week 48	04JAN2017/12:05	1 - 9 /HPF		No
	Urine Nitrite	Screening	14JAN2016/13:30	NEGATIVE		No
		Day 1	04FEB2016/09:50	NEGATIVE		Yes
		Week 2	16FEB2016/14:10	NEGATIVE		No
		Week 4	03MAR2016/12:20	NEGATIVE		No
		Week 6	17MAR2016/11:32	NEGATIVE		No
		Week 8	31MAR2016/11:25	NEGATIVE		No
		Week 12	26APR2016/08:20	NEGATIVE		Yes
		Week 16	25MAY2016/11:58	NEGATIVE		No
		Week 20	23JUN2016/12:50	POSITIVE		No
		Week 24	19JUL2016/12:05	NEGATIVE		Yes
		Week 28	18AUG2016/12:20	NEGATIVE		No
		Week 32	13SEP2016/11:50	NEGATIVE		No
		Week 36	13OCT2016/12:15	NEGATIVE		No
		Week 40	08NOV2016/11:10	NEGATIVE		No
		Week 44	08DEC2016/11:05	NEGATIVE		No
		Week 48	04JAN2017/12:05	NEGATIVE		No
	Urine Organisms	Screening	14JAN2016/13:30	NOT SEEN		No
		Day 1	04FEB2016/09:50	NOT SEEN		Yes
		Week 2	16FEB2016/14:10	NOT SEEN		No
		Week 4	03MAR2016/12:20	NOT SEEN		No
		Week 6	17MAR2016/11:32	NOT SEEN		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Urine Organisms	Week 8	31MAR2016/11:25	NOT SEEN		No
		Week 12	26APR2016/08:20	NOT SEEN		Yes
		Week 16	25MAY2016/11:58	NOT SEEN		No
		Week 20	23JUN2016/12:50	NOT SEEN		No
		Week 24	19JUL2016/12:05	NOT SEEN		Yes
		Week 28	18AUG2016/12:20	NOT SEEN		No
		Week 32	13SEP2016/11:50	NOT SEEN		No
		Week 36	13OCT2016/12:15	NOT SEEN		No
		Week 40	08NOV2016/11:10	NOT SEEN		No
		Week 44	08DEC2016/11:05	NOT SEEN		No
		Week 48	04JAN2017/12:05	NOT SEEN		No
	Urine Protein	Screening	14JAN2016/13:30	NEGATIVE		No
		Day 1	04FEB2016/09:50	NEGATIVE		Yes
		Week 2	16FEB2016/14:10	NEGATIVE		No
		Week 4	03MAR2016/12:20	NEGATIVE		No
		Week 6	17MAR2016/11:32	NEGATIVE		No
		Week 8	31MAR2016/11:25	NEGATIVE		No
		Week 12	26APR2016/08:20	NEGATIVE		Yes
		Week 16	25MAY2016/11:58	TRACE		No
		Week 20	23JUN2016/12:50	TRACE		No
		Week 24	19JUL2016/12:05	NEGATIVE		Yes
		Week 28	18AUG2016/12:20	NEGATIVE		No
		Week 32	13SEP2016/11:50	NEGATIVE		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-006	Urine Protein	Week 36	13OCT2016/12:15	NEGATIVE		No
		Week 40	08NOV2016/11:10	NEGATIVE		No
		Week 44	08DEC2016/11:05	NEGATIVE		No
		Week 48	04JAN2017/12:05	NEGATIVE		No
	Urine Specific Gravity	Screening	14JAN2016/13:30	1.018	1 - 1.03	No
		Day 1	04FEB2016/09:50	1.016	1 - 1.03	Yes
		Week 2	16FEB2016/14:10	1.012	1 - 1.03	No
		Week 4	03MAR2016/12:20	1.015	1 - 1.03	No
		Week 6	17MAR2016/11:32	1.009	1 - 1.03	No
		Week 8	31MAR2016/11:25	1.010	1 - 1.03	No
		Week 12	26APR2016/08:20	1.009	1 - 1.03	Yes
		Week 16	25MAY2016/11:58	1.014	1 - 1.03	No
		Week 20	23JUN2016/12:50	1.016	1 - 1.03	No
		Week 24	19JUL2016/12:05	1.011	1 - 1.03	Yes
		Week 28	18AUG2016/12:20	1.014	1 - 1.03	No
		Week 32	13SEP2016/11:50	1.016	1 - 1.03	No
		Week 36	13OCT2016/12:15	1.015	1 - 1.03	No
		Week 40	08NOV2016/11:10	1.017	1 - 1.03	No
		Week 44	08DEC2016/11:05	1.010	1 - 1.03	No
		Week 48	04JAN2017/12:05	1.014	1 - 1.03	No
	Urine Urobilinogen	Screening	14JAN2016/13:30	NORMAL		No
		Day 1	04FEB2016/09:50	NORMAL		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-006	Urine Urobilinogen	Week 2	16FEB2016/14:10	NORMAL		No	
		Week 4	03MAR2016/12:20	NORMAL		No	
		Week 6	17MAR2016/11:32	NORMAL		No	
		Week 8	31MAR2016/11:25	NORMAL		No	
		Week 12	26APR2016/08:20	NORMAL		Yes	
		Week 16	25MAY2016/11:58	NORMAL		No	
		Week 20	23JUN2016/12:50	NORMAL		No	
		Week 24	19JUL2016/12:05	NORMAL		Yes	
		Week 28	18AUG2016/12:20	NORMAL		No	
		Week 32	13SEP2016/11:50	NORMAL		No	
		Week 36	13OCT2016/12:15	NORMAL		No	
		Week 40	08NOV2016/11:10	NORMAL		No	
		Week 44	08DEC2016/11:05	NORMAL		No	
		Week 48	04JAN2017/12:05	NORMAL		No	

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Urine Bilirubin	Screening	17FEB2016/13:30	NEGATIVE		Yes
		Week 1	15MAR2016/09:25	NEGATIVE		No
		Week 2	23MAR2016/09:10	NEGATIVE		No
		Week 4	05APR2016/10:20	NEGATIVE		No
		Week 6	19APR2016/09:50	NEGATIVE		No
		Week 8	28APR2016/10:10	NEGATIVE		No
		Week 12	01JUN2016/08:32	NEGATIVE		Yes
		Week 16	29JUN2016/09:25	NEGATIVE		No
		Week 20	26JUL2016/09:50	NEGATIVE		No
		Week 24	24AUG2016/09:40	NEGATIVE		Yes
		Week 28	20SEP2016/12:05	NEGATIVE		No
		Week 32	19OCT2016/11:05	NEGATIVE		No
		Week 36	15NOV2016/11:30	NEGATIVE		No
		Week 40	14DEC2016/09:40	NEGATIVE		No
		Week 44	11JAN2017/11:05	NEGATIVE		No
		Week 48	08FEB2017/11:55	NEGATIVE		No
	Urine Blood	Screening	17FEB2016/13:30	+		Yes
		Week 1	15MAR2016/09:25	NEGATIVE		No
		Week 2	23MAR2016/09:10	NEGATIVE		No
		Week 4	05APR2016/10:20	NEGATIVE		No
		Week 6	19APR2016/09:50	NEGATIVE		No
		Week 8	28APR2016/10:10	NEGATIVE		No
		Week 12	01JUN2016/08:32	NEGATIVE		Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Urine Blood	Week 16	29JUN2016/09:25	NEGATIVE		No
		Week 20	26JUL2016/09:50	NEGATIVE		No
		Week 24	24AUG2016/09:40	NEGATIVE		Yes
		Week 28	20SEP2016/12:05	TRACE		No
		Week 32	19OCT2016/11:05	NEGATIVE		No
		Week 36	15NOV2016/11:30	NEGATIVE		No
		Week 40	14DEC2016/09:40	NEGATIVE		No
		Week 44	11JAN2017/11:05	NEGATIVE		No
		Week 48	08FEB2017/11:55	NEGATIVE		No
	Urine Cellular Casts	Screening	17FEB2016/13:30	NOT SEEN		Yes
		Week 1	15MAR2016/09:25	NOT SEEN		No
		Week 2	23MAR2016/09:10	NOT SEEN		No
		Week 4	05APR2016/10:20	NOT SEEN		No
		Week 6	19APR2016/09:50	NOT SEEN		No
		Week 8	28APR2016/10:10	NOT SEEN		No
		Week 12	01JUN2016/08:32	NOT SEEN		Yes
		Week 16	29JUN2016/09:25	NOT SEEN		No
		Week 20	26JUL2016/09:50	NOT SEEN		No
		Week 24	24AUG2016/09:40	NOT SEEN		Yes
		Week 28	20SEP2016/12:05	NOT SEEN		No
		Week 32	19OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/11:30	NOT SEEN		No
		Week 40	14DEC2016/09:40	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Urine Cellular Casts	Week 44	11JAN2017/11:05	NOT SEEN		No
		Week 48	08FEB2017/11:55	NOT SEEN		No
	Urine Crystals	Screening	17FEB2016/13:30	NOT SEEN		Yes
		Week 1	15MAR2016/09:25	NOT SEEN		No
		Week 2	23MAR2016/09:10	NOT SEEN		No
		Week 4	05APR2016/10:20	NOT SEEN		No
		Week 6	19APR2016/09:50	NOT SEEN		No
		Week 8	28APR2016/10:10	NOT SEEN		No
		Week 12	01JUN2016/08:32	NOT SEEN		Yes
		Week 16	29JUN2016/09:25	NOT SEEN		No
		Week 20	26JUL2016/09:50	NOT SEEN		No
		Week 24	24AUG2016/09:40	NOT SEEN		Yes
		Week 28	20SEP2016/12:05	NOT SEEN		No
		Week 32	19OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/11:30	NOT SEEN		No
		Week 40	14DEC2016/09:40	NOT SEEN		No
		Week 44	11JAN2017/11:05	NOT SEEN		No
		Week 48	08FEB2017/11:55	NOT SEEN		No
	Urine Epithelial Cells	Screening	17FEB2016/13:30	+		Yes
		Week 1	15MAR2016/09:25	NOT SEEN		No
		Week 2	23MAR2016/09:10	NOT SEEN		No
		Week 4	05APR2016/10:20	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Urine Epithelial Cells	Week 6	19APR2016/09:50	NOT SEEN		No
		Week 8	28APR2016/10:10	NOT SEEN		No
		Week 12	01JUN2016/08:32	NOT SEEN		Yes
		Week 16	29JUN2016/09:25	NOT SEEN		No
		Week 20	26JUL2016/09:50	NOT SEEN		No
		Week 24	24AUG2016/09:40	NOT SEEN		Yes
		Week 28	20SEP2016/12:05	NOT SEEN		No
		Week 32	19OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/11:30	NOT SEEN		No
		Week 40	14DEC2016/09:40	NOT SEEN		No
		Week 44	11JAN2017/11:05	NOT SEEN		No
		Week 48	08FEB2017/11:55	NOT SEEN		No
	Urine Erythrocytes (/HPF)	Screening	17FEB2016/13:30	1 - 9 /HPF		Yes
		Week 1	15MAR2016/09:25	NOT SEEN		No
		Week 2	23MAR2016/09:10	NOT SEEN		No
		Week 4	05APR2016/10:20	1 - 9 /HPF		No
		Week 6	19APR2016/09:50	NOT SEEN		No
		Week 8	28APR2016/10:10	1 - 9 /HPF		No
		Week 12	01JUN2016/08:32	NOT SEEN		Yes
		Week 16	29JUN2016/09:25	NOT SEEN		No
		Week 20	26JUL2016/09:50	1 - 9 /HPF		No
		Week 24	24AUG2016/09:40	1 - 9 /HPF		Yes
		Week 28	20SEP2016/12:05	1 - 9 /HPF		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Urine Erythrocytes (/HPF)	Week 32	19OCT2016/11:05	1 - 9 /HPF		No
		Week 36	15NOV2016/11:30	1 - 9 /HPF		No
		Week 40	14DEC2016/09:40	1 - 9 /HPF		No
		Week 44	11JAN2017/11:05	NOT SEEN		No
		Week 48	08FEB2017/11:55	1 - 9 /HPF		No
	Urine Granular Casts	Screening	17FEB2016/13:30	NOT SEEN		Yes
		Week 1	15MAR2016/09:25	NOT SEEN		No
		Week 2	23MAR2016/09:10	NOT SEEN		No
		Week 4	05APR2016/10:20	NOT SEEN		No
		Week 6	19APR2016/09:50	NOT SEEN		No
		Week 8	28APR2016/10:10	NOT SEEN		No
		Week 12	01JUN2016/08:32	NOT SEEN		Yes
		Week 16	29JUN2016/09:25	NOT SEEN		No
		Week 20	26JUL2016/09:50	NOT SEEN		No
		Week 24	24AUG2016/09:40	NOT SEEN		Yes
		Week 28	20SEP2016/12:05	NOT SEEN		No
		Week 32	19OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/11:30	NOT SEEN		No
		Week 40	14DEC2016/09:40	NOT SEEN		No
		Week 44	11JAN2017/11:05	NOT SEEN		No
		Week 48	08FEB2017/11:55	NOT SEEN		No
	Urine Hyaline Casts	Screening	17FEB2016/13:30	NOT SEEN		Yes

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Urine Hyaline Casts	Week 1	15MAR2016/09:25	NOT SEEN		No
		Week 2	23MAR2016/09:10	NOT SEEN		No
		Week 4	05APR2016/10:20	NOT SEEN		No
		Week 6	19APR2016/09:50	NOT SEEN		No
		Week 8	28APR2016/10:10	NOT SEEN		No
		Week 12	01JUN2016/08:32	NOT SEEN		Yes
		Week 16	29JUN2016/09:25	NOT SEEN		No
		Week 20	26JUL2016/09:50	NOT SEEN		No
		Week 24	24AUG2016/09:40	NOT SEEN		Yes
		Week 28	20SEP2016/12:05	NOT SEEN		No
		Week 32	19OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/11:30	NOT SEEN		No
		Week 40	14DEC2016/09:40	NOT SEEN		No
		Week 44	11JAN2017/11:05	NOT SEEN		No
		Week 48	08FEB2017/11:55	NOT SEEN		No
	Urine Ketones	Screening	17FEB2016/13:30	NEGATIVE		Yes
		Week 1	15MAR2016/09:25	NEGATIVE		No
		Week 2	23MAR2016/09:10	NEGATIVE		No
		Week 4	05APR2016/10:20	NEGATIVE		No
		Week 6	19APR2016/09:50	NEGATIVE		No
		Week 8	28APR2016/10:10	NEGATIVE		No
		Week 12	01JUN2016/08:32	NEGATIVE		Yes
		Week 16	29JUN2016/09:25	NEGATIVE		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Urine Ketones	Week 20	26JUL2016/09:50	NEGATIVE		No
		Week 24	24AUG2016/09:40	NEGATIVE		Yes
		Week 28	20SEP2016/12:05	NEGATIVE		No
		Week 32	19OCT2016/11:05	NEGATIVE		No
		Week 36	15NOV2016/11:30	NEGATIVE		No
		Week 40	14DEC2016/09:40	NEGATIVE		No
		Week 44	11JAN2017/11:05	NEGATIVE		No
		Week 48	08FEB2017/11:55	NEGATIVE		No
	Urine Leukocytes (/HPF)	Screening	17FEB2016/13:30	1 - 9 /HPF		Yes
		Week 1	15MAR2016/09:25	NOT SEEN		No
		Week 2	23MAR2016/09:10	NOT SEEN		No
		Week 4	05APR2016/10:20	NOT SEEN		No
		Week 6	19APR2016/09:50	NOT SEEN		No
		Week 8	28APR2016/10:10	NOT SEEN		No
		Week 12	01JUN2016/08:32	NOT SEEN		Yes
		Week 16	29JUN2016/09:25	NOT SEEN		No
		Week 20	26JUL2016/09:50	NOT SEEN		No
		Week 24	24AUG2016/09:40	NOT SEEN		Yes
		Week 28	20SEP2016/12:05	NOT SEEN		No
		Week 32	19OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/11:30	NOT SEEN		No
		Week 40	14DEC2016/09:40	NOT SEEN		No
		Week 44	11JAN2017/11:05	NOT SEEN		No

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Urine Leukocytes (/HPF)	Week 48	08FEB2017/11:55	NOT SEEN		No
	Urine Nitrite	Screening	17FEB2016/13:30	NEGATIVE		Yes
		Week 1	15MAR2016/09:25	NEGATIVE		No
		Week 2	23MAR2016/09:10	NEGATIVE		No
		Week 4	05APR2016/10:20	NEGATIVE		No
		Week 6	19APR2016/09:50	NEGATIVE		No
		Week 8	28APR2016/10:10	NEGATIVE		No
		Week 12	01JUN2016/08:32	NEGATIVE		Yes
		Week 16	29JUN2016/09:25	NEGATIVE		No
		Week 20	26JUL2016/09:50	NEGATIVE		No
		Week 24	24AUG2016/09:40	NEGATIVE		Yes
		Week 28	20SEP2016/12:05	NEGATIVE		No
		Week 32	19OCT2016/11:05	NEGATIVE		No
		Week 36	15NOV2016/11:30	NEGATIVE		No
		Week 40	14DEC2016/09:40	NEGATIVE		No
		Week 44	11JAN2017/11:05	NEGATIVE		No
		Week 48	08FEB2017/11:55	NEGATIVE		No
	Urine Organisms	Screening	17FEB2016/13:30	NOT SEEN		Yes
		Week 1	15MAR2016/09:25	NOT SEEN		No
		Week 2	23MAR2016/09:10	+		No
		Week 4	05APR2016/10:20	NOT SEEN		No
		Week 6	19APR2016/09:50	NOT SEEN		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Urine Organisms	Week 8	28APR2016/10:10	NOT SEEN		No
		Week 12	01JUN2016/08:32	NOT SEEN		Yes
		Week 16	29JUN2016/09:25	++		No
		Week 20	26JUL2016/09:50	NOT SEEN		No
		Week 24	24AUG2016/09:40	NOT SEEN		Yes
		Week 28	20SEP2016/12:05	NOT SEEN		No
		Week 32	19OCT2016/11:05	NOT SEEN		No
		Week 36	15NOV2016/11:30	NOT SEEN		No
		Week 40	14DEC2016/09:40	NOT SEEN		No
		Week 44	11JAN2017/11:05	NOT SEEN		No
		Week 48	08FEB2017/11:55	NOT SEEN		No
	Urine Protein	Screening	17FEB2016/13:30	NEGATIVE		Yes
		Week 1	15MAR2016/09:25	NEGATIVE		No
		Week 2	23MAR2016/09:10	NEGATIVE		No
		Week 4	05APR2016/10:20	NEGATIVE		No
		Week 6	19APR2016/09:50	NEGATIVE		No
		Week 8	28APR2016/10:10	NEGATIVE		No
		Week 12	01JUN2016/08:32	NEGATIVE		Yes
		Week 16	29JUN2016/09:25	NEGATIVE		No
		Week 20	26JUL2016/09:50	NEGATIVE		No
		Week 24	24AUG2016/09:40	NEGATIVE		Yes
		Week 28	20SEP2016/12:05	NEGATIVE		No
		Week 32	19OCT2016/11:05	NEGATIVE		No

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-017	Urine Protein	Week 36	15NOV2016/11:30	NEGATIVE		No
		Week 40	14DEC2016/09:40	NEGATIVE		No
		Week 44	11JAN2017/11:05	NEGATIVE		No
		Week 48	08FEB2017/11:55	NEGATIVE		No
	Urine Specific Gravity	Screening	17FEB2016/13:30	1.020	1 - 1.03	Yes
		Week 1	15MAR2016/09:25	1.005	1 - 1.03	No
		Week 2	23MAR2016/09:10	1.007	1 - 1.03	No
		Week 4	05APR2016/10:20	1.006	1 - 1.03	No
		Week 6	19APR2016/09:50	1.005	1 - 1.03	No
		Week 8	28APR2016/10:10	1.004	1 - 1.03	No
		Week 12	01JUN2016/08:32	1.007	1 - 1.03	Yes
		Week 16	29JUN2016/09:25	1.004	1 - 1.03	No
		Week 20	26JUL2016/09:50	1.005	1 - 1.03	No
		Week 24	24AUG2016/09:40	1.005	1 - 1.03	Yes
		Week 28	20SEP2016/12:05	1.006	1 - 1.03	No
		Week 32	19OCT2016/11:05	1.006	1 - 1.03	No
		Week 36	15NOV2016/11:30	1.005	1 - 1.03	No
		Week 40	14DEC2016/09:40	1.009	1 - 1.03	No
		Week 44	11JAN2017/11:05	1.006	1 - 1.03	No
		Week 48	08FEB2017/11:55	1.007	1 - 1.03	No
	Urine Urobilinogen	Screening	17FEB2016/13:30	NORMAL		Yes
		Week 1	15MAR2016/09:25	NORMAL		No

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?	Grade
301-017	Urine Urobilinogen	Week 2	23MAR2016/09:10	NORMAL		No	
		Week 4	05APR2016/10:20	NORMAL		No	
		Week 6	19APR2016/09:50	NORMAL		No	
		Week 8	28APR2016/10:10	NORMAL		No	
		Week 12	01JUN2016/08:32	NORMAL		Yes	
		Week 16	29JUN2016/09:25	NORMAL		No	
		Week 20	26JUL2016/09:50	NORMAL		No	
		Week 24	24AUG2016/09:40	NORMAL		Yes	
		Week 28	20SEP2016/12:05	NORMAL		No	
		Week 32	19OCT2016/11:05	NORMAL		No	
		Week 36	15NOV2016/11:30	NORMAL		No	
		Week 40	14DEC2016/09:40	NORMAL		No	
		Week 44	11JAN2017/11:05	NORMAL		No	
		Week 48	08FEB2017/11:55	NORMAL		No	

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-004	Urine Bilirubin	Screening	16DEC2015/11:55	NEGATIVE		Yes
	Urine Blood	Screening	16DEC2015/11:55	NEGATIVE		Yes
	Urine Cellular Casts	Screening	16DEC2015/11:55	NOT SEEN		Yes
	Urine Crystals	Screening	16DEC2015/11:55	NOT SEEN		Yes
	Urine Epithelial Cells	Screening	16DEC2015/11:55	+		Yes
	Urine Erythrocytes (/HPF)	Screening	16DEC2015/11:55	1 - 9 /HPF		Yes
	Urine Granular Casts	Screening	16DEC2015/11:55	NOT SEEN		Yes
	Urine Hyaline Casts	Screening	16DEC2015/11:55	NOT SEEN		Yes
	Urine Ketones	Screening	16DEC2015/11:55	NEGATIVE		Yes
	Urine Leukocytes (/HPF)	Screening	16DEC2015/11:55	1 - 9 /HPF		Yes
	Urine Nitrite	Screening	16DEC2015/11:55	NEGATIVE		Yes
	Urine Organisms	Screening	16DEC2015/11:55	NOT SEEN		Yes

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CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-004	Urine Protein	Screening	16DEC2015/11:55	NEGATIVE		Yes
	Urine Specific Gravity	Screening	16DEC2015/11:55	1.019	1 - 1.03	Yes
	Urine Urobilinogen	Screening	16DEC2015/11:55	NORMAL		Yes
301-012	Urine Bilirubin	Screening	26JAN2016/13:00	NEGATIVE		Yes
	Urine Blood	Screening	26JAN2016/13:00	NEGATIVE		Yes
	Urine Cellular Casts	Screening	26JAN2016/13:00	NOT SEEN		Yes
	Urine Crystals	Screening	26JAN2016/13:00	NOT SEEN		Yes
	Urine Epithelial Cells	Screening	26JAN2016/13:00	NOT SEEN		Yes
	Urine Erythrocytes (/HPF)	Screening	26JAN2016/13:00	NOT SEEN		Yes
	Urine Granular Casts	Screening	26JAN2016/13:00	NOT SEEN		Yes
	Urine Hyaline Casts	Screening	26JAN2016/13:00	NOT SEEN		Yes
	Urine Ketones	Screening	26JAN2016/13:00	NEGATIVE		Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

Source: D:\TriStat\Eiger\EIG\_LNF\_002\_LOWR\_4\tasks\final\version3\prog\l-lab.sas 11JUL2017 22:20

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-012	Urine Leukocytes (/HPF)	Screening	26JAN2016/13:00	NOT SEEN		Yes
	Urine Nitrite	Screening	26JAN2016/13:00	NEGATIVE		Yes
	Urine Organisms	Screening	26JAN2016/13:00	NOT SEEN		Yes
	Urine Protein	Screening	26JAN2016/13:00	NEGATIVE		Yes
	Urine Specific Gravity	Screening	26JAN2016/13:00	1.016	1 - 1.03	Yes
	Urine Urobilinogen	Screening	26JAN2016/13:00	NORMAL		Yes
301-013	Urine Bilirubin	Screening	26JAN2016/13:10	NEGATIVE		Yes
	Urine Blood	Screening	26JAN2016/13:10	NEGATIVE		Yes
	Urine Cellular Casts	Screening	26JAN2016/13:10	NOT SEEN		Yes
	Urine Crystals	Screening	26JAN2016/13:10	NOT SEEN		Yes
	Urine Epithelial Cells	Screening	26JAN2016/13:10	NOT SEEN		Yes
	Urine Erythrocytes (/HPF)	Screening	26JAN2016/13:10	NOT SEEN		Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.4  
Laboratory Results - Urinalysis  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting? Grade
301-013	Urine Granular Casts	Screening	26JAN2016/13:10	NOT SEEN		Yes
	Urine Hyaline Casts	Screening	26JAN2016/13:10	NOT SEEN		Yes
	Urine Ketones	Screening	26JAN2016/13:10	NEGATIVE		Yes
	Urine Leukocytes (/HPF)	Screening	26JAN2016/13:10	NOT SEEN		Yes
	Urine Nitrite	Screening	26JAN2016/13:10	NEGATIVE		Yes
	Urine Organisms	Screening	26JAN2016/13:10	NOT SEEN		Yes
	Urine Protein	Screening	26JAN2016/13:10	NEGATIVE		Yes
	Urine Specific Gravity	Screening	26JAN2016/13:10	1.010	1 - 1.03	Yes
	Urine Urobilinogen	Screening	26JAN2016/13:10	NORMAL		Yes

[1] H = High; L = Low; A = Abnormal

CTCAE Grade: 1=Mild; 2=Moderate; 3=Severe; 4=Life-Threatening. Severity grades were defined by CTCAE Version 4.03.

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Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-007	Anti-HBC (IgG/IgM)	Screening	05JAN2016/11:00	POSITIVE	Yes
		Day 1	26JAN2016/10:00	POSITIVE	No
		Week 1	01FEB2016/10:30	POSITIVE	No
		Week 2	11FEB2016/12:00	POSITIVE	No
		Week 4	24FEB2016/13:00	POSITIVE	No
		Week 6	08MAR2016/11:30	POSITIVE	No
		Week 8	24MAR2016/10:52	POSITIVE	No
		Early Term	21APR2016/08:00	POSITIVE	Yes
		Week 28	19MAY2016/12:20	POSITIVE	No
		Week 32	16JUN2016/10:25	POSITIVE	No
		Week 40	11AUG2016/12:00	POSITIVE	No
		Week 44	08SEP2016/12:10	POSITIVE	No
		Week 48	06OCT2016/12:30	POSITIVE	No
		Anti-HBE	Screening	05JAN2016/11:00	NEGATIVE
	Day 1		26JAN2016/10:00	NEGATIVE	No
	HCV Viral Load	Screening	05JAN2016/11:00	POSITIVE	Yes
	HIV-1/2 Antibody	Screening	05JAN2016/11:00	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	05JAN2016/11:00	NOT DETECTED	Yes
			26JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 1	01FEB2016/10:30	NOT DETECTED	No
		Week 2	11FEB2016/12:00	NOT DETECTED	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-007	Hepatitis B DNA (IU/mL)	Week 4	24FEB2016/13:00	NOT DETECTED	No
		Week 6	08MAR2016/11:30	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 8	24MAR2016/10:52	NOT DETECTED	No
		Early Term	21APR2016/08:00	NOT DETECTED	Yes
		Week 28	19MAY2016/12:20	NOT DETECTED	No
		Week 32	16JUN2016/10:25	NOT DETECTED	No
		Week 40	11AUG2016/12:00	1020000	No
		Week 44	08SEP2016/12:10	332	No
		Week 48	06OCT2016/12:30	59	No
	Hepatitis B DNA (log10 IU/mL)	Screening	05JAN2016/11:00	NOT DETECTED	Yes
		Day 1	26JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 1	01FEB2016/10:30	NOT DETECTED	No
		Week 2	11FEB2016/12:00	NOT DETECTED	No
		Week 4	24FEB2016/13:00	NOT DETECTED	No
		Week 6	08MAR2016/11:30	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 8	24MAR2016/10:52	NOT DETECTED	No
		Early Term	21APR2016/08:00	NOT DETECTED	Yes
		Week 28	19MAY2016/12:20	NOT DETECTED	No
		Week 32	16JUN2016/10:25	NOT DETECTED	No
		Week 40	11AUG2016/12:00	6.01	No



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-007	Hepatitis B DNA (log10 IU/mL)	Week 44	08SEP2016/12:10	2.52	No
		Week 48	06OCT2016/12:30	1.77	No
	Hepatitis B Virus Surface Antibody	Screening	05JAN2016/11:00	POSITIVE	Yes
		Day 1	26JAN2016/10:00	POSITIVE	No
		Week 1	01FEB2016/10:30	POSITIVE	No
		Week 2	11FEB2016/12:00	POSITIVE	No
		Week 4	24FEB2016/13:00	POSITIVE	No
		Week 6	08MAR2016/11:30	POSITIVE	No
		Week 8	24MAR2016/10:52	POSITIVE	No
		Early Term	21APR2016/08:00	POSITIVE	Yes
		Week 28	19MAY2016/12:20	POSITIVE	No
		Week 32	16JUN2016/10:25	POSITIVE	No
		Week 40	11AUG2016/12:00	POSITIVE	No
		Week 44	08SEP2016/12:10	POSITIVE	No
		Week 48	06OCT2016/12:30	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	05JAN2016/11:00	NEGATIVE	Yes
		Day 1	26JAN2016/10:00	NEGATIVE	No
	Hepatitis B surface antigen (quantitativ IU/mL)	Day 1	26JAN2016/10:00	12198.61	No
		Early Term	21APR2016/08:00	10723.99	No
		Week 48	06OCT2016/12:30	15633.84	No
	Hepatitis C RNA	Screening	05JAN2016/11:00	NOT DETECTED	Yes

