

Table 14-6.04

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
Week	Shift to		Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
CHEMISTRY								

ALANINE AMINOTRANSFERASE	2	n	81	2	77	1	78	0
		Normal	81 (100%)	0	77 (100%)	0	78 (100%)	0
		High	0	2 (100%)	0	1 (100%)	0	0
	4	n	77	2	69	1	72	0
		Normal	77 (100%)	1 (50%)	69 (100%)	0	72 (100%)	0
		High	0	1 (50%)	0	1 (100%)	0	0
	6	n	72	1	59	1	66	0
		Normal	71 (99%)	1 (100%)	59 (100%)	0	66 (100%)	0
		High	1 (1%)	0	0	1 (100%)	0	0
	8	n	71	1	57	1	56	0
		Normal	71 (100%)	0	57 (100%)	0	54 (96%)	0
		High	0	1 (100%)	0	1 (100%)	2 (4%)	0
	12	n	66	1	49	1	50	0
		Normal	65 (98%)	1 (100%)	48 (98%)	1 (100%)	49 (98%)	0
		High	1 (2%)	0	1 (2%)	0	1 (2%)	0
	16	n	67	1	40	0	37	0
		Normal	67 (100%)	1 (100%)	40 (100%)	0	37 (100%)	0
	20	n	64	1	29	0	31	0

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

There were no subjects with abnormal low values at baseline.

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		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
	Normal	64 (100%)	1 (100%)	29 (100%)	0	31 (100%)	0
24	n	56	1	25	0	30	0
	Normal	55 (98%)	1 (100%)	25 (100%)	0	30 (100%)	0
	High	1 (2%)	0	0	0	0	0
26	n	56	1	24	0	27	0
	Normal	56 (100%)	1 (100%)	23 (96%)	0	27 (100%)	0
	High	0	0	1 (4%)	0	0	0
ALBUMIN	2	83	0	78	0	78	0
	Normal	83 (100%)	0	78 (100%)	0	78 (100%)	0
4	n	79	0	70	0	72	0
	Normal	79 (100%)	0	70 (100%)	0	72 (100%)	0
6	n	73	0	60	0	66	0
	Normal	73 (100%)	0	60 (100%)	0	66 (100%)	0
8	n	72	0	58	0	56	0
	Normal	72 (100%)	0	58 (100%)	0	56 (100%)	0
12	n	67	0	50	0	50	0
	Normal	67 (100%)	0	50 (100%)	0	50 (100%)	0
16	n	68	0	40	0	37	0
	Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0

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	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
ALKALINE PHOSPHATASE	20	n	65	0	29	0	31	0
		Normal	65 (100%)	0	29 (100%)	0	31 (100%)	0
	24	n	57	0	25	0	30	0
		Normal	57 (100%)	0	25 (100%)	0	30 (100%)	0
	26	n	57	0	24	0	27	0
		Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0
	2	n	82	2	78	0	77	1
		Normal	82 (100%)	0	78 (100%)	0	77 (100%)	0
		High	0	2 (100%)	0	0	0	1 (100%)
	4	n	80	2	69	0	71	1
		Normal	80 (100%)	0	69 (100%)	0	71 (100%)	0
		High	0	2 (100%)	0	0	0	1 (100%)
6	n	75	0	62	0	66	1	
	Normal	75 (100%)	0	62 (100%)	0	66 (100%)	0	
	High	0	0	0	0	0	1 (100%)	
8	n	72	1	58	0	55	1	
	Normal	72 (100%)	0	57 (98%)	0	55 (100%)	0	
	High	0	1 (100%)	1 (2%)	0	0	1 (100%)	
12	n	66	1	50	0	49	1	

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		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)		
Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	
	Normal	66 (100%)	0	50 (100%)	0	49 (100%)	0	
	High	0	1 (100%)	0	0	0	1 (100%)	
16	n	67	1	40	0	36	1	
	Normal	67 (100%)	0	40 (100%)	0	36 (100%)	0	
	High	0	1 (100%)	0	0	0	1 (100%)	
20	n	64	1	30	0	30	1	
	Normal	63 (98%)	0	30 (100%)	0	30 (100%)	0	
	High	1 (2%)	1 (100%)	0	0	0	1 (100%)	
24	n	55	1	26	0	30	0	
	Normal	54 (98%)	0	26 (100%)	0	30 (100%)	0	
	High	1 (2%)	1 (100%)	0	0	0	0	
26	n	56	1	24	0	27	0	
	Normal	55 (98%)	0	24 (100%)	0	27 (100%)	0	
	High	1 (2%)	1 (100%)	0	0	0	0	
ASPARTATE AMINOTRANSFERASE	2	n	81	2	78	0	78	0
		Normal	80 (99%)	1 (50%)	77 (99%)	0	78 (100%)	0
		High	1 (1%)	1 (50%)	1 (1%)	0	0	0
	4	n	77	2	69	1	72	0
		Normal	76 (99%)	1 (50%)	69 (100%)	1 (100%)	72 (100%)	0
		High	1 (1%)	1 (50%)	0	0	0	0

