

Table 14.2.10.4
Summary of Adrenal Axis Suppression Immunoassay (Cortisol (First in Morning))
Safety Population

	Treatments				Total (N=48)
	Dose Group 1 0.25 mg/kg/day (N=12)	Dose Group 2 0.75 mg/kg/day (N=12)	Dose Group 3 2.0 mg/kg/day (N=12)	Dose Group 4 6.0 mg/kg/day (N=12)	
Week 2 (pre-dose)					
Subjects with morning cortisol result	11	11	11	10	43
Subjects with less than 100 nmol/L (3.6 micrograms/dL)	0	0	2 (18.2)	6 (60.0)	8 (18.6)

Table 14.2.10.5
Summary of Cortisol (First in Morning)
Safety Population

Parameter: Morning Cortisol (mcg/dL)

Visit	Statistic	Treatments				Total (N=48)
		Dose Group 1 0.25 mg/kg/day (N=12)	Dose Group 2 0.75 mg/kg/day (N=12)	Dose Group 3 2.0 mg/kg/day (N=12)	Dose Group 4 6.0 mg/kg/day (N=12)	
Week 2 (pre-dose)	n	11	11	11	10	43
	Mean	10.425	9.755	7.321	3.010	7.735
	SD	1.7358	2.7614	3.0322	1.0141	3.6423
	Median	11.060	9.880	7.330	2.755	8.110
	Minimum	8.12	6.06	2.23	1.71	1.71
	Maximum	12.71	14.17	12.41	4.43	14.17
	Interquartile Range	9.030, 12.110	7.080, 11.850	5.680, 9.740	2.250, 4.030	4.250, 11.060