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Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-007 Hepatitis D RNA (IU/mL)	Screening	05JAN2016/11:00	4520	Yes
	Day 1	26JAN2016/10:00	1440	No
	Week 1	01FEB2016/10:30	418	No
	Week 2	11FEB2016/12:00	24	No
	Week 4	24FEB2016/13:00	63	No
	Week 6	08MAR2016/11:30	92	No
	Week 8	24MAR2016/10:52	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
	Early Term	21APR2016/08:00	34	Yes
	Week 28	19MAY2016/12:20	17	No
	Week 32	16JUN2016/10:25	45	No
	Week 40	11AUG2016/12:00	2650	No
	Week 44	08SEP2016/12:10	21100	No
	Week 48	06OCT2016/12:30	113000	No
	Screening	05JAN2016/11:00	3.66	Yes
	Day 1	26JAN2016/10:00	3.16	No
	Week 1	01FEB2016/10:30	2.62	No
	Week 2	11FEB2016/12:00	1.38	No
	Week 4	24FEB2016/13:00	1.8	No
	Week 6	08MAR2016/11:30	1.96	No
	Week 8	24MAR2016/10:52	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
	Early Term	21APR2016/08:00	1.53	Yes
	Week 28	19MAY2016/12:20	1.23	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-007	Hepatitis D RNA (log10 IU/mL)	Week 32	16JUN2016/10:25	1.65	No
		Week 40	11AUG2016/12:00	3.42	No
		Week 44	08SEP2016/12:10	4.32	No
		Week 48	06OCT2016/12:30	5.05	No
	Hepatitis Delta Ab	Screening	05JAN2016/11:00	POSITIVE	Yes
		Day 1	26JAN2016/10:00		No
		Unscheduled Visit	26JAN2016/12:48	POSITIVE	No
		Week 2	11FEB2016/12:00	POSITIVE	No
		Week 4	24FEB2016/13:00	POSITIVE	No
		Week 6	08MAR2016/11:30	POSITIVE	No
		Week 8	24MAR2016/10:52	POSITIVE	No
		Early Term	21APR2016/08:00	POSITIVE	Yes
		Week 28	19MAY2016/12:20	POSITIVE	No
		Week 32	16JUN2016/10:25	POSITIVE	No
		Week 40	11AUG2016/12:00	POSITIVE	No
		Week 44	08SEP2016/12:10	POSITIVE	No
		Week 48	06OCT2016/12:30	POSITIVE	No
301-011	Anti-HBC (IgG/IgM)	Screening	07JAN2016/12:00	POSITIVE	Yes
		Day 1	27JAN2016/08:30	POSITIVE	Yes
		Week 1	03FEB2016/11:00	POSITIVE	Yes
		Week 2	11FEB2016/11:30	POSITIVE	Yes
		Week 4	26FEB2016/10:20	POSITIVE	No
		Week 6	10MAR2016/10:45	POSITIVE	No
		Week 8	24MAR2016/09:31	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-011	Anti-HBC (IgG/IgM)	Week 12	19APR2016/09:20	POSITIVE	Yes
		Week 16	18MAY2016/10:10	POSITIVE	No
		Week 20	21JUN2016/10:35	POSITIVE	No
		Week 24	12JUL2016/10:00	POSITIVE	Yes
		Week 28	09AUG2016/09:50	POSITIVE	No
		Week 32	06SEP2016/09:00	POSITIVE	No
		Week 36	06OCT2016/09:50	POSITIVE	No
		Week 40	03NOV2016/11:00	POSITIVE	No
		Week 44	06DEC2016/10:30	POSITIVE	No
		Week 48	03JAN2017/10:45	POSITIVE	No
	Anti-HBE	Screening	07JAN2016/12:00	NEGATIVE	Yes
		Day 1	27JAN2016/08:30	NEGATIVE	Yes
		Week 24	12JUL2016/10:00	POSITIVE	Yes
	HCV Viral Load	Screening	07JAN2016/12:00	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	07JAN2016/12:00	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	07JAN2016/12:00	84500	Yes
		Day 1	27JAN2016/08:30	73000	Yes
		Week 1	03FEB2016/11:00	80400	Yes
		Week 2	11FEB2016/11:30	98600	Yes
		Week 4	26FEB2016/10:20	143000	No
		Week 6	10MAR2016/10:45	374000	No
		Week 8	24MAR2016/09:31	695000	No
		Week 12	19APR2016/09:20	16000000	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-011	Hepatitis B DNA (IU/mL)	Week 16	18MAY2016/10:10	212000	No
		Week 20	21JUN2016/10:35	36800	No
		Week 24	12JUL2016/10:00	6050	Yes
		Week 28	09AUG2016/09:50	720	No
		Week 32	06SEP2016/09:00	196	No
		Week 36	06OCT2016/09:50	135	No
		Week 40	03NOV2016/11:00	43	No
		Week 44	06DEC2016/10:30	NOT DETECTED	No
		Week 48	03JAN2017/10:45	NOT DETECTED	No
	Hepatitis B DNA (log10 IU/mL)	Screening	07JAN2016/12:00	4.93	Yes
		Day 1	27JAN2016/08:30	4.86	Yes
		Week 1	03FEB2016/11:00	4.91	Yes
		Week 2	11FEB2016/11:30	4.99	Yes
		Week 4	26FEB2016/10:20	5.16	No
		Week 6	10MAR2016/10:45	5.57	No
		Week 8	24MAR2016/09:31	5.84	No
		Week 12	19APR2016/09:20	7.2	Yes
		Week 16	18MAY2016/10:10	5.33	No
		Week 20	21JUN2016/10:35	4.57	No
		Week 24	12JUL2016/10:00	3.78	Yes
		Week 28	09AUG2016/09:50	2.86	No
		Week 32	06SEP2016/09:00	2.29	No
		Week 36	06OCT2016/09:50	2.13	No
		Week 40	03NOV2016/11:00	1.63	No
		Week 44	06DEC2016/10:30	NOT DETECTED	No
		Week 48	03JAN2017/10:45	NOT DETECTED	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-011	Hepatitis B Virus Surface Antibody	Screening	07JAN2016/12:00	POSITIVE	Yes
		Day 1	27JAN2016/08:30	POSITIVE	Yes
		Week 1	03FEB2016/11:00	POSITIVE	Yes
		Week 2	11FEB2016/11:30	POSITIVE	Yes
		Week 4	26FEB2016/10:20	POSITIVE	No
		Week 6	10MAR2016/10:45	POSITIVE	No
		Week 8	24MAR2016/09:31	POSITIVE	No
		Week 12	19APR2016/09:20	POSITIVE	Yes
		Week 16	18MAY2016/10:10	POSITIVE	No
		Week 20	21JUN2016/10:35	POSITIVE	No
		Week 24	12JUL2016/10:00	POSITIVE	Yes
		Week 28	09AUG2016/09:50	POSITIVE	No
		Week 32	06SEP2016/09:00	POSITIVE	No
		Week 36	06OCT2016/09:50	POSITIVE	No
		Week 40	03NOV2016/11:00	POSITIVE	No
		Week 44	06DEC2016/10:30	POSITIVE	No
		Week 48	03JAN2017/10:45	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	07JAN2016/12:00	POSITIVE	Yes
		Day 1	27JAN2016/08:30	POSITIVE	Yes
		Week 24	12JUL2016/10:00	POSITIVE	Yes
	Hepatitis B surface antigen (quantitativ (IU/mL))	Day 1	27JAN2016/08:30	15522.75	No
		Week 48	03JAN2017/10:45	13215.04	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-011 Hepatitis D RNA (IU/mL)	Screening	07JAN2016/12:00	37800	Yes
	Day 1	27JAN2016/08:30	19300	Yes
	Week 1	03FEB2016/11:00	4320	Yes
	Week 2	11FEB2016/11:30	375	Yes
	Week 4	26FEB2016/10:20	1030	No
	Week 6	10MAR2016/10:45	228	No
	Week 8	24MAR2016/09:31	347	No
	Week 12	19APR2016/09:20	49	Yes
	Week 16	18MAY2016/10:10	24	No
	Week 20	21JUN2016/10:35	975	No
	Week 24	12JUL2016/10:00	526	Yes
	Week 28	09AUG2016/09:50	4160	No
	Week 32	06SEP2016/09:00	1810	No
	Week 36	06OCT2016/09:50	6100	No
	Week 40	03NOV2016/11:00	20000	No
	Week 44	06DEC2016/10:30	7110	No
	Week 48	03JAN2017/10:45	13400	No
Hepatitis D RNA (log10 IU/mL)	Screening	07JAN2016/12:00	4.58	Yes
	Day 1	27JAN2016/08:30	4.29	Yes
	Week 1	03FEB2016/11:00	3.64	Yes
	Week 2	11FEB2016/11:30	2.57	Yes
	Week 4	26FEB2016/10:20	3.01	No
	Week 6	10MAR2016/10:45	2.36	No
	Week 8	24MAR2016/09:31	2.54	No
	Week 12	19APR2016/09:20	1.69	Yes
	Week 16	18MAY2016/10:10	1.38	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-011	Hepatitis D RNA (log10 IU/mL)	Week 20	21JUN2016/10:35	2.99	No
		Week 24	12JUL2016/10:00	2.72	Yes
		Week 28	09AUG2016/09:50	3.62	No
		Week 32	06SEP2016/09:00	3.26	No
		Week 36	06OCT2016/09:50	3.79	No
		Week 40	03NOV2016/11:00	4.3	No
		Week 44	06DEC2016/10:30	3.85	No
		Week 48	03JAN2017/10:45	4.13	No
	Hepatitis Delta Ab	Screening	07JAN2016/12:00	POSITIVE	Yes
		Day 1	27JAN2016/08:30	POSITIVE	Yes
		Week 2	11FEB2016/11:30	POSITIVE	Yes
		Week 4	26FEB2016/10:20	POSITIVE	No
		Week 6	10MAR2016/10:45	POSITIVE	No
		Week 8	24MAR2016/09:31	POSITIVE	No
		Week 12	19APR2016/09:20	POSITIVE	Yes
		Week 16	18MAY2016/10:10	POSITIVE	No
		Week 20	21JUN2016/10:35	POSITIVE	No
		Week 24	12JUL2016/10:00	POSITIVE	Yes
		Week 28	09AUG2016/09:50	POSITIVE	No
		Week 32	06SEP2016/09:00	POSITIVE	No
		Week 36	06OCT2016/09:50	POSITIVE	No
		Week 40	03NOV2016/11:00	POSITIVE	No
		Week 44	06DEC2016/10:30	POSITIVE	No
		Week 48	03JAN2017/10:45	POSITIVE	No



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-001	Anti-HBC (IgG/IgM)	Screening	06JAN2016/11:00	POSITIVE	Yes
		Day 1	02FEB2016/11:10	POSITIVE	Yes
		Week 1	09FEB2016/10:00	POSITIVE	No
		Week 2	16FEB2016/11:00	POSITIVE	No
		Week 4	01MAR2016/10:30	POSITIVE	No
		Week 6	16MAR2016/11:45	POSITIVE	No
		Week 8	31MAR2016/09:52	POSITIVE	No
		Week 12	28APR2016/08:15	POSITIVE	Yes
		Week 16	26MAY2016/12:10	POSITIVE	No
		Week 20	22JUN2016/09:55	POSITIVE	No
		Week 24	20JUL2016/09:30	POSITIVE	Yes
		Week 28	18AUG2016/10:45	POSITIVE	No
		Week 32	15SEP2016/10:00	POSITIVE	No
		Week 36	13OCT2016/12:30	POSITIVE	No
		Week 40	10NOV2016/10:15	POSITIVE	No
		Week 44	06DEC2016/11:00	POSITIVE	No
		Week 48	03JAN2017/12:00	POSITIVE	No
	Anti-HBE	Screening	06JAN2016/11:00	NEGATIVE	Yes
		Day 1	02FEB2016/11:10	NEGATIVE	Yes
		Week 24	20JUL2016/09:30	NEGATIVE	Yes
	HCV Viral Load	Screening	06JAN2016/11:00	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	06JAN2016/11:00	NEGATIVE	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-001 Hepatitis B DNA (IU/mL)	Screening	06JAN2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
	Day 1	02FEB2016/11:10	41	Yes
	Week 1	09FEB2016/10:00	48	No
	Week 2	16FEB2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
	Week 4	01MAR2016/10:30	54	No
	Week 6	16MAR2016/11:45	81	No
	Week 8	31MAR2016/09:52	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
	Week 12	28APR2016/08:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes
	Week 16	26MAY2016/12:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
	Week 20	22JUN2016/09:55	NOT DETECTED	No
	Week 24	20JUL2016/09:30	NOT DETECTED	Yes
	Week 28	18AUG2016/10:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
	Week 32	15SEP2016/10:00	NOT DETECTED	No
	Week 36	13OCT2016/12:30	28	No
	Week 40	10NOV2016/10:15	NOT DETECTED	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-001	Hepatitis B DNA (IU/mL)	Week 44	06DEC2016/11:00	NOT DETECTED	No
		Week 48	03JAN2017/12:00	NOT DETECTED	No
	Hepatitis B DNA (log10 IU/mL)	Screening	06JAN2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	02FEB2016/11:10	1.61	Yes
		Week 1	09FEB2016/10:00	1.68	No
		Week 2	16FEB2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 4	01MAR2016/10:30	1.73	No
		Week 6	16MAR2016/11:45	1.91	No
		Week 8	31MAR2016/09:52	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 12	28APR2016/08:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes
		Week 16	26MAY2016/12:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 20	22JUN2016/09:55	NOT DETECTED	No
		Week 24	20JUL2016/09:30	NOT DETECTED	Yes
		Week 28	18AUG2016/10:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-001	Hepatitis B DNA (log10 IU/mL)	Week 32	15SEP2016/10:00	NOT DETECTED	No
		Week 36	13OCT2016/12:30	1.45	No
		Week 40	10NOV2016/10:15	NOT DETECTED	No
		Week 44	06DEC2016/11:00	NOT DETECTED	No
		Week 48	03JAN2017/12:00	NOT DETECTED	No
	Hepatitis B Virus Surface Antibody	Screening	06JAN2016/11:00	POSITIVE	Yes
		Day 1	02FEB2016/11:10	POSITIVE	Yes
		Week 1	09FEB2016/10:00	POSITIVE	No
		Week 2	16FEB2016/11:00	POSITIVE	No
		Week 4	01MAR2016/10:30	POSITIVE	No
		Week 6	16MAR2016/11:45	POSITIVE	No
		Week 8	31MAR2016/09:52	POSITIVE	No
		Week 12	28APR2016/08:15	POSITIVE	Yes
		Week 16	26MAY2016/12:10	POSITIVE	No
		Week 20	22JUN2016/09:55	POSITIVE	No
		Week 24	20JUL2016/09:30	POSITIVE	Yes
		Week 28	18AUG2016/10:45	POSITIVE	No
		Week 32	15SEP2016/10:00	POSITIVE	No
		Week 36	13OCT2016/12:30	POSITIVE	No
		Week 40	10NOV2016/10:15	POSITIVE	No
		Week 44	06DEC2016/11:00	POSITIVE	No
		Week 48	03JAN2017/12:00	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	06JAN2016/11:00	NEGATIVE	Yes
		Day 1	02FEB2016/11:10	NEGATIVE	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-001	Hepatitis B Virus e Antigen	Week 24	20JUL2016/09:30	NEGATIVE	Yes
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	02FEB2016/11:10	17958.38	No
		Week 24	20JUL2016/09:30	17767.74	No
		Week 24	03JAN2017/12:00	16782.11	No
	Hepatitis D RNA (IU/mL)	Screening	06JAN2016/11:00	14220	Yes
		Day 1	02FEB2016/11:10	19900	Yes
		Week 1	09FEB2016/10:00	2090	No
		Week 2	16FEB2016/11:00	81	No
		Week 4	01MAR2016/10:30	3370	No
		Week 6	16MAR2016/11:45	538	No
		Week 8	31MAR2016/09:52	2470	No
		Week 12	28APR2016/08:15	305	Yes
		Week 16	26MAY2016/12:10	1270	No
		Week 20	22JUN2016/09:55	34800	No
		Week 24	20JUL2016/09:30	2180	Yes
		Week 28	18AUG2016/10:45	2570	No
		Week 32	15SEP2016/10:00	22100	No
		Week 36	13OCT2016/12:30	48500	No
		Week 40	10NOV2016/10:15	205000	No
		Week 44	06DEC2016/11:00	73700	No
		Week 48	03JAN2017/12:00	602000	No
	Hepatitis D RNA (log10 IU/mL)	Screening	06JAN2016/11:00	4.15	Yes
		Day 1	02FEB2016/11:10	4.3	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-001	Hepatitis D RNA (log10 IU/mL)	Week 1	09FEB2016/10:00	3.32	No
		Week 2	16FEB2016/11:00	1.91	No
		Week 4	01MAR2016/10:30	3.53	No
		Week 6	16MAR2016/11:45	2.73	No
		Week 8	31MAR2016/09:52	3.39	No
		Week 12	28APR2016/08:15	2.48	Yes
		Week 16	26MAY2016/12:10	3.1	No
		Week 20	22JUN2016/09:55	4.54	No
		Week 24	20JUL2016/09:30	3.34	Yes
		Week 28	18AUG2016/10:45	3.41	No
		Week 32	15SEP2016/10:00	4.34	No
		Week 36	13OCT2016/12:30	4.69	No
		Week 40	10NOV2016/10:15	5.31	No
		Week 44	06DEC2016/11:00	4.87	No
		Week 48	03JAN2017/12:00	5.78	No
	Hepatitis Delta Ab	Screening	06JAN2016/11:00	POSITIVE	Yes
		Day 1	02FEB2016/11:10	POSITIVE	Yes
		Week 2	16FEB2016/11:00	POSITIVE	No
		Week 4	01MAR2016/10:30	POSITIVE	No
		Week 6	16MAR2016/11:45	POSITIVE	No
		Week 8	31MAR2016/09:52	POSITIVE	No
		Week 12	28APR2016/08:15	POSITIVE	Yes
		Week 16	26MAY2016/12:10	POSITIVE	No
		Week 20	22JUN2016/09:55	POSITIVE	No
		Week 24	20JUL2016/09:30	POSITIVE	Yes
		Week 28	18AUG2016/10:45	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-001	Hepatitis Delta Ab	Week 32	15SEP2016/10:00	POSITIVE	No
		Week 36	13OCT2016/12:30	POSITIVE	No
		Week 40	10NOV2016/10:15	POSITIVE	No
		Week 44	06DEC2016/11:00	POSITIVE	No
		Week 48	03JAN2017/12:00	POSITIVE	No
301-002	Anti-HBC (IgG/IgM)	Screening	15DEC2015/09:00	POSITIVE	Yes
		Day 1	05JAN2016/09:00	POSITIVE	Yes
		Week 1	14JAN2016/10:00	POSITIVE	No
		Week 2	20JAN2016/10:00	POSITIVE	No
		Week 4	03FEB2016/09:45	POSITIVE	No
		Week 6	17FEB2016/13:00	POSITIVE	No
		Week 8	01MAR2016/09:00	POSITIVE	No
		Week 12	30MAR2016/09:50	POSITIVE	No
		Week 16	26APR2016/10:25	POSITIVE	No
		Week 20	24MAY2016/11:40	POSITIVE	No
		Week 24	21JUN2016/11:30	POSITIVE	No
		Week 28	20JUL2016/11:45	POSITIVE	No
		Week 32	18AUG2016/10:30	POSITIVE	No
		Week 36	13SEP2016/11:00	POSITIVE	No
		Week 40	11OCT2016/12:05	POSITIVE	No
		Week 44	09NOV2016/12:30	POSITIVE	No
		Week 48	06DEC2016/13:00	POSITIVE	No
	Anti-HBE	Screening	15DEC2015/09:00	POSITIVE	Yes
		Day 1	05JAN2016/09:00	POSITIVE	Yes
		Week 24	21JUN2016/11:30	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-002	HCV Viral Load	Screening	15DEC2015/09:00	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	15DEC2015/09:00	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	15DEC2015/09:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	05JAN2016/09:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 1	14JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 2	20JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 4	03FEB2016/09:45	74	No
		Week 6	17FEB2016/13:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 8	01MAR2016/09:00	27	No
		Week 12	30MAR2016/09:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 16	26APR2016/10:25	24	No



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-002	Hepatitis B DNA (IU/mL)	Week 20	24MAY2016/11:40	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 24	21JUN2016/11:30	26	No
		Week 28	20JUL2016/11:45	NOT DETECTED	No
		Week 32	18AUG2016/10:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 36	13SEP2016/11:00	NOT DETECTED	No
		Week 40	11OCT2016/12:05	NOT DETECTED	No
		Week 44	09NOV2016/12:30	NOT DETECTED	No
		Week 48	06DEC2016/13:00	NOT DETECTED	No
	Hepatitis B DNA (log10 IU/mL)	Screening	15DEC2015/09:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	05JAN2016/09:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 1	14JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 2	20JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 4	03FEB2016/09:45	1.87	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-002	Hepatitis B DNA (log10 IU/mL)	Week 6	17FEB2016/13:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 8	01MAR2016/09:00	1.43	No
		Week 12	30MAR2016/09:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 16	26APR2016/10:25	1.38	No
		Week 20	24MAY2016/11:40	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 24	21JUN2016/11:30	1.41	No
		Week 28	20JUL2016/11:45	NOT DETECTED	No
		Week 32	18AUG2016/10:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 36	13SEP2016/11:00	NOT DETECTED	No
		Week 40	11OCT2016/12:05	NOT DETECTED	No
		Week 44	09NOV2016/12:30	NOT DETECTED	No
		Week 48	06DEC2016/13:00	NOT DETECTED	No
	Hepatitis B Virus Surface Antibody	Screening	15DEC2015/09:00	POSITIVE	Yes
		Day 1	05JAN2016/09:00	POSITIVE	Yes
		Week 1	14JAN2016/10:00	POSITIVE	No
		Week 2	20JAN2016/10:00	POSITIVE	No
		Week 4	03FEB2016/09:45	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-002	Hepatitis B Virus Surface Antibody	Week 6	17FEB2016/13:00	POSITIVE	No
		Week 8	01MAR2016/09:00	POSITIVE	No
		Week 12	30MAR2016/09:50	POSITIVE	No
		Week 16	26APR2016/10:25	POSITIVE	No
		Week 20	24MAY2016/11:40	POSITIVE	No
		Week 24	21JUN2016/11:30	POSITIVE	No
		Week 28	20JUL2016/11:45	POSITIVE	No
		Week 32	18AUG2016/10:30	POSITIVE	No
		Week 36	13SEP2016/11:00	POSITIVE	No
		Week 40	11OCT2016/12:05	POSITIVE	No
		Week 44	09NOV2016/12:30	POSITIVE	No
		Week 48	06DEC2016/13:00	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	15DEC2015/09:00	NEGATIVE	Yes
		Day 1	05JAN2016/09:00	NEGATIVE	Yes
		Week 24	21JUN2016/11:30	NEGATIVE	No
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	05JAN2016/09:00	10117.90	No
		Week 24	21JUN2016/11:30	10142.72	No
		Day 1	06DEC2016/13:00	12518.37	No
	Hepatitis D RNA (IU/mL)	Screening	15DEC2015/09:00	1640000	Yes
		Day 1	05JAN2016/09:00	1100000	Yes
		Week 1	14JAN2016/10:00	101000	No
		Week 2	20JAN2016/10:00	50100	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-002	Hepatitis D RNA (IU/mL)	Week 4	03FEB2016/09:45	40200	No
		Week 6	17FEB2016/13:00	6850	No
		Week 8	01MAR2016/09:00	1100	No
		Week 12	30MAR2016/09:50	3890	No
		Week 16	26APR2016/10:25	440	No
		Week 20	24MAY2016/11:40	249	No
		Week 24	21JUN2016/11:30	93	No
		Week 28	20JUL2016/11:45	19600	No
		Week 32	18AUG2016/10:30	74700	No
		Week 36	13SEP2016/11:00	783000	No
		Week 40	11OCT2016/12:05	1540000	No
		Week 44	09NOV2016/12:30	78600	No
		Week 48	06DEC2016/13:00	502000	No
	Hepatitis D RNA (log10 IU/mL)	Screening	15DEC2015/09:00	6.21	Yes
		Day 1	05JAN2016/09:00	6.04	Yes
		Week 1	14JAN2016/10:00	5	No
		Week 2	20JAN2016/10:00	4.7	No
		Week 4	03FEB2016/09:45	4.6	No
		Week 6	17FEB2016/13:00	3.84	No
		Week 8	01MAR2016/09:00	3.04	No
		Week 12	30MAR2016/09:50	3.59	No
		Week 16	26APR2016/10:25	2.64	No
		Week 20	24MAY2016/11:40	2.4	No
		Week 24	21JUN2016/11:30	1.97	No
		Week 28	20JUL2016/11:45	4.29	No
		Week 32	18AUG2016/10:30	4.87	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-002	Hepatitis D RNA (log10 IU/mL)	Week 36	13SEP2016/11:00	5.89	No
		Week 40	11OCT2016/12:05	6.19	No
		Week 44	09NOV2016/12:30	4.9	No
		Week 48	06DEC2016/13:00	5.7	No
	Hepatitis Delta Ab	Screening	15DEC2015/09:00	POSITIVE	Yes
		Day 1	05JAN2016/09:00	POSITIVE	Yes
		Week 2	20JAN2016/10:00	POSITIVE	No
		Week 4	03FEB2016/09:45	POSITIVE	No
		Week 6	17FEB2016/13:00	POSITIVE	No
		Week 8	01MAR2016/09:00	POSITIVE	No
		Week 12	30MAR2016/09:50	POSITIVE	No
		Week 16	26APR2016/10:25	POSITIVE	No
		Week 20	24MAY2016/11:40	POSITIVE	No
		Week 24	21JUN2016/11:30	POSITIVE	No
		Week 28	20JUL2016/11:45	POSITIVE	No
		Week 32	18AUG2016/10:30	POSITIVE	No
		Week 36	13SEP2016/11:00	POSITIVE	No
		Week 40	11OCT2016/12:05	POSITIVE	No
		Week 44	09NOV2016/12:30	POSITIVE	No
		Week 48	06DEC2016/13:00	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-003	Anti-HBC (IgG/IgM)	Screening	15DEC2015/12:00	POSITIVE	Yes
		Day 1	06JAN2016/11:00	POSITIVE	Yes
		Week 1	13JAN2016/11:00	POSITIVE	No
		Week 2	20JAN2016/11:00	POSITIVE	No
		Week 4	03FEB2016/11:00	POSITIVE	No
		Week 6	18FEB2016/13:30	POSITIVE	No
		Week 8	08MAR2016/08:35	POSITIVE	No
		Week 12	29MAR2016/09:15	POSITIVE	No
		Week 16	25APR2016/08:50	POSITIVE	No
		Week 20	26MAY2016/12:50	POSITIVE	No
		Week 24	22JUN2016/12:30	POSITIVE	No
		Week 28	19JUL2016/10:10	POSITIVE	No
		Week 32	16AUG2016/12:10	POSITIVE	No
		Week 36	15SEP2016/12:35	POSITIVE	No
		Week 40	12OCT2016/11:20	POSITIVE	Yes
		Week 44	09NOV2016/12:00	POSITIVE	No
		Week 48	14DEC2016/12:00	POSITIVE	No
	Anti-HBE	Screening	15DEC2015/12:00	POSITIVE	Yes
		Day 1	06JAN2016/11:00	POSITIVE	Yes
		Week 24	22JUN2016/12:30	POSITIVE	No
	HCV Viral Load	Screening	15DEC2015/12:00	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	15DEC2015/12:00	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	15DEC2015/12:00	NOT DETECTED	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-003 Hepatitis B DNA (IU/mL)	Day 1	06JAN2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
	Week 1	13JAN2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
	Week 2	20JAN2016/11:00	NOT DETECTED	No
	Week 4	03FEB2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
	Week 6	18FEB2016/13:30	NOT DETECTED	No
	Week 8	08MAR2016/08:35	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
	Week 12	29MAR2016/09:15	NOT DETECTED	No
	Week 16	25APR2016/08:50	NOT DETECTED	No
	Week 20	26MAY2016/12:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
	Week 24	22JUN2016/12:30	NOT DETECTED	No
	Week 28	19JUL2016/10:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
	Week 32	16AUG2016/12:10	NOT DETECTED	No
	Week 36	15SEP2016/12:35	25	No
	Week 40	12OCT2016/11:20	NOT DETECTED	Yes
	Week 44	09NOV2016/12:00	NOT DETECTED	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-003	Hepatitis B DNA (IU/mL)	Week 48	14DEC2016/12:00	NOT DETECTED	No
	Hepatitis B DNA (log10 IU/mL)	Screening Day 1	15DEC2015/12:00	NOT DETECTED	Yes
			06JAN2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 1	13JAN2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 2	20JAN2016/11:00	NOT DETECTED	No
		Week 4	03FEB2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 6	18FEB2016/13:30	NOT DETECTED	No
		Week 8	08MAR2016/08:35	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 12	29MAR2016/09:15	NOT DETECTED	No
		Week 16	25APR2016/08:50	NOT DETECTED	No
		Week 20	26MAY2016/12:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 24	22JUN2016/12:30	NOT DETECTED	No
		Week 28	19JUL2016/10:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 32	16AUG2016/12:10	NOT DETECTED	No

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Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-003	Hepatitis B DNA (log10 IU/mL)	Week 36	15SEP2016/12:35	1.4	No
		Week 40	12OCT2016/11:20	NOT DETECTED	Yes
		Week 44	09NOV2016/12:00	NOT DETECTED	No
		Week 48	14DEC2016/12:00	NOT DETECTED	No
	Hepatitis B Virus Surface Antibody	Screening	15DEC2015/12:00	POSITIVE	Yes
		Day 1	06JAN2016/11:00	POSITIVE	Yes
		Week 1	13JAN2016/11:00	POSITIVE	No
		Week 2	20JAN2016/11:00	POSITIVE	No
		Week 4	03FEB2016/11:00	POSITIVE	No
		Week 6	18FEB2016/13:30	POSITIVE	No
		Week 8	08MAR2016/08:35	POSITIVE	No
		Week 12	29MAR2016/09:15	POSITIVE	No
		Week 16	25APR2016/08:50	POSITIVE	No
		Week 20	26MAY2016/12:50	POSITIVE	No
		Week 24	22JUN2016/12:30	POSITIVE	No
		Week 28	19JUL2016/10:10	POSITIVE	No
		Week 32	16AUG2016/12:10	POSITIVE	No
		Week 36	15SEP2016/12:35	POSITIVE	No
		Week 40	12OCT2016/11:20	POSITIVE	Yes
		Week 44	09NOV2016/12:00	POSITIVE	No
		Week 48	14DEC2016/12:00	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	15DEC2015/12:00	NEGATIVE	Yes
		Day 1	06JAN2016/11:00	NEGATIVE	Yes
		Week 24	22JUN2016/12:30	NEGATIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-003	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	06JAN2016/11:00	26363.06	No
		Week 48	22JUN2016/12:30	26756.16	No
		Week 48	14DEC2016/12:00	28238.41	No
	Hepatitis D RNA (IU/mL)	Screening	15DEC2015/12:00	11300	Yes
		Day 1	06JAN2016/11:00	39600	Yes
		Week 1	13JAN2016/11:00	541	No
		Week 2	20JAN2016/11:00	4210	No
		Week 4	03FEB2016/11:00	471	No
		Week 6	18FEB2016/13:30	20	No
		Week 8	08MAR2016/08:35	91	No
		Week 12	29MAR2016/09:15	87	No
		Week 16	25APR2016/08:50	26	No
		Week 20	26MAY2016/12:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 24	22JUN2016/12:30	NEGATIVE	No
		Week 28	19JUL2016/10:10	18	No
		Week 32	16AUG2016/12:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 36	15SEP2016/12:35	15	No
		Week 40	12OCT2016/11:20	269	Yes
		Week 44	09NOV2016/12:00	186	No
		Week 48	14DEC2016/12:00	125	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-003	Hepatitis D RNA (log10 IU/mL)	Screening	15DEC2015/12:00	4.05	Yes
		Day 1	06JAN2016/11:00	4.6	Yes
		Week 1	13JAN2016/11:00	2.73	No
		Week 2	20JAN2016/11:00	3.62	No
		Week 4	03FEB2016/11:00	2.67	No
		Week 6	18FEB2016/13:30	1.3	No
		Week 8	08MAR2016/08:35	1.96	No
		Week 12	29MAR2016/09:15	1.94	No
		Week 16	25APR2016/08:50	1.41	No
		Week 20	26MAY2016/12:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 24	22JUN2016/12:30	NEGATIVE	No
		Week 28	19JUL2016/10:10	1.26	No
		Week 32	16AUG2016/12:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 36	15SEP2016/12:35	1.18	No
		Week 40	12OCT2016/11:20	2.43	Yes
		Week 44	09NOV2016/12:00	2.27	No
		Week 48	14DEC2016/12:00	2.1	No
	Hepatitis Delta Ab	Screening	15DEC2015/12:00	POSITIVE	Yes
		Day 1	06JAN2016/11:00	POSITIVE	Yes
		Week 2	20JAN2016/11:00	POSITIVE	No
		Week 4	03FEB2016/11:00	POSITIVE	No
		Week 6	18FEB2016/13:30	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-003 Hepatitis Delta Ab	Week 8	08MAR2016/08:35	POSITIVE	No
	Week 12	29MAR2016/09:15	POSITIVE	No
	Week 16	25APR2016/08:50	POSITIVE	No
	Week 20	26MAY2016/12:50	POSITIVE	No
	Week 24	22JUN2016/12:30	POSITIVE	No
	Week 28	19JUL2016/10:10	POSITIVE	No
	Week 32	16AUG2016/12:10	POSITIVE	No
	Week 36	15SEP2016/12:35	POSITIVE	No
	Week 40	12OCT2016/11:20	POSITIVE	Yes
	Week 44	09NOV2016/12:00	POSITIVE	No
	Week 48	14DEC2016/12:00	POSITIVE	No
301-005 Anti-HBC (IgG/IgM)	Screening	16DEC2015/08:45	POSITIVE	Yes
	Day 1	07JAN2016/10:00	POSITIVE	Yes
	Week 1	13JAN2016/09:30	POSITIVE	No
	Week 2	21JAN2016/10:00	POSITIVE	No
	Week 4	02FEB2016/09:00	POSITIVE	No
	Week 6	17FEB2016/13:00	POSITIVE	No
	Week 8	02MAR2016/09:15	POSITIVE	No
	Week 12	31MAR2016/10:15	POSITIVE	No
	Week 16	26APR2016/10:00	POSITIVE	No
	Week 20	26MAY2016/12:30	POSITIVE	No
	Week 24	23JUN2016/11:45	POSITIVE	No
	Week 28	26JUL2016/09:15	POSITIVE	No
	Week 32	16AUG2016/10:45	POSITIVE	No
	Week 36	14SEP2016/12:00	POSITIVE	No
	Week 40	12OCT2016/12:10	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-005	Anti-HBC (IgG/IgM)	Week 44	10NOV2016/11:00	POSITIVE	No
		Week 48	07DEC2016/12:00	POSITIVE	No
	Anti-HBE	Screening	16DEC2015/08:45	NEGATIVE	Yes
		Day 1	07JAN2016/10:00	NEGATIVE	Yes
		Week 24	23JUN2016/11:45	NEGATIVE	No
	HCV Viral Load	Screening	16DEC2015/08:45	EQUIVOCAL	Yes
	HIV-1/2 Antibody	Screening	16DEC2015/08:45	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	16DEC2015/08:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	07JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 1	13JAN2016/09:30	NOT DETECTED	No
		Week 2	21JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 4	02FEB2016/09:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 6	17FEB2016/13:00	25	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-005	Hepatitis B DNA (IU/mL)	Week 8	02MAR2016/09:15	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 12	31MAR2016/10:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION PLEASE NOTE THAT THIS SAMPLE WAS DILUTED DUE TO THE SMA	No
		Week 16	26APR2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 20	26MAY2016/12:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 24	23JUN2016/11:45	54	No
		Week 28	26JUL2016/09:15	78	No
		Week 32	16AUG2016/10:45	99	No
		Week 36	14SEP2016/12:00	29	No
		Week 40	12OCT2016/12:10	NOT DETECTED	No
		Week 48	07DEC2016/12:00	NOT DETECTED	No
	Hepatitis B DNA (log10 IU/mL)	Screening	16DEC2015/08:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-005	Hepatitis B DNA (log10 IU/mL)	Day 1	07JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 1	13JAN2016/09:30	NOT DETECTED	No
		Week 2	21JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 4	02FEB2016/09:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 6	17FEB2016/13:00	1.4	No
		Week 8	02MAR2016/09:15	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 12	31MAR2016/10:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION PLEASE NOTE THAT THIS SAMPLE WAS DILUTED DUE TO THE SMA	No
		Week 16	26APR2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 20	26MAY2016/12:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-005	Hepatitis B DNA (log10 IU/mL)	Week 24	23JUN2016/11:45	1.73	No
		Week 28	26JUL2016/09:15	1.89	No
		Week 32	16AUG2016/10:45	2	No
		Week 36	14SEP2016/12:00	1.46	No
		Week 40	12OCT2016/12:10	NOT DETECTED	No
		Week 48	07DEC2016/12:00	NOT DETECTED	No
	Hepatitis B Virus Surface Antibody	Screening	16DEC2015/08:45	POSITIVE	Yes
		Day 1	07JAN2016/10:00	POSITIVE	Yes
		Week 1	13JAN2016/09:30	POSITIVE	No
		Week 2	21JAN2016/10:00	POSITIVE	No
		Week 4	02FEB2016/09:00	POSITIVE	No
		Week 6	17FEB2016/13:00	POSITIVE	No
		Week 8	02MAR2016/09:15	POSITIVE	No
		Week 12	31MAR2016/10:15	POSITIVE	No
		Week 16	26APR2016/10:00	POSITIVE	No
		Week 20	26MAY2016/12:30	POSITIVE	No
		Week 24	23JUN2016/11:45	POSITIVE	No
		Week 28	26JUL2016/09:15	POSITIVE	No
		Week 32	16AUG2016/10:45	POSITIVE	No
		Week 36	14SEP2016/12:00	POSITIVE	No
		Week 40	12OCT2016/12:10	POSITIVE	No
		Week 44	10NOV2016/11:00	POSITIVE	No
		Week 48	07DEC2016/12:00	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	16DEC2015/08:45	NEGATIVE	Yes