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Week	Shift to	Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
		Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
6	n	72	1	60	0	66	0
	Normal	71 (99%)	1 (100%)	60 (100%)	0	65 (98%)	0
	High	1 (1%)	0	0	0	1 (2%)	0
8	n	71	1	58	0	56	0
	Normal	70 (99%)	1 (100%)	58 (100%)	0	55 (98%)	0
	High	1 (1%)	0	0	0	1 (2%)	0
12	n	66	1	50	0	50	0
	Normal	65 (98%)	1 (100%)	49 (98%)	0	50 (100%)	0
	High	1 (2%)	0	1 (2%)	0	0	0
16	n	67	1	40	0	37	0
	Normal	67 (100%)	1 (100%)	39 (98%)	0	37 (100%)	0
	High	0	0	1 (3%)	0	0	0
20	n	64	1	29	0	31	0
	Normal	64 (100%)	1 (100%)	29 (100%)	0	31 (100%)	0
24	n	56	1	25	0	30	0
	Normal	54 (96%)	1 (100%)	24 (96%)	0	30 (100%)	0
	High	2 (4%)	0	1 (4%)	0	0	0
26	n	56	1	24	0	27	0
	Normal	55 (98%)	1 (100%)	23 (96%)	0	27 (100%)	0
	High	1 (2%)	0	1 (4%)	0	0	0

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			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
Week	Shift to		Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
BILIRUBIN	2	n	83	0	78	0	77	1
		Normal	82 (99%)	0	78 (100%)	0	77 (100%)	1 (100%)
		High	1 (1%)	0	0	0	0	0
	4	n	79	0	70	0	71	1
		Normal	78 (99%)	0	70 (100%)	0	71 (100%)	0
		High	1 (1%)	0	0	0	0	1 (100%)
	6	n	73	0	60	0	65	1
		Normal	73 (100%)	0	60 (100%)	0	65 (100%)	1 (100%)
	8	n	72	0	58	0	55	1
		Normal	72 (100%)	0	58 (100%)	0	55 (100%)	1 (100%)
	12	n	67	0	50	0	49	1
		Normal	67 (100%)	0	50 (100%)	0	48 (98%)	1 (100%)
		High	0	0	0	0	1 (2%)	0
	16	n	68	0	40	0	36	1
		Normal	68 (100%)	0	40 (100%)	0	36 (100%)	1 (100%)
	20	n	65	0	29	0	30	1
		Normal	65 (100%)	0	29 (100%)	0	29 (97%)	1 (100%)
		High	0	0	0	0	1 (3%)	0
	24	n	57	0	25	0	29	1

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		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
	Normal	57 (100%)	0	25 (100%)	0	29 (100%)	1 (100%)
CALCIUM	26 n	57	0	24	0	26	1
	Normal	57 (100%)	0	23 (96%)	0	26 (100%)	1 (100%)
	High	0	0	1 (4%)	0	0	0
	2 n	84	0	78	0	78	0
	Normal	84 (100%)	0	78 (100%)	0	78 (100%)	0
	4 n	82	0	70	0	72	0
	Normal	82 (100%)	0	70 (100%)	0	72 (100%)	0
	6 n	75	0	62	0	67	0
	Normal	75 (100%)	0	62 (100%)	0	67 (100%)	0
	8 n	73	0	58	0	56	0
	Normal	73 (100%)	0	58 (100%)	0	56 (100%)	0
	12 n	67	0	50	0	50	0
	Normal	67 (100%)	0	50 (100%)	0	50 (100%)	0
	16 n	68	0	40	0	37	0
	Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0
	20 n	66	0	30	0	31	0
	Normal	66 (100%)	0	30 (100%)	0	31 (100%)	0

