

Table 13.2: Statistical Analysis and Comparisons of aGFR (mL/min) Between Visits by Baseline eGFR (< 50 vs. >= 50 mL/min) and Overall PD Substudy Analysis Set

Parameters	Treatment				Statistical Comparison						
	Test		Reference		Ratio		90% Confidence Interval	Model			
	n	GLS Mean	n	GLS Mean	Test/Reference	(%)		rMSE	rInter		
-----											
Analyte: Actual GFR Week 2/4/8 vs Baseline				Group: All Subjects							
-----											
aGFR (mL/min)	32	56.59	32	57.20	Week 2/4/8/BL	98.94	(93.71,104.46)	0.130	0.296		
-----											
Analyte: Actual GFR Week 24 vs Baseline				Group: All Subjects							
-----											
aGFR (mL/min)	30	58.72	32	57.20	Week 24/BL	102.66	(97.11,108.53)	0.130	0.296		

GLS Mean = Geometric Least Squares Mean.

Mixed model covariance parameter estimates: rMSE = square root of mean square error; rInter = square root of intersubject variance.

Actual GFR (aGFR) using iohexol plasma clearance (mL/min) = iohexol dose / iohexol AUCinf.

All subjects in the PK/PD/PBMC Substudy analysis set are from Cohort 1 (Treatment-experienced).

Data Extracted: CRF Data: 17SEP2014, Lab Data: 19SEP2014, Dexa Data: 18SEP2014

Source: ../version1/prog/t-pkstats-agfr.sas v9.2 20SEP2014:10:43