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-005	Hepatitis B Virus e Antigen	Day 1	07JAN2016/10:00	NEGATIVE	Yes
		Week 24	23JUN2016/11:45	NEGATIVE	No
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	07JAN2016/10:00	6596.810	No
		Week 24	23JUN2016/11:45	6170.550	No
		Week 24	07DEC2016/12:00	1895.780	No
	Hepatitis C RNA	Screening	16DEC2015/08:45	NOT DETECTED	Yes
	Hepatitis D RNA (IU/mL)	Screening	16DEC2015/08:45	370000	Yes
		Day 1	07JAN2016/10:00	363000	Yes
		Week 1	13JAN2016/09:30	316000	No
		Week 2	21JAN2016/10:00	245000	No
		Week 4	02FEB2016/09:00	215000	No
		Week 6	17FEB2016/13:00	57400	No
		Week 8	02MAR2016/09:15	37100	No
		Week 12	31MAR2016/10:15	66100	No
		Week 16	26APR2016/10:00	23300	No
		Week 20	26MAY2016/12:30	80700	No
		Week 24	23JUN2016/11:45	20700	No
		Week 28	26JUL2016/09:15	195000	No
		Week 32	16AUG2016/10:45	18600	No
		Week 36	14SEP2016/12:00	14700	No
		Week 40	12OCT2016/12:10	1430	No
		Week 44	10NOV2016/11:00	527	No
		Week 48	07DEC2016/12:00	299	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-005	Hepatitis D RNA (log10 IU/mL)	Screening	16DEC2015/08:45	5.57	Yes
		Day 1	07JAN2016/10:00	5.56	Yes
		Week 1	13JAN2016/09:30	5.5	No
		Week 2	21JAN2016/10:00	5.39	No
		Week 4	02FEB2016/09:00	5.33	No
		Week 6	17FEB2016/13:00	4.76	No
		Week 8	02MAR2016/09:15	4.57	No
		Week 12	31MAR2016/10:15	4.82	No
		Week 16	26APR2016/10:00	4.37	No
		Week 20	26MAY2016/12:30	4.91	No
		Week 24	23JUN2016/11:45	4.32	No
		Week 28	26JUL2016/09:15	5.29	No
		Week 32	16AUG2016/10:45	4.27	No
		Week 36	14SEP2016/12:00	4.17	No
		Week 40	12OCT2016/12:10	3.16	No
		Week 44	10NOV2016/11:00	2.72	No
		Week 48	07DEC2016/12:00	2.48	No
	Hepatitis Delta Ab	Screening	16DEC2015/08:45	POSITIVE	Yes
		Day 1	07JAN2016/10:00	POSITIVE	Yes
		Week 2	21JAN2016/10:00	POSITIVE	No
		Week 4	02FEB2016/09:00	POSITIVE	No
		Week 6	17FEB2016/13:00	POSITIVE	No
		Week 8	02MAR2016/09:15	POSITIVE	No
		Week 12	31MAR2016/10:15	POSITIVE	No
		Week 16	26APR2016/10:00	POSITIVE	No
		Week 20	26MAY2016/12:30	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-005	Hepatitis Delta Ab	Week 24	23JUN2016/11:45	POSITIVE	No
		Week 28	26JUL2016/09:15	POSITIVE	No
		Week 32	16AUG2016/10:45	POSITIVE	No
		Week 36	14SEP2016/12:00	POSITIVE	No
		Week 40	12OCT2016/12:10	POSITIVE	No
		Week 44	10NOV2016/11:00	POSITIVE	No
		Week 48	07DEC2016/12:00	POSITIVE	No
301-008	Anti-HBC (IgG/IgM)	Screening	19JAN2016/12:00	POSITIVE	Yes
		Day 1	11FEB2016/09:00	POSITIVE	No
		Week 1	17FEB2016/11:00	POSITIVE	No
		Week 2	24FEB2016/08:35	POSITIVE	No
		Week 4	10MAR2016/08:00	POSITIVE	No
		Week 6	24MAR2016/08:02	POSITIVE	No
		Week 8	07APR2016/08:30	POSITIVE	Yes
		Early Term	13APR2016/12:20	POSITIVE	Yes
		Week 28	17MAY2016/08:30	POSITIVE	No
		Week 32	09JUN2016/08:30	POSITIVE	No
		Week 36	06JUL2016/08:25	POSITIVE	No
		Week 40	03AUG2016/08:45	POSITIVE	No
		Week 44	07SEP2016/07:55	POSITIVE	No
		Week 48	19OCT2016/07:20	POSITIVE	No
	Anti-HBE	Screening	19JAN2016/12:00	POSITIVE	Yes
		Day 1	11FEB2016/09:00	POSITIVE	No
	HCV Viral Load	Screening	19JAN2016/12:00	NEGATIVE	Yes

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Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-008	HIV-1/2 Antibody	Screening	19JAN2016/12:00	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	19JAN2016/12:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	11FEB2016/09:00	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 1	17FEB2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 2	24FEB2016/08:35	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 4	10MAR2016/08:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 6	24MAR2016/08:02	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 8	07APR2016/08:30	24	Yes
		Early Term	13APR2016/12:20	POSITIVE -BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 28	17MAY2016/08:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-008	Hepatitis B DNA (IU/mL)	Week 32	09JUN2016/08:30	31	No
		Week 36	06JUL2016/08:25	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 40	03AUG2016/08:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 44	07SEP2016/07:55	NOT DETECTED.	No
		Week 48	19OCT2016/07:20	26	No
	Hepatitis B DNA (log10 IU/mL)	Screening	19JAN2016/12:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	11FEB2016/09:00	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 1	17FEB2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 2	24FEB2016/08:35	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 4	10MAR2016/08:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-008	Hepatitis B DNA (log10 IU/mL)	Week 6	24MAR2016/08:02	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 8	07APR2016/08:30	1.38	Yes
		Early Term	13APR2016/12:20	POSITIVE -BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 28	17MAY2016/08:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 32	09JUN2016/08:30	1.49	No
		Week 36	06JUL2016/08:25	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 40	03AUG2016/08:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 44	07SEP2016/07:55	NOT DETECTED.	No
		Week 48	19OCT2016/07:20	1.41	No
	Hepatitis B Virus Surface Antibody	Screening	19JAN2016/12:00	POSITIVE	Yes
		Day 1	11FEB2016/09:00	POSITIVE	No
		Week 1	17FEB2016/11:00	POSITIVE	No
		Week 2	24FEB2016/08:35	POSITIVE	No
		Week 4	10MAR2016/08:00	POSITIVE	No
		Week 6	24MAR2016/08:02	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-008	Hepatitis B Virus Surface Antibody	Week 8	07APR2016/08:30	POSITIVE	Yes
		Early Term	13APR2016/12:20	POSITIVE	Yes
		Week 28	17MAY2016/08:30	POSITIVE	No
		Week 32	09JUN2016/08:30	POSITIVE	No
		Week 36	06JUL2016/08:25	POSITIVE	No
		Week 40	03AUG2016/08:45	POSITIVE	No
		Week 44	07SEP2016/07:55	POSITIVE	No
		Week 48	19OCT2016/07:20	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	19JAN2016/12:00	NEGATIVE	Yes
		Day 1	11FEB2016/09:00	NEGATIVE	No
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	11FEB2016/09:00	20244.52	No
		Early Term	13APR2016/12:20	20360.85	No
		Week 48	19OCT2016/07:20	23516.66	No
	Hepatitis D RNA (IU/mL)	Screening	19JAN2016/12:00	879000	Yes
		Day 1	11FEB2016/09:00	204000	No
		Week 1	17FEB2016/11:00	38300	No
		Week 2	24FEB2016/08:35	6430	No
		Week 4	10MAR2016/08:00	10900	No
		Week 6	24MAR2016/08:02	16500	No
		Week 8	07APR2016/08:30	8430	Yes
		Early Term	13APR2016/12:20	8230	Yes
		Week 28	17MAY2016/08:30	33400	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-008	Hepatitis D RNA (IU/mL)	Week 32	09JUN2016/08:30	74900	No
		Week 36	06JUL2016/08:25	213000	No
		Week 40	03AUG2016/08:45	517000	No
		Week 44	07SEP2016/07:55	362000	No
		Week 48	19OCT2016/07:20	1520000	No
	Hepatitis D RNA (log10 IU/mL)	Screening	19JAN2016/12:00	5.94	Yes
		Day 1	11FEB2016/09:00	5.31	No
		Week 1	17FEB2016/11:00	4.58	No
		Week 2	24FEB2016/08:35	3.81	No
		Week 4	10MAR2016/08:00	4.04	No
		Week 6	24MAR2016/08:02	4.22	No
		Week 8	07APR2016/08:30	3.93	Yes
		Early Term	13APR2016/12:20	3.92	Yes
		Week 28	17MAY2016/08:30	4.52	No
		Week 32	09JUN2016/08:30	4.87	No
		Week 36	06JUL2016/08:25	5.33	No
		Week 40	03AUG2016/08:45	5.71	No
		Week 44	07SEP2016/07:55	5.56	No
		Week 48	19OCT2016/07:20	6.18	No
	Hepatitis Delta Ab	Screening	19JAN2016/12:00	POSITIVE	Yes
		Day 1	11FEB2016/09:00	POSITIVE	No
		Week 2	24FEB2016/08:35	POSITIVE	No
		Week 4	10MAR2016/08:00	POSITIVE	No
		Week 6	24MAR2016/08:02	POSITIVE	No
		Week 8	07APR2016/08:30	POSITIVE	Yes



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-008	Hepatitis Delta Ab	Early Term	13APR2016/12:20	POSITIVE	Yes
		Week 28	17MAY2016/08:30	POSITIVE	No
		Week 32	09JUN2016/08:30	POSITIVE	No
		Week 36	06JUL2016/08:25	POSITIVE	No
		Week 40	03AUG2016/08:45	POSITIVE	No
		Week 44	07SEP2016/07:55	POSITIVE	No
		Week 48	19OCT2016/07:20	POSITIVE	No
301-009	Anti-HBC (IgG/IgM)	Screening	06JAN2016/11:00	POSITIVE	Yes
		Day 1	27JAN2016/11:00	POSITIVE	No
		Week 1	02FEB2016/12:00	POSITIVE	No
		Week 2	10FEB2016/12:45	POSITIVE	No
		Week 4	25FEB2016/11:30	POSITIVE	No
		Week 6	09MAR2016/12:00	POSITIVE	Yes
		Week 8	22MAR2016/08:20	POSITIVE	No
		Week 12	19APR2016/11:20	POSITIVE	No
		Week 16	18MAY2016/12:20	POSITIVE	No
		Week 20	15JUN2016/12:15	POSITIVE	No
		Week 24	20JUL2016/13:50	POSITIVE	Yes
		Week 28	09AUG2016/12:10	POSITIVE	No
		Week 32	06SEP2016/13:10	POSITIVE	No
		Week 36	04OCT2016/12:30	POSITIVE	No
		Week 40	01NOV2016/12:30	POSITIVE	No
		Week 44	29NOV2016/13:15	POSITIVE	No
		Week 48	02JAN2017/12:00	POSITIVE	No
	Anti-HBE	Screening	06JAN2016/11:00	POSITIVE	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-009	Anti-HBE	Day 1	27JAN2016/11:00	POSITIVE	No
		Week 24	20JUL2016/13:50	POSITIVE	Yes
	HCV Viral Load	Screening	06JAN2016/11:00	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	06JAN2016/11:00	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	06JAN2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	27JAN2016/11:00	NOT DETECTED	No
		Week 1	02FEB2016/12:00	NOT DETECTED	No
		Week 2	10FEB2016/12:45	NOT DETECTED	No
		Week 4	25FEB2016/11:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 6	09MAR2016/12:00	NOT DETECTED	Yes
		Week 8	22MAR2016/08:20	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 12	19APR2016/11:20	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 16	18MAY2016/12:20	NOT DETECTED	No
		Week 20	15JUN2016/12:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-009	Hepatitis B DNA (IU/mL)	Week 24	20JUL2016/13:50	NOT DETECTED	Yes
		Week 28	09AUG2016/12:10	NOT DETECTED	No
		Week 32	06SEP2016/13:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 36	04OCT2016/12:30	NOT DETECTED	No
		Week 40	01NOV2016/12:30	NOT DETECTED	No
		Week 44	29NOV2016/13:15	NOT DETECTED	No
		Week 48	02JAN2017/12:00	NOT DETECTED	No
	Hepatitis B DNA (log10 IU/mL)	Screening	06JAN2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	27JAN2016/11:00	NOT DETECTED	No
		Week 1	02FEB2016/12:00	NOT DETECTED	No
		Week 2	10FEB2016/12:45	NOT DETECTED	No
		Week 4	25FEB2016/11:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 6	09MAR2016/12:00	NOT DETECTED	Yes
		Week 8	22MAR2016/08:20	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 12	19APR2016/11:20	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 16	18MAY2016/12:20	NOT DETECTED	No

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Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-009	Hepatitis B DNA (log10 IU/mL)	Week 20	15JUN2016/12:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 24	20JUL2016/13:50	NOT DETECTED	Yes
		Week 28	09AUG2016/12:10	NOT DETECTED	No
		Week 32	06SEP2016/13:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 36	04OCT2016/12:30	NOT DETECTED	No
		Week 40	01NOV2016/12:30	NOT DETECTED	No
		Week 44	29NOV2016/13:15	NOT DETECTED	No
		Week 48	02JAN2017/12:00	NOT DETECTED	No
	Hepatitis B Virus Surface Antibody	Screening	06JAN2016/11:00	POSITIVE	Yes
		Day 1	27JAN2016/11:00	POSITIVE	No
		Week 1	02FEB2016/12:00	POSITIVE	No
		Week 2	10FEB2016/12:45	POSITIVE	No
		Week 4	25FEB2016/11:30	POSITIVE	No
		Week 6	09MAR2016/12:00	POSITIVE	Yes
		Week 8	22MAR2016/08:20	POSITIVE	No
		Week 12	19APR2016/11:20	POSITIVE	No
		Week 16	18MAY2016/12:20	POSITIVE	No
		Week 20	15JUN2016/12:15	POSITIVE	No
		Week 24	20JUL2016/13:50	POSITIVE	Yes
		Week 28	09AUG2016/12:10	POSITIVE	No
		Week 32	06SEP2016/13:10	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-009	Hepatitis B Virus Surface Antibody	Week 36	04OCT2016/12:30	POSITIVE	No
		Week 40	01NOV2016/12:30	POSITIVE	No
		Week 44	29NOV2016/13:15	POSITIVE	No
		Week 48	02JAN2017/12:00	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	06JAN2016/11:00	NEGATIVE	Yes
		Day 1	27JAN2016/11:00	NEGATIVE	No
		Week 24	20JUL2016/13:50	NEGATIVE	Yes
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	27JAN2016/11:00	6866.600	No
		Week 24	20JUL2016/13:20	7249.010	No
		Week 24	02JAN2017/12:00	3540.220	No
	Hepatitis D RNA (IU/mL)	Screening	06JAN2016/11:00	92600	Yes
		Day 1	27JAN2016/11:00	194000	No
		Week 1	02FEB2016/12:00	3530	No
		Week 2	10FEB2016/12:45	1760	No
		Week 4	25FEB2016/11:30	188	No
		Week 6	09MAR2016/12:00	1640	Yes
		Week 8	22MAR2016/08:20	1290	No
		Week 12	19APR2016/11:20	1710	No
		Week 16	18MAY2016/12:20	902	No
		Week 20	15JUN2016/12:15	562	No
		Week 24	20JUL2016/13:50	5190	Yes
		Week 28	09AUG2016/12:10	188000	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-009	Hepatitis D RNA (IU/mL)	Week 32	06SEP2016/13:10	1460	No
		Week 36	04OCT2016/12:30	3140	No
		Week 40	01NOV2016/12:30	38600	No
		Week 44	29NOV2016/13:15	4710	No
		Week 48	02JAN2017/12:00	36100	No
	Hepatitis D RNA (log10 IU/mL)	Screening	06JAN2016/11:00	4.97	Yes
		Day 1	27JAN2016/11:00	5.29	No
		Week 1	02FEB2016/12:00	3.55	No
		Week 2	10FEB2016/12:45	3.25	No
		Week 4	25FEB2016/11:30	2.27	No
		Week 6	09MAR2016/12:00	3.21	Yes
		Week 8	22MAR2016/08:20	3.11	No
		Week 12	19APR2016/11:20	3.23	No
		Week 16	18MAY2016/12:20	2.96	No
		Week 20	15JUN2016/12:15	2.75	No
		Week 24	20JUL2016/13:50	3.72	Yes
		Week 28	09AUG2016/12:10	5.27	No
		Week 32	06SEP2016/13:10	3.16	No
		Week 36	04OCT2016/12:30	3.5	No
		Week 40	01NOV2016/12:30	4.59	No
		Week 44	29NOV2016/13:15	3.67	No
		Week 48	02JAN2017/12:00	4.56	No
	Hepatitis Delta Ab	Screening	06JAN2016/11:00	POSITIVE	Yes
		Day 1	27JAN2016/11:00	POSITIVE	No
		Week 2	10FEB2016/12:45	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-009 Hepatitis Delta Ab	Week 4	25FEB2016/11:30	POSITIVE	No
	Week 6	09MAR2016/12:00	POSITIVE	Yes
	Week 8	22MAR2016/08:20	POSITIVE	No
	Week 12	19APR2016/11:20	POSITIVE	No
	Week 16	18MAY2016/12:20	POSITIVE	No
	Week 20	15JUN2016/12:15	POSITIVE	No
	Week 24	20JUL2016/13:50	POSITIVE	Yes
	Week 28	09AUG2016/12:10	POSITIVE	No
	Week 32	06SEP2016/13:10	POSITIVE	No
	Week 36	04OCT2016/12:30	POSITIVE	No
	Week 40	01NOV2016/12:30	POSITIVE	No
	Week 44	29NOV2016/13:15	POSITIVE	No
	Week 48	02JAN2017/12:00	POSITIVE	No
301-010 Anti-HBC (IgG/IgM)	Screening	07JAN2016/09:30	POSITIVE	Yes
	Day 1	27JAN2016/10:00	POSITIVE	Yes
	Week 1	04FEB2016/10:30	POSITIVE	No
	Week 2	09FEB2016/12:00	POSITIVE	No
	Week 4	24FEB2016/14:00	POSITIVE	No
	Week 6	09MAR2016/11:30	POSITIVE	No
	Week 8	22MAR2016/08:30	POSITIVE	No
	Week 12	19APR2016/11:32	POSITIVE	No
	Week 16	17MAY2016/12:55	POSITIVE	No
	Week 20	20JUN2016/12:12	POSITIVE	No
	Week 24	12JUL2016/11:40	POSITIVE	Yes
	Week 28	08AUG2016/12:30	POSITIVE	No
	Week 32	06SEP2016/11:10	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-010	Anti-HBC (IgG/IgM)	Week 36	04OCT2016/12:40	POSITIVE	No
		Week 40	01NOV2016/12:50	POSITIVE	No
		Week 44	28NOV2016/11:45	POSITIVE	No
		Week 48	03JAN2017/13:00	POSITIVE	No
	Anti-HBE	Screening	07JAN2016/09:30	POSITIVE	Yes
		Day 1	27JAN2016/10:00	POSITIVE	Yes
		Week 24	12JUL2016/11:40	POSITIVE	Yes
	HCV Viral Load	Screening	07JAN2016/09:30	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	07JAN2016/09:30	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	07JAN2016/09:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	27JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 1	04FEB2016/10:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 2	09FEB2016/12:00	57	No
		Week 4	24FEB2016/14:00	67	No
		Week 6	09MAR2016/11:30	426	No
		Week 8	22MAR2016/08:30	1490	No
		Week 12	19APR2016/11:32	37800	No



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-010	Hepatitis B DNA (IU/mL)	Week 16	17MAY2016/12:55	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 20	20JUN2016/12:12	NOT DETECTED	No
		Week 24	12JUL2016/11:40	NOT DETECTED	Yes
		Week 28	08AUG2016/12:30	NOT DETECTED	No
		Week 32	06SEP2016/11:10	NOT DETECTED.	No
		Week 36	04OCT2016/12:40	NOT DETECTED	No
		Week 40	01NOV2016/12:50	NOT DETECTED	No
		Week 44	28NOV2016/11:45	NOT DETECTED	No
		Week 48	03JAN2017/13:00	NOT DETECTED	No
	Hepatitis B DNA (log10 IU/mL)	Screening	07JAN2016/09:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	27JAN2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 1	04FEB2016/10:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 2	09FEB2016/12:00	1.76	No
		Week 4	24FEB2016/14:00	1.83	No
		Week 6	09MAR2016/11:30	2.63	No
		Week 8	22MAR2016/08:30	3.17	No
		Week 12	19APR2016/11:32	4.58	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-010	Hepatitis B DNA (log10 IU/mL)	Week 16	17MAY2016/12:55	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 20	20JUN2016/12:12	NOT DETECTED	No
		Week 24	12JUL2016/11:40	NOT DETECTED	Yes
		Week 28	08AUG2016/12:30	NOT DETECTED	No
		Week 32	06SEP2016/11:10	NOT DETECTED	No
		Week 36	04OCT2016/12:40	NOT DETECTED	No
		Week 40	01NOV2016/12:50	NOT DETECTED	No
		Week 44	28NOV2016/11:45	NOT DETECTED	No
		Week 48	03JAN2017/13:00	NOT DETECTED	No
	Hepatitis B Virus Surface Antibody	Screening	07JAN2016/09:30	POSITIVE	Yes
		Day 1	27JAN2016/10:00	POSITIVE	Yes
		Week 1	04FEB2016/10:30	POSITIVE	No
		Week 2	09FEB2016/12:00	POSITIVE	No
		Week 4	24FEB2016/14:00	POSITIVE	No
		Week 6	09MAR2016/11:30	POSITIVE	No
		Week 8	22MAR2016/08:30	POSITIVE	No
		Week 12	19APR2016/11:32	POSITIVE	No
		Week 16	17MAY2016/12:55	POSITIVE	No
		Week 20	20JUN2016/12:12	POSITIVE	No
		Week 24	12JUL2016/11:40	POSITIVE	Yes
		Week 28	08AUG2016/12:30	POSITIVE	No
		Week 32	06SEP2016/11:10	POSITIVE	No
		Week 36	04OCT2016/12:40	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-010	Hepatitis B Virus Surface Antibody	Week 40	01NOV2016/12:50	POSITIVE	No
		Week 44	28NOV2016/11:45	POSITIVE	No
		Week 48	03JAN2017/13:00	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	07JAN2016/09:30	NEGATIVE	Yes
		Day 1	27JAN2016/10:00	NEGATIVE	Yes
		Week 24	12JUL2016/11:40	NEGATIVE	Yes
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	27JAN2016/10:00	9754.740	No
		Week 24	12JUL2016/11:40	9583.970	No
		Week 48	03JAN2017/13:00	11779.96	No
	Hepatitis D RNA (IU/mL)	Screening	07JAN2016/09:30	6080	Yes
		Day 1	27JAN2016/10:00	18300	Yes
		Week 1	04FEB2016/10:30	134	No
		Week 2	09FEB2016/12:00	78	No
		Week 4	24FEB2016/14:00	POSITIVE - BELOW LIMIT OF QUANTIFICATION.	No
		Week 6	09MAR2016/11:30	239	No
		Week 8	22MAR2016/08:30	14	No
		Week 12	19APR2016/11:32	37	No
		Week 16	17MAY2016/12:55	47	No
		Week 20	20JUN2016/12:12	142	No
		Week 24	12JUL2016/11:40	172	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-010	Hepatitis D RNA (IU/mL)	Week 28	08AUG2016/12:30	11400	No
		Week 32	06SEP2016/11:10	15800	No
		Week 36	04OCT2016/12:40	15300	No
		Week 40	01NOV2016/12:50	40100	No
		Week 44	28NOV2016/11:45	11400	No
		Week 48	03JAN2017/13:00	28100	No
	Hepatitis D RNA (log10 IU/mL)	Screening	07JAN2016/09:30	3.78	Yes
		Day 1	27JAN2016/10:00	4.26	Yes
		Week 1	04FEB2016/10:30	2.13	No
		Week 2	09FEB2016/12:00	1.89	No
		Week 4	24FEB2016/14:00	POSITIVE - BELOW LIMIT OF QUANTIFICATION.	No
		Week 6	09MAR2016/11:30	2.38	No
		Week 8	22MAR2016/08:30	1.15	No
		Week 12	19APR2016/11:32	1.57	No
		Week 16	17MAY2016/12:55	1.67	No
		Week 20	20JUN2016/12:12	2.15	No
		Week 24	12JUL2016/11:40	2.24	Yes
		Week 28	08AUG2016/12:30	4.06	No
		Week 32	06SEP2016/11:10	4.2	No
		Week 36	04OCT2016/12:40	4.18	No
		Week 40	01NOV2016/12:50	4.6	No
		Week 44	28NOV2016/11:45	4.06	No
		Week 48	03JAN2017/13:00	4.45	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-010 Hepatitis Delta Ab	Screening	07JAN2016/09:30	POSITIVE	Yes
	Day 1	27JAN2016/10:00	POSITIVE	Yes
	Week 2	09FEB2016/12:00	POSITIVE	No
	Week 4	24FEB2016/14:00	POSITIVE	No
	Week 6	09MAR2016/11:30	POSITIVE	No
	Week 8	22MAR2016/08:30	POSITIVE	No
	Week 12	19APR2016/11:32	POSITIVE	No
	Week 16	17MAY2016/12:55	POSITIVE	No
	Week 20	20JUN2016/12:12	POSITIVE	No
	Week 24	12JUL2016/11:40	POSITIVE	Yes
	Week 28	08AUG2016/12:30	POSITIVE	No
	Week 32	06SEP2016/11:10	POSITIVE	No
	Week 36	04OCT2016/12:40	POSITIVE	No
	Week 40	01NOV2016/12:50	POSITIVE	No
	Week 44	28NOV2016/11:45	POSITIVE	No
	Week 48	03JAN2017/13:00	POSITIVE	No
301-014 Anti-HBC (IgG/IgM)	Screening	27JAN2016/11:30	POSITIVE	Yes
	Day 1	23FEB2016/13:00	POSITIVE	Yes
	Week 1	01MAR2016/11:30	POSITIVE	No
	Week 2	09MAR2016/10:45	POSITIVE	No
	Week 4	22MAR2016/10:15	POSITIVE	No
	Week 6	05APR2016/11:47	POSITIVE	No
	Week 8	20APR2016/09:15	POSITIVE	Yes
	Week 12	19MAY2016/11:55	POSITIVE	No
	Week 16	14JUN2016/11:08	POSITIVE	No
	Week 20	13JUL2016/11:20	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-014	Anti-HBC (IgG/IgM)	Week 24	10AUG2016/10:50	POSITIVE	Yes
		Week 28	07SEP2016/11:30	POSITIVE	No
		Week 32	05OCT2016/11:00	POSITIVE	No
		Week 36	02NOV2016/12:00	POSITIVE	No
		Week 40	30NOV2016/10:45	POSITIVE	No
		Week 44	22DEC2016/12:00	POSITIVE	No
		Week 48	25JAN2017/11:00	POSITIVE	No
	Anti-HBE	Screening	27JAN2016/11:30	POSITIVE	Yes
		Day 1	23FEB2016/13:00	POSITIVE	Yes
		Week 24	10AUG2016/10:50	POSITIVE	Yes
	HCV Viral Load	Screening	27JAN2016/11:30	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	27JAN2016/11:30	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	27JAN2016/11:30	42	Yes
		Day 1	23FEB2016/13:00	728	Yes
		Week 1	01MAR2016/11:30	30	No
		Week 2	09MAR2016/10:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 4	22MAR2016/10:15	35	No
		Week 6	05APR2016/11:47	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-014	Hepatitis B DNA (IU/mL)	Week 8	20APR2016/09:15	POSITIVE - BELOW TEH LEVEL OF QUANTIFICATION	Yes
		Week 12	19MAY2016/11:55	40	No
		Week 16	14JUN2016/11:08	26	No
		Week 20	13JUL2016/11:20	32	No
		Week 24	10AUG2016/10:50	33	Yes
		Week 28	07SEP2016/11:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 32	05OCT2016/11:00	48	No
		Week 36	02NOV2016/12:00	NOT DETECTED	No
		Week 40	30NOV2016/10:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATIN.	No
		Week 44	22DEC2016/12:00	NOT DETECTED	No
		Week 48	25JAN2017/11:00	27	No
	Hepatitis B DNA (log10 IU/mL)	Screening	27JAN2016/11:30	1.62	Yes
		Day 1	23FEB2016/13:00	2.86	Yes
		Week 1	01MAR2016/11:30	1.48	No
		Week 2	09MAR2016/10:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 4	22MAR2016/10:15	1.54	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-014	Hepatitis B DNA (log10 IU/mL)	Week 6	05APR2016/11:47	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 8	20APR2016/09:15	POSITIVE - BELOW THE LEVEL OF QUANTIFICATION	Yes
		Week 12	19MAY2016/11:55	1.6	No
		Week 16	14JUN2016/11:08	1.41	No
		Week 20	13JUL2016/11:20	1.51	No
		Week 24	10AUG2016/10:50	1.52	Yes
		Week 28	07SEP2016/11:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 32	05OCT2016/11:00	1.68	No
		Week 36	02NOV2016/12:00	NOT DETECTED	No
		Week 40	30NOV2016/10:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 44	22DEC2016/12:00	NOT DETECTED	No
		Week 48	25JAN2017/11:00	1.43	No
	Hepatitis B Virus Surface Antibody	Screening	27JAN2016/11:30	POSITIVE	Yes
		Day 1	23FEB2016/13:00	POSITIVE	Yes
		Week 1	01MAR2016/11:30	POSITIVE	No
		Week 2	09MAR2016/10:45	POSITIVE	No
		Week 4	22MAR2016/10:15	POSITIVE	No