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			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
CHLORIDE	24	n	57	0	26	0	30	0
		Normal	57 (100%)	0	26 (100%)	0	30 (100%)	0
	26	n	57	0	24	0	27	0
		Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0
	2	n	84	0	78	0	76	0
		Normal	84 (100%)	0	78 (100%)	0	76 (100%)	0
	4	n	82	0	70	0	71	0
		Normal	82 (100%)	0	70 (100%)	0	71 (100%)	0
	6	n	75	0	62	0	66	0
		Normal	75 (100%)	0	62 (100%)	0	66 (100%)	0
	8	n	73	0	58	0	56	0
		Normal	73 (100%)	0	58 (100%)	0	56 (100%)	0
	12	n	67	0	50	0	49	0
		Normal	67 (100%)	0	50 (100%)	0	49 (100%)	0
	16	n	68	0	40	0	37	0
		Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0
	20	n	65	0	30	0	31	0
		Normal	65 (100%)	0	30 (100%)	0	31 (100%)	0

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	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
CHOLESTEROL	24	n	57	0	26	0	30	0
		Normal	57 (100%)	0	26 (100%)	0	30 (100%)	0
	26	n	57	0	24	0	27	0
		Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0
	2	n	84	0	78	0	78	0
		Normal	84 (100%)	0	78 (100%)	0	78 (100%)	0
	4	n	82	0	70	0	72	0
		Normal	82 (100%)	0	70 (100%)	0	72 (100%)	0
	6	n	75	0	62	0	67	0
		Normal	75 (100%)	0	62 (100%)	0	67 (100%)	0
	8	n	73	0	58	0	56	0
		Normal	73 (100%)	0	58 (100%)	0	56 (100%)	0
	12	n	67	0	50	0	50	0
		Normal	67 (100%)	0	50 (100%)	0	50 (100%)	0
	16	n	68	0	40	0	37	0
		Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0
	20	n	66	0	30	0	31	0
		Normal	66 (100%)	0	30 (100%)	0	31 (100%)	0

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			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
CREATINE KINASE	24	n	57	0	26	0	30	0
		Normal	57 (100%)	0	26 (100%)	0	30 (100%)	0
	26	n	57	0	24	0	27	0
		Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0
	2	n	83	0	77	1	75	3
		Normal	81 (98%)	0	74 (96%)	1 (100%)	74 (99%)	3 (100%)
		High	2 (2%)	0	3 (4%)	0	1 (1%)	0
	4	n	79	0	69	1	69	3
		Normal	78 (99%)	0	68 (99%)	1 (100%)	68 (99%)	3 (100%)
		High	1 (1%)	0	1 (1%)	0	1 (1%)	0
	6	n	73	0	59	1	63	3
		Normal	73 (100%)	0	58 (98%)	1 (100%)	61 (97%)	2 (67%)
		High	0	0	1 (2%)	0	2 (3%)	1 (33%)
	8	n	72	0	57	1	54	2
		Normal	71 (99%)	0	57 (100%)	1 (100%)	53 (98%)	2 (100%)
		High	1 (1%)	0	0	0	1 (2%)	0
12	n	67	0	49	1	48	2	
	Normal	65 (97%)	0	48 (98%)	1 (100%)	47 (98%)	1 (50%)	
	High	2 (3%)	0	1 (2%)	0	1 (2%)	1 (50%)	
16	n	68	0	39	1	36	1	

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		Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
CREATININE	Normal	66 (97%)	0	39 (100%)	1 (100%)	36 (100%)	1 (100%)
	High	2 (3%)	0	0	0	0	0
	20 n	65	0	29	0	30	1
	Normal	65 (100%)	0	27 (93%)	0	29 (97%)	1 (100%)
	High	0	0	2 (7%)	0	1 (3%)	0
	24 n	57	0	25	0	29	1
	Normal	55 (96%)	0	25 (100%)	0	29 (100%)	1 (100%)
	High	2 (4%)	0	0	0	0	0
	26 n	57	0	24	0	26	1
	Normal	57 (100%)	0	24 (100%)	0	25 (96%)	1 (100%)
	High	0	0	0	0	1 (4%)	0
	2 n	84	0	78	0	78	0
	Normal	84 (100%)	0	78 (100%)	0	78 (100%)	0
	4 n	82	0	70	0	72	0
	Normal	82 (100%)	0	70 (100%)	0	72 (100%)	0
	6 n	75	0	62	0	67	0
	Normal	75 (100%)	0	62 (100%)	0	67 (100%)	0
	8 n	73	0	58	0	56	0
	Normal	73 (100%)	0	58 (100%)	0	56 (100%)	0

