

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										
ALBUMIN	10 (12%)	71 (85%)	3 (4%)	6 (7%)	72 (88%)	4 (5%)	5 (6%)	66 (83%)	9 (11%)	0.235
ALKALINE PHOSPHATASE	1 (1%)	78 (93%)	5 (6%)	0	79 (98%)	2 (2%)	0	77 (96%)	3 (4%)	0.599
AMINOTRANSFERASE	4 (5%)	75 (89%)	5 (6%)	6 (7%)	69 (84%)	7 (9%)	7 (9%)	68 (85%)	5 (6%)	0.820
ASPARTATE AMINOTRANSFERASE	2 (2%)	73 (87%)	9 (11%)	8 (10%)	71 (87%)	3 (4%)	3 (4%)	75 (94%)	2 (3%)	0.045
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 TRANSFERASE	1 (1%)	81 (96%)	2 (2%)	4 (5%)	72 (88%)	6 (7%)	2 (3%)	74 (93%)	4 (5%)	0.378
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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	Placebo (N=86)			Xan. Low (N=84)			Xan. High (N=84)			p-val [1]
	Low	Normal	High	Low	Normal	High	Low	Normal	High	
HEMATOLOGY										
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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