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-014	Hepatitis B Virus Surface Antibody	Week 6	05APR2016/11:47	POSITIVE	No
		Week 8	20APR2016/09:15	POSITIVE	Yes
		Week 12	19MAY2016/11:55	POSITIVE	No
		Week 16	14JUN2016/11:08	POSITIVE	No
		Week 20	13JUL2016/11:20	POSITIVE	No
		Week 24	10AUG2016/10:50	POSITIVE	Yes
		Week 28	07SEP2016/11:30	POSITIVE	No
		Week 32	05OCT2016/11:00	POSITIVE	No
		Week 36	02NOV2016/12:00	POSITIVE	No
		Week 40	30NOV2016/10:45	POSITIVE	No
		Week 44	22DEC2016/12:00	POSITIVE	No
		Week 48	25JAN2017/11:00	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	27JAN2016/11:30	NEGATIVE	Yes
		Day 1	23FEB2016/13:00	NEGATIVE	Yes
		Week 24	10AUG2016/10:50	NEGATIVE	Yes
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	23FEB2016/13:00	18798.39	No
		Week 24	10AUG2016/10:50	18806.36	No
		Week 48	25JAN2017/11:00	13602.00	No
	Hepatitis D RNA (IU/mL)	Screening	27JAN2016/11:30	5900	Yes
		Day 1	23FEB2016/13:00	6200	Yes
		Week 1	01MAR2016/11:30	565	No
		Week 2	09MAR2016/10:45	955	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-014	Hepatitis D RNA (IU/mL)	Week 4	22MAR2016/10:15	568	No
		Week 6	05APR2016/11:47	166	No
		Week 8	20APR2016/09:15	147	Yes
		Week 12	19MAY2016/11:55	29	No
		Week 16	14JUN2016/11:08	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 20	13JUL2016/11:20	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 24	10AUG2016/10:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 28	07SEP2016/11:30	45	No
		Week 32	05OCT2016/11:00	432	No
		Week 36	02NOV2016/12:00	521	No
		Week 40	30NOV2016/10:45	15	No
		Week 44	22DEC2016/12:00	<14	No
		Week 48	25JAN2017/11:00	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
	Hepatitis D RNA (log10 IU/mL)	Screening	27JAN2016/11:30	3.77	Yes
		Day 1	23FEB2016/13:00	3.79	Yes
		Week 1	01MAR2016/11:30	2.75	No
		Week 2	09MAR2016/10:45	2.98	No
		Week 4	22MAR2016/10:15	2.75	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-014	Hepatitis D RNA (log10 IU/mL)	Week 6	05APR2016/11:47	2.22	No
		Week 8	20APR2016/09:15	2.17	Yes
		Week 12	19MAY2016/11:55	1.46	No
		Week 16	14JUN2016/11:08	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 20	13JUL2016/11:20	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 24	10AUG2016/10:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 28	07SEP2016/11:30	1.65	No
		Week 32	05OCT2016/11:00	2.64	No
		Week 36	02NOV2016/12:00	2.72	No
		Week 40	30NOV2016/10:45	1.18	No
		Week 44	22DEC2016/12:00	1.15	No
		Week 48	25JAN2017/11:00	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
	Hepatitis Delta Ab	Screening	27JAN2016/11:30	POSITIVE	Yes
		Day 1	23FEB2016/13:00	POSITIVE	Yes
		Week 2	09MAR2016/10:45	POSITIVE	No
		Week 4	22MAR2016/10:15	POSITIVE	No
		Week 6	05APR2016/11:47	POSITIVE	No
		Week 8	20APR2016/09:15	POSITIVE	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-014 Hepatitis Delta Ab	Week 12	19MAY2016/11:55	POSITIVE	No
	Week 16	14JUN2016/11:08	POSITIVE	No
	Week 20	13JUL2016/11:20	POSITIVE	No
	Week 24	10AUG2016/10:50	POSITIVE	Yes
	Week 28	07SEP2016/11:30	POSITIVE	No
	Week 32	05OCT2016/11:00	POSITIVE	No
	Week 36	02NOV2016/12:00	POSITIVE	No
	Week 40	30NOV2016/10:45	POSITIVE	No
	Week 44	22DEC2016/12:00	POSITIVE	No
	Week 48	25JAN2017/11:00	POSITIVE	No
301-016 Anti-HBC (IgG/IgM)	Screening	03FEB2016/13:00	POSITIVE	Yes
	Day 1	25FEB2016/11:50	POSITIVE	No
	Week 1	02MAR2016/11:30	POSITIVE	No
	Week 2	08MAR2016/11:00	POSITIVE	No
	Week 4	24MAR2016/11:35	POSITIVE	No
	Week 6	07APR2016/11:10	POSITIVE	No
	Week 8	19APR2016/09:00	POSITIVE	Yes
	Week 12	24MAY2016/11:56	POSITIVE	No
	Week 16	14JUN2016/10:30	POSITIVE	No
	Week 20	13JUL2016/11:50	POSITIVE	No
	Week 24	28JUL2016/11:00	POSITIVE	Yes
	Week 28	06SEP2016/10:10	POSITIVE	No
	Week 32	05OCT2016/11:30	POSITIVE	No
	Week 36	02NOV2016/11:45	POSITIVE	No
	Week 40	29NOV2016/11:00	POSITIVE	No
	Week 44	21DEC2016/11:30	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-016	Anti-HBC (IgG/IgM)	Week 48	24JAN2017/12:00	POSITIVE	No
	Anti-HBE	Screening	03FEB2016/13:00	POSITIVE	Yes
		Day 1	25FEB2016/11:50	POSITIVE	No
		Week 24	28JUL2016/11:00	POSITIVE	Yes
	HCV Viral Load	Screening	03FEB2016/13:00	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	03FEB2016/13:00	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	03FEB2016/13:00	33	Yes
		Day 1	25FEB2016/11:50	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 1	02MAR2016/11:30	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 2	08MAR2016/11:00	41	No
		Week 4	24MAR2016/11:35	33	No
		Week 6	07APR2016/11:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 8	19APR2016/09:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-016	Hepatitis B DNA (IU/mL)	Week 12	24MAY2016/11:56	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 16	14JUN2016/10:30	30	No
		Week 20	13JUL2016/11:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 24	28JUL2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 28	06SEP2016/10:10	82	No
		Week 32	05OCT2016/11:30	NOT DETECTED	No
		Week 36	02NOV2016/11:45	NOT DETECTED	No
		Week 40	29NOV2016/11:00	50	No
		Week 44	21DEC2016/11:30	NOT DETECTED	No
		Week 48	24JAN2017/12:00	NOT DETECTED	No
	Hepatitis B DNA (log10 IU/mL)	Screening	03FEB2016/13:00	1.52	Yes
		Day 1	25FEB2016/11:50	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 1	02MAR2016/11:30	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 2	08MAR2016/11:00	1.61	No
		Week 4	24MAR2016/11:35	1.52	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-016	Hepatitis B DNA (log10 IU/mL)	Week 6	07APR2016/11:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 8	19APR2016/09:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes
		Week 12	24MAY2016/11:56	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 16	14JUN2016/10:30	1.48	No
		Week 20	13JUL2016/11:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 24	28JUL2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 28	06SEP2016/10:10	1.91	No
		Week 32	05OCT2016/11:30	NOT DETECTED	No
		Week 36	02NOV2016/11:45	NOT DETECTED	No
		Week 40	29NOV2016/11:00	1.7	No
		Week 44	21DEC2016/11:30	NOT DETECTED	No
		Week 48	24JAN2017/12:00	NOT DETECTED	No
	Hepatitis B Virus Surface Antibody	Screening	03FEB2016/13:00	POSITIVE	Yes
		Day 1	25FEB2016/11:50	POSITIVE	No
		Week 1	02MAR2016/11:30	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-016	Hepatitis B Virus Surface Antibody	Week 2	08MAR2016/11:00	POSITIVE	No
		Week 4	24MAR2016/11:35	POSITIVE	No
		Week 6	07APR2016/11:10	POSITIVE	No
		Week 8	19APR2016/09:00	POSITIVE	Yes
		Week 12	24MAY2016/11:56	POSITIVE	No
		Week 16	14JUN2016/10:30	POSITIVE	No
		Week 20	13JUL2016/11:50	POSITIVE	No
		Week 24	28JUL2016/11:00	POSITIVE	Yes
		Week 28	06SEP2016/10:10	POSITIVE	No
		Week 32	05OCT2016/11:30	POSITIVE	No
		Week 36	02NOV2016/11:45	POSITIVE	No
		Week 40	29NOV2016/11:00	POSITIVE	No
		Week 44	21DEC2016/11:30	POSITIVE	No
		Week 48	24JAN2017/12:00	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	03FEB2016/13:00	NEGATIVE	Yes
		Day 1	25FEB2016/11:50	NEGATIVE	No
		Week 24	28JUL2016/11:00	NEGATIVE	Yes
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	25FEB2016/11:50	80820.83	No
		Week 24	28JUL2016/11:00	69216.64	No
		Week 48	24JAN2017/12:00	71854.47	No
	Hepatitis D RNA (IU/mL)	Screening	03FEB2016/13:00	461000	Yes
		Day 1	25FEB2016/11:50	60000	No



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-016 Hepatitis D RNA (IU/mL)	Week 1	02MAR2016/11:30	3900	No
	Week 2	08MAR2016/11:00	29500	No
	Week 4	24MAR2016/11:35	10500	No
	Week 6	07APR2016/11:10	113	No
	Week 8	19APR2016/09:00	7290	Yes
	Week 12	24MAY2016/11:56	11700	No
	Week 16	14JUN2016/10:30	2620	No
	Week 20	13JUL2016/11:50	13300	No
	Week 24	28JUL2016/11:00	32300	Yes
	Week 28	06SEP2016/10:10	1720000	No
	Week 32	05OCT2016/11:30	7520000	No
	Week 36	02NOV2016/11:45	2710000	No
	Week 40	29NOV2016/11:00	2500000	No
	Week 44	21DEC2016/11:30	1280000	No
	Week 48	24JAN2017/12:00	540000	No
	Hepatitis D RNA (log10 IU/mL)	Screening	5.66	Yes
		Day 1	4.78	No
		Week 1	3.59	No
		Week 2	4.47	No
		Week 4	4.02	No
		Week 6	2.05	No
		Week 8	3.86	Yes
		Week 12	4.07	No
		Week 16	3.42	No
		Week 20	4.12	No
		Week 24	4.51	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-016	Hepatitis D RNA (log10 IU/mL)	Week 28	06SEP2016/10:10	6.24	No
		Week 32	05OCT2016/11:30	6.88	No
		Week 36	02NOV2016/11:45	6.43	No
		Week 40	29NOV2016/11:00	6.4	No
		Week 44	21DEC2016/11:30	6.11	No
		Week 48	24JAN2017/12:00	5.73	No
	Hepatitis Delta Ab	Screening	03FEB2016/13:00	POSITIVE	Yes
		Day 1	25FEB2016/11:50	POSITIVE	No
		Week 2	08MAR2016/11:00	POSITIVE	No
		Week 4	24MAR2016/11:35	POSITIVE	No
		Week 6	07APR2016/11:10	POSITIVE	No
		Week 8	19APR2016/09:00	POSITIVE	Yes
		Week 12	24MAY2016/11:56	POSITIVE	No
		Week 16	14JUN2016/10:30	POSITIVE	No
		Week 20	13JUL2016/11:50	POSITIVE	No
		Week 24	28JUL2016/11:00	POSITIVE	Yes
		Week 28	06SEP2016/10:10	POSITIVE	No
		Week 32	05OCT2016/11:30	POSITIVE	No
		Week 36	02NOV2016/11:45	POSITIVE	No
		Week 40	29NOV2016/11:00	POSITIVE	No
		Week 44	21DEC2016/11:30	POSITIVE	No
		Week 48	24JAN2017/12:00	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-015	Anti-HBC (IgG/IgM)	Screening	02FEB2016/10:50	POSITIVE	Yes
		Day 1	23FEB2016/13:40	POSITIVE	Yes
		Week 1	03MAR2016/12:00	POSITIVE	No
		Week 2	08MAR2016/10:10	POSITIVE	No
		Week 4	23MAR2016/11:32	POSITIVE	No
		Week 6	06APR2016/11:45	POSITIVE	No
		Week 8	20APR2016/09:00	POSITIVE	Yes
		Week 12	17MAY2016/11:55	POSITIVE	No
		Week 16	16JUN2016/12:50	POSITIVE	No
		Week 20	14JUL2016/11:50	POSITIVE	No
		Week 24	10AUG2016/10:20	POSITIVE	Yes
		Week 28	07SEP2016/09:45	POSITIVE	No
		Week 40	30NOV2016/09:50	POSITIVE	No
		Week 44	28DEC2016/11:00	POSITIVE	No
		Week 48	26JAN2017/12:45	POSITIVE	No
	Anti-HBE	Screening	02FEB2016/10:50	POSITIVE	Yes
		Day 1	23FEB2016/13:40	POSITIVE	Yes
		Week 24	10AUG2016/10:20	POSITIVE	Yes
	HCV Viral Load	Screening	02FEB2016/10:50	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	02FEB2016/10:50	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	02FEB2016/10:50	NOT DETECTED	Yes
		Day 1	23FEB2016/13:40	NOT DETECTED	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-015 Hepatitis B DNA (IU/mL)	Week 1	03MAR2016/12:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
	Week 2	08MAR2016/10:10	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
	Week 4	23MAR2016/11:32	NOT DETECTED	No
	Week 6	06APR2016/11:45	NOT DETECTED	No
	Week 8	20APR2016/09:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION PLEASE NOTE THAT THE SAMPLE WAS DILUTED DUE TO THE SMAL	Yes
	Week 12	17MAY2016/11:55	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
	Week 16	16JUN2016/12:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
	Week 20	14JUL2016/11:50	NOT DETECTED	No
	Week 24	10AUG2016/10:20	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-015	Hepatitis B DNA (IU/mL)	Week 28	07SEP2016/09:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 40	30NOV2016/09:50	<9	No
		Week 44	28DEC2016/11:00	NOT DETECTED	No
		Week 48	26JAN2017/12:45	NOT DETECTED	No
	Hepatitis B DNA (log10 IU/mL)	Screening	02FEB2016/10:50	NOT DETECTED	Yes
		Day 1	23FEB2016/13:40	NOT DETECTED	Yes
		Week 1	03MAR2016/12:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 2	08MAR2016/10:10	POSITIVE-BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 4	23MAR2016/11:32	NOT DETECTED	No
		Week 6	06APR2016/11:45	NOT DETECTED	No
		Week 8	20APR2016/09:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes
				PLEASE NOTE THAT THE SAMPLE WAS DILUTED DUE TO THE SMAL	
		Week 12	17MAY2016/11:55	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-015	Hepatitis B DNA (log10 IU/mL)	Week 16	16JUN2016/12:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 20	14JUL2016/11:50	NOT DETECTED	No
		Week 24	10AUG2016/10:20	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 28	07SEP2016/09:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 40	30NOV2016/09:50	0.95	No
		Week 44	28DEC2016/11:00	NOT DETECTED	No
		Week 48	26JAN2017/12:45	NOT DETECTED	No
	Hepatitis B Virus Surface Antibody	Screening	02FEB2016/10:50	POSITIVE	Yes
		Day 1	23FEB2016/13:40	POSITIVE	Yes
		Week 1	03MAR2016/12:00	POSITIVE	No
		Week 2	08MAR2016/10:10	POSITIVE	No
		Week 4	23MAR2016/11:32	POSITIVE	No
		Week 6	06APR2016/11:45	POSITIVE	No
		Week 8	20APR2016/09:00	POSITIVE	Yes
		Week 12	17MAY2016/11:55	POSITIVE	No
		Week 16	16JUN2016/12:50	POSITIVE	No
		Week 20	14JUL2016/11:50	POSITIVE	No
		Week 24	10AUG2016/10:20	POSITIVE	Yes
		Week 28	07SEP2016/09:45	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-015	Hepatitis B Virus Surface Antibody	Week 40	30NOV2016/09:50	POSITIVE	No
		Week 44	28DEC2016/11:00	POSITIVE	No
		Week 48	26JAN2017/12:45	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	02FEB2016/10:50	NEGATIVE	Yes
		Day 1	23FEB2016/13:40	NEGATIVE	Yes
		Week 24	10AUG2016/10:20	NEGATIVE	Yes
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	23FEB2016/13:40	1742.220	No
		Week 24	10AUG2016/10:20	1128.020	No
		Week 48	26JAN2017/12:45	1463.140	No
	Hepatitis D RNA (IU/mL)	Screening	02FEB2016/10:50	156	Yes
		Day 1	23FEB2016/13:40	2090	Yes
		Week 1	03MAR2016/12:00	371	No
		Week 2	08MAR2016/10:10	617	No
		Week 4	23MAR2016/11:32	516	No
		Week 6	06APR2016/11:45	6650	No
		Week 8	20APR2016/09:00	274	Yes
		Week 12	17MAY2016/11:55	28	No
		Week 16	16JUN2016/12:50	28	No
		Week 20	14JUL2016/11:50	18	No
		Week 24	10AUG2016/10:20	47	Yes
		Week 28	07SEP2016/09:45	832	No
		Week 40	30NOV2016/09:50	59400	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-015	Hepatitis D RNA (IU/mL)	Week 44	28DEC2016/11:00	8220	No
		Week 48	26JAN2017/12:45	2430	No
	Hepatitis D RNA (log10 IU/mL)	Screening	02FEB2016/10:50	2.19	Yes
		Day 1	23FEB2016/13:40	3.32	Yes
		Week 1	03MAR2016/12:00	2.57	No
		Week 2	08MAR2016/10:10	2.79	No
		Week 4	23MAR2016/11:32	2.71	No
		Week 6	06APR2016/11:45	3.82	No
		Week 8	20APR2016/09:00	2.44	Yes
		Week 12	17MAY2016/11:55	1.45	No
		Week 16	16JUN2016/12:50	1.45	No
		Week 20	14JUL2016/11:50	1.26	No
		Week 24	10AUG2016/10:20	1.67	Yes
		Week 28	07SEP2016/09:45	2.92	No
		Week 40	30NOV2016/09:50	4.77	No
		Week 44	28DEC2016/11:00	3.91	No
		Week 48	26JAN2017/12:45	3.39	No
	Hepatitis Delta Ab	Screening	02FEB2016/10:50	POSITIVE	Yes
		Day 1	23FEB2016/13:40	POSITIVE	Yes
		Week 2	08MAR2016/10:10	POSITIVE	No
		Week 4	23MAR2016/11:32	POSITIVE	No
		Week 6	06APR2016/11:45	POSITIVE	No
		Week 8	20APR2016/09:00	POSITIVE	Yes
		Week 12	17MAY2016/11:55	POSITIVE	No
		Week 16	16JUN2016/12:50	POSITIVE	No



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-015	Hepatitis Delta Ab	Week 20	14JUL2016/11:50	POSITIVE	No
		Week 24	10AUG2016/10:20	POSITIVE	Yes
		Week 28	07SEP2016/09:45	POSITIVE	No
		Week 40	30NOV2016/09:50	POSITIVE	No
		Week 44	28DEC2016/11:00	POSITIVE	No
		Week 48	26JAN2017/12:45	POSITIVE	No
301-018	Anti-HBC (IgG/IgM)	Screening	17FEB2016/14:45	POSITIVE	Yes
		Day 1	09MAR2016/10:15	POSITIVE	Yes
		Week 1	16MAR2016/11:05	POSITIVE	No
		Week 2	23MAR2016/09:35	POSITIVE	No
		Week 4	06APR2016/10:10	POSITIVE	No
		Week 6	21APR2016/10:20	POSITIVE	No
		Week 8	28APR2016/09:45	POSITIVE	No
		Week 12	01JUN2016/08:40	POSITIVE	Yes
		Week 16	29JUN2016/09:45	POSITIVE	No
		Week 20	27JUL2016/09:50	POSITIVE	No
		Week 24	23AUG2016/10:00	POSITIVE	Yes
		Week 28	20SEP2016/11:30	POSITIVE	No
		Week 32	18OCT2016/11:00	POSITIVE	No
		Week 36	15NOV2016/12:00	POSITIVE	No
		Week 40	14DEC2016/12:00	POSITIVE	No
		Week 44	10JAN2017/11:30	POSITIVE	No
		Week 48	07FEB2017/10:30	POSITIVE	No
	Anti-HBE	Screening	17FEB2016/14:45	POSITIVE	Yes
		Day 1	09MAR2016/10:15	POSITIVE	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-018	Anti-HBE	Week 24	23AUG2016/10:00	POSITIVE	Yes
	HCV Viral Load	Screening	17FEB2016/14:45	EQUIVOCAL	Yes
	HIV-1/2 Antibody	Screening	17FEB2016/14:45	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening Day 1	17FEB2016/14:45	22	Yes
			09MAR2016/10:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes
		Week 1	16MAR2016/11:05	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 2	23MAR2016/09:35	63	No
		Week 4	06APR2016/10:10	<40	No
		Week 6	21APR2016/10:20	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 8	28APR2016/09:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 12	01JUN2016/08:40	24	Yes
		Week 16	29JUN2016/09:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-018	Hepatitis B DNA (IU/mL)	Week 20	27JUL2016/09:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 24	23AUG2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 28	20SEP2016/11:30	34	No
		Week 32	18OCT2016/11:00	NOT DETECTED	No
		Week 36	15NOV2016/12:00	NOT DETECTED	No
		Week 40	14DEC2016/12:00	23	No
		Week 44	10JAN2017/11:30	28	No
		Week 48	07FEB2017/10:30	<20	No
	Hepatitis B DNA (log10 IU/mL)	Screening	17FEB2016/14:45	1.34	Yes
		Day 1	09MAR2016/10:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes
		Week 1	16MAR2016/11:05	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 2	23MAR2016/09:35	1.8	No
		Week 4	06APR2016/10:10	1.6	No
		Week 6	21APR2016/10:20	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-018	Hepatitis B DNA (log10 IU/mL)	Week 8	28APR2016/09:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 12	01JUN2016/08:40	1.38	Yes
		Week 16	29JUN2016/09:45	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 20	27JUL2016/09:50	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 24	23AUG2016/10:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 28	20SEP2016/11:30	1.53	No
		Week 32	18OCT2016/11:00	NOT DETECTED	No
		Week 36	15NOV2016/12:00	NOT DETECTED	No
		Week 40	14DEC2016/12:00	1.36	No
		Week 44	10JAN2017/11:30	1.45	No
		Week 48	07FEB2017/10:30	1.3	No
	Hepatitis B Virus Surface Antibody	Screening	17FEB2016/14:45	POSITIVE	Yes
		Day 1	09MAR2016/10:15	POSITIVE	Yes
		Week 1	16MAR2016/11:05	POSITIVE	No
		Week 2	23MAR2016/09:35	POSITIVE	No
		Week 4	06APR2016/10:10	POSITIVE	No
		Week 6	21APR2016/10:20	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-018	Hepatitis B Virus Surface Antibody	Week 8	28APR2016/09:45	POSITIVE	No
		Week 12	01JUN2016/08:40	POSITIVE	Yes
		Week 16	29JUN2016/09:45	POSITIVE	No
		Week 20	27JUL2016/09:50	POSITIVE	No
		Week 24	23AUG2016/10:00	POSITIVE	Yes
		Week 28	20SEP2016/11:30	POSITIVE	No
		Week 32	18OCT2016/11:00	POSITIVE	No
		Week 36	15NOV2016/12:00	POSITIVE	No
		Week 40	14DEC2016/12:00	POSITIVE	No
		Week 44	10JAN2017/11:30	POSITIVE	No
		Week 48	07FEB2017/10:30	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	17FEB2016/14:45	NEGATIVE	Yes
		Day 1	09MAR2016/10:15	NEGATIVE	Yes
		Week 24	23AUG2016/10:00	NEGATIVE	Yes
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	09MAR2016/10:15	23406.04	No
		Week 24	23AUG2016/10:00	24312.53	No
		Week 48	07FEB2017/10:30	22254.56	No
	Hepatitis C RNA	Screening	17FEB2016/14:45	NOT DETECTED	No
		Day 1	09MAR2016/10:15	NOT DETECTED	Yes
	Hepatitis D RNA (IU/mL)	Screening	17FEB2016/14:45	65100	Yes
		Day 1	09MAR2016/10:15	71100	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-018 Hepatitis D RNA (IU/mL)	Week 1	16MAR2016/11:05	14100	No
	Week 2	23MAR2016/09:35	21800	No
	Week 4	06APR2016/10:10	3660	No
	Week 6	21APR2016/10:20	1540	No
	Week 8	28APR2016/09:45	1570	No
	Week 12	01JUN2016/08:40	882	Yes
	Week 16	29JUN2016/09:45	869	No
	Week 20	27JUL2016/09:50	2730	No
	Week 24	23AUG2016/10:00	13300	Yes
	Week 28	20SEP2016/11:30	521000	No
	Week 32	18OCT2016/11:00	491000	No
	Week 36	15NOV2016/12:00	1090000	No
	Week 40	14DEC2016/12:00	242000	No
	Week 44	10JAN2017/11:30	870000	No
	Week 48	07FEB2017/10:30	79900	No
	Hepatitis D RNA (log10 IU/mL) Screening	17FEB2016/14:45	4.81	Yes
	Day 1	09MAR2016/10:15	4.85	Yes
	Week 1	16MAR2016/11:05	4.15	No
	Week 2	23MAR2016/09:35	4.34	No
	Week 4	06APR2016/10:10	3.56	No
	Week 6	21APR2016/10:20	3.19	No
	Week 8	28APR2016/09:45	3.2	No
	Week 12	01JUN2016/08:40	2.95	Yes
	Week 16	29JUN2016/09:45	2.94	No
	Week 20	27JUL2016/09:50	3.44	No
	Week 24	23AUG2016/10:00	4.12	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-018	Hepatitis D RNA (log10 IU/mL)	Week 28	20SEP2016/11:30	5.72	No
		Week 32	18OCT2016/11:00	5.69	No
		Week 36	15NOV2016/12:00	6.04	No
		Week 40	14DEC2016/12:00	5.38	No
		Week 44	10JAN2017/11:30	5.94	No
		Week 48	07FEB2017/10:30	4.9	No
	Hepatitis Delta Ab	Screening	17FEB2016/14:45	POSITIVE	Yes
		Day 1	09MAR2016/10:15	POSITIVE	Yes
		Week 2	23MAR2016/09:35	POSITIVE	No
		Week 4	06APR2016/10:10	POSITIVE	No
		Week 6	21APR2016/10:20	POSITIVE	No
		Week 8	28APR2016/09:45	POSITIVE	No
		Week 12	01JUN2016/08:40	POSITIVE	Yes
		Week 16	29JUN2016/09:45	POSITIVE	No
		Week 20	27JUL2016/09:50	POSITIVE	No
		Week 24	23AUG2016/10:00	POSITIVE	Yes
		Week 28	20SEP2016/11:30	POSITIVE	No
		Week 32	18OCT2016/11:00	POSITIVE	No
		Week 36	15NOV2016/12:00	POSITIVE	No
		Week 40	14DEC2016/12:00	POSITIVE	No
		Week 44	10JAN2017/11:30	POSITIVE	No
		Week 48	07FEB2017/10:30	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-006	Anti-HBC (IgG/IgM)	Day 1	04FEB2016/09:45	POSITIVE	Yes
		Week 1	10FEB2016/13:00	POSITIVE	No
		Week 2	16FEB2016/14:00	POSITIVE	No
		Week 4	03MAR2016/12:15	POSITIVE	No
		Week 6	17MAR2016/11:31	POSITIVE	No
		Week 8	31MAR2016/11:22	POSITIVE	No
		Week 12	26APR2016/08:15	POSITIVE	Yes
		Week 16	25MAY2016/11:55	POSITIVE	No
		Week 20	23JUN2016/12:45	POSITIVE	No
		Week 24	19JUL2016/12:00	POSITIVE	Yes
		Week 28	18AUG2016/12:15	POSITIVE	No
		Week 32	13SEP2016/11:45	POSITIVE	No
		Week 36	13OCT2016/12:10	POSITIVE	No
		Week 40	08NOV2016/11:00	POSITIVE	No
		Week 44	08DEC2016/11:00	POSITIVE	No
		Week 48	03JAN2017/12:00	POSITIVE	No
	Anti-HBE	Screening	14JAN2016/13:30	POSITIVE	Yes
		Day 1	04FEB2016/09:45	POSITIVE	Yes
		Week 24	19JUL2016/12:00	NEGATIVE	Yes
	HCV Viral Load	Screening	14JAN2016/13:30	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	14JAN2016/13:30	NEGATIVE	Yes



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-006	Hepatitis B DNA (IU/mL)	Screening	14JAN2016/13:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	04FEB2016/09:45	144	Yes
		Week 1	10FEB2016/13:00	108	No
		Week 2	16FEB2016/14:00	522	No
		Week 4	03MAR2016/12:15	4140	No
		Week 6	17MAR2016/11:31	26500	No
		Week 8	31MAR2016/11:22	179000	No
		Week 12	26APR2016/08:15	12400000	Yes
		Week 16	25MAY2016/11:55	575000	No
		Week 20	23JUN2016/12:45	242000	No
		Week 24	19JUL2016/12:00	169000	Yes
		Week 28	18AUG2016/12:15	68300	No
		Week 32	13SEP2016/11:45	11600	No
		Week 36	13OCT2016/12:10	5349	No
		Week 40	08NOV2016/11:00	1454	No
		Week 44	08DEC2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 48	03JAN2017/12:00	475	No
	Hepatitis B DNA (log10 IU/mL)	Screening	14JAN2016/13:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Day 1	04FEB2016/09:45	2.16	Yes
		Week 1	10FEB2016/13:00	2.03	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-006	Hepatitis B DNA (log10 IU/mL)	Week 2	16FEB2016/14:00	2.72	No
		Week 4	03MAR2016/12:15	3.62	No
		Week 6	17MAR2016/11:31	4.42	No
		Week 8	31MAR2016/11:22	5.25	No
		Week 12	26APR2016/08:15	7.09	Yes
		Week 16	25MAY2016/11:55	5.76	No
		Week 20	23JUN2016/12:45	5.38	No
		Week 24	19JUL2016/12:00	5.23	Yes
		Week 28	18AUG2016/12:15	4.83	No
		Week 32	13SEP2016/11:45	4.06	No
		Week 36	13OCT2016/12:10	3.73	No
		Week 40	08NOV2016/11:00	3.16	No
		Week 44	08DEC2016/11:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 48	03JAN2017/12:00	2.68	No
	Hepatitis B Virus Surface Antibody	Screening	14JAN2016/13:30	POSITIVE	Yes
		Day 1	04FEB2016/09:45	POSITIVE	Yes
		Week 1	10FEB2016/13:00	POSITIVE	No
		Week 2	16FEB2016/14:00	POSITIVE	No
		Week 4	03MAR2016/12:15	POSITIVE	No
		Week 6	17MAR2016/11:31	POSITIVE	No
		Week 8	31MAR2016/11:22	POSITIVE	No
		Week 12	26APR2016/08:15	POSITIVE	Yes
		Week 16	25MAY2016/11:55	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-006	Hepatitis B Virus Surface Antibody	Week 20	23JUN2016/12:45	POSITIVE	No
		Week 24	19JUL2016/12:00	POSITIVE	Yes
		Week 28	18AUG2016/12:15	POSITIVE	No
		Week 32	13SEP2016/11:45	POSITIVE	No
		Week 36	13OCT2016/12:10	POSITIVE	No
		Week 40	08NOV2016/11:00	POSITIVE	No
		Week 44	08DEC2016/11:00	POSITIVE	No
		Week 48	03JAN2017/12:00	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	14JAN2016/13:30	NEGATIVE	Yes
		Day 1	04FEB2016/09:45	NEGATIVE	Yes
		Week 24	19JUL2016/12:00	POSITIVE	Yes
	Hepatitis B surface antigen (quantitativ (IU/mL)	Day 1	04FEB2016/09:45	4153.630	No
		Week 24	19JUL2016/12:00	5634.480	No
		Week 24	03JAN2017/12:00	4770.320	No
	Hepatitis D RNA (IU/mL)	Screening	14JAN2016/13:30	3940	Yes
		Day 1	04FEB2016/09:45	154	Yes
		Week 1	10FEB2016/13:00	328	No
		Week 2	16FEB2016/14:00	5430	No
		Week 4	03MAR2016/12:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 6	17MAR2016/11:31	56	No

