

Table 14-6.02

## Frequency of Normal and Abnormal (Beyond Normal Range) 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	16 ( 19%)	65 ( 77%)	3 ( 4%)	15 ( 18%)	66 ( 80%)	1 ( 1%)	5 ( 6%)	74 ( 93%)	1 ( 1%)	0.042
ALKALINE	4 ( 5%)	72 ( 86%)	8 ( 10%)	2 ( 2%)	74 ( 90%)	6 ( 7%)	3 ( 4%)	73 ( 91%)	4 ( 5%)	0.776
PHOSPHATASE										
ALANINE	1 ( 1%)	74 ( 88%)	9 ( 11%)	5 ( 6%)	68 ( 83%)	9 ( 11%)	0	70 ( 88%)	10 ( 13%)	0.185
AMINOTRANSFERASE										
ASPARTATE	0	74 ( 88%)	10 ( 12%)	0	72 ( 88%)	10 ( 12%)	0	72 ( 90%)	8 ( 10%)	0.907
AMINOTRANSFERASE										
BILIRUBIN	0	78 ( 93%)	6 ( 7%)	0	79 ( 98%)	2 ( 2%)	0	75 ( 94%)	5 ( 6%)	0.402
UREA NITROGEN	0	75 ( 89%)	9 ( 11%)	0	60 ( 73%)	22 ( 27%)	0	68 ( 85%)	12 ( 15%)	0.023
CALCIUM	5 ( 6%)	78 ( 93%)	1 ( 1%)	7 ( 9%)	72 ( 88%)	3 ( 4%)	7 ( 9%)	71 ( 89%)	2 ( 3%)	0.789
CHOLESTEROL	5 ( 6%)	73 ( 87%)	6 ( 7%)	6 ( 7%)	72 ( 88%)	4 ( 5%)	6 ( 8%)	70 ( 88%)	4 ( 5%)	0.962
CREATINE KINASE	1 ( 1%)	66 ( 79%)	17 ( 20%)	1 ( 1%)	68 ( 83%)	13 ( 16%)	0	67 ( 84%)	13 ( 16%)	0.816
CHLORIDE	0	74 ( 88%)	10 ( 12%)	0	74 ( 90%)	8 ( 10%)	0	78 ( 98%)	2 ( 3%)	0.058
CREATININE	0	80 ( 95%)	4 ( 5%)	0	76 ( 93%)	6 ( 7%)	0	73 ( 91%)	7 ( 9%)	0.572
GAMMA GLUTAMYL	4 ( 5%)	73 ( 87%)	7 ( 8%)	4 ( 5%)	69 ( 84%)	9 ( 11%)	1 ( 1%)	71 ( 89%)	8 ( 10%)	0.689
TRANSFERASE										
GLUCOSE	0	82 ( 98%)	2 ( 2%)	0	81 ( 99%)	1 ( 1%)	0	77 ( 96%)	3 ( 4%)	0.534
POTASSIUM	3 ( 4%)	80 ( 95%)	1 ( 1%)	3 ( 4%)	79 ( 96%)	0	2 ( 3%)	78 ( 98%)	0	1.000
SODIUM	4 ( 5%)	75 ( 89%)	5 ( 6%)	3 ( 4%)	74 ( 90%)	5 ( 6%)	7 ( 9%)	62 ( 78%)	11 ( 14%)	0.177
PHOSPHATE	1 ( 1%)	83 ( 99%)	0	0	80 ( 98%)	2 ( 2%)	1 ( 1%)	78 ( 98%)	1 ( 1%)	0.518
PROTEIN	1 ( 1%)	76 ( 90%)	7 ( 8%)	2 ( 2%)	75 ( 91%)	5 ( 6%)	1 ( 1%)	77 ( 96%)	2 ( 3%)	0.536
URATE	3 ( 4%)	77 ( 92%)	4 ( 5%)	1 ( 1%)	75 ( 91%)	6 ( 7%)	4 ( 5%)	69 ( 86%)	7 ( 9%)	0.564
HEMATOLOGY										

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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	Placebo (N=86)			Xan. Low (N=84)			Xan. High (N=84)			p-val [1]
	Low	Normal	High	Low	Normal	High	Low	Normal	High	
BASOPHILS	0	84 (100%)	0	0	82 (100%)	0	0	81 (100%)	0	
EOSINOPHILS	0	84 (100%)	0	0	71 ( 87%)	11 ( 13%)	0	74 ( 91%)	7 ( 9%)	0.001
HEMATOCRIT	5 ( 6%)	74 ( 89%)	4 ( 5%)	9 ( 11%)	72 ( 88%)	1 ( 1%)	1 ( 1%)	78 ( 96%)	2 ( 2%)	0.052
HEMOGLOBIN	14 ( 17%)	68 ( 81%)	2 ( 2%)	10 ( 12%)	72 ( 88%)	0	5 ( 6%)	73 ( 90%)	3 ( 4%)	0.093
LYMPHOCYTES	6 ( 7%)	73 ( 87%)	5 ( 6%)	4 ( 5%)	69 ( 84%)	9 ( 11%)	4 ( 5%)	76 ( 94%)	1 ( 1%)	0.103
ERY. MEAN	0	81 ( 96%)	3 ( 4%)	0	81 ( 99%)	1 ( 1%)	1 ( 1%)	75 ( 93%)	5 ( 6%)	0.186
CORPUSCULAR										
HEMOGLOBIN										
ERY. MEAN	15 ( 18%)	68 ( 82%)	0	17 ( 21%)	65 ( 79%)	0	9 ( 11%)	72 ( 89%)	0	0.231
CORPUSCULAR HB										
CONCENTRATION										
ERY. MEAN	1 ( 1%)	53 ( 64%)	29 ( 35%)	0	64 ( 78%)	18 ( 22%)	1 ( 1%)	64 ( 79%)	16 ( 20%)	0.077
CORPUSCULAR VOLUME										
MONOCYTES	2 ( 2%)	80 ( 95%)	2 ( 2%)	1 ( 1%)	77 ( 94%)	4 ( 5%)	0	79 ( 98%)	2 ( 2%)	0.626
PLATELET	0	81 ( 96%)	3 ( 4%)	2 ( 2%)	77 ( 94%)	3 ( 4%)	2 ( 2%)	77 ( 95%)	2 ( 2%)	0.681
ERYTHROCYTES	13 ( 15%)	71 ( 85%)	0	18 ( 22%)	64 ( 78%)	0	11 ( 14%)	68 ( 84%)	2 ( 2%)	0.238
LEUKOCYTES	7 ( 8%)	73 ( 87%)	4 ( 5%)	6 ( 7%)	68 ( 83%)	8 ( 10%)	4 ( 5%)	74 ( 91%)	3 ( 4%)	0.462

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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