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			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
GAMMA GLUTAMYL TRANSFERASE	12	n	67	0	50	0	50	0
		Normal	67 (100%)	0	50 (100%)	0	50 (100%)	0
	16	n	68	0	40	0	37	0
		Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0
	20	n	66	0	30	0	31	0
		Normal	66 (100%)	0	30 (100%)	0	31 (100%)	0
	24	n	57	0	26	0	30	0
		Normal	57 (100%)	0	26 (100%)	0	30 (100%)	0
	26	n	57	0	24	0	27	0
		Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0
	2	n	82	2	76	2	76	2
		Normal	82 (100%)	1 (50%)	75 (99%)	1 (50%)	75 (99%)	1 (50%)
		High	0	1 (50%)	1 (1%)	1 (50%)	1 (1%)	1 (50%)
	4	n	80	2	68	2	70	2
		Normal	80 (100%)	1 (50%)	68 (100%)	1 (50%)	70 (100%)	1 (50%)
		High	0	1 (50%)	0	1 (50%)	0	1 (50%)
	6	n	74	1	61	1	66	1
		Normal	74 (100%)	0	61 (100%)	1 (100%)	66 (100%)	0
	High	0	1 (100%)	0	0	0	1 (100%)	

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Week	Shift to	Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
		Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
8	n	72	1	57	1	55	1
	Normal	72 (100%)	0	56 (98%)	1 (100%)	54 (98%)	0
	High	0	1 (100%)	1 (2%)	0	1 (2%)	1 (100%)
12	n	66	1	49	1	49	1
	Normal	66 (100%)	0	49 (100%)	1 (100%)	49 (100%)	0
	High	0	1 (100%)	0	0	0	1 (100%)
16	n	67	1	39	1	36	1
	Normal	67 (100%)	1 (100%)	39 (100%)	1 (100%)	36 (100%)	0
	High	0	0	0	0	0	1 (100%)
20	n	65	1	29	1	31	0
	Normal	65 (100%)	0	29 (100%)	0	31 (100%)	0
	High	0	1 (100%)	0	1 (100%)	0	0
24	n	56	1	26	0	29	1
	Normal	54 (96%)	1 (100%)	25 (96%)	0	29 (100%)	0
	High	2 (4%)	0	1 (4%)	0	0	1 (100%)
26	n	56	1	24	0	26	1
	Normal	55 (98%)	1 (100%)	23 (96%)	0	26 (100%)	0
	High	1 (2%)	0	1 (4%)	0	0	1 (100%)
GLUCOSE	2 n	82	1	78	0	78	0
	Normal	82 (100%)	1 (100%)	78 (100%)	0	77 (99%)	0

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Week	Shift to	Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
		Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
	High	0	0	0	0	1 (1%)	0
4	n	78	1	69	0	72	0
	Normal	78 (100%)	1 (100%)	69 (100%)	0	72 (100%)	0
6	n	72	1	60	0	66	0
	Normal	72 (100%)	1 (100%)	60 (100%)	0	65 (98%)	0
	High	0	0	0	0	1 (2%)	0
8	n	71	1	57	0	56	0
	Normal	71 (100%)	1 (100%)	57 (100%)	0	56 (100%)	0
12	n	66	1	50	0	49	0
	Normal	66 (100%)	1 (100%)	49 (98%)	0	49 (100%)	0
	High	0	0	1 (2%)	0	0	0
16	n	67	1	40	0	37	0
	Normal	67 (100%)	1 (100%)	40 (100%)	0	37 (100%)	0
20	n	64	1	29	0	31	0
	Normal	64 (100%)	1 (100%)	29 (100%)	0	31 (100%)	0
24	n	56	1	25	0	30	0
	Normal	56 (100%)	1 (100%)	25 (100%)	0	30 (100%)	0
26	n	56	1	24	0	27	0
	Normal	56 (100%)	1 (100%)	24 (100%)	0	27 (100%)	0

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

There were no subjects with abnormal low values at baseline.