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Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-006	Hepatitis D RNA (IU/mL)	Week 8	31MAR2016/11:22	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 12	26APR2016/08:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
		Week 16	25MAY2016/11:55	507	No
		Week 20	23JUN2016/12:45	232	No
		Week 24	19JUL2016/12:00	17300	Yes
		Week 28	18AUG2016/12:15	1940000	No
		Week 32	13SEP2016/11:45	78800	No
		Week 36	13OCT2016/12:10	6020	No
		Week 40	08NOV2016/11:00	6770	No
		Week 44	08DEC2016/11:00	2880	No
		Week 48	03JAN2017/12:00	1820	No
	Hepatitis D RNA (log10 IU/mL)	Screening	14JAN2016/13:30	3.6	Yes
		Day 1	04FEB2016/09:45	2.19	Yes
		Week 1	10FEB2016/13:00	2.52	No
		Week 2	16FEB2016/14:00	3.73	No
		Week 4	03MAR2016/12:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No
		Week 6	17MAR2016/11:31	1.75	No
		Week 8	31MAR2016/11:22	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-006 Hepatitis D RNA (log10 IU/mL)	Week 12	26APR2016/08:15	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION.	Yes
	Week 16	25MAY2016/11:55	2.71	No
	Week 20	23JUN2016/12:45	2.37	No
	Week 24	19JUL2016/12:00	4.24	Yes
	Week 28	18AUG2016/12:15	6.29	No
	Week 32	13SEP2016/11:45	4.9	No
	Week 36	13OCT2016/12:10	3.78	No
	Week 40	08NOV2016/11:00	3.83	No
	Week 44	08DEC2016/11:00	3.46	No
	Week 48	03JAN2017/12:00	3.26	No
	Hepatitis Delta Ab Screening	14JAN2016/13:30	POSITIVE	Yes
	Day 1	04FEB2016/09:45	POSITIVE	Yes
	Week 2	16FEB2016/14:00	POSITIVE	No
	Week 4	03MAR2016/12:15	POSITIVE	No
	Week 6	17MAR2016/11:31	POSITIVE	No
	Week 8	31MAR2016/11:22	POSITIVE	No
	Week 12	26APR2016/08:15	POSITIVE	Yes
	Week 16	25MAY2016/11:55	POSITIVE	No
	Week 20	23JUN2016/12:45	POSITIVE	No
	Week 24	19JUL2016/12:00	POSITIVE	Yes
	Week 28	18AUG2016/12:15	POSITIVE	No
	Week 32	13SEP2016/11:45	POSITIVE	No
	Week 36	13OCT2016/12:10	POSITIVE	No
	Week 40	08NOV2016/11:00	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-006	Hepatitis Delta Ab	Week 44	08DEC2016/11:00	POSITIVE	No
		Week 48	03JAN2017/12:00	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-017 Anti-HBC (IgG/IgM)	Screening	17FEB2016/13:00	POSITIVE	Yes
	Day 1	08MAR2016/10:50	POSITIVE	No
	Week 1	15MAR2016/09:25	POSITIVE	No
	Week 2	23MAR2016/09:08	POSITIVE	No
	Week 4	05APR2016/10:15	POSITIVE	No
	Week 6	19APR2016/09:45	POSITIVE	No
	Week 8	28APR2016/10:10	POSITIVE	No
	Week 12	01JUN2016/08:30	POSITIVE	Yes
	Week 16	29JUN2016/09:23	POSITIVE	No
	Week 20	26JUL2016/09:45	POSITIVE	No
	Week 24	24AUG2016/09:30	POSITIVE	Yes
	Week 28	20SEP2016/12:00	POSITIVE	No
	Week 32	19OCT2016/11:00	POSITIVE	No
	Week 36	15NOV2016/11:15	POSITIVE	No
	Week 40	14DEC2016/09:30	POSITIVE	No
	Week 44	11JAN2017/11:00	POSITIVE	No
	Week 48	08FEB2017/11:50	POSITIVE	No
Anti-HBE	Screening	17FEB2016/13:00	POSITIVE	Yes
	Day 1	08MAR2016/10:50	POSITIVE	No
	Week 1	15MAR2016/09:25	POSITIVE	No
	Week 24	24AUG2016/09:30	POSITIVE	Yes
HCV Viral Load	Screening	17FEB2016/13:00	NEGATIVE	Yes
HIV-1/2 Antibody	Screening	17FEB2016/13:00	NEGATIVE	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-017 Hepatitis B DNA (IU/mL)	Screening	17FEB2016/13:00	33	Yes
	Day 1	08MAR2016/10:50	25	No
	Week 1	15MAR2016/09:25	80	No
	Week 2	23MAR2016/09:08	80	No
	Week 4	05APR2016/10:15	39	No
	Week 6	19APR2016/09:45	95	No
	Week 8	28APR2016/10:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
	Week 12	01JUN2016/08:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes
	Week 16	29JUN2016/09:23	NOT DETECTED	No
	Week 20	26JUL2016/09:45	NOT DETECTED	No
	Week 24	24AUG2016/09:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
	Week 28	20SEP2016/12:00	33	No
	Week 32	19OCT2016/11:00	46	No
	Week 36	15NOV2016/11:15	213	No
	Week 40	14DEC2016/09:30	NOT DETECTED	No
	Week 44	11JAN2017/11:00	91	No
	Week 48	08FEB2017/11:50	NOT DETECTED	No
Hepatitis B DNA (log10 IU/mL)	Screening	17FEB2016/13:00	1.52	Yes
	Day 1	08MAR2016/10:50	1.4	No
	Week 1	15MAR2016/09:25	1.9	No



Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-017	Hepatitis B DNA (log10 IU/mL)	Week 2	23MAR2016/09:08	1.9	No
		Week 4	05APR2016/10:15	1.59	No
		Week 6	19APR2016/09:45	1.98	No
		Week 8	28APR2016/10:10	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 12	01JUN2016/08:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes
		Week 16	29JUN2016/09:23	NOT DETECTED	No
		Week 20	26JUL2016/09:45	NOT DETECTED	No
		Week 24	24AUG2016/09:30	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	No
		Week 28	20SEP2016/12:00	1.52	No
		Week 32	19OCT2016/11:00	1.66	No
		Week 36	15NOV2016/11:15	2.33	No
		Week 40	14DEC2016/09:30	NOT DETECTED	No
		Week 44	11JAN2017/11:00	1.96	No
		Week 48	08FEB2017/11:50	NOT DETECTED	No
	Hepatitis B Virus Surface Antibody	Screening	17FEB2016/13:00	POSITIVE	Yes
		Day 1	08MAR2016/10:50	POSITIVE	No
		Week 1	15MAR2016/09:25	POSITIVE	No
		Week 2	23MAR2016/09:08	POSITIVE	No
		Week 4	05APR2016/10:15	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-017	Hepatitis B Virus Surface Antibody	Week 6	19APR2016/09:45	POSITIVE	No
		Week 8	28APR2016/10:10	POSITIVE	No
		Week 12	01JUN2016/08:30	POSITIVE	Yes
		Week 16	29JUN2016/09:23	POSITIVE	No
		Week 20	26JUL2016/09:45	POSITIVE	No
		Week 24	24AUG2016/09:30	POSITIVE	Yes
		Week 28	20SEP2016/12:00	POSITIVE	No
		Week 32	19OCT2016/11:00	POSITIVE	No
		Week 36	15NOV2016/11:15	POSITIVE	No
		Week 40	14DEC2016/09:30	POSITIVE	No
		Week 44	11JAN2017/11:00	POSITIVE	No
		Week 48	08FEB2017/11:50	POSITIVE	No
	Hepatitis B Virus e Antigen	Screening	17FEB2016/13:00	NEGATIVE	Yes
		Day 1	08MAR2016/10:50	NEGATIVE	No
		Week 1	15MAR2016/09:25	NEGATIVE	No
		Week 24	24AUG2016/09:30	NEGATIVE	Yes
	Hepatitis B surface antigen (quantitativ (IU/mL))	Day 1	08MAR2016/10:50	25969.79	No
		Week 24	24AUG2016/09:30	36319.87	No
		Week 48	08FEB2017/11:50	22058.34	No
	Hepatitis D RNA (IU/mL)	Screening	17FEB2016/13:00	3070000	Yes
		Day 1	08MAR2016/10:50	1160000	No
		Week 1	15MAR2016/09:25	49500	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-017 Hepatitis D RNA (IU/mL)	Week 2	23MAR2016/09:08	64000	No
	Week 4	05APR2016/10:15	7190	No
	Week 6	19APR2016/09:45	6510	No
	Week 8	28APR2016/10:10	4910	No
	Week 12	01JUN2016/08:30	3170	Yes
	Week 16	29JUN2016/09:23	2730	No
	Week 20	26JUL2016/09:45	3470	No
	Week 24	24AUG2016/09:30	5310	Yes
	Week 28	20SEP2016/12:00	15600000	No
	Week 32	19OCT2016/11:00	49500000	No
	Week 36	15NOV2016/11:15	33400000	No
	Week 40	14DEC2016/09:30	3120000	No
	Week 44	11JAN2017/11:00	15600000	No
	Week 48	08FEB2017/11:50	9100000	No
Hepatitis D RNA (log10 IU/mL)	Screening	17FEB2016/13:00	6.49	Yes
	Day 1	08MAR2016/10:50	6.06	No
	Week 1	15MAR2016/09:25	4.69	No
	Week 2	23MAR2016/09:08	4.81	No
	Week 4	05APR2016/10:15	3.86	No
	Week 6	19APR2016/09:45	3.81	No
	Week 8	28APR2016/10:10	3.69	No
	Week 12	01JUN2016/08:30	3.5	Yes
	Week 16	29JUN2016/09:23	3.44	No
	Week 20	26JUL2016/09:45	3.54	No
	Week 24	24AUG2016/09:30	3.73	Yes
	Week 28	20SEP2016/12:00	7.19	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-017	Hepatitis D RNA (log10 IU/mL)	Week 32	19OCT2016/11:00	7.69	No
		Week 36	15NOV2016/11:15	7.52	No
		Week 40	14DEC2016/09:30	6.49	No
		Week 44	11JAN2017/11:00	7.19	No
		Week 48	08FEB2017/11:50	6.96	No
	Hepatitis Delta Ab	Screening	17FEB2016/13:00	POSITIVE	Yes
		Day 1	08MAR2016/10:50	POSITIVE	No
		Week 1	15MAR2016/09:25	POSITIVE	No
		Week 2	23MAR2016/09:08	POSITIVE	No
		Week 4	05APR2016/10:15	POSITIVE	No
		Week 6	19APR2016/09:45	POSITIVE	No
		Week 8	28APR2016/10:10	POSITIVE	No
		Week 12	01JUN2016/08:30	POSITIVE	Yes
		Week 16	29JUN2016/09:23	POSITIVE	No
		Week 20	26JUL2016/09:45	POSITIVE	No
		Week 24	24AUG2016/09:30	POSITIVE	Yes
		Week 28	20SEP2016/12:00	POSITIVE	No
		Week 32	19OCT2016/11:00	POSITIVE	No
		Week 36	15NOV2016/11:15	POSITIVE	No
		Week 40	14DEC2016/09:30	POSITIVE	No
		Week 44	11JAN2017/11:00	POSITIVE	No
		Week 48	08FEB2017/11:50	POSITIVE	No

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-004	Anti-HBC (IgG/IgM)	Screening	16DEC2015/11:50	POSITIVE	Yes
	Anti-HBE	Screening	16DEC2015/11:50	POSITIVE	Yes
	HCV Viral Load	Screening	16DEC2015/11:50	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	16DEC2015/11:50	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	16DEC2015/11:50	100	Yes
	Hepatitis B DNA (log10 IU/mL)	Screening	16DEC2015/11:50	2	Yes
	Hepatitis B Virus Surface Antibody	Screening	16DEC2015/11:50	POSITIVE	Yes
	Hepatitis B Virus e Antigen	Screening	16DEC2015/11:50	NEGATIVE	Yes
	Hepatitis D RNA (IU/mL)	Screening	16DEC2015/11:50	13300	Yes
	Hepatitis D RNA (log10 IU/mL)	Screening	16DEC2015/11:50	4.12	Yes
	Hepatitis Delta Ab	Screening	16DEC2015/11:50	POSITIVE	Yes
301-012	Anti-HBC (IgG/IgM)	Screening	26JAN2016/13:00	POSITIVE	Yes
	Anti-HBE	Screening	26JAN2016/13:00	POSITIVE	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-012	HCV Viral Load	Screening	26JAN2016/13:00	NEGATIVE	Yes
	HIV-1/2 Antibody	Screening	26JAN2016/13:00	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	26JAN2016/13:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes
	Hepatitis B DNA (log10 IU/mL)	Screening	26JAN2016/13:00	POSITIVE - BELOW THE LIMIT OF QUANTIFICATION	Yes
	Hepatitis B Virus Surface Antibody	Screening	26JAN2016/13:00	POSITIVE	Yes
	Hepatitis B Virus e Antigen	Screening	26JAN2016/13:00	NEGATIVE	Yes
	Hepatitis D RNA (IU/mL)	Screening	26JAN2016/13:00	1210000	Yes
	Hepatitis D RNA (log10 IU/mL)	Screening	26JAN2016/13:00	6.08	Yes
	Hepatitis Delta Ab	Screening	26JAN2016/13:00	POSITIVE	Yes
301-013	Anti-HBC (IgG/IgM)	Screening	26JAN2016/13:00	POSITIVE	Yes
	Anti-HBE	Screening	26JAN2016/13:00	NEGATIVE	Yes

Listing 16.2.7.5  
Laboratory Results - Viral Serology  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Fasting?
301-013	HCV Viral Load	Screening	26JAN2016/13:00	POSITIVE	Yes
	HIV-1/2 Antibody	Screening	26JAN2016/13:00	NEGATIVE	Yes
	Hepatitis B DNA (IU/mL)	Screening	26JAN2016/13:00	13000000	Yes
	Hepatitis B DNA (log10 IU/mL)	Screening	26JAN2016/13:00	7.11	Yes
	Hepatitis B Virus Surface Antibody	Screening	26JAN2016/13:00	POSITIVE	Yes
	Hepatitis B Virus e Antigen	Screening	26JAN2016/13:00	POSITIVE	Yes
	Hepatitis C RNA	Screening	26JAN2016/13:00	NOT DETECTED	Yes
	Hepatitis D RNA (IU/mL)	Screening	26JAN2016/13:00	2000000	Yes
	Hepatitis D RNA (log10 IU/mL)	Screening	26JAN2016/13:00	6.3	Yes
	Hepatitis Delta Ab	Screening	26JAN2016/13:00	POSITIVE	Yes

Listing 16.2.7.7  
Urine Pregnancy Test  
(All Female Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Visit	Is female patient of childbearing potential?	Was a urine pregnancy test performed?	Date/Time of Collection	Result
301-007	Day 1	No	No		
	Week 4	No	No		
	Week 6	No	No		
	Week 8	No	No		
	Week 24	No	No		
	Week 28	No	No		
	Week 32	No	No		
	Week 40	No	No		
	Week 44	No	No		
	Week 48	No	No		
301-011	Day 1	No	No		
	Week 4	No	No		
	Week 6	No	No		
	Week 8	No	No		
	Week 12	No	No		
	Week 16	No	No		
	Week 20	No	No		
	Week 24	No	No		
	Week 28	No	No		
	Week 32	No	No		
	Week 36	No	No		
	Week 40	No	No		
	Week 44	No	No		
	Week 48	No	No		

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.7  
Urine Pregnancy Test  
(All Female Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Visit	Is female patient of childbearing potential?	Was a urine pregnancy test performed?	Date/Time of Collection	Result
301-003	Day 1	Yes	Yes	06JAN2016	Negative
	Week 4	Yes	Yes	03FEB2016	Negative
	Week 6	Yes	Yes	18FEB2016	Negative
	Week 8	Yes	Yes	08MAR2016	Negative
	Week 12	Yes	Yes	29MAR2016	Negative
	Week 16	Yes	Yes	25APR2016	Negative
	Week 20	Yes	Yes	26MAY2016	Negative
	Week 24	Yes	Yes	22JUN2016	Negative
	Week 28	Yes	Yes	19JUL2016	Negative
	Week 32	Yes	Yes	16AUG2016	Negative
	Week 36	Yes	Yes	15SEP2016	Negative
	Week 40	Yes	Yes	12OCT2016	Negative
	Week 44	Yes	Yes	09NOV2016	Negative
	Week 48	Yes	Yes	14DEC2016	Negative
301-017	Day 1	No	No		
	Week 4	No	No		
	Week 6	No	No		
	Week 8	No	No		
	Week 12	No	No		
	Week 16	No	No		
	Week 20	No	No		
	Week 24	No	No		
	Week 28	No	No		
	Week 32	No	No		

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.7  
Urine Pregnancy Test  
(All Female Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Visit	Is female patient of childbearing potential?	Was a urine pregnancy test performed?	Date/Time of Collection	Result
301-017	Week 36	No	No		
	Week 40	No	No		
	Week 44	No	No		
	Week 48	No	No		

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-007	17 Hydroxyprogesterone (nmol/L)	Day 1	26JAN2016/10:00		0.91 - 7.58	No
		Unscheduled Visit	26JAN2016/12:48	1.20	0.91 - 7.58	No
		Week 4	24FEB2016/13:00	0.87 L	0.91 - 7.58	No
		Week 6	08MAR2016/11:30	0.68 L	0.91 - 7.58	No
		Week 8	24MAR2016/10:52	0.58 L	0.91 - 7.58	No
		Early Term	21APR2016/08:00	1.61	0.91 - 7.58	Yes
		Week 28	19MAY2016/12:20	0.98	0.91 - 7.58	No
		Week 32	16JUN2016/10:25	0.68 L	0.91 - 7.58	No
		Week 40	11AUG2016/12:00	0.46 L	0.91 - 7.58	No
		Week 44	08SEP2016/12:10	0.49 L	0.91 - 7.58	No
		Week 48	06OCT2016/12:30	1.38	0.91 - 7.58	No
	17-Beta-Oestradiol (pmol/L)	Day 1	26JAN2016/10:00	<44	0 - 1153	No
		Week 4	24FEB2016/13:00	<44	0 - 1153	No
		Week 6	08MAR2016/11:30	<44	0 - 1153	No
		Week 8	24MAR2016/10:52	<44	0 - 1153	No
		Early Term	21APR2016/08:00	<44	0 - 1153	Yes
		Week 28	19MAY2016/12:20	<44	0 - 1153	No
		Week 32	16JUN2016/10:25	<44	0 - 1153	No
		Week 40	11AUG2016/12:00	<44	0 - 1153	No
		Week 44	08SEP2016/12:10	<44	0 - 1153	No
		Week 48	06OCT2016/12:30	<44	0 - 1153	No

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-007	Androstenedione (nmol/L)	Day 1	26JAN2016/10:00	2.95	1 - 12.9	No
		Week 4	24FEB2016/13:00	1.07	1 - 12.9	No
		Week 6	08MAR2016/11:30	<1.05	1 - 12.9	No
		Week 8	24MAR2016/10:52	<1.05	1 - 12.9	No
		Early Term	21APR2016/08:00	1.52	1 - 12.9	Yes
		Week 28	19MAY2016/12:20	1.14	1 - 12.9	No
		Week 32	16JUN2016/10:25	1.16	1 - 12.9	No
		Week 40	11AUG2016/12:00	1.05	1 - 12.9	No
		Week 44	08SEP2016/12:10	2.34	1 - 12.9	No
		Week 48	06OCT2016/12:30	1.74	1 - 12.9	No
	Anti-Mullerian Hormone (pmol/L)	Day 1	26JAN2016/10:00	<0.2 L	0.3 - 14.7	No
		Week 4	24FEB2016/13:00	<0.2 L	0.3 - 14.7	No
		Week 6	08MAR2016/11:30	<0.2 L	0.3 - 14.7	No
		Week 8	24MAR2016/10:52	<0.2 L	0.3 - 14.7	No
		Early Term	21APR2016/08:00	<0.2 L	0.3 - 14.7	Yes
		Week 28	19MAY2016/12:20	<0.2 L	0.3 - 14.7	No
		Week 32	16JUN2016/10:25	<0.2 L	0.3 - 14.7	No
		Week 40	11AUG2016/12:00	<0.2 L	0.3 - 14.7	No
		Week 44	08SEP2016/12:10	<0.2 L	0.3 - 14.7	No
		Week 48	06OCT2016/12:30	<0.2 L	0.3 - 14.7	No
	Dehydroepiandrosterone (nmol/L)	Day 1	26JAN2016/10:00	9.3	4.1 - 28	No

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-007	Dehydroepiandrosterone (nmol/L)	Week 4	24FEB2016/13:00	9.7	4.1 - 28	No
		Week 6	08MAR2016/11:30	7.8	4.1 - 28	No
		Week 8	24MAR2016/10:52	6.4	4.1 - 28	No
		Early Term	21APR2016/08:00	7.9	4.1 - 28	Yes
		Week 28	19MAY2016/12:20	7.4	4.1 - 28	No
		Week 32	16JUN2016/10:25	6.8	4.1 - 28	No
		Week 40	11AUG2016/12:00	7.0	4.1 - 28	No
		Week 44	08SEP2016/12:10	4.6	4.1 - 28	No
		Week 48	06OCT2016/12:30	5.2	4.1 - 28	No
	Dehydroepiandrosterone Sulfate (umol/L)	Day 1	26JAN2016/10:00	3.6	0.26 - 11	No
		Week 4	24FEB2016/13:00	5.1	0.26 - 11	No
		Week 6	08MAR2016/11:30	4.0	0.26 - 11	No
		Week 8	24MAR2016/10:52	3.1	0.26 - 11	No
		Early Term	21APR2016/08:00	3.9	0.26 - 11	Yes
		Week 28	19MAY2016/12:20	2.5	0.26 - 11	No
		Week 32	16JUN2016/10:25	2.4	0.26 - 11	No
		Week 40	11AUG2016/12:00	1.3	0.26 - 11	No
		Week 44	08SEP2016/12:10	1.6	0.26 - 11	No
		Week 48	06OCT2016/12:30	2.1	0.26 - 11	No
	Follicle Stimulating Hormone (IU/L)	Day 1	26JAN2016/10:00	64.5	1.7 - 134.8	No

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-007	Follicle Stimulating Hormone (IU/L)	Week 4	24FEB2016/13:00	65.9	1.7 - 134.8	No
		Week 6	08MAR2016/11:30	65.7	1.7 - 134.8	No
		Week 8	24MAR2016/10:52	62.5	1.7 - 134.8	No
		Early Term	21APR2016/08:00	64.5	1.7 - 134.8	Yes
		Week 28	19MAY2016/12:20	59.0	1.7 - 134.8	No
		Week 32	16JUN2016/10:25	61.1	1.7 - 134.8	No
		Week 40	11AUG2016/12:00	67.0	1.7 - 134.8	No
		Week 44	08SEP2016/12:10	58.5	1.7 - 134.8	No
		Week 48	06OCT2016/12:30	60.1	1.7 - 134.8	No
	Luteinizing Hormone (IU/L)	Day 1	26JAN2016/10:00	27.2	1 - 95.6	No
		Week 4	24FEB2016/13:00	28.0	1 - 95.6	No
		Week 6	08MAR2016/11:30	28.5	1 - 95.6	No
		Week 8	24MAR2016/10:52	26.1	1 - 95.6	No
		Early Term	21APR2016/08:00	29.1	1 - 95.6	Yes
		Week 28	19MAY2016/12:20	22.8	1 - 95.6	No
		Week 32	16JUN2016/10:25	26.7	1 - 95.6	No
		Week 40	11AUG2016/12:00	24.2	1 - 95.6	No
		Week 44	08SEP2016/12:10	23.3	1 - 95.6	No
		Week 48	06OCT2016/12:30	26.9	1 - 95.6	No
	Progesterone (nmol/L)	Day 1	26JAN2016/10:00	0.8	0.3 - 86	No
		Week 4	24FEB2016/13:00	1.1	0.3 - 86	No
		Week 6	08MAR2016/11:30	0.8	0.3 - 86	No

[1] H = High; L = Low; A = Abnormal

Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-007	Progesterone (nmol/L)	Week 8	24MAR2016/10:52	0.6	0.3 - 86	No
		Early Term	21APR2016/08:00	0.9	0.3 - 86	Yes
		Week 28	19MAY2016/12:20	<0.5	0.3 - 86	No
		Week 32	16JUN2016/10:25	<0.5	0.3 - 86	No
		Week 40	11AUG2016/12:00	<0.5	0.3 - 86	No
		Week 44	08SEP2016/12:10	<0.5	0.3 - 86	No
		Week 48	06OCT2016/12:30	0.7	0.3 - 86	No
	Sex Hormone Binding Globulin (nmol/L)	Day 1	26JAN2016/10:00	77	22 - 142	No
		Week 4	24FEB2016/13:00	82	22 - 142	No
		Week 6	08MAR2016/11:30	78	22 - 142	No
		Week 8	24MAR2016/10:52	85	22 - 142	No
		Early Term	21APR2016/08:00	83	22 - 142	Yes
		Week 28	19MAY2016/12:20	67	22 - 142	No
		Week 32	16JUN2016/10:25	75	22 - 142	No
		Week 40	11AUG2016/12:00	92	22 - 142	No
		Week 44	08SEP2016/12:10	81	22 - 142	No
		Week 48	06OCT2016/12:30	86	22 - 142	No
	Testosterone (nmol/L)	Day 1	26JAN2016/10:00	<0.4	0 - 1.8	No
		Week 4	24FEB2016/13:00	<0.4	0 - 1.8	No
		Week 6	08MAR2016/11:30	<0.4	0 - 1.8	No
		Week 8	24MAR2016/10:52	<0.4	0 - 1.8	No
		Early Term	21APR2016/08:00	<0.4	0 - 1.8	Yes

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-007	Testosterone (nmol/L)	Week 28	19MAY2016/12:20	<0.4	0 - 1.8	No
		Week 32	16JUN2016/10:25	<0.4	0 - 1.8	No
		Week 40	11AUG2016/12:00	<0.4	0 - 1.8	No
		Week 44	08SEP2016/12:10	<0.4	0 - 1.8	No
		Week 48	06OCT2016/12:30	<0.4	0 - 1.8	No
	Testosterone, Free (pg/mL)	Day 1	26JAN2016/10:00		0 - 2.2	No
		Unscheduled Visit	26JAN2016/12:48	2.48 H	0 - 2.2	No
		Week 4	24FEB2016/13:00	0.77	0 - 2.2	No
		Week 6	08MAR2016/11:30	0.57	0 - 2.2	No
		Week 8	24MAR2016/10:52	0.42	0 - 2.2	No
		Early Term	21APR2016/08:00	0.69	0 - 2.2	Yes
		Week 28	19MAY2016/12:20	0.48	0 - 2.2	No
		Week 32	16JUN2016/10:25	0.46	0 - 2.2	No
		Week 40	11AUG2016/12:00	0.55	0 - 2.2	No
		Week 44	08SEP2016/12:10	0.49	0 - 2.2	No
		Week 48	06OCT2016/12:30	0.53	0 - 2.2	No
	17 Hydroxyprogesterone (nmol/L)	Day 1	27JAN2016/08:30	0.64 L	0.91 - 7.58	Yes
		Week 4	26FEB2016/10:20	0.90 L	0.91 - 7.58	No
		Week 6	10MAR2016/10:45	1.40	0.91 - 7.58	No
		Week 8	24MAR2016/09:31	1.21	0.91 - 7.58	No
		Week 12	19APR2016/09:20	1.00	0.91 - 7.58	Yes

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-011	17 Hydroxyprogesterone (nmol/L)	Week 16	18MAY2016/10:10	1.02	0.91 - 7.58	No
		Week 20	21JUN2016/10:35	0.55 L	0.91 - 7.58	No
		Week 24	12JUL2016/10:00	0.71 L	0.91 - 7.58	Yes
		Week 28	09AUG2016/09:50	0.64 L	0.91 - 7.58	No
		Week 32	06SEP2016/09:00	0.69 L	0.91 - 7.58	No
		Week 36	06OCT2016/09:50	0.80 L	0.91 - 7.58	No
		Week 40	03NOV2016/11:00	0.70 L	0.91 - 7.58	No
		Week 44	06DEC2016/10:30	1.32	0.91 - 7.58	No
		Week 48	03JAN2017/10:45	1.36	0.91 - 7.58	No
	17-Beta-Oestradiol (pmol/L)	Day 1	27JAN2016/08:30	52	0 - 1153	Yes
		Week 4	26FEB2016/10:20	63	0 - 1153	No
		Week 6	10MAR2016/10:45	45	0 - 1153	No
		Week 8	24MAR2016/09:31	54	0 - 1153	No
		Week 12	19APR2016/09:20	66	0 - 1153	Yes
		Week 16	18MAY2016/10:10	78	0 - 1153	No
		Week 20	21JUN2016/10:35	58	0 - 1153	No
		Week 24	12JUL2016/10:00	70	0 - 1153	Yes
		Week 28	09AUG2016/09:50	52	0 - 1153	No
		Week 32	06SEP2016/09:00	66	0 - 1153	No
		Week 36	06OCT2016/09:50	61	0 - 1153	No
		Week 40	03NOV2016/11:00	53	0 - 1153	No
		Week 44	06DEC2016/10:30	<44	0 - 1153	No
		Week 48	03JAN2017/10:45	59	0 - 1153	No

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-011	Androstenedione (nmol/L)	Day 1	27JAN2016/08:30	2.34	1 - 12.9	Yes
		Week 4	26FEB2016/10:20	2.59	1 - 12.9	No
		Week 6	10MAR2016/10:45	2.83	1 - 12.9	No
		Week 8	24MAR2016/09:31	2.91	1 - 12.9	No
		Week 12	19APR2016/09:20	1.34	1 - 12.9	Yes
		Week 16	18MAY2016/10:10	1.92	1 - 12.9	No
		Week 20	21JUN2016/10:35	1.74	1 - 12.9	No
		Week 24	12JUL2016/10:00	1.32	1 - 12.9	Yes
		Week 28	09AUG2016/09:50	1.84	1 - 12.9	No
		Week 32	06SEP2016/09:00	1.47	1 - 12.9	No
		Week 36	06OCT2016/09:50	2.03	1 - 12.9	No
		Week 40	03NOV2016/11:00	1.41	1 - 12.9	No
		Week 44	06DEC2016/10:30	1.70	1 - 12.9	No
		Week 48	03JAN2017/10:45	3.05	1 - 12.9	No
	Anti-Mullerian Hormone (pmol/L)	Day 1	27JAN2016/08:30	<0.2 L	0.3 - 14.7	Yes
		Week 4	26FEB2016/10:20	<0.2 L	0.3 - 14.7	No
		Week 6	10MAR2016/10:45	<0.2 L	0.3 - 14.7	No
		Week 8	24MAR2016/09:31	<0.2 L	0.3 - 14.7	No
		Week 12	19APR2016/09:20	<0.2 L	0.3 - 14.7	Yes
		Week 16	18MAY2016/10:10	<0.2 L	0.3 - 14.7	No
		Week 20	21JUN2016/10:35	<0.2 L	0.3 - 14.7	No
		Week 24	12JUL2016/10:00	<0.2 L	0.3 - 14.7	Yes
		Week 28	09AUG2016/09:50	<0.2 L	0.3 - 14.7	No

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-011	Anti-Mullerian Hormone (pmol/L)	Week 32	06SEP2016/09:00	<0.2 L	0.3 - 14.7	No
		Week 36	06OCT2016/09:50	<0.2 L	0.3 - 14.7	No
		Week 40	03NOV2016/11:00	<0.2 L	0.3 - 14.7	No
		Week 44	06DEC2016/10:30	<0.2 L	0.3 - 14.7	No
		Week 48	03JAN2017/10:45	<0.2 L	0.3 - 14.7	No
	Dehydroepiandrosterone (nmol/L)	Day 1	27JAN2016/08:30	6.5	4.1 - 28	Yes
		Week 4	26FEB2016/10:20	15.2	4.1 - 28	No
		Week 6	10MAR2016/10:45	11.5	4.1 - 28	No
		Week 8	24MAR2016/09:31	17.4	4.1 - 28	No
		Week 12	19APR2016/09:20	12.6	4.1 - 28	Yes
		Week 16	18MAY2016/10:10	15.4	4.1 - 28	No
		Week 20	21JUN2016/10:35	5.1	4.1 - 28	No
		Week 24	12JUL2016/10:00	25.7	4.1 - 28	Yes
		Week 28	09AUG2016/09:50	9.2	4.1 - 28	No
		Week 32	06SEP2016/09:00	5.9	4.1 - 28	No
		Week 36	06OCT2016/09:50	4.3	4.1 - 28	No
		Week 40	03NOV2016/11:00	7.2	4.1 - 28	No
		Week 44	06DEC2016/10:30	13.8	4.1 - 28	No
		Week 48	03JAN2017/10:45	7.8	4.1 - 28	No
	Dehydroepiandrosterone Sulfate (umol/L)	Day 1	27JAN2016/08:30	3.1	0.26 - 11	Yes

