

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										

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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