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_labshiftweek.sas

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Table 14-6.04

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
Week	Shift to		Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
PHOSPHATE	2	n	84	0	78	0	78	0
		Normal	84 (100%)	0	78 (100%)	0	78 (100%)	0
	4	n	82	0	68	0	72	0
		Normal	82 (100%)	0	68 (100%)	0	72 (100%)	0
	6	n	75	0	62	0	67	0
		Normal	75 (100%)	0	62 (100%)	0	67 (100%)	0
	8	n	73	0	58	0	56	0
		Normal	73 (100%)	0	58 (100%)	0	56 (100%)	0
	12	n	67	0	50	0	50	0
		Normal	67 (100%)	0	50 (100%)	0	50 (100%)	0
	16	n	68	0	40	0	37	0
		Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0
	20	n	65	0	30	0	31	0
		Normal	65 (100%)	0	30 (100%)	0	31 (100%)	0
	24	n	56	0	26	0	30	0
		Normal	56 (100%)	0	26 (100%)	0	30 (100%)	0
	26	n	57	0	24	0	27	0
		Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0

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

There were no subjects with abnormal low values at baseline.

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Table 14-6.04

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
POTASSIUM	2	n	84	0	78	0	76	0
		Normal	84 (100%)	0	78 (100%)	0	76 (100%)	0
	4	n	82	0	68	0	71	0
		Normal	82 (100%)	0	68 (100%)	0	71 (100%)	0
	6	n	75	0	62	0	66	0
		Normal	75 (100%)	0	62 (100%)	0	66 (100%)	0
	8	n	73	0	58	0	56	0
		Normal	73 (100%)	0	58 (100%)	0	56 (100%)	0
	12	n	67	0	50	0	49	0
		Normal	67 (100%)	0	50 (100%)	0	49 (100%)	0
	16	n	68	0	40	0	37	0
		Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0
	20	n	64	0	30	0	31	0
		Normal	64 (100%)	0	30 (100%)	0	31 (100%)	0
	24	n	56	0	26	0	30	0
		Normal	56 (100%)	0	26 (100%)	0	30 (100%)	0
	26	n	57	0	24	0	27	0
		Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0

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

There were no subjects with abnormal low values at baseline.

Source: C:\cdisc_pilot\PROGRAMS\Draft\TFLs\rt_labshiftweek.sas

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Table 14-6.04

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
PROTEIN	2	n	84	0	78	0	78	0
		Normal	84 (100%)	0	78 (100%)	0	78 (100%)	0
	4	n	82	0	70	0	72	0
		Normal	82 (100%)	0	70 (100%)	0	72 (100%)	0
	6	n	75	0	62	0	67	0
		Normal	75 (100%)	0	62 (100%)	0	67 (100%)	0
	8	n	73	0	58	0	56	0
		Normal	73 (100%)	0	58 (100%)	0	56 (100%)	0
	12	n	67	0	50	0	50	0
		Normal	67 (100%)	0	50 (100%)	0	50 (100%)	0
	16	n	68	0	40	0	37	0
		Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0
	20	n	66	0	30	0	31	0
		Normal	66 (100%)	0	30 (100%)	0	31 (100%)	0
	24	n	57	0	26	0	30	0
		Normal	57 (100%)	0	26 (100%)	0	30 (100%)	0
	26	n	57	0	24	0	27	0
		Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0

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

There were no subjects with abnormal low values at baseline.

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Table 14-6.04

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
			Normal at	High at	Normal at	High at	Normal at	High at
Week	Shift to		Baseline	Baseline	Baseline	Baseline	Baseline	Baseline
SODIUM	2	n	84	0	78	0	76	0
		Normal	84 (100%)	0	78 (100%)	0	76 (100%)	0
	4	n	82	0	70	0	71	0
		Normal	82 (100%)	0	70 (100%)	0	71 (100%)	0
	6	n	75	0	62	0	66	0
		Normal	75 (100%)	0	62 (100%)	0	66 (100%)	0
	8	n	73	0	58	0	56	0
		Normal	73 (100%)	0	58 (100%)	0	56 (100%)	0
	12	n	67	0	50	0	49	0
		Normal	67 (100%)	0	50 (100%)	0	49 (100%)	0
	16	n	68	0	40	0	37	0
		Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0
	20	n	65	0	30	0	31	0
		Normal	65 (100%)	0	30 (100%)	0	31 (100%)	0
	24	n	57	0	26	0	30	0
		Normal	57 (100%)	0	26 (100%)	0	30 (100%)	0
	26	n	57	0	24	0	27	0
		Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0

