

Table 14-6.03

**Frequency of Normal and Abnormal (Clinically Significant Change from Previous Visit) Laboratory Values During Treatment**

	Placebo (N=86)			Xan. Low (N=84)			Xan. High (N=84)			p-val [1]	
	Low	Normal	High	Low	Normal	High	Low	Normal	High		
CHEMISTRY											
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ALBUMIN	10 ( 12%)	71 ( 85%)	3 ( 4%)	6 ( 7%)	72 ( 88%)	4 ( 5%)	5 ( 6%)	66 ( 83%)	9 ( 11%)	0.235	
ALKALINE	1 ( 1%)	78 ( 93%)	5 ( 6%)	0	79 ( 98%)	2 ( 2%)	0	77 ( 96%)	3 ( 4%)	0.599	
PHOSPHATASE											
ALANINE	4 ( 5%)	75 ( 89%)	5 ( 6%)	6 ( 7%)	69 ( 84%)	7 ( 9%)	7 ( 9%)	68 ( 85%)	5 ( 6%)	0.820	
AMINOTRANSFERASE											
ASPARTATE	2 ( 2%)	73 ( 87%)	9 ( 11%)	8 ( 10%)	71 ( 87%)	3 ( 4%)	3 ( 4%)	75 ( 94%)	2 ( 3%)	0.045	
AMINOTRANSFERASE											
BILIRUBIN	0	79 ( 94%)	5 ( 6%)	1 ( 1%)	79 ( 98%)	1 ( 1%)	2 ( 3%)	75 ( 94%)	3 ( 4%)	0.296	
UREA NITROGEN	0	83 ( 99%)	1 ( 1%)	1 ( 1%)	79 ( 96%)	2 ( 2%)	1 ( 1%)	78 ( 98%)	1 ( 1%)	0.796	
CALCIUM	6 ( 7%)	76 ( 90%)	2 ( 2%)	4 ( 5%)	76 ( 93%)	2 ( 2%)	0	77 ( 96%)	3 ( 4%)	0.140	
CHOLESTEROL	1 ( 1%)	81 ( 96%)	2 ( 2%)	0	82 (100%)	0	1 ( 1%)	79 ( 99%)	0	0.500	
CREATINE KINASE	8 ( 10%)	64 ( 76%)	12 ( 14%)	6 ( 7%)	71 ( 87%)	5 ( 6%)	7 ( 9%)	65 ( 81%)	8 ( 10%)	0.474	
CHLORIDE	3 ( 4%)	78 ( 93%)	3 ( 4%)	0	80 ( 98%)	2 ( 2%)	2 ( 3%)	77 ( 96%)	1 ( 1%)	0.496	
CREATININE	0	82 ( 98%)	2 ( 2%)	0	81 ( 99%)	1 ( 1%)	0	80 (100%)	0	0.775	
GAMMA GLUTAMYL	1 ( 1%)	81 ( 96%)	2 ( 2%)	4 ( 5%)	72 ( 88%)	6 ( 7%)	2 ( 3%)	74 ( 93%)	4 ( 5%)	0.378	
TRANSFERASE											
GLUCOSE	1 ( 1%)	81 ( 96%)	2 ( 2%)	1 ( 1%)	81 ( 99%)	0	3 ( 4%)	74 ( 93%)	3 ( 4%)	0.317	
POTASSIUM	2 ( 2%)	82 ( 98%)	0	2 ( 2%)	78 ( 96%)	1 ( 1%)	3 ( 4%)	74 ( 93%)	3 ( 4%)	0.464	
SODIUM	10 ( 12%)	60 ( 71%)	14 ( 17%)	7 ( 9%)	62 ( 76%)	13 ( 16%)	12 ( 15%)	58 ( 73%)	10 ( 13%)	0.728	
PHOSPHATE	1 ( 1%)	82 ( 98%)	1 ( 1%)	0	79 ( 98%)	2 ( 2%)	2 ( 3%)	76 ( 95%)	2 ( 3%)	0.661	
PROTEIN	5 ( 6%)	73 ( 87%)	6 ( 7%)	1 ( 1%)	80 ( 98%)	1 ( 1%)	5 ( 6%)	74 ( 93%)	1 ( 1%)	0.062	
URATE	2 ( 2%)	81 ( 96%)	1 ( 1%)	0	82 (100%)	0	0	80 (100%)	0	0.331	

Note: Percentages are based on the number of subjects with non-missing assessments (i.e., the total of the subjects in the low, normal, and high categories) within each treatment group.

Source: C:\cdisc\_pilot\PROGRAMS\DRAFT\TFLs\rt\_labnormfreq.sas

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*Frequency of Normal and Abnormal (Clinically Significant Change from Previous Visit) Laboratory Values During Treatment*

	Placebo (N=86)			Xan. Low (N=84)			Xan. High (N=84)			p-val [1]
	Low	Normal	High	Low	Normal	High	Low	Normal	High	
HEMATOLOGY										
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BASOPHILS	1 ( 1%)	82 ( 98%)	1 ( 1%)	2 ( 2%)	80 ( 98%)	0	1 ( 1%)	79 ( 99%)	0	0.948
EOSINOPHILS	4 ( 5%)	80 ( 95%)	0	3 ( 4%)	70 ( 85%)	9 ( 11%)	4 ( 5%)	68 ( 85%)	8 ( 10%)	0.010
HEMATOCRIT	2 ( 2%)	79 ( 95%)	2 ( 2%)	4 ( 5%)	77 ( 95%)	0	1 ( 1%)	76 ( 95%)	3 ( 4%)	0.351
HEMOGLOBIN	0	84 (100%)	0	2 ( 2%)	80 ( 98%)	0	0	80 (100%)	0	0.215
LYMPHOCYTES	4 ( 5%)	76 ( 90%)	4 ( 5%)	2 ( 2%)	79 ( 96%)	1 ( 1%)	2 ( 3%)	77 ( 96%)	1 ( 1%)	0.498
ERY. MEAN	1 ( 1%)	83 ( 99%)	0	0	81 ( 99%)	1 ( 1%)	0	80 (100%)	0	0.884
CORPUSCULAR										
HEMOGLOBIN										
ERY. MEAN	1 ( 1%)	82 ( 99%)	0	0	80 ( 99%)	1 ( 1%)	0	80 (100%)	0	0.885
CORPUSCULAR HB										
CONCENTRATION										
ERY. MEAN	0	80 ( 96%)	3 ( 4%)	2 ( 2%)	78 ( 96%)	1 ( 1%)	1 ( 1%)	75 ( 94%)	4 ( 5%)	0.396
CORPUSCULAR VOLUME										
MONOCYTES	5 ( 6%)	74 ( 88%)	5 ( 6%)	1 ( 1%)	80 ( 98%)	1 ( 1%)	1 ( 1%)	78 ( 98%)	1 ( 1%)	0.081
PLATELET	0	84 (100%)	0	1 ( 1%)	80 ( 98%)	1 ( 1%)	0	79 ( 99%)	1 ( 1%)	0.546
ERYTHROCYTES	0	83 ( 99%)	1 ( 1%)	1 ( 1%)	81 ( 99%)	0	0	80 (100%)	0	0.884
LEUKOCYTES	4 ( 5%)	78 ( 93%)	2 ( 2%)	2 ( 2%)	77 ( 94%)	3 ( 4%)	3 ( 4%)	74 ( 93%)	3 ( 4%)	0.934

Note: Percentages are based on the number of subjects with non-missing assessments (i.e., the total of the subjects in the low, normal, and high categories) within each treatment group.

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