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-011	Dehydroepiandrosterone Sulfate (umol/L)	Week 4	26FEB2016/10:20	5.8	0.26 - 11	No
		Week 6	10MAR2016/10:45	6.2	0.26 - 11	No
		Week 8	24MAR2016/09:31	5.0	0.26 - 11	No
		Week 12	19APR2016/09:20	6.5	0.26 - 11	Yes
		Week 16	18MAY2016/10:10	6.3	0.26 - 11	No
		Week 20	21JUN2016/10:35	4.5	0.26 - 11	No
		Week 24	12JUL2016/10:00	5.0	0.26 - 11	Yes
		Week 28	09AUG2016/09:50	2.6	0.26 - 11	No
		Week 32	06SEP2016/09:00	1.9	0.26 - 11	No
		Week 36	06OCT2016/09:50	2.1	0.26 - 11	No
		Week 40	03NOV2016/11:00	2.8	0.26 - 11	No
		Week 44	06DEC2016/10:30	2.3	0.26 - 11	No
		Week 48	03JAN2017/10:45	2.8	0.26 - 11	No
	Follicle Stimulating Hormone (IU/L)	Day 1	27JAN2016/08:30	93.7	1.7 - 134.8	Yes
		Week 4	26FEB2016/10:20	129.0	1.7 - 134.8	No
		Week 6	10MAR2016/10:45	125.7	1.7 - 134.8	No
		Week 8	24MAR2016/09:31	125.9	1.7 - 134.8	No
		Week 12	19APR2016/09:20	117.4	1.7 - 134.8	Yes
		Week 16	18MAY2016/10:10	135.5 H	1.7 - 134.8	No
		Week 20	21JUN2016/10:35	117.2	1.7 - 134.8	No
		Week 24	12JUL2016/10:00	114.1	1.7 - 134.8	Yes
		Week 28	09AUG2016/09:50	109.9	1.7 - 134.8	No

[1] H = High; L = Low; A = Abnormal

Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-011	Follicle Stimulating Hormone (IU/L)	Week 32	06SEP2016/09:00	113.1	1.7 - 134.8	No
		Week 36	06OCT2016/09:50	107.1	1.7 - 134.8	No
		Week 40	03NOV2016/11:00	120.6	1.7 - 134.8	No
		Week 44	06DEC2016/10:30	122.0	1.7 - 134.8	No
		Week 48	03JAN2017/10:45	108.9	1.7 - 134.8	No
	Luteinizing Hormone (IU/L)	Day 1	27JAN2016/08:30	41.1	1 - 95.6	Yes
		Week 4	26FEB2016/10:20	58.4	1 - 95.6	No
		Week 6	10MAR2016/10:45	59.6	1 - 95.6	No
		Week 8	24MAR2016/09:31	47.4	1 - 95.6	No
		Week 12	19APR2016/09:20	42.3	1 - 95.6	Yes
		Week 16	18MAY2016/10:10	58.7	1 - 95.6	No
		Week 20	21JUN2016/10:35	43.1	1 - 95.6	No
		Week 24	12JUL2016/10:00	40.2	1 - 95.6	Yes
		Week 28	09AUG2016/09:50	45.0	1 - 95.6	No
		Week 32	06SEP2016/09:00	49.2	1 - 95.6	No
		Week 36	06OCT2016/09:50	42.3	1 - 95.6	No
		Week 40	03NOV2016/11:00	42.4	1 - 95.6	No
		Week 44	06DEC2016/10:30	43.7	1 - 95.6	No
		Week 48	03JAN2017/10:45	41.5	1 - 95.6	No
	Progesterone (nmol/L)	Day 1	27JAN2016/08:30	0.6	0.3 - 86	Yes
		Week 4	26FEB2016/10:20	1.4	0.3 - 86	No
		Week 6	10MAR2016/10:45	1.6	0.3 - 86	No

[1] H = High; L = Low; A = Abnormal

Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-011	Progesterone (nmol/L)	Week 8	24MAR2016/09:31	1.0	0.3 - 86	No
		Week 12	19APR2016/09:20	1.5	0.3 - 86	Yes
		Week 16	18MAY2016/10:10	1.9	0.3 - 86	No
		Week 20	21JUN2016/10:35	0.8	0.3 - 86	No
		Week 24	12JUL2016/10:00	0.8	0.3 - 86	Yes
		Week 28	09AUG2016/09:50	<0.5	0.3 - 86	No
		Week 32	06SEP2016/09:00	0.5	0.3 - 86	No
		Week 36	06OCT2016/09:50	0.6	0.3 - 86	No
		Week 40	03NOV2016/11:00	0.5	0.3 - 86	No
		Week 44	06DEC2016/10:30	<0.5	0.3 - 86	No
		Week 48	03JAN2017/10:45	<0.5	0.3 - 86	No
	Sex Hormone Binding Globulin (nmol/L)	Day 1	27JAN2016/08:30	97	22 - 142	Yes
		Week 4	26FEB2016/10:20	151 H	22 - 142	No
		Week 6	10MAR2016/10:45	153 H	22 - 142	No
		Week 8	24MAR2016/09:31	149 H	22 - 142	No
		Week 12	19APR2016/09:20	148 H	22 - 142	Yes
		Week 16	18MAY2016/10:10	147 H	22 - 142	No
		Week 20	21JUN2016/10:35	118	22 - 142	No
		Week 24	12JUL2016/10:00	136	22 - 142	Yes
		Week 28	09AUG2016/09:50	139	22 - 142	No
		Week 32	06SEP2016/09:00	139	22 - 142	No
		Week 36	06OCT2016/09:50	130	22 - 142	No
		Week 40	03NOV2016/11:00	154 H	22 - 142	No

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-011	Sex Hormone Binding Globulin (nmol/L)	Week 44	06DEC2016/10:30	147 H	22 - 142	No
		Week 48	03JAN2017/10:45	142	22 - 142	No
	Testosterone (nmol/L)	Day 1	27JAN2016/08:30	0.6	0 - 1.8	Yes
		Week 4	26FEB2016/10:20	0.9	0 - 1.8	No
		Week 6	10MAR2016/10:45	0.9	0 - 1.8	No
		Week 8	24MAR2016/09:31	0.6	0 - 1.8	No
		Week 12	19APR2016/09:20	0.7	0 - 1.8	Yes
		Week 16	18MAY2016/10:10	0.8	0 - 1.8	No
		Week 20	21JUN2016/10:35	0.6	0 - 1.8	No
		Week 24	12JUL2016/10:00	0.4	0 - 1.8	Yes
		Week 28	09AUG2016/09:50	<0.4	0 - 1.8	No
		Week 32	06SEP2016/09:00	0.4	0 - 1.8	No
		Week 36	06OCT2016/09:50	0.4	0 - 1.8	No
		Week 40	03NOV2016/11:00	<0.4	0 - 1.8	No
		Week 44	06DEC2016/10:30	<0.4	0 - 1.8	No
		Week 48	03JAN2017/10:45	0.5	0 - 1.8	No
	Testosterone, Free (pg/mL)	Day 1	27JAN2016/08:30	0.93	0 - 2.2	Yes
		Week 4	26FEB2016/10:20	1.18	0 - 2.2	No
		Week 6	10MAR2016/10:45	1.03	0 - 2.2	No
		Week 8	24MAR2016/09:31	0.79	0 - 2.2	No
		Week 12	19APR2016/09:20	0.70	0 - 2.2	Yes
		Week 16	18MAY2016/10:10	0.70	0 - 2.2	No

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-011	Testosterone, Free (pg/mL)	Week 20	21JUN2016/10:35	0.52	0 - 2.2	No
		Week 24	12JUL2016/10:00	0.59	0 - 2.2	Yes
		Week 28	09AUG2016/09:50	0.60	0 - 2.2	No
		Week 32	06SEP2016/09:00	0.37	0 - 2.2	No
		Week 36	06OCT2016/09:50	0.51	0 - 2.2	No
		Week 40	03NOV2016/11:00	0.41	0 - 2.2	No
		Week 44	06DEC2016/10:30	0.54	0 - 2.2	No
		Week 48	03JAN2017/10:45	0.50	0 - 2.2	No

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-003	17 Hydroxyprogesterone (nmol/L)	Day 1	06JAN2016/11:00	2.67	0.91 - 7.58	Yes
		Week 4	03FEB2016/11:00	1.28	0.91 - 7.58	No
		Week 6	18FEB2016/13:30	2.37	0.91 - 7.58	No
		Week 8	08MAR2016/08:35	2.29	0.91 - 7.58	No
		Week 12	29MAR2016/09:15	1.65	0.91 - 7.58	No
		Week 16	25APR2016/08:50	1.18	0.91 - 7.58	No
		Week 20	26MAY2016/12:50	1.30	0.91 - 7.58	No
		Week 24	22JUN2016/12:30	0.91	0.91 - 7.58	No
		Week 28	19JUL2016/10:10	2.74	0.91 - 7.58	No
		Week 32	16AUG2016/12:10	0.48 L	0.91 - 7.58	No
		Week 36	15SEP2016/12:35	1.36	0.91 - 7.58	No
		Week 40	12OCT2016/11:20	1.11	0.91 - 7.58	Yes
		Week 44	09NOV2016/12:00	2.43	0.91 - 7.58	No
		Week 48	14DEC2016/12:00	1.33	0.91 - 7.58	No
	17-Beta-Oestradiol (pmol/L)	Day 1	06JAN2016/11:00	272	0 - 1153	Yes
		Week 4	03FEB2016/11:00	223	0 - 1153	No
		Week 6	18FEB2016/13:30	274	0 - 1153	No
		Week 8	08MAR2016/08:35	381	0 - 1153	No
		Week 12	29MAR2016/09:15	227	0 - 1153	No
		Week 16	25APR2016/08:50	57	0 - 1153	No
		Week 20	26MAY2016/12:50	695	0 - 1153	No
		Week 24	22JUN2016/12:30	<44	0 - 1153	No
		Week 28	19JUL2016/10:10	108	0 - 1153	No

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-003	17-Beta-Oestradiol (pmol/L)	Week 32	16AUG2016/12:10	<44	0 - 1153	No
		Week 36	15SEP2016/12:35	48	0 - 1153	No
		Week 40	12OCT2016/11:20	93	0 - 1153	Yes
		Week 44	09NOV2016/12:00	450	0 - 1153	No
		Week 48	14DEC2016/12:00	100	0 - 1153	No
	Androstenedione (nmol/L)	Day 1	06JAN2016/11:00	10.00	1 - 12.9	Yes
		Week 4	03FEB2016/11:00	8.96	1 - 12.9	No
		Week 6	18FEB2016/13:30	8.19	1 - 12.9	No
		Week 8	08MAR2016/08:35	7.49	1 - 12.9	No
		Week 12	29MAR2016/09:15	7.95	1 - 12.9	No
		Week 16	25APR2016/08:50	3.78	1 - 12.9	No
		Week 20	26MAY2016/12:50	7.60	1 - 12.9	No
		Week 24	22JUN2016/12:30	5.60	1 - 12.9	No
		Week 28	19JUL2016/10:10	8.54	1 - 12.9	No
		Week 32	16AUG2016/12:10	5.29	1 - 12.9	No
		Week 36	15SEP2016/12:35	7.95	1 - 12.9	No
		Week 40	12OCT2016/11:20	5.46	1 - 12.9	Yes
		Week 44	09NOV2016/12:00	9.66	1 - 12.9	No
		Week 48	14DEC2016/12:00	6.13	1 - 12.9	No
	Anti-Mullerian Hormone (pmol/L)	Day 1	06JAN2016/11:00	87.2 H	13.1 - 53.8	Yes
		Week 4	03FEB2016/11:00	101.6 H	13.1 - 53.8	No
		Week 6	18FEB2016/13:30	90.6 H	13.1 - 53.8	No

[1] H = High; L = Low; A = Abnormal

Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-003	Anti-Mullerian Hormone (pmol/L)	Week 8	08MAR2016/08:35	112.2 H	13.1 - 53.8	No
		Week 12	29MAR2016/09:15	133.6 H	13.1 - 53.8	No
		Week 16	25APR2016/08:50	95.8 H	13.1 - 53.8	No
		Week 20	26MAY2016/12:50	93.9 H	13.1 - 53.8	No
		Week 24	22JUN2016/12:30	77.8 H	13.1 - 53.8	No
		Week 28	19JUL2016/10:10	74.5 H	13.1 - 53.8	No
		Week 32	16AUG2016/12:10	43.0	13.1 - 53.8	No
		Week 36	15SEP2016/12:35	62.2 H	13.1 - 53.8	No
		Week 40	12OCT2016/11:20	40.4	13.1 - 53.8	Yes
		Week 44	09NOV2016/12:00	64.9 H	13.1 - 53.8	No
		Week 48	14DEC2016/12:00	71.7 H	13.1 - 53.8	No
	Dehydroepiandrosterone (nmol/L)	Day 1	06JAN2016/11:00	21.5	4.1 - 28	Yes
		Week 4	03FEB2016/11:00	23.1	4.1 - 28	No
		Week 6	18FEB2016/13:30	27.4	4.1 - 28	No
		Week 8	08MAR2016/08:35	24.1	4.1 - 28	No
		Week 12	29MAR2016/09:15	23.6	4.1 - 28	No
		Week 16	25APR2016/08:50	17.5	4.1 - 28	No
		Week 24	22JUN2016/12:30	23.5	4.1 - 28	No
		Week 28	19JUL2016/10:10	31.2 H	4.1 - 28	No
		Week 32	16AUG2016/12:10	33.5 H	4.1 - 28	No
		Week 36	15SEP2016/12:35	21.6	4.1 - 28	No
		Week 40	12OCT2016/11:20	22.6	4.1 - 28	Yes

[1] H = High; L = Low; A = Abnormal

Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-003	Dehydroepiandrosterone (nmol/L)	Week 44	09NOV2016/12:00	31.1 H	4.1 - 28	No
		Week 48	14DEC2016/12:00	26.8	4.1 - 28	No
	Dehydroepiandrosterone Sulfate (umol/L)	Day 1	06JAN2016/11:00	11.8 H	0.26 - 11	Yes
		Week 4	03FEB2016/11:00	13.3 H	0.26 - 11	No
		Week 6	18FEB2016/13:30	15.0 H	0.26 - 11	No
		Week 8	08MAR2016/08:35	13.7 H	0.26 - 11	No
		Week 12	29MAR2016/09:15	12.1 H	0.26 - 11	No
		Week 16	25APR2016/08:50	12.4 H	0.26 - 11	No
		Week 20	26MAY2016/12:50	12.8 H	0.26 - 11	No
		Week 24	22JUN2016/12:30	12.1 H	0.26 - 11	No
		Week 28	19JUL2016/10:10	11.4 H	0.26 - 11	No
		Week 32	16AUG2016/12:10	6.9	0.26 - 11	No
		Week 36	15SEP2016/12:35	8.9	0.26 - 11	No
		Week 40	12OCT2016/11:20	7.6	0.26 - 11	Yes
		Week 44	09NOV2016/12:00	10.6	0.26 - 11	No
		Week 48	14DEC2016/12:00	8.6	0.26 - 11	No
	Follicle Stimulating Hormone (IU/L)	Day 1	06JAN2016/11:00	6.8	1.7 - 134.8	Yes
		Week 4	03FEB2016/11:00	6.9	1.7 - 134.8	No
		Week 6	18FEB2016/13:30	2.4	1.7 - 134.8	No
		Week 8	08MAR2016/08:35	3.9	1.7 - 134.8	No

[1] H = High; L = Low; A = Abnormal

Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-003	Follicle Stimulating Hormone (IU/L)	Week 12	29MAR2016/09:15	6.2	1.7 - 134.8	No
		Week 16	25APR2016/08:50	2.4	1.7 - 134.8	No
		Week 20	26MAY2016/12:50	4.9	1.7 - 134.8	No
		Week 24	22JUN2016/12:30	0.6 L	1.7 - 134.8	No
		Week 28	19JUL2016/10:10	6.5	1.7 - 134.8	No
		Week 32	16AUG2016/12:10	0.8 L	1.7 - 134.8	No
		Week 36	15SEP2016/12:35	4.5	1.7 - 134.8	No
		Week 40	12OCT2016/11:20	6.1	1.7 - 134.8	Yes
		Week 44	09NOV2016/12:00	6.6	1.7 - 134.8	No
		Week 48	14DEC2016/12:00	6.5	1.7 - 134.8	No
	Luteinizing Hormone (IU/L)	Day 1	06JAN2016/11:00	15.2	1 - 95.6	Yes
		Week 4	03FEB2016/11:00	7.7	1 - 95.6	No
		Week 6	18FEB2016/13:30	1.3	1 - 95.6	No
		Week 8	08MAR2016/08:35	7.8	1 - 95.6	No
		Week 12	29MAR2016/09:15	5.5	1 - 95.6	No
		Week 16	25APR2016/08:50	1.1	1 - 95.6	No
		Week 20	26MAY2016/12:50	18.8	1 - 95.6	No
		Week 24	22JUN2016/12:30	<0.1 L	1 - 95.6	No
		Week 28	19JUL2016/10:10	10.9	1 - 95.6	No
		Week 32	16AUG2016/12:10	<0.1 L	1 - 95.6	No
		Week 36	15SEP2016/12:35	1.8	1 - 95.6	No
		Week 40	12OCT2016/11:20	7.6	1 - 95.6	Yes
		Week 44	09NOV2016/12:00	12.7	1 - 95.6	No

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-003	Luteinizing Hormone (IU/L)	Week 48	14DEC2016/12:00	6.4	1 - 95.6	No
	Progesterone (nmol/L)	Day 1	06JAN2016/11:00	2.6	0.3 - 86	Yes
		Week 4	03FEB2016/11:00	2.3	0.3 - 86	No
		Week 6	18FEB2016/13:30	7.1	0.3 - 86	No
		Week 8	08MAR2016/08:35	2.7	0.3 - 86	No
		Week 12	29MAR2016/09:15	2.4	0.3 - 86	No
		Week 16	25APR2016/08:50	2.1	0.3 - 86	No
		Week 20	26MAY2016/12:50	2.1	0.3 - 86	No
		Week 24	22JUN2016/12:30	1.9	0.3 - 86	No
		Week 28	19JUL2016/10:10	2.0	0.3 - 86	No
		Week 32	16AUG2016/12:10	1.2	0.3 - 86	No
		Week 36	15SEP2016/12:35	1.7	0.3 - 86	No
		Week 40	12OCT2016/11:20	1.5	0.3 - 86	Yes
		Week 44	09NOV2016/12:00	1.8	0.3 - 86	No
		Week 48	14DEC2016/12:00	1.4	0.3 - 86	No
	Serum B-HCG	Screening	15DEC2015/12:00	NEGATIVE		Yes
	Sex Hormone Binding Globulin (nmol/L)	Day 1	06JAN2016/11:00	85	27 - 146	Yes
		Week 4	03FEB2016/11:00	72	27 - 146	No
		Week 6	18FEB2016/13:30	76	27 - 146	No
		Week 8	08MAR2016/08:35	78	27 - 146	No
		Week 12	29MAR2016/09:15	120	27 - 146	No

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-003	Sex Hormone Binding Globulin (nmol/L)	Week 16	25APR2016/08:50	114	27 - 146	No
		Week 20	26MAY2016/12:50	99	27 - 146	No
		Week 24	22JUN2016/12:30	157 H	27 - 146	No
		Week 28	19JUL2016/10:10	88	27 - 146	No
		Week 32	16AUG2016/12:10	>200 H	27 - 146	No
		Week 36	15SEP2016/12:35	210 H	27 - 146	No
		Week 40	12OCT2016/11:20	>200 H	27 - 146	Yes
		Week 44	09NOV2016/12:00	155 H	27 - 146	No
		Week 48	14DEC2016/12:00	248 H	27 - 146	No
	Testosterone (nmol/L)	Day 1	06JAN2016/11:00	2.0 H	0 - 1.8	Yes
		Week 4	03FEB2016/11:00	1.4	0 - 1.8	No
		Week 6	18FEB2016/13:30	1.4	0 - 1.8	No
		Week 8	08MAR2016/08:35	1.2	0 - 1.8	No
		Week 12	29MAR2016/09:15	1.2	0 - 1.8	No
		Week 16	25APR2016/08:50	0.5	0 - 1.8	No
		Week 20	26MAY2016/12:50	1.6	0 - 1.8	No
		Week 24	22JUN2016/12:30	0.9	0 - 1.8	No
		Week 28	19JUL2016/10:10	1.2	0 - 1.8	No
		Week 32	16AUG2016/12:10	1.1	0 - 1.8	No
		Week 36	15SEP2016/12:35	1.5	0 - 1.8	No
		Week 40	12OCT2016/11:20	1.4	0 - 1.8	Yes
		Week 44	09NOV2016/12:00	1.9 H	0 - 1.8	No
		Week 48	14DEC2016/12:00	1.0	0 - 1.8	No

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-003	Testosterone, Free (pg/mL)	Day 1	06JAN2016/11:00	2.05	0 - 2.6	Yes
		Week 4	03FEB2016/11:00	1.31	0 - 2.6	No
		Week 6	18FEB2016/13:30	2.76 H	0 - 2.6	No
		Week 8	08MAR2016/08:35	1.28	0 - 2.6	No
		Week 12	29MAR2016/09:15	1.09	0 - 2.6	No
		Week 16	25APR2016/08:50	0.82	0 - 2.6	No
		Week 20	26MAY2016/12:50	1.20	0 - 2.6	No
		Week 24	22JUN2016/12:30	1.14	0 - 2.6	No
		Week 28	19JUL2016/10:10	1.37	0 - 2.6	No
		Week 32	16AUG2016/12:10	0.73	0 - 2.6	No
		Week 36	15SEP2016/12:35	0.77	0 - 2.6	No
		Week 40	12OCT2016/11:20	1.31	0 - 2.6	Yes
		Week 44	09NOV2016/12:00	1.29	0 - 2.6	No
		Week 48	14DEC2016/12:00	0.68	0 - 2.6	No

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-017	17 Hydroxyprogesterone (nmol/L)	Day 1	08MAR2016/10:50	0.90 L	0.91 - 7.58	No
		Week 1	15MAR2016/09:25	1.39	0.91 - 7.58	No
		Week 4	05APR2016/10:15	1.22	0.91 - 7.58	No
		Week 6	19APR2016/09:45	1.02	0.91 - 7.58	No
		Week 8	28APR2016/10:10	1.51	0.91 - 7.58	No
		Week 12	01JUN2016/08:30	1.22	0.91 - 7.58	Yes
		Week 16	29JUN2016/09:23	0.76 L	0.91 - 7.58	No
		Week 20	26JUL2016/09:45	0.39 L	0.91 - 7.58	No
		Week 24	24AUG2016/09:30	1.14	0.91 - 7.58	Yes
		Week 28	20SEP2016/12:00	0.86 L	0.91 - 7.58	No
		Week 32	19OCT2016/11:00	0.72 L	0.91 - 7.58	No
		Week 36	15NOV2016/11:15	0.79 L	0.91 - 7.58	No
		Week 40	14DEC2016/09:30	1.73	0.91 - 7.58	No
		Week 44	11JAN2017/11:00	1.02	0.91 - 7.58	No
		Week 48	08FEB2017/11:50	1.21	0.91 - 7.58	No
	17-Beta-Oestradiol (pmol/L)	Day 1	08MAR2016/10:50	<44	0 - 1153	No
		Week 1	15MAR2016/09:25	<44	0 - 1153	No
		Week 4	05APR2016/10:15	<44	0 - 1153	No
		Week 6	19APR2016/09:45	<44	0 - 1153	No
		Week 8	28APR2016/10:10	<44	0 - 1153	No
		Week 12	01JUN2016/08:30	<44	0 - 1153	Yes
		Week 16	29JUN2016/09:23	<44	0 - 1153	No
		Week 20	26JUL2016/09:45	<44	0 - 1153	No

[1] H = High; L = Low; A = Abnormal

Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-017	17-Beta-Oestradiol (pmol/L)	Week 24	24AUG2016/09:30	<44	0 - 1153	Yes
		Week 28	20SEP2016/12:00	<44	0 - 1153	No
		Week 32	19OCT2016/11:00	44	0 - 1153	No
		Week 36	15NOV2016/11:15	<44	0 - 1153	No
		Week 40	14DEC2016/09:30	<44	0 - 1153	No
		Week 44	11JAN2017/11:00	50	0 - 1153	No
		Week 48	08FEB2017/11:50	<44	0 - 1153	No
	Androstenedione (nmol/L)	Day 1	08MAR2016/10:50	2.85	1 - 12.9	No
		Week 1	15MAR2016/09:25	2.00	1 - 12.9	No
		Week 4	05APR2016/10:15	2.73	1 - 12.9	No
		Week 6	19APR2016/09:45	1.43	1 - 12.9	No
		Week 8	28APR2016/10:10	1.96	1 - 12.9	No
		Week 12	01JUN2016/08:30	1.62	1 - 12.9	Yes
		Week 16	29JUN2016/09:23	1.61	1 - 12.9	No
		Week 20	26JUL2016/09:45	1.63	1 - 12.9	No
		Week 24	24AUG2016/09:30	2.21	1 - 12.9	Yes
		Week 28	20SEP2016/12:00	1.80	1 - 12.9	No
		Week 32	19OCT2016/11:00	1.38	1 - 12.9	No
		Week 36	15NOV2016/11:15	<1.05	1 - 12.9	No
		Week 40	14DEC2016/09:30	3.14	1 - 12.9	No
		Week 44	11JAN2017/11:00	2.89	1 - 12.9	No
		Week 48	08FEB2017/11:50	2.42	1 - 12.9	No

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-017	Anti-Mullerian Hormone (pmol/L)	Day 1	08MAR2016/10:50	<0.2 L	0.3 - 14.7	No
		Week 1	15MAR2016/09:25	<0.2 L	0.3 - 14.7	No
		Week 4	05APR2016/10:15	<0.2 L	0.3 - 14.7	No
		Week 6	19APR2016/09:45	<0.2 L	0.3 - 14.7	No
		Week 8	28APR2016/10:10	<0.2 L	0.3 - 14.7	No
		Week 12	01JUN2016/08:30	<0.2 L	0.3 - 14.7	Yes
		Week 16	29JUN2016/09:23	<0.2 L	0.3 - 14.7	No
		Week 20	26JUL2016/09:45	<0.2 L	0.3 - 14.7	No
		Week 24	24AUG2016/09:30	<0.2 L	0.3 - 14.7	Yes
		Week 28	20SEP2016/12:00	<0.2 L	0.3 - 14.7	No
		Week 32	19OCT2016/11:00	<0.2 L	0.3 - 14.7	No
		Week 36	15NOV2016/11:15	<0.2 L	0.3 - 14.7	No
		Week 40	14DEC2016/09:30	<0.2 L	0.3 - 14.7	No
		Week 44	11JAN2017/11:00	<0.2 L	0.3 - 14.7	No
		Week 48	08FEB2017/11:50	<0.2 L	0.3 - 14.7	No
	Dehydroepiandrosterone (nmol/L)	Day 1	08MAR2016/10:50	9.0	4.1 - 28	No
		Week 1	15MAR2016/09:25	10.9	4.1 - 28	No
		Week 4	05APR2016/10:15	14.9	4.1 - 28	No
		Week 6	19APR2016/09:45	10.6	4.1 - 28	No
		Week 8	28APR2016/10:10	7.5	4.1 - 28	No
		Week 12	01JUN2016/08:30	7.9	4.1 - 28	Yes
		Week 16	29JUN2016/09:23	7.8	4.1 - 28	No

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-017	Dehydroepiandrosterone (nmol/L)	Week 20	26JUL2016/09:45	5.5	4.1 - 28	No
		Week 24	24AUG2016/09:30	11.8	4.1 - 28	Yes
		Week 28	20SEP2016/12:00	6.8	4.1 - 28	No
		Week 32	19OCT2016/11:00	7.8	4.1 - 28	No
		Week 36	15NOV2016/11:15	4.0 L	4.1 - 28	No
		Week 40	14DEC2016/09:30	1.9 L	4.1 - 28	No
		Week 44	11JAN2017/11:00	7.1	4.1 - 28	No
		Week 48	08FEB2017/11:50	6.7	4.1 - 28	No
	Dehydroepiandrosterone Sulfate (umol/L)	Day 1	08MAR2016/10:50	2.8	0.26 - 11	No
		Week 1	15MAR2016/09:25	4.2	0.26 - 11	No
		Week 4	05APR2016/10:15	6.6	0.26 - 11	No
		Week 6	19APR2016/09:45	6.3	0.26 - 11	No
		Week 8	28APR2016/10:10	5.7	0.26 - 11	No
		Week 12	01JUN2016/08:30	4.1	0.26 - 11	Yes
		Week 16	29JUN2016/09:23	3.9	0.26 - 11	No
		Week 20	26JUL2016/09:45	3.8	0.26 - 11	No
		Week 24	24AUG2016/09:30	3.5	0.26 - 11	Yes
		Week 28	20SEP2016/12:00	2.1	0.26 - 11	No
		Week 32	19OCT2016/11:00	2.4	0.26 - 11	No
		Week 36	15NOV2016/11:15	1.7	0.26 - 11	No
		Week 40	14DEC2016/09:30	1.7	0.26 - 11	No
		Week 44	11JAN2017/11:00	2.0	0.26 - 11	No

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-017	Dehydroepiandrosterone Sulfate (umol/L)	Week 48	08FEB2017/11:50	1.9	0.26 - 11	No
	Follicle Stimulating Hormone (IU/L)	Day 1	08MAR2016/10:50	94.6	1.7 - 134.8	No
		Week 1	15MAR2016/09:25	103.0	1.7 - 134.8	No
		Week 4	05APR2016/10:15	112.8	1.7 - 134.8	No
		Week 6	19APR2016/09:45	129.6	1.7 - 134.8	No
		Week 8	28APR2016/10:10	122.4	1.7 - 134.8	No
		Week 12	01JUN2016/08:30	106.7	1.7 - 134.8	Yes
		Week 16	29JUN2016/09:23	103.8	1.7 - 134.8	No
		Week 20	26JUL2016/09:45	103.2	1.7 - 134.8	No
		Week 24	24AUG2016/09:30	111.9	1.7 - 134.8	Yes
		Week 28	20SEP2016/12:00	104.0	1.7 - 134.8	No
		Week 32	19OCT2016/11:00	91.6	1.7 - 134.8	No
		Week 36	15NOV2016/11:15	94.2	1.7 - 134.8	No
		Week 40	14DEC2016/09:30	88.5	1.7 - 134.8	No
		Week 44	11JAN2017/11:00	90.7	1.7 - 134.8	No
		Week 48	08FEB2017/11:50	86.8	1.7 - 134.8	No
	Luteinizing Hormone (IU/L)	Day 1	08MAR2016/10:50	53.9	1 - 95.6	No
		Week 1	15MAR2016/09:25	58.6	1 - 95.6	No
		Week 4	05APR2016/10:15	56.3	1 - 95.6	No
		Week 6	19APR2016/09:45	65.0	1 - 95.6	No
		Week 8	28APR2016/10:10	51.2	1 - 95.6	No

[1] H = High; L = Low; A = Abnormal

Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-017	Luteinizing Hormone (IU/L)	Week 12	01JUN2016/08:30	45.3	1 - 95.6	Yes
		Week 16	29JUN2016/09:23	49.6	1 - 95.6	No
		Week 20	26JUL2016/09:45	56.8	1 - 95.6	No
		Week 24	24AUG2016/09:30	61.6	1 - 95.6	Yes
		Week 28	20SEP2016/12:00	59.1	1 - 95.6	No
		Week 32	19OCT2016/11:00	54.0	1 - 95.6	No
		Week 36	15NOV2016/11:15	61.6	1 - 95.6	No
		Week 40	14DEC2016/09:30	58.3	1 - 95.6	No
		Week 44	11JAN2017/11:00	56.6	1 - 95.6	No
		Week 48	08FEB2017/11:50	56.3	1 - 95.6	No
	Progesterone (nmol/L)	Day 1	08MAR2016/10:50	0.6	0.3 - 86	No
		Week 1	15MAR2016/09:25	0.9	0.3 - 86	No
		Week 4	05APR2016/10:15	1.6	0.3 - 86	No
		Week 6	19APR2016/09:45	1.4	0.3 - 86	No
		Week 8	28APR2016/10:10	1.1	0.3 - 86	No
		Week 12	01JUN2016/08:30	0.7	0.3 - 86	Yes
		Week 16	29JUN2016/09:23	0.8	0.3 - 86	No
		Week 20	26JUL2016/09:45	0.6	0.3 - 86	No
		Week 24	24AUG2016/09:30	0.8	0.3 - 86	Yes
		Week 28	20SEP2016/12:00	<0.5	0.3 - 86	No
		Week 32	19OCT2016/11:00	<0.5	0.3 - 86	No
		Week 36	15NOV2016/11:15	<0.5	0.3 - 86	No
		Week 40	14DEC2016/09:30	<0.5	0.3 - 86	No
		Week 44	11JAN2017/11:00	<0.5	0.3 - 86	No