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Table 14-6.04

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
Week	Shift to		Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
URATE	2	n	84	0	78	0	78	0
		Normal	84 (100%)	0	78 (100%)	0	78 (100%)	0
	4	n	82	0	70	0	72	0
		Normal	82 (100%)	0	70 (100%)	0	72 (100%)	0
	6	n	75	0	62	0	67	0
		Normal	75 (100%)	0	62 (100%)	0	67 (100%)	0
	8	n	73	0	58	0	56	0
		Normal	73 (100%)	0	58 (100%)	0	56 (100%)	0
	12	n	67	0	50	0	50	0
		Normal	67 (100%)	0	50 (100%)	0	50 (100%)	0
	16	n	68	0	40	0	37	0
		Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0
	20	n	66	0	30	0	31	0
		Normal	66 (100%)	0	30 (100%)	0	31 (100%)	0
	24	n	57	0	26	0	30	0
		Normal	57 (100%)	0	26 (100%)	0	30 (100%)	0
	26	n	57	0	24	0	27	0
		Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0

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Table 14-6.04

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
			Normal at	High at	Normal at	High at	Normal at	High at
			Baseline	Baseline	Baseline	Baseline	Baseline	Baseline
Week	Shift to							
UREA NITROGEN	2	n	84	0	76	2	78	0
		Normal	84 (100%)	0	76 (100%)	2 (100%)	77 (99%)	0
		High	0	0	0	0	1 (1%)	0
	4	n	82	0	68	2	72	0
		Normal	82 (100%)	0	68 (100%)	2 (100%)	72 (100%)	0
	6	n	75	0	60	2	67	0
		Normal	75 (100%)	0	60 (100%)	2 (100%)	67 (100%)	0
	8	n	73	0	56	2	56	0
		Normal	73 (100%)	0	56 (100%)	2 (100%)	56 (100%)	0
	12	n	67	0	49	1	50	0
		Normal	67 (100%)	0	49 (100%)	1 (100%)	50 (100%)	0
	16	n	68	0	39	1	37	0
		Normal	68 (100%)	0	39 (100%)	1 (100%)	37 (100%)	0
	20	n	66	0	29	1	31	0
		Normal	66 (100%)	0	29 (100%)	1 (100%)	31 (100%)	0
	24	n	57	0	25	1	30	0
		Normal	57 (100%)	0	25 (100%)	1 (100%)	30 (100%)	0
	26	n	57	0	23	1	27	0

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

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Table 14-6.04
Shifts of Laboratory Values During Treatment, Categorized Based on Threshold Ranges, by Visit

		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
	Normal	57 (100%)	0	23 (100%)	1 (100%)	26 (96%)	0
	High	0	0	0	0	1 (4%)	0
HEMATOLOGY							

BASOPHILS							
2	n	82	0	77	0	77	0
	Normal	82 (100%)	0	77 (100%)	0	77 (100%)	0
4	n	78	0	69	0	69	0
	Normal	78 (100%)	0	69 (100%)	0	69 (100%)	0
6	n	72	0	59	0	62	0
	Normal	72 (100%)	0	59 (100%)	0	62 (100%)	0
8	n	71	0	56	0	55	0
	Normal	71 (100%)	0	56 (100%)	0	55 (100%)	0
12	n	65	0	48	0	49	0
	Normal	65 (100%)	0	48 (100%)	0	49 (100%)	0
16	n	67	0	39	0	36	0
	Normal	67 (100%)	0	39 (100%)	0	36 (100%)	0
20	n	64	0	29	0	31	0
	Normal	64 (100%)	0	29 (100%)	0	31 (100%)	0

NOTES: Only subjects with baseline results are included in the summary.
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Table 14-6.04

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
EOSINOPHILS	24	n	57	0	24	0	29	0
		Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
	26	n	56	0	24	0	26	0
		Normal	56 (100%)	0	24 (100%)	0	26 (100%)	0
	2	n	82	0	76	1	77	0
		Normal	82 (100%)	0	74 (97%)	1 (100%)	77 (100%)	0
		High	0	0	2 (3%)	0	0	0
	4	n	78	0	69	0	69	0
		Normal	78 (100%)	0	69 (100%)	0	68 (99%)	0
		High	0	0	0	0	1 (1%)	0
	6	n	72	0	59	0	62	0
		Normal	72 (100%)	0	59 (100%)	0	58 (94%)	0
		High	0	0	0	0	4 (6%)	0
	8	n	71	0	56	0	55	0
		Normal	71 (100%)	0	53 (95%)	0	52 (95%)	0
		High	0	0	3 (5%)	0	3 (5%)	0
12	n	65	0	48	0	49	0	
	Normal	65 (100%)	0	46 (96%)	0	49 (100%)	0	
	High	0	0	2 (4%)	0	0	0	
16	n	67	0	39	0	36	0	

