

Table 14-6.05

Shifts of Laboratory Values During Treatment, Categorized Based on Threshold Ranges

		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)			
		Shift	Normal at	High at	Normal at	High at	Normal at	High at	p-
		[1]	Baseline	Baseline	Baseline	Baseline	Baseline	Baseline	value
CHEMISTRY									

ALANINE AMINOTRANSFERASE	n		82	2	79	1	80	0	0.828
	Normal		80 (98%)	0	78 (99%)	0	78 (98%)	0	
	High		2 (2%)	2 (100%)	1 (1%)	1 (100%)	2 (3%)	0	
ALBUMIN	n		84	0	80	0	80	0	
	Normal		84 (100%)	0	80 (100%)	0	80 (100%)	0	
ALKALINE PHOSPHATASE	n		82	2	79	0	79	1	0.611
	Normal		81 (99%)	0	78 (99%)	0	79 (100%)	0	
	High		1 (1%)	2 (100%)	1 (1%)	0	0	1 (100%)	
ASPARTATE AMINOTRANSFERASE	n		82	2	79	1	80	0	0.770
	Normal		79 (96%)	1 (50%)	77 (97%)	1 (100%)	78 (98%)	0	
	High		3 (4%)	1 (50%)	2 (3%)	0	2 (3%)	0	
BILIRUBIN	n		84	0	80	0	79	1	0.353
	Normal		83 (99%)	0	80 (100%)	0	77 (97%)	0	

NOTES: Only subjects with baseline results are included in the summary.

There were no subjects with abnormal low values at baseline.

[1] A subject is counted only once for each analyte. A change will be considered shifting from normal at baseline to abnormal or from abnormal at baseline to normal at any visit during the treatment. The treatment period is defined as any planned visit after Week 0 (Visit 3), up to and including Week 24 (Visit 12).

[2] CMH test for general association, controlling for status at baseline.

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	Shift [1]	Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)		p- value [2]
		Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	
	High	1 (1%)	0	0	0	2 (3%)	1 (100%)	
CALCIUM	n	84	0	80	0	80	0	
	Normal	84 (100%)	0	80 (100%)	0	80 (100%)	0	
CHLORIDE	n	84	0	80	0	79	0	
	Normal	84 (100%)	0	80 (100%)	0	79 (100%)	0	
CHOLESTEROL	n	84	0	80	0	80	0	
	Normal	84 (100%)	0	80 (100%)	0	80 (100%)	0	
CREATINE KINASE	n	84	0	79	1	77	3	0.811
	Normal	77 (92%)	0	74 (94%)	1 (100%)	72 (94%)	1 (33%)	
	High	7 (8%)	0	5 (6%)	0	5 (6%)	2 (67%)	
CREATININE	n	84	0	80	0	80	0	
	Normal	84 (100%)	0	80 (100%)	0	80 (100%)	0	
GAMMA GLUTAMYL TRANSFERASE	n	82	2	78	2	78	2	0.898
	Normal	80 (98%)	0	75 (96%)	1 (50%)	76 (97%)	1 (50%)	

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	Shift [1]	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	
	High	2 (2%)	2 (100%)	3 (4%)	1 (50%)	2 (3%)	1 (50%)	
GLUCOSE	n	83	1	80	0	80	0	0.354
	Normal	83 (100%)	1 (100%)	79 (99%)	0	78 (98%)	0	
	High	0	0	1 (1%)	0	2 (3%)	0	
PHOSPHATE	n	84	0	79	0	80	0	
	Normal	84 (100%)	0	79 (100%)	0	80 (100%)	0	
POTASSIUM	n	84	0	79	0	79	0	
	Normal	84 (100%)	0	79 (100%)	0	79 (100%)	0	
PROTEIN	n	84	0	80	0	80	0	
	Normal	84 (100%)	0	80 (100%)	0	80 (100%)	0	
SODIUM	n	84	0	80	0	79	0	
	Normal	84 (100%)	0	80 (100%)	0	79 (100%)	0	
URATE	n	84	0	80	0	80	0	
	Normal	84 (100%)	0	80 (100%)	0	80 (100%)	0	

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		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)		
	Shift	Normal at	High at	Normal at	High at	Normal at	High at	p-
	[1]	Baseline	Baseline	Baseline	Baseline	Baseline	Baseline	value
UREA NITROGEN	n	84	0	78	2	80	0	0.363
	Normal	84 (100%)	0	78 (100%)	2 (100%)	79 (99%)	0	
	High	0	0	0	0	1 (1%)	0	
HEMATOLOGY								

BASOPHILS	n	83	0	79	0	78	0	0.044
	Normal	83 (100%)	0	79 (100%)	0	78 (100%)	0	
EOSINOPHILS	n	83	0	78	1	78	0	
	Normal	83 (100%)	0	73 (94%)	1 (100%)	72 (92%)	0	
	High	0	0	5 (6%)	0	6 (8%)	0	
ERY. MEAN CORPUSCULAR HBn CONCENTRATION	n	82	0	78	0	77	0	
	Normal	82 (100%)	0	78 (100%)	0	77 (100%)	0	
ERY. MEAN CORPUSCULAR HEMOGLOBIN	n	83	0	79	0	78	0	
	Normal	83 (100%)	0	79 (100%)	0	78 (100%)	0	

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	Shift [1]	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	
ERY. MEAN CORPUSCULAR VOLUME	n	82	0	78	0	77	0	0.388
	Normal	82 (100%)	0	78 (100%)	0	77 (100%)	0	
ERYTHROCYTES	n	83	0	79	0	78	0	
	Normal	83 (100%)	0	79 (100%)	0	78 (100%)	0	
HEMATOCRIT	n	82	0	78	0	77	0	
	Normal	82 (100%)	0	78 (100%)	0	77 (100%)	0	
HEMOGLOBIN	n	83	0	79	0	78	0	
	Normal	83 (100%)	0	79 (100%)	0	78 (100%)	0	
LEUKOCYTES	n	83	0	79	0	78	0	
	Normal	83 (100%)	0	79 (100%)	0	78 (100%)	0	
LYMPHOCYTES	n	83	0	79	0	78	0	
	Normal	82 (99%)	0	79 (100%)	0	78 (100%)	0	
	High	1 (1%)	0	0	0	0	0	

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	Shift [1]	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	
MONOCYTES	n	83	0	79	0	78	0	0.150
	Normal	81 (98%)	0	79 (100%)	0	78 (100%)	0	
	Low	2 (2%)	0	0	0	0	0	
PLATELET	n	83	0	77	0	78	0	
	Normal	83 (100%)	0	77 (100%)	0	78 (100%)	0	

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