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-017	Progesterone (nmol/L)	Week 48	08FEB2017/11:50	<0.5	0.3 - 86	No
	Sex Hormone Binding Globulin (nmol/L)	Day 1	08MAR2016/10:50	175 H	22 - 142	No
		Week 1	15MAR2016/09:25	195 H	22 - 142	No
		Week 4	05APR2016/10:15	183 H	22 - 142	No
		Week 6	19APR2016/09:45	221 H	22 - 142	No
		Week 8	28APR2016/10:10	>200 H	22 - 142	No
		Week 12	01JUN2016/08:30	196 H	22 - 142	Yes
		Week 16	29JUN2016/09:23	181 H	22 - 142	No
		Week 20	26JUL2016/09:45	198 H	22 - 142	No
		Week 24	24AUG2016/09:30	>200 H	22 - 142	Yes
		Week 28	20SEP2016/12:00	195 H	22 - 142	No
		Week 32	19OCT2016/11:00	195 H	22 - 142	No
		Week 36	15NOV2016/11:15	199 H	22 - 142	No
		Week 40	14DEC2016/09:30	194 H	22 - 142	No
		Week 44	11JAN2017/11:00	186 H	22 - 142	No
		Week 48	08FEB2017/11:50	>200 H	22 - 142	No
	Testosterone (nmol/L)	Day 1	08MAR2016/10:50	1.2	0 - 1.8	No
		Week 1	15MAR2016/09:25	1.1	0 - 1.8	No
		Week 4	05APR2016/10:15	1.2	0 - 1.8	No
		Week 6	19APR2016/09:45	1.0	0 - 1.8	No
		Week 8	28APR2016/10:10	1.0	0 - 1.8	No
		Week 12	01JUN2016/08:30	0.9	0 - 1.8	Yes

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-017	Testosterone (nmol/L)	Week 16	29JUN2016/09:23	0.8	0 - 1.8	No
		Week 20	26JUL2016/09:45	1.0	0 - 1.8	No
		Week 24	24AUG2016/09:30	1.1	0 - 1.8	Yes
		Week 28	20SEP2016/12:00	0.8	0 - 1.8	No
		Week 32	19OCT2016/11:00	0.7	0 - 1.8	No
		Week 36	15NOV2016/11:15	0.6	0 - 1.8	No
		Week 40	14DEC2016/09:30	1.0	0 - 1.8	No
		Week 44	11JAN2017/11:00	1.1	0 - 1.8	No
		Week 48	08FEB2017/11:50	1.2	0 - 1.8	No
	Testosterone, Free (pg/mL)	Day 1	08MAR2016/10:50	0.91	0 - 2.2	No
		Week 1	15MAR2016/09:25	0.67	0 - 2.2	No
		Week 4	05APR2016/10:15	1.05	0 - 2.2	No
		Week 6	19APR2016/09:45	0.75	0 - 2.2	No
		Week 8	28APR2016/10:10	0.80	0 - 2.2	No
		Week 12	01JUN2016/08:30	0.42	0 - 2.2	Yes
		Week 16	29JUN2016/09:23	0.63	0 - 2.2	No
		Week 20	26JUL2016/09:45	0.50	0 - 2.2	No
		Week 24	24AUG2016/09:30	0.82	0 - 2.2	Yes
		Week 28	20SEP2016/12:00	0.57	0 - 2.2	No
		Week 32	19OCT2016/11:00	0.39	0 - 2.2	No
		Week 36	15NOV2016/11:15	0.47	0 - 2.2	No
		Week 40	14DEC2016/09:30	0.62	0 - 2.2	No
		Week 44	11JAN2017/11:00	0.61	0 - 2.2	No
		Week 48	08FEB2017/11:50	1.10	0 - 2.2	No

[1] H = High; L = Low; A = Abnormal

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Listing 16.2.7.8  
Laboratory Summary - Reproductive Serology (Females)  
(All Patients)

Treatment Sequence: Screen Failure

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-004	Serum B-HCG	Screening	16DEC2015/11:50	NEGATIVE		Yes

[1] H = High; L = Low; A = Abnormal

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-001	Follicle Stimulating Hormone (IU/L)	Day 1	02FEB2016/11:10	14.3 H	1.5 - 12.4	Yes
		Week 4	01MAR2016/10:30	21.7 H	1.5 - 12.4	No
		Week 6	16MAR2016/11:45	22.7 H	1.5 - 12.4	No
		Week 8	31MAR2016/09:52	22.9 H	1.5 - 12.4	No
		Week 12	28APR2016/08:15	27.6 H	1.5 - 12.4	Yes
		Week 16	26MAY2016/12:10	31.4 H	1.5 - 12.4	No
		Week 20	22JUN2016/09:55	25.3 H	1.5 - 12.4	No
		Week 24	20JUL2016/09:30	28.4 H	1.5 - 12.4	Yes
		Week 28	18AUG2016/10:45	26.8 H	1.5 - 12.4	No
		Week 32	15SEP2016/10:00	22.9 H	1.5 - 12.4	No
		Week 36	13OCT2016/12:30	20.8 H	1.5 - 12.4	No
		Week 40	10NOV2016/10:15	18.1 H	1.5 - 12.4	No
		Week 44	06DEC2016/11:00	19.3 H	1.5 - 12.4	No
		Week 48	03JAN2017/12:00	21.1 H	1.5 - 12.4	No
	Inhibin B (ng/L)	Day 1	02FEB2016/11:10	56.3 L	100 - 400	Yes
		Week 4	01MAR2016/10:30	26.2 L	100 - 400	No
		Week 6	16MAR2016/11:45	19.8 L	100 - 400	No
		Week 8	31MAR2016/09:52	12.1 L	100 - 400	No
		Week 12	28APR2016/08:15	7.9 L	100 - 400	Yes
		Week 16	26MAY2016/12:10	12.0 L	100 - 400	No
		Week 20	22JUN2016/09:55	7.9 L	100 - 400	No
		Week 24	20JUL2016/09:30	9.5 L	100 - 400	Yes
		Week 28	18AUG2016/10:45	18.3 L	100 - 400	No
		Week 32	15SEP2016/10:00	24.4 L	100 - 400	No
		Week 36	13OCT2016/12:30	33.6 L	100 - 400	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-001	Inhibin B (ng/L)	Week 40	10NOV2016/10:15	33.9 L	100 - 400	No
		Week 44	06DEC2016/11:00	30.6 L	100 - 400	No
		Week 48	03JAN2017/12:00	50.3 L	100 - 400	No
	Luteinizing Hormone (IU/L)	Day 1	02FEB2016/11:10	6.9	1.7 - 8.6	Yes
		Week 4	01MAR2016/10:30	10.0 H	1.7 - 8.6	No
		Week 6	16MAR2016/11:45	9.3 H	1.7 - 8.6	No
		Week 8	31MAR2016/09:52	8.6	1.7 - 8.6	No
		Week 12	28APR2016/08:15	10.5 H	1.7 - 8.6	Yes
		Week 16	26MAY2016/12:10	15.5 H	1.7 - 8.6	No
		Week 20	22JUN2016/09:55	10.6 H	1.7 - 8.6	No
		Week 24	20JUL2016/09:30	12.5 H	1.7 - 8.6	Yes
		Week 28	18AUG2016/10:45	14.3 H	1.7 - 8.6	No
		Week 32	15SEP2016/10:00	11.2 H	1.7 - 8.6	No
		Week 36	13OCT2016/12:30	9.3 H	1.7 - 8.6	No
		Week 40	10NOV2016/10:15	8.7 H	1.7 - 8.6	No
		Week 44	06DEC2016/11:00	11.1 H	1.7 - 8.6	No
		Week 48	03JAN2017/12:00	12.0 H	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	02FEB2016/11:10	18.4	7.6 - 31.4	Yes
		Week 4	01MAR2016/10:30	19.3	7.6 - 31.4	No
		Week 6	16MAR2016/11:45	18.3	7.6 - 31.4	No
		Week 8	31MAR2016/09:52	23.6	7.6 - 31.4	No
		Week 12	28APR2016/08:15	23.2	7.6 - 31.4	Yes
		Week 16	26MAY2016/12:10	24.7	7.6 - 31.4	No
		Week 20	22JUN2016/09:55	20.6	7.6 - 31.4	No
		Week 24	20JUL2016/09:30	13.8	7.6 - 31.4	Yes

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-001	Testosterone (nmol/L)	Week 28	18AUG2016/10:45	16.5	7.6 - 31.4	No
		Week 32	15SEP2016/10:00	15.9	7.6 - 31.4	No
		Week 36	13OCT2016/12:30	20.5	7.6 - 31.4	No
		Week 40	10NOV2016/10:15	21.0	7.6 - 31.4	No
		Week 44	06DEC2016/11:00	17.3	7.6 - 31.4	No
		Week 48	03JAN2017/12:00	20.6	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	02FEB2016/11:10	6.49	4.2 - 18.4	Yes
		Week 4	01MAR2016/10:30	4.71	4.2 - 18.4	No
		Week 6	16MAR2016/11:45	5.42	4.2 - 18.4	No
		Week 8	31MAR2016/09:52	5.48	4.2 - 18.4	No
		Week 12	28APR2016/08:15	4.85	4.2 - 18.4	Yes
		Week 16	26MAY2016/12:10	5.81	4.2 - 18.4	No
		Week 20	22JUN2016/09:55	4.30	4.2 - 18.4	No
		Week 24	20JUL2016/09:30	4.27	4.2 - 18.4	Yes
		Week 28	18AUG2016/10:45	4.22	4.2 - 18.4	No
		Week 32	15SEP2016/10:00	4.50	4.2 - 18.4	No
		Week 36	13OCT2016/12:30	6.24	4.2 - 18.4	No
		Week 40	10NOV2016/10:15	6.63	4.2 - 18.4	No
		Week 44	06DEC2016/11:00	6.77	4.2 - 18.4	No
		Week 48	03JAN2017/12:00	5.67	4.2 - 18.4	No
301-002	Follicle Stimulating Hormone (IU/L)	Day 1	05JAN2016/09:00	2.7	1.5 - 12.4	Yes
		Week 4	03FEB2016/09:45	6.1	1.5 - 12.4	No
		Week 6	17FEB2016/13:00	9.7	1.5 - 12.4	No
		Week 8	01MAR2016/09:00	12.1	1.5 - 12.4	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-002	Follicle Stimulating Hormone (IU/L)	Week 12	30MAR2016/09:50	14.0 H	1.5 - 12.4	No
		Week 16	26APR2016/10:25	13.8 H	1.5 - 12.4	No
		Week 20	24MAY2016/11:40	14.5 H	1.5 - 12.4	No
		Week 24	21JUN2016/11:30	14.3 H	1.5 - 12.4	No
		Week 28	20JUL2016/11:45	12.8 H	1.5 - 12.4	No
		Week 32	18AUG2016/10:30	12.5 H	1.5 - 12.4	No
		Week 36	13SEP2016/11:00	11.5	1.5 - 12.4	No
		Week 40	11OCT2016/12:05	10.1	1.5 - 12.4	No
		Week 44	09NOV2016/12:30	9.0	1.5 - 12.4	No
		Week 48	06DEC2016/13:00	9.1	1.5 - 12.4	No
	Inhibin B (ng/L)	Day 1	05JAN2016/09:00	230	100 - 400	Yes
		Week 4	03FEB2016/09:45	133	100 - 400	No
		Week 6	17FEB2016/13:00	89.6 L	100 - 400	No
		Week 8	01MAR2016/09:00	83.4 L	100 - 400	No
		Week 12	30MAR2016/09:50	71.8 L	100 - 400	No
		Week 16	26APR2016/10:25	54.2 L	100 - 400	No
		Week 20	24MAY2016/11:40	44.5 L	100 - 400	No
		Week 24	21JUN2016/11:30	53.0 L	100 - 400	No
		Week 28	20JUL2016/11:45	48.0 L	100 - 400	No
		Week 32	18AUG2016/10:30	82.6 L	100 - 400	No
		Week 36	13SEP2016/11:00	93.6 L	100 - 400	No
		Week 40	11OCT2016/12:05	108	100 - 400	No
		Week 44	09NOV2016/12:30	94.7 L	100 - 400	No
		Week 48	06DEC2016/13:00	121	100 - 400	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-002	Luteinizing Hormone (IU/L)	Day 1	05JAN2016/09:00	7.3	1.7 - 8.6	Yes
		Week 4	03FEB2016/09:45	5.0	1.7 - 8.6	No
		Week 6	17FEB2016/13:00	7.9	1.7 - 8.6	No
		Week 8	01MAR2016/09:00	6.5	1.7 - 8.6	No
		Week 12	30MAR2016/09:50	6.0	1.7 - 8.6	No
		Week 16	26APR2016/10:25	5.1	1.7 - 8.6	No
		Week 20	24MAY2016/11:40	7.5	1.7 - 8.6	No
		Week 24	21JUN2016/11:30	6.0	1.7 - 8.6	No
		Week 28	20JUL2016/11:45	6.1	1.7 - 8.6	No
		Week 32	18AUG2016/10:30	6.5	1.7 - 8.6	No
		Week 36	13SEP2016/11:00	6.7	1.7 - 8.6	No
		Week 40	11OCT2016/12:05	7.1	1.7 - 8.6	No
		Week 44	09NOV2016/12:30	6.4	1.7 - 8.6	No
		Week 48	06DEC2016/13:00	5.4	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	05JAN2016/09:00	33.8 H	7.6 - 31.4	Yes
		Week 4	03FEB2016/09:45	>52.0 H	7.6 - 31.4	No
		Week 6	17FEB2016/13:00	>52.0 H	7.6 - 31.4	No
		Week 8	01MAR2016/09:00	44.0 H	7.6 - 31.4	No
		Week 12	30MAR2016/09:50	48.7 H	7.6 - 31.4	No
		Week 16	26APR2016/10:25	45.3 H	7.6 - 31.4	No
		Week 20	24MAY2016/11:40	44.1 H	7.6 - 31.4	No
		Week 24	21JUN2016/11:30	49.7 H	7.6 - 31.4	No
		Week 28	20JUL2016/11:45	33.7 H	7.6 - 31.4	No
		Week 32	18AUG2016/10:30	30.5	7.6 - 31.4	No
		Week 36	13SEP2016/11:00	37.6 H	7.6 - 31.4	No
		Week 40	11OCT2016/12:05	37.2 H	7.6 - 31.4	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-002	Testosterone (nmol/L)	Week 44	09NOV2016/12:30	44.3 H	7.6 - 31.4	No
		Week 48	06DEC2016/13:00	32.8 H	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	05JAN2016/09:00	17.0	7.6 - 36.2	Yes
		Week 4	03FEB2016/09:45	20.7	7.6 - 36.2	No
		Week 6	17FEB2016/13:00	17.2	7.6 - 36.2	No
		Week 8	01MAR2016/09:00	16.1	7.6 - 36.2	No
		Week 12	30MAR2016/09:50	20.8	7.6 - 36.2	No
		Week 16	26APR2016/10:25	14.6	7.6 - 36.2	No
		Week 20	24MAY2016/11:40	14.8	7.6 - 36.2	No
		Week 24	21JUN2016/11:30	19.7	7.6 - 36.2	No
		Week 28	20JUL2016/11:45	13.6	7.6 - 36.2	No
		Week 32	18AUG2016/10:30	9.39	7.6 - 36.2	No
		Week 36	13SEP2016/11:00	13.6	7.6 - 36.2	No
		Week 40	11OCT2016/12:05	12.1	7.6 - 36.2	No
		Week 44	09NOV2016/12:30	13.3	7.6 - 36.2	No
		Week 48	06DEC2016/13:00	14.3	7.6 - 36.2	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-005	Follicle Stimulating Hormone (IU/L)	Day 1	07JAN2016/10:00	3.5	1.5 - 12.4	Yes
		Week 4	02FEB2016/09:00	5.8	1.5 - 12.4	No
		Week 6	17FEB2016/13:00	5.8	1.5 - 12.4	No
		Week 8	02MAR2016/09:15	8.9	1.5 - 12.4	No
		Week 12	31MAR2016/10:15	12.5 H	1.5 - 12.4	No
		Week 16	26APR2016/10:00	15.4 H	1.5 - 12.4	No
		Week 20	26MAY2016/12:30	14.0 H	1.5 - 12.4	No
		Week 24	23JUN2016/11:45	14.0 H	1.5 - 12.4	No
		Week 28	26JUL2016/09:15	10.3	1.5 - 12.4	No
		Week 32	16AUG2016/10:45	7.5	1.5 - 12.4	No
		Week 36	14SEP2016/12:00	5.7	1.5 - 12.4	No
		Week 40	12OCT2016/12:10	5.4	1.5 - 12.4	No
		Week 44	10NOV2016/11:00	5.6	1.5 - 12.4	No
		Week 48	07DEC2016/12:00	4.5	1.5 - 12.4	No
	Inhibin B (ng/L)	Day 1	07JAN2016/10:00	187	100 - 400	Yes
		Week 4	02FEB2016/09:00	170	100 - 400	No
		Week 6	17FEB2016/13:00	133.0	100 - 400	No
		Week 8	02MAR2016/09:15	98.0 L	100 - 400	No
		Week 12	31MAR2016/10:15	79.3 L	100 - 400	No
		Week 16	26APR2016/10:00	56.9 L	100 - 400	No
		Week 20	26MAY2016/12:30	54.3 L	100 - 400	No
		Week 24	23JUN2016/11:45	49.8 L	100 - 400	No
		Week 28	26JUL2016/09:15	91.7 L	100 - 400	No
		Week 32	16AUG2016/10:45	156.0	100 - 400	No
		Week 36	14SEP2016/12:00	181.0	100 - 400	No



Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-005	Inhibin B (ng/L)	Week 40	12OCT2016/12:10	169	100 - 400	No
		Week 44	10NOV2016/11:00	135.0	100 - 400	No
		Week 48	07DEC2016/12:00	197.0	100 - 400	No
	Luteinizing Hormone (IU/L)	Day 1	07JAN2016/10:00	6.2	1.7 - 8.6	Yes
		Week 4	02FEB2016/09:00	7.5	1.7 - 8.6	No
		Week 6	17FEB2016/13:00	7.4	1.7 - 8.6	No
		Week 8	02MAR2016/09:15	9.3 H	1.7 - 8.6	No
		Week 12	31MAR2016/10:15	6.8	1.7 - 8.6	No
		Week 16	26APR2016/10:00	8.8 H	1.7 - 8.6	No
		Week 20	26MAY2016/12:30	6.5	1.7 - 8.6	No
		Week 24	23JUN2016/11:45	6.1	1.7 - 8.6	No
		Week 28	26JUL2016/09:15	6.4	1.7 - 8.6	No
		Week 32	16AUG2016/10:45	5.0	1.7 - 8.6	No
		Week 36	14SEP2016/12:00	7.0	1.7 - 8.6	No
		Week 40	12OCT2016/12:10	8.7 H	1.7 - 8.6	No
		Week 44	10NOV2016/11:00	7.7	1.7 - 8.6	No
		Week 48	07DEC2016/12:00	5.0	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	07JAN2016/10:00	37.2 H	7.6 - 31.4	Yes
		Week 4	02FEB2016/09:00	37.5 H	7.6 - 31.4	No
		Week 6	17FEB2016/13:00	31.6 H	7.6 - 31.4	No
		Week 8	02MAR2016/09:15	32.9 H	7.6 - 31.4	No
		Week 12	31MAR2016/10:15	29.0	7.6 - 31.4	No
		Week 16	26APR2016/10:00	35.3 H	7.6 - 31.4	No
		Week 20	26MAY2016/12:30	33.4 H	7.6 - 31.4	No
		Week 24	23JUN2016/11:45	31.7 H	7.6 - 31.4	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-005	Testosterone (nmol/L)	Week 28	26JUL2016/09:15	26.1	7.6 - 31.4	No
		Week 32	16AUG2016/10:45	34.4 H	7.6 - 31.4	No
		Week 36	14SEP2016/12:00	44.2 H	7.6 - 31.4	No
		Week 40	12OCT2016/12:10	30.1	7.6 - 31.4	No
		Week 44	10NOV2016/11:00	26.9	7.6 - 31.4	No
		Week 48	07DEC2016/12:00	22.2	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	07JAN2016/10:00	14.0	7.6 - 36.2	Yes
		Week 4	02FEB2016/09:00	16.9	7.6 - 36.2	No
		Week 6	17FEB2016/13:00	16.4	7.6 - 36.2	No
		Week 8	02MAR2016/09:15	19.4	7.6 - 36.2	No
		Week 12	31MAR2016/10:15	19.4	7.6 - 36.2	No
		Week 16	26APR2016/10:00	20.8	7.6 - 36.2	No
		Week 20	26MAY2016/12:30	19.3	7.6 - 36.2	No
		Week 24	23JUN2016/11:45	18.7	7.6 - 36.2	No
		Week 28	26JUL2016/09:15	12.4	7.6 - 36.2	No
		Week 32	16AUG2016/10:45	13.8	7.6 - 36.2	No
		Week 36	14SEP2016/12:00	15.5	7.6 - 36.2	No
		Week 40	12OCT2016/12:10	13.9	7.6 - 36.2	No
		Week 44	10NOV2016/11:00	17.4	7.6 - 36.2	No
		Week 48	07DEC2016/12:00	16.9	7.6 - 36.2	No
301-008	Follicle Stimulating Hormone (IU/L)	Day 1	11FEB2016/09:00	3.0	1.5 - 12.4	No
		Week 4	10MAR2016/08:00	5.7	1.5 - 12.4	No
		Week 6	24MAR2016/08:02	7.8	1.5 - 12.4	No
		Week 8	07APR2016/08:30	10.7	1.5 - 12.4	Yes

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-008	Follicle Stimulating Hormone (IU/L)	Early Term	13APR2016/12:20	9.3	1.5 - 12.4	Yes
		Week 28	17MAY2016/08:30	6.2	1.5 - 12.4	No
		Week 32	09JUN2016/08:30	4.1	1.5 - 12.4	No
		Week 36	06JUL2016/08:25	3.6	1.5 - 12.4	No
		Week 40	03AUG2016/08:45	3.8	1.5 - 12.4	No
		Week 44	07SEP2016/07:55	3.1	1.5 - 12.4	No
		Week 48	19OCT2016/07:20	3.3	1.5 - 12.4	No
	Inhibin B (ng/L)	Day 1	11FEB2016/09:00	329.0	100 - 400	No
		Week 4	10MAR2016/08:00	202	100 - 400	No
		Week 6	24MAR2016/08:02	159.0	100 - 400	No
		Week 8	07APR2016/08:30	123.0	100 - 400	Yes
		Early Term	13APR2016/12:20	126	100 - 400	Yes
		Week 28	17MAY2016/08:30	198.0	100 - 400	No
		Week 32	09JUN2016/08:30	291.0	100 - 400	No
		Week 36	06JUL2016/08:25	311.0	100 - 400	No
		Week 40	03AUG2016/08:45	307	100 - 400	No
		Week 44	07SEP2016/07:55	319.0	100 - 400	No
		Week 48	19OCT2016/07:20	410.0 H	100 - 400	No
	Luteinizing Hormone (IU/L)	Day 1	11FEB2016/09:00	5.4	1.7 - 8.6	No
		Week 4	10MAR2016/08:00	6.8	1.7 - 8.6	No
		Week 6	24MAR2016/08:02	6.2	1.7 - 8.6	No
		Week 8	07APR2016/08:30	9.4 H	1.7 - 8.6	Yes
		Early Term	13APR2016/12:20	9.6 H	1.7 - 8.6	Yes
		Week 28	17MAY2016/08:30	7.5	1.7 - 8.6	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-008	Luteinizing Hormone (IU/L)	Week 32	09JUN2016/08:30	6.2	1.7 - 8.6	No
		Week 36	06JUL2016/08:25	4.2	1.7 - 8.6	No
		Week 40	03AUG2016/08:45	6.9	1.7 - 8.6	No
		Week 44	07SEP2016/07:55	6.5	1.7 - 8.6	No
		Week 48	19OCT2016/07:20	4.9	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	11FEB2016/09:00	37.9 H	7.6 - 31.4	No
		Week 4	10MAR2016/08:00	38.1 H	7.6 - 31.4	No
		Week 6	24MAR2016/08:02	37.1 H	7.6 - 31.4	No
		Week 8	07APR2016/08:30	34.9 H	7.6 - 31.4	Yes
		Early Term	13APR2016/12:20	43.0 H	7.6 - 31.4	Yes
		Week 28	17MAY2016/08:30	33.4 H	7.6 - 31.4	No
		Week 32	09JUN2016/08:30	41.2 H	7.6 - 31.4	No
		Week 36	06JUL2016/08:25	43.9 H	7.6 - 31.4	No
		Week 40	03AUG2016/08:45	43.4 H	7.6 - 31.4	No
		Week 44	07SEP2016/07:55	34.8 H	7.6 - 31.4	No
		Week 48	19OCT2016/07:20	45.0 H	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	11FEB2016/09:00	15.3	7.6 - 36.2	No
		Week 4	10MAR2016/08:00	14.8	7.6 - 36.2	No
		Week 6	24MAR2016/08:02	15.9	7.6 - 36.2	No
		Week 8	07APR2016/08:30	11.2	7.6 - 36.2	Yes
		Early Term	13APR2016/12:20	10.7	7.6 - 36.2	Yes
		Week 28	17MAY2016/08:30	15.9	7.6 - 36.2	No
		Week 32	09JUN2016/08:30	11.3	7.6 - 36.2	No
		Week 36	06JUL2016/08:25	17.3	7.6 - 36.2	No
		Week 40	03AUG2016/08:45	18.6	7.6 - 36.2	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-008	Testosterone, Free (pg/mL)	Week 44	07SEP2016/07:55	14.2	7.6 - 36.2	No
		Week 48	19OCT2016/07:20	15.8	7.6 - 36.2	No
301-009	Follicle Stimulating Hormone (IU/L)	Day 1	27JAN2016/11:00	8.2	1.5 - 12.4	No
		Week 4	25FEB2016/11:30	13.8 H	1.5 - 12.4	No
		Week 6	09MAR2016/12:00	15.6 H	1.5 - 12.4	Yes
		Week 8	22MAR2016/08:20	16.8 H	1.5 - 12.4	No
		Week 12	19APR2016/11:20	21.9 H	1.5 - 12.4	No
		Week 16	18MAY2016/12:20	21.7 H	1.5 - 12.4	No
		Week 20	15JUN2016/12:15	20.8 H	1.5 - 12.4	No
		Week 24	20JUL2016/13:50	23.0 H	1.5 - 12.4	Yes
		Week 28	09AUG2016/12:10	22.7 H	1.5 - 12.4	No
		Week 32	06SEP2016/13:10	13.0 H	1.5 - 12.4	No
		Week 36	04OCT2016/12:30	11.1	1.5 - 12.4	No
		Week 40	01NOV2016/12:30	11.6	1.5 - 12.4	No
		Week 44	29NOV2016/13:15	10.4	1.5 - 12.4	No
		Week 48	02JAN2017/12:00	8.5	1.5 - 12.4	No
	Inhibin B (ng/L)	Day 1	27JAN2016/11:00	97.5 L	100 - 400	No
		Week 4	25FEB2016/11:30	51.4 L	100 - 400	No
		Week 6	09MAR2016/12:00	35.1 L	100 - 400	Yes
		Week 8	22MAR2016/08:20	18.5 L	100 - 400	No
		Week 12	19APR2016/11:20	20.7 L	100 - 400	No
		Week 16	18MAY2016/12:20	17.8 L	100 - 400	No
		Week 20	15JUN2016/12:15	11.3 L	100 - 400	No
		Week 24	20JUL2016/13:50	16.8 L	100 - 400	Yes

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-009	Inhibin B (ng/L)	Week 28	09AUG2016/12:10	35.3 L	100 - 400	No
		Week 32	06SEP2016/13:10	89.8 L	100 - 400	No
		Week 36	04OCT2016/12:30	96.4 L	100 - 400	No
		Week 40	01NOV2016/12:30	88.0 L	100 - 400	No
		Week 44	29NOV2016/13:15	83.7 L	100 - 400	No
		Week 48	02JAN2017/12:00	96.6 L	100 - 400	No
	Luteinizing Hormone (IU/L)	Day 1	27JAN2016/11:00	6.9	1.7 - 8.6	No
		Week 4	25FEB2016/11:30	7.2	1.7 - 8.6	No
		Week 6	09MAR2016/12:00	9.3 H	1.7 - 8.6	Yes
		Week 8	22MAR2016/08:20	7.3	1.7 - 8.6	No
		Week 12	19APR2016/11:20	11.5 H	1.7 - 8.6	No
		Week 16	18MAY2016/12:20	7.9	1.7 - 8.6	No
		Week 20	15JUN2016/12:15	11.7 H	1.7 - 8.6	No
		Week 24	20JUL2016/13:50	10.5 H	1.7 - 8.6	Yes
		Week 28	09AUG2016/12:10	10.0 H	1.7 - 8.6	No
		Week 32	06SEP2016/13:10	10.0 H	1.7 - 8.6	No
		Week 36	04OCT2016/12:30	5.4	1.7 - 8.6	No
		Week 40	01NOV2016/12:30	8.9 H	1.7 - 8.6	No
		Week 44	29NOV2016/13:15	8.3	1.7 - 8.6	No
		Week 48	02JAN2017/12:00	6.5	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	27JAN2016/11:00	15.9	7.6 - 31.4	No
		Week 4	25FEB2016/11:30	22.5	7.6 - 31.4	No
		Week 6	09MAR2016/12:00	23.6	7.6 - 31.4	Yes
		Week 8	22MAR2016/08:20	23.2	7.6 - 31.4	No
		Week 12	19APR2016/11:20	27.3	7.6 - 31.4	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-009	Testosterone (nmol/L)	Week 16	18MAY2016/12:20	29.7	7.6 - 31.4	No
		Week 20	15JUN2016/12:15	18.6	7.6 - 31.4	No
		Week 24	20JUL2016/13:50	24.0	7.6 - 31.4	Yes
		Week 28	09AUG2016/12:10	17.4	7.6 - 31.4	No
		Week 32	06SEP2016/13:10	18.6	7.6 - 31.4	No
		Week 36	04OCT2016/12:30	21.2	7.6 - 31.4	No
		Week 40	01NOV2016/12:30	28.0	7.6 - 31.4	No
		Week 44	29NOV2016/13:15	22.3	7.6 - 31.4	No
		Week 48	02JAN2017/12:00	16.7	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	27JAN2016/11:00	8.62	7.6 - 36.2	No
		Week 4	25FEB2016/11:30	9.51	7.6 - 36.2	No
		Week 6	09MAR2016/12:00	13.2	7.6 - 36.2	Yes
		Week 8	22MAR2016/08:20	11.6	7.6 - 36.2	No
		Week 12	19APR2016/11:20	10.5	7.6 - 36.2	No
		Week 16	18MAY2016/12:20	8.80	7.6 - 36.2	No
		Week 20	15JUN2016/12:15	8.80	7.6 - 36.2	No
		Week 24	20JUL2016/13:50	9.87	7.6 - 36.2	Yes
		Week 28	09AUG2016/12:10	9.95	7.6 - 36.2	No
		Week 32	06SEP2016/13:10	8.68	7.6 - 36.2	No
		Week 36	04OCT2016/12:30	9.55	7.6 - 36.2	No
		Week 40	01NOV2016/12:30	12.4	7.6 - 36.2	No
		Week 44	29NOV2016/13:15	11.3	7.6 - 36.2	No
		Week 48	02JAN2017/12:00	8.16	4.6 - 25.6	No
301-010	Follicle Stimulating Hormone (IU/L)	Day 1	27JAN2016/10:00	6.9	1.5 - 12.4	Yes

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-010	Follicle Stimulating Hormone (IU/L)	Week 4	24FEB2016/14:00	10.6	1.5 - 12.4	No
		Week 6	09MAR2016/11:30	12.8 H	1.5 - 12.4	No
		Week 8	22MAR2016/08:30	14.1 H	1.5 - 12.4	No
		Week 12	19APR2016/11:32	19.8 H	1.5 - 12.4	No
		Week 16	17MAY2016/12:55	19.3 H	1.5 - 12.4	No
		Week 20	20JUN2016/12:12	18.2 H	1.5 - 12.4	No
		Week 24	12JUL2016/11:40	21.8 H	1.5 - 12.4	Yes
		Week 28	08AUG2016/12:30	19.6 H	1.5 - 12.4	No
		Week 32	06SEP2016/11:10	14.6 H	1.5 - 12.4	No
		Week 36	04OCT2016/12:40	12.4	1.5 - 12.4	No
		Week 40	01NOV2016/12:50	13.0 H	1.5 - 12.4	No
		Week 44	28NOV2016/11:45	11.4	1.5 - 12.4	No
		Week 48	03JAN2017/13:00	9.0	1.5 - 12.4	No
	Inhibin B (ng/L)	Day 1	27JAN2016/10:00	170.0	100 - 400	Yes
		Week 4	24FEB2016/14:00	89.9 L	100 - 400	No
		Week 6	09MAR2016/11:30	74.5 L	100 - 400	No
		Week 8	22MAR2016/08:30	49.2 L	100 - 400	No
		Week 12	19APR2016/11:32	41.8 L	100 - 400	No
		Week 16	17MAY2016/12:55	30.3 L	100 - 400	No
		Week 20	20JUN2016/12:12	20.4 L	100 - 400	No
		Week 24	12JUL2016/11:40	22.4 L	100 - 400	Yes
		Week 28	08AUG2016/12:30	71.1 L	100 - 400	No
		Week 32	06SEP2016/11:10	110.0	100 - 400	No
		Week 36	04OCT2016/12:40	136	100 - 400	No
		Week 40	01NOV2016/12:50	112.0	100 - 400	No



Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-010	Inhibin B (ng/L)	Week 44	28NOV2016/11:45	120.0	100 - 400	No
		Week 48	03JAN2017/13:00	154.0	100 - 400	No
	Luteinizing Hormone (IU/L)	Day 1	27JAN2016/10:00	4.4	1.7 - 8.6	Yes
		Week 4	24FEB2016/14:00	5.4	1.7 - 8.6	No
		Week 6	09MAR2016/11:30	5.4	1.7 - 8.6	No
		Week 8	22MAR2016/08:30	5.1	1.7 - 8.6	No
		Week 12	19APR2016/11:32	12.8 H	1.7 - 8.6	No
		Week 16	17MAY2016/12:55	6.5	1.7 - 8.6	No
		Week 20	20JUN2016/12:12	5.0	1.7 - 8.6	No
		Week 24	12JUL2016/11:40	7.8	1.7 - 8.6	Yes
		Week 28	08AUG2016/12:30	7.0	1.7 - 8.6	No
		Week 32	06SEP2016/11:10	6.9	1.7 - 8.6	No
		Week 36	04OCT2016/12:40	5.6	1.7 - 8.6	No
		Week 40	01NOV2016/12:50	7.8	1.7 - 8.6	No
		Week 44	28NOV2016/11:45	6.8	1.7 - 8.6	No
		Week 48	03JAN2017/13:00	5.1	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	27JAN2016/10:00	23.1	7.6 - 31.4	Yes
		Week 4	24FEB2016/14:00	29.0	7.6 - 31.4	No
		Week 6	09MAR2016/11:30	32.2 H	7.6 - 31.4	No
		Week 8	22MAR2016/08:30	36.1 H	7.6 - 31.4	No
		Week 12	19APR2016/11:32	27.6	7.6 - 31.4	No
		Week 16	17MAY2016/12:55	28.1	7.6 - 31.4	No
		Week 20	20JUN2016/12:12	26.3	7.6 - 31.4	No
		Week 24	12JUL2016/11:40	21.8	7.6 - 31.4	Yes
		Week 28	08AUG2016/12:30	25.8	7.6 - 31.4	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-010	Testosterone (nmol/L)	Week 32	06SEP2016/11:10	35.8 H	7.6 - 31.4	No
		Week 36	04OCT2016/12:40	36.2 H	7.6 - 31.4	No
		Week 40	01NOV2016/12:50	31.6 H	7.6 - 31.4	No
		Week 44	28NOV2016/11:45	33.1 H	7.6 - 31.4	No
		Week 48	03JAN2017/13:00	32.3 H	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	27JAN2016/10:00	9.85	4.6 - 25.6	Yes
		Week 4	24FEB2016/14:00	11.1	4.6 - 25.6	No
		Week 6	09MAR2016/11:30	13.1	4.6 - 25.6	No
		Week 8	22MAR2016/08:30	15.5	4.6 - 25.6	No
		Week 12	19APR2016/11:32	9.69	4.6 - 25.6	No
		Week 16	17MAY2016/12:55	11.6	4.6 - 25.6	No
		Week 20	20JUN2016/12:12	11.0	4.6 - 25.6	No
		Week 24	12JUL2016/11:40	6.82	4.6 - 25.6	Yes
		Week 28	08AUG2016/12:30	13.8	4.6 - 25.6	No
		Week 32	06SEP2016/11:10	15.1	4.6 - 25.6	No
		Week 36	04OCT2016/12:40	11.0	4.6 - 25.6	No
		Week 40	01NOV2016/12:50	11.0	4.6 - 25.6	No
		Week 44	28NOV2016/11:45	11.1	4.6 - 25.6	No
		Week 48	03JAN2017/13:00	10.9	4.6 - 25.6	No
301-014	Follicle Stimulating Hormone (IU/L)	Day 1	23FEB2016/13:00	8.9	1.5 - 12.4	Yes
		Week 4	22MAR2016/10:15	11.1	1.5 - 12.4	No
		Week 6	05APR2016/11:47	10.5	1.5 - 12.4	No
		Week 8	20APR2016/09:15	13.3 H	1.5 - 12.4	Yes
		Week 12	19MAY2016/11:55	12.4	1.5 - 12.4	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-014	Follicle Stimulating Hormone (IU/L)	Week 16	14JUN2016/11:08	13.9 H	1.5 - 12.4	No
		Week 20	13JUL2016/11:20	13.4 H	1.5 - 12.4	No
		Week 24	10AUG2016/10:50	14.2 H	1.5 - 12.4	Yes
		Week 28	07SEP2016/11:30	13.4 H	1.5 - 12.4	No
		Week 32	05OCT2016/11:00	10.8	1.5 - 12.4	No
		Week 36	02NOV2016/12:00	11.4	1.5 - 12.4	No
		Week 40	30NOV2016/10:45	12.7 H	1.5 - 12.4	No
		Week 44	22DEC2016/12:00	12.9 H	1.5 - 12.4	No
		Week 48	25JAN2017/11:00	10.6	1.5 - 12.4	No
	Inhibin B (ng/L)	Day 1	23FEB2016/13:00	111.0	100 - 400	Yes
		Week 4	22MAR2016/10:15	47.7 L	100 - 400	No
		Week 6	05APR2016/11:47	40.1 L	100 - 400	No
		Week 8	20APR2016/09:15	46.5 L	100 - 400	Yes
		Week 12	19MAY2016/11:55	43.6 L	100 - 400	No
		Week 16	14JUN2016/11:08	38.3 L	100 - 400	No
		Week 20	13JUL2016/11:20	26.8 L	100 - 400	No
		Week 24	10AUG2016/10:50	28.3 L	100 - 400	Yes
		Week 28	07SEP2016/11:30	32.9 L	100 - 400	No
		Week 32	05OCT2016/11:00	53.6 L	100 - 400	No
		Week 36	02NOV2016/12:00	53.5 L	100 - 400	No
		Week 40	30NOV2016/10:45	50.7 L	100 - 400	No
		Week 44	22DEC2016/12:00	67.3 L	100 - 400	No
		Week 48	25JAN2017/11:00	63.0 L	100 - 400	No
	Luteinizing Hormone (IU/L)	Day 1	23FEB2016/13:00	12.4 H	1.7 - 8.6	Yes

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-014	Luteinizing Hormone (IU/L)	Week 4	22MAR2016/10:15	6.7	1.7 - 8.6	No
		Week 6	05APR2016/11:47	5.2	1.7 - 8.6	No
		Week 8	20APR2016/09:15	8.3	1.7 - 8.6	Yes
		Week 12	19MAY2016/11:55	7.1	1.7 - 8.6	No
		Week 16	14JUN2016/11:08	9.0 H	1.7 - 8.6	No
		Week 20	13JUL2016/11:20	9.2 H	1.7 - 8.6	No
		Week 24	10AUG2016/10:50	9.7 H	1.7 - 8.6	Yes
		Week 28	07SEP2016/11:30	8.1	1.7 - 8.6	No
		Week 32	05OCT2016/11:00	9.0 H	1.7 - 8.6	No
		Week 36	02NOV2016/12:00	9.7 H	1.7 - 8.6	No
		Week 40	30NOV2016/10:45	8.7 H	1.7 - 8.6	No
		Week 44	22DEC2016/12:00	13.9 H	1.7 - 8.6	No
		Week 48	25JAN2017/11:00	7.4	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	23FEB2016/13:00	22.4	7.6 - 31.4	Yes
		Week 4	22MAR2016/10:15	29.5	7.6 - 31.4	No
		Week 6	05APR2016/11:47	21.0	7.6 - 31.4	No
		Week 8	20APR2016/09:15	25.1	7.6 - 31.4	Yes
		Week 12	19MAY2016/11:55	25.2	7.6 - 31.4	No
		Week 16	14JUN2016/11:08	21.9	7.6 - 31.4	No
		Week 20	13JUL2016/11:20	20.3	7.6 - 31.4	No
		Week 24	10AUG2016/10:50	24.0	7.6 - 31.4	Yes
		Week 28	07SEP2016/11:30	22.7	7.6 - 31.4	No
		Week 32	05OCT2016/11:00	16.6	7.6 - 31.4	No
		Week 36	02NOV2016/12:00	23.1	7.6 - 31.4	No
		Week 40	30NOV2016/10:45	26.7	7.6 - 31.4	No
		Week 44	22DEC2016/12:00	18.9	7.6 - 31.4	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-014	Testosterone (nmol/L)	Week 48	25JAN2017/11:00	19.3	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	23FEB2016/13:00	11.3	4.6 - 25.6	Yes
		Week 4	22MAR2016/10:15	11.4	4.6 - 25.6	No
		Week 6	05APR2016/11:47	7.82	4.6 - 25.6	No
		Week 8	20APR2016/09:15	10.7	4.6 - 25.6	Yes
		Week 12	19MAY2016/11:55	7.77	4.6 - 25.6	No
		Week 16	14JUN2016/11:08	8.30	4.6 - 25.6	No
		Week 20	13JUL2016/11:20	6.50	4.6 - 25.6	No
		Week 24	10AUG2016/10:50	9.84	4.6 - 25.6	Yes
		Week 28	07SEP2016/11:30	9.65	4.6 - 25.6	No
		Week 32	05OCT2016/11:00	6.68	4.6 - 25.6	No
		Week 36	02NOV2016/12:00	12.4	4.6 - 25.6	No
		Week 40	30NOV2016/10:45	15.3	4.6 - 25.6	No
		Week 44	22DEC2016/12:00	11.1	4.6 - 25.6	No
		Week 48	25JAN2017/11:00	9.35	4.6 - 25.6	No
301-016	Follicle Stimulating Hormone (IU/L)	Day 1	25FEB2016/11:50	3.2	1.5 - 12.4	No
		Week 4	24MAR2016/11:35	5.9	1.5 - 12.4	No
		Week 6	07APR2016/11:10	9.2	1.5 - 12.4	No
		Week 8	19APR2016/09:00	11.7	1.5 - 12.4	Yes
		Week 12	24MAY2016/11:56	13.3 H	1.5 - 12.4	No
		Week 16	14JUN2016/10:30	11.7	1.5 - 12.4	No
		Week 20	13JUL2016/11:50	13.9 H	1.5 - 12.4	No
		Week 24	28JUL2016/11:00	16.4 H	1.5 - 12.4	Yes
		Week 28	06SEP2016/10:10	8.8	1.5 - 12.4	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-016	Follicle Stimulating Hormone (IU/L)	Week 32	05OCT2016/11:30	5.0	1.5 - 12.4	No
		Week 36	02NOV2016/11:45	5.5	1.5 - 12.4	No
		Week 40	29NOV2016/11:00	5.9	1.5 - 12.4	No
		Week 44	21DEC2016/11:30	5.3	1.5 - 12.4	No
		Week 48	24JAN2017/12:00	5.0	1.5 - 12.4	No
	Inhibin B (ng/L)	Day 1	25FEB2016/11:50	276.0	100 - 400	No
		Week 4	24MAR2016/11:35	146.0	100 - 400	No
		Week 6	07APR2016/11:10	94.6 L	100 - 400	No
		Week 8	19APR2016/09:00	65.1 L	100 - 400	Yes
		Week 12	24MAY2016/11:56	76.7 L	100 - 400	No
		Week 16	14JUN2016/10:30	69.6 L	100 - 400	No
		Week 20	13JUL2016/11:50	64.8 L	100 - 400	No
		Week 24	28JUL2016/11:00	67.0 L	100 - 400	Yes
		Week 28	06SEP2016/10:10	151.0	100 - 400	No
		Week 32	05OCT2016/11:30	224	100 - 400	No
		Week 36	02NOV2016/11:45	211.0	100 - 400	No
		Week 40	29NOV2016/11:00	172.0	100 - 400	No
		Week 44	21DEC2016/11:30	192.0	100 - 400	No
		Week 48	24JAN2017/12:00	220.0	100 - 400	No
	Luteinizing Hormone (IU/L)	Day 1	25FEB2016/11:50	5.1	1.7 - 8.6	No
		Week 4	24MAR2016/11:35	5.0	1.7 - 8.6	No
		Week 6	07APR2016/11:10	7.5	1.7 - 8.6	No
		Week 8	19APR2016/09:00	8.3	1.7 - 8.6	Yes
		Week 12	24MAY2016/11:56	10.0 H	1.7 - 8.6	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-016	Luteinizing Hormone (IU/L)	Week 16	14JUN2016/10:30	5.3	1.7 - 8.6	No
		Week 20	13JUL2016/11:50	6.1	1.7 - 8.6	No
		Week 24	28JUL2016/11:00	8.3	1.7 - 8.6	Yes
		Week 28	06SEP2016/10:10	6.6	1.7 - 8.6	No
		Week 32	05OCT2016/11:30	5.4	1.7 - 8.6	No
		Week 36	02NOV2016/11:45	8.0	1.7 - 8.6	No
		Week 40	29NOV2016/11:00	6.7	1.7 - 8.6	No
		Week 44	21DEC2016/11:30	5.6	1.7 - 8.6	No
		Week 48	24JAN2017/12:00	10.1 H	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	25FEB2016/11:50	10.8	7.6 - 31.4	No
		Week 4	24MAR2016/11:35	14.7	7.6 - 31.4	No
		Week 6	07APR2016/11:10	15.9	7.6 - 31.4	No
		Week 8	19APR2016/09:00	15.7	7.6 - 31.4	Yes
		Week 12	24MAY2016/11:56	16.4	7.6 - 31.4	No
		Week 16	14JUN2016/10:30	11.9	7.6 - 31.4	No
		Week 20	13JUL2016/11:50	19.6	7.6 - 31.4	No
		Week 24	28JUL2016/11:00	23.6	7.6 - 31.4	Yes
		Week 28	06SEP2016/10:10	19.1	7.6 - 31.4	No
		Week 32	05OCT2016/11:30	24.4	7.6 - 31.4	No
		Week 36	02NOV2016/11:45	19.9	7.6 - 31.4	No
		Week 40	29NOV2016/11:00	16.4	7.6 - 31.4	No
		Week 44	21DEC2016/11:30	17.6	7.6 - 31.4	No
		Week 48	24JAN2017/12:00	16.0	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	25FEB2016/11:50	9.68	7.6 - 36.2	No
		Week 4	24MAR2016/11:35	8.78	7.6 - 36.2	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-016	Testosterone, Free (pg/mL)	Week 6	07APR2016/11:10	7.43 L	7.6 - 36.2	No
		Week 8	19APR2016/09:00	7.89	7.6 - 36.2	Yes
		Week 12	24MAY2016/11:56	11.8	7.6 - 36.2	No
		Week 16	14JUN2016/10:30	5.86 L	7.6 - 36.2	No
		Week 20	13JUL2016/11:50	10.3	7.6 - 36.2	No
		Week 24	28JUL2016/11:00	14.2	7.6 - 36.2	Yes
		Week 28	06SEP2016/10:10	13.2	7.6 - 36.2	No
		Week 32	05OCT2016/11:30	12.0	7.6 - 36.2	No
		Week 36	02NOV2016/11:45	12.3	7.6 - 36.2	No
		Week 40	29NOV2016/11:00	11.9	7.6 - 36.2	No
		Week 44	21DEC2016/11:30	11.2	7.6 - 36.2	No
		Week 48	24JAN2017/12:00	9.10	7.6 - 36.2	No



Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-015	Follicle Stimulating Hormone (IU/L)	Day 1	23FEB2016/13:40	6.0	1.5 - 12.4	Yes
		Week 4	23MAR2016/11:32	10.5	1.5 - 12.4	No
		Week 6	06APR2016/11:45	10.9	1.5 - 12.4	No
		Week 8	20APR2016/09:00	13.3 H	1.5 - 12.4	Yes
		Week 12	17MAY2016/11:55	15.7 H	1.5 - 12.4	No
		Week 16	16JUN2016/12:50	15.5 H	1.5 - 12.4	No
		Week 20	14JUL2016/11:50	18.9 H	1.5 - 12.4	No
		Week 24	10AUG2016/10:20	19.2 H	1.5 - 12.4	Yes
		Week 28	07SEP2016/09:45	15.4 H	1.5 - 12.4	No
		Week 40	30NOV2016/09:50	11.6	1.5 - 12.4	No
	Inhibin B (ng/L)	Week 44	28DEC2016/11:00	7.5	1.5 - 12.4	No
		Week 48	26JAN2017/12:45	7.7	1.5 - 12.4	No
		Day 1	23FEB2016/13:40	228.0	100 - 400	Yes
		Week 4	23MAR2016/11:32	130.0	100 - 400	No
		Week 6	06APR2016/11:45	87.6 L	100 - 400	No
		Week 8	20APR2016/09:00	76.0 L	100 - 400	Yes
		Week 12	17MAY2016/11:55	67.1 L	100 - 400	No
		Week 16	16JUN2016/12:50	56.5 L	100 - 400	No
		Week 20	14JUL2016/11:50	34.7 L	100 - 400	No
		Week 24	10AUG2016/10:20	31.7 L	100 - 400	Yes
		Week 28	07SEP2016/09:45	77.7 L	100 - 400	No
		Week 40	30NOV2016/09:50	149	100 - 400	No
		Week 44	28DEC2016/11:00	198.0	100 - 400	No
		Week 48	26JAN2017/12:45	229.0	100 - 400	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-015	Luteinizing Hormone (IU/L)	Day 1	23FEB2016/13:40	4.9	1.7 - 8.6	Yes
		Week 4	23MAR2016/11:32	9.0 H	1.7 - 8.6	No
		Week 6	06APR2016/11:45	7.7	1.7 - 8.6	No
		Week 8	20APR2016/09:00	6.8	1.7 - 8.6	Yes
		Week 12	17MAY2016/11:55	7.3	1.7 - 8.6	No
		Week 16	16JUN2016/12:50	5.8	1.7 - 8.6	No
		Week 20	14JUL2016/11:50	10.7 H	1.7 - 8.6	No
		Week 24	10AUG2016/10:20	9.1 H	1.7 - 8.6	Yes
		Week 28	07SEP2016/09:45	7.3	1.7 - 8.6	No
		Week 40	30NOV2016/09:50	11.9 H	1.7 - 8.6	No
		Week 44	28DEC2016/11:00	8.9 H	1.7 - 8.6	No
		Week 48	26JAN2017/12:45	11.7 H	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	23FEB2016/13:40	27.0	7.6 - 31.4	Yes
		Week 4	23MAR2016/11:32	27.2	7.6 - 31.4	No
		Week 6	06APR2016/11:45	24.4	7.6 - 31.4	No
		Week 8	20APR2016/09:00	26.3	7.6 - 31.4	Yes
		Week 12	17MAY2016/11:55	26.3	7.6 - 31.4	No
		Week 16	16JUN2016/12:50	27.0	7.6 - 31.4	No
		Week 20	14JUL2016/11:50	27.6	7.6 - 31.4	No
		Week 24	10AUG2016/10:20	31.5 H	7.6 - 31.4	Yes
		Week 28	07SEP2016/09:45	32.0 H	7.6 - 31.4	No
		Week 40	30NOV2016/09:50	30.9	7.6 - 31.4	No
		Week 44	28DEC2016/11:00	29.6	7.6 - 31.4	No
		Week 48	26JAN2017/12:45	28.6	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	23FEB2016/13:40	10.0	4.6 - 25.6	Yes

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-015	Testosterone, Free (pg/mL)	Week 4	23MAR2016/11:32	10.5	4.6 - 25.6	No
		Week 6	06APR2016/11:45	10.1	4.6 - 25.6	No
		Week 8	20APR2016/09:00	6.01	4.6 - 25.6	Yes
		Week 12	17MAY2016/11:55	10.4	4.6 - 25.6	No
		Week 16	16JUN2016/12:50	8.72	4.6 - 25.6	No
		Week 20	14JUL2016/11:50	9.90	4.6 - 25.6	No
		Week 24	10AUG2016/10:20	9.27	4.6 - 25.6	Yes
		Week 28	07SEP2016/09:45	12.7	4.6 - 25.6	No
		Week 40	30NOV2016/09:50	13.3	4.6 - 25.6	No
		Week 44	28DEC2016/11:00	9.64	4.6 - 25.6	No
		Week 48	26JAN2017/12:45	10.8	4.6 - 25.6	No
301-018	Follicle Stimulating Hormone (IU/L)	Day 1	09MAR2016/10:15	3.1	1.5 - 12.4	Yes
		Week 4	06APR2016/10:10	6.4	1.5 - 12.4	No
		Week 6	21APR2016/10:20	9.0	1.5 - 12.4	No
		Week 8	28APR2016/09:45	9.1	1.5 - 12.4	No
		Week 12	01JUN2016/08:40	18.5 H	1.5 - 12.4	Yes
		Week 16	29JUN2016/09:45	14.7 H	1.5 - 12.4	No
		Week 20	27JUL2016/09:50	12.4	1.5 - 12.4	No
		Week 24	23AUG2016/10:00	16.1 H	1.5 - 12.4	Yes
		Week 28	20SEP2016/11:30	10.9	1.5 - 12.4	No
		Week 32	18OCT2016/11:00	5.0	1.5 - 12.4	No
		Week 36	15NOV2016/12:00	5.3	1.5 - 12.4	No
		Week 40	14DEC2016/12:00	6.1	1.5 - 12.4	No
		Week 44	10JAN2017/11:30	5.2	1.5 - 12.4	No
		Week 48	07FEB2017/10:30	4.6	1.5 - 12.4	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-018	Inhibin B (ng/L)	Day 1	09MAR2016/10:15	114.0	100 - 400	Yes
		Week 4	06APR2016/10:10	61.8 L	100 - 400	No
		Week 6	21APR2016/10:20	27.6 L	100 - 400	No
		Week 8	28APR2016/09:45	30.4 L	100 - 400	No
		Week 12	01JUN2016/08:40	22.7 L	100 - 400	Yes
		Week 16	29JUN2016/09:45	15.9 L	100 - 400	No
		Week 20	27JUL2016/09:50	12.7 L	100 - 400	No
		Week 24	23AUG2016/10:00	17.9 L	100 - 400	Yes
		Week 28	20SEP2016/11:30	47.1 L	100 - 400	No
		Week 32	18OCT2016/11:00	99.5 L	100 - 400	No
		Week 36	15NOV2016/12:00	59.3 L	100 - 400	No
		Week 40	14DEC2016/12:00	117.0	100 - 400	No
		Week 44	10JAN2017/11:30	102.0	100 - 400	No
		Week 48	07FEB2017/10:30	114	100 - 400	No
	Luteinizing Hormone (IU/L)	Day 1	09MAR2016/10:15	3.8	1.7 - 8.6	Yes
		Week 4	06APR2016/10:10	5.5	1.7 - 8.6	No
		Week 6	21APR2016/10:20	5.8	1.7 - 8.6	No
		Week 8	28APR2016/09:45	6.5	1.7 - 8.6	No
		Week 12	01JUN2016/08:40	11.3 H	1.7 - 8.6	Yes
		Week 16	29JUN2016/09:45	7.9	1.7 - 8.6	No
		Week 20	27JUL2016/09:50	5.3	1.7 - 8.6	No
		Week 24	23AUG2016/10:00	9.0 H	1.7 - 8.6	Yes
		Week 28	20SEP2016/11:30	5.4	1.7 - 8.6	No
		Week 32	18OCT2016/11:00	5.5	1.7 - 8.6	No
		Week 36	15NOV2016/12:00	5.8	1.7 - 8.6	No
		Week 40	14DEC2016/12:00	8.7 H	1.7 - 8.6	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-018	Luteinizing Hormone (IU/L)	Week 44	10JAN2017/11:30	10.4 H	1.7 - 8.6	No
		Week 48	07FEB2017/10:30	9.8 H	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	09MAR2016/10:15	24.0	7.6 - 31.4	Yes
		Week 4	06APR2016/10:10	23.1	7.6 - 31.4	No
		Week 6	21APR2016/10:20	24.4	7.6 - 31.4	No
		Week 8	28APR2016/09:45	22.2	7.6 - 31.4	No
		Week 12	01JUN2016/08:40	37.6 H	7.6 - 31.4	Yes
		Week 16	29JUN2016/09:45	24.7	7.6 - 31.4	No
		Week 20	27JUL2016/09:50	22.3	7.6 - 31.4	No
		Week 24	23AUG2016/10:00	22.5	7.6 - 31.4	Yes
		Week 28	20SEP2016/11:30	21.6	7.6 - 31.4	No
		Week 32	18OCT2016/11:00	27.4	7.6 - 31.4	No
		Week 36	15NOV2016/12:00	20.5	7.6 - 31.4	No
		Week 40	14DEC2016/12:00	20.9	7.6 - 31.4	No
		Week 44	10JAN2017/11:30	25.8	7.6 - 31.4	No
		Week 48	07FEB2017/10:30	26.2	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	09MAR2016/10:15	7.35	4.6 - 25.6	Yes
		Week 4	06APR2016/10:10	6.26	4.6 - 25.6	No
		Week 6	21APR2016/10:20	7.95	4.6 - 25.6	No
		Week 8	28APR2016/09:45	6.49	4.6 - 25.6	No
		Week 12	01JUN2016/08:40	9.62	4.6 - 25.6	Yes
		Week 16	29JUN2016/09:45	7.51	4.6 - 25.6	No
		Week 20	27JUL2016/09:50	5.60	4.6 - 25.6	No
		Week 24	23AUG2016/10:00	6.41	4.6 - 25.6	Yes
		Week 28	20SEP2016/11:30	7.63	4.6 - 25.6	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 50 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-018	Testosterone, Free (pg/mL)	Week 32	18OCT2016/11:00	8.40	4.6 - 25.6	No
		Week 36	15NOV2016/12:00	3.77 L	4.6 - 25.6	No
		Week 40	14DEC2016/12:00	6.83	4.6 - 25.6	No
		Week 44	10JAN2017/11:30	9.16	4.6 - 25.6	No
		Week 48	07FEB2017/10:30	10.6	4.6 - 25.6	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-006	Follicle Stimulating Hormone (IU/L)	Day 1	04FEB2016/09:45	10.0	1.5 - 12.4	Yes
		Week 4	03MAR2016/12:15	10.7	1.5 - 12.4	No
		Week 6	17MAR2016/11:31	13.0 H	1.5 - 12.4	No
		Week 8	31MAR2016/11:22	11.2	1.5 - 12.4	No
		Week 12	26APR2016/08:15	11.9	1.5 - 12.4	Yes
		Week 16	25MAY2016/11:55	12.8 H	1.5 - 12.4	No
		Week 20	23JUN2016/12:45	12.8 H	1.5 - 12.4	No
		Week 24	19JUL2016/12:00	13.8 H	1.5 - 12.4	Yes
		Week 28	18AUG2016/12:15	16.2 H	1.5 - 12.4	No
		Week 32	13SEP2016/11:45	17.1 H	1.5 - 12.4	No
		Week 36	13OCT2016/12:10	17.7 H	1.5 - 12.4	No
		Week 40	08NOV2016/11:00	17.9 H	1.5 - 12.4	No
		Week 44	08DEC2016/11:00	16.4 H	1.5 - 12.4	No
		Week 48	03JAN2017/12:00	17.3 H	1.5 - 12.4	No
	Inhibin B (ng/L)	Day 1	04FEB2016/09:45	67.9 L	100 - 400	Yes
		Week 4	03MAR2016/12:15	42.7 L	100 - 400	No
		Week 6	17MAR2016/11:31	24.8 L	100 - 400	No
		Week 8	31MAR2016/11:22	25.7 L	100 - 400	No
		Week 12	26APR2016/08:15	22.0 L	100 - 400	Yes
		Week 16	25MAY2016/11:55	29.4 L	100 - 400	No
		Week 20	23JUN2016/12:45	18.5 L	100 - 400	No
		Week 24	19JUL2016/12:00	23.0 L	100 - 400	Yes
		Week 28	18AUG2016/12:15	25.5 L	100 - 400	No
		Week 32	13SEP2016/11:45	28.1 L	100 - 400	No
		Week 36	13OCT2016/12:10	29.6 L	100 - 400	No

Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-006	Inhibin B (ng/L)	Week 40	08NOV2016/11:00	25.6 L	100 - 400	No
		Week 44	08DEC2016/11:00	33.5 L	100 - 400	No
		Week 48	03JAN2017/12:00	41.8 L	100 - 400	No
	Luteinizing Hormone (IU/L)	Day 1	04FEB2016/09:45	8.4	1.7 - 8.6	Yes
		Week 4	03MAR2016/12:15	7.2	1.7 - 8.6	No
		Week 6	17MAR2016/11:31	13.1 H	1.7 - 8.6	No
		Week 8	31MAR2016/11:22	6.1	1.7 - 8.6	No
		Week 12	26APR2016/08:15	7.9	1.7 - 8.6	Yes
		Week 16	25MAY2016/11:55	11.4 H	1.7 - 8.6	No
		Week 20	23JUN2016/12:45	9.5 H	1.7 - 8.6	No
		Week 24	19JUL2016/12:00	8.4	1.7 - 8.6	Yes
		Week 28	18AUG2016/12:15	9.4 H	1.7 - 8.6	No
		Week 32	13SEP2016/11:45	10.8 H	1.7 - 8.6	No
		Week 36	13OCT2016/12:10	11.4 H	1.7 - 8.6	No
		Week 40	08NOV2016/11:00	12.8 H	1.7 - 8.6	No
		Week 44	08DEC2016/11:00	8.8 H	1.7 - 8.6	No
		Week 48	03JAN2017/12:00	13.9 H	1.7 - 8.6	No
	Testosterone (nmol/L)	Day 1	04FEB2016/09:45	16.3	7.6 - 31.4	Yes
		Week 4	03MAR2016/12:15	17.0	7.6 - 31.4	No
		Week 6	17MAR2016/11:31	20.3	7.6 - 31.4	No
		Week 8	31MAR2016/11:22	19.0	7.6 - 31.4	No
		Week 12	26APR2016/08:15	18.5	7.6 - 31.4	Yes
		Week 16	25MAY2016/11:55	18.1	7.6 - 31.4	No
		Week 20	23JUN2016/12:45	16.2	7.6 - 31.4	No
		Week 24	19JUL2016/12:00	18.2	7.6 - 31.4	Yes



Listing 16.2.7.9  
Laboratory Summary - Reproductive Serology (Males)  
(All Patients)

Treatment Sequence: 50 mg/100 mg - 75 mg/100 mg - 100 mg/100 mg - 75 mg/100 mg

Subject ID	Lab Test (unit)	Visit	Date/Time of Collection	Result [1]	Reference Range	Fasting?
301-006	Testosterone (nmol/L)	Week 28	18AUG2016/12:15	17.5	7.6 - 31.4	No
		Week 32	13SEP2016/11:45	22.5	7.6 - 31.4	No
		Week 36	13OCT2016/12:10	21.2	7.6 - 31.4	No
		Week 40	08NOV2016/11:00	19.3	7.6 - 31.4	No
		Week 44	08DEC2016/11:00	17.0	7.6 - 31.4	No
		Week 48	03JAN2017/12:00	15.3	7.6 - 31.4	No
	Testosterone, Free (pg/mL)	Day 1	04FEB2016/09:45	8.99	7.6 - 36.2	Yes
		Week 4	03MAR2016/12:15	13.0	7.6 - 36.2	No
		Week 6	17MAR2016/11:31	14.9	7.6 - 36.2	No
		Week 8	31MAR2016/11:22	13.6	7.6 - 36.2	No
		Week 12	26APR2016/08:15	12.7	7.6 - 36.2	Yes
		Week 16	25MAY2016/11:55	11.4	7.6 - 36.2	No
		Week 20	23JUN2016/12:45	9.60	7.6 - 36.2	No
		Week 24	19JUL2016/12:00	12.2	7.6 - 36.2	Yes
		Week 28	18AUG2016/12:15	7.68	7.6 - 36.2	No
		Week 32	13SEP2016/11:45	9.40	7.6 - 36.2	No
		Week 36	13OCT2016/12:10	9.94	7.6 - 36.2	No
		Week 40	08NOV2016/11:00	7.99	7.6 - 36.2	No
		Week 44	08DEC2016/11:00	9.31	7.6 - 36.2	No
		Week 48	03JAN2017/12:00	11.9	7.6 - 36.2	No