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

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Table 14-6.04

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

		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)		
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
ERY. MEAN CORPUSCULAR HB CONCENTRATION		Normal	67 (100%)	0	39 (100%)	0	35 (97%)	0
		High	0	0	0	0	1 (3%)	0
	20	n	64	0	29	0	31	0
		Normal	64 (100%)	0	29 (100%)	0	31 (100%)	0
	24	n	57	0	24	0	29	0
		Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
	26	n	56	0	24	0	26	0
		Normal	56 (100%)	0	24 (100%)	0	26 (100%)	0
	2	n	82	0	76	0	76	0
		Normal	82 (100%)	0	76 (100%)	0	76 (100%)	0
	4	n	76	0	67	0	67	0
		Normal	76 (100%)	0	67 (100%)	0	67 (100%)	0
	6	n	71	0	57	0	63	0
		Normal	71 (100%)	0	57 (100%)	0	63 (100%)	0
	8	n	70	0	53	0	55	0
		Normal	70 (100%)	0	53 (100%)	0	55 (100%)	0
12	n	64	0	47	0	49	0	
	Normal	64 (100%)	0	47 (100%)	0	49 (100%)	0	

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

There were no subjects with abnormal low values at baseline.

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Table 14-6.04
Shifts of Laboratory Values During Treatment, Categorized Based on Threshold Ranges, by Visit

		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
ERY. MEAN CORPUSCULAR HEMOGLOBIN	16 n	67	0	39	0	36	0
	Normal	67 (100%)	0	39 (100%)	0	36 (100%)	0
	20 n	63	0	29	0	31	0
	Normal	63 (100%)	0	29 (100%)	0	31 (100%)	0
	24 n	57	0	24	0	29	0
	Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
	26 n	55	0	24	0	26	0
	Normal	55 (100%)	0	24 (100%)	0	26 (100%)	0
	2 n	82	0	77	0	77	0
	Normal	82 (100%)	0	77 (100%)	0	77 (100%)	0
	4 n	78	0	69	0	69	0
	Normal	78 (100%)	0	69 (100%)	0	69 (100%)	0
	6 n	72	0	59	0	63	0
	Normal	72 (100%)	0	59 (100%)	0	63 (100%)	0
	8 n	71	0	56	0	55	0
	Normal	71 (100%)	0	56 (100%)	0	55 (100%)	0
	12 n	65	0	48	0	49	0

NOTES: Only subjects with baseline results are included in the summary.
There were no subjects with abnormal low values at baseline.

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Table 14-6.04

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

		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)		
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
ERY. MEAN CORPUSCULAR VOLUME		Normal	65 (100%)	0	48 (100%)	0	49 (100%)	0
	16	n	67	0	39	0	36	0
		Normal	67 (100%)	0	39 (100%)	0	36 (100%)	0
	20	n	64	0	29	0	31	0
		Normal	64 (100%)	0	29 (100%)	0	31 (100%)	0
	24	n	57	0	24	0	29	0
		Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
	26	n	56	0	24	0	26	0
		Normal	56 (100%)	0	24 (100%)	0	26 (100%)	0
	2	n	82	0	76	0	76	0
		Normal	82 (100%)	0	76 (100%)	0	76 (100%)	0
	4	n	76	0	67	0	67	0
		Normal	76 (100%)	0	67 (100%)	0	67 (100%)	0
	6	n	71	0	57	0	63	0
		Normal	71 (100%)	0	57 (100%)	0	63 (100%)	0
	8	n	70	0	53	0	55	0
Normal		70 (100%)	0	53 (100%)	0	55 (100%)	0	

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

There were no subjects with abnormal low values at baseline.

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
ERYTHROCYTES	12	n	64	0	47	0	49	0
		Normal	64 (100%)	0	47 (100%)	0	49 (100%)	0
	16	n	67	0	39	0	36	0
		Normal	67 (100%)	0	39 (100%)	0	36 (100%)	0
	20	n	63	0	29	0	31	0
		Normal	63 (100%)	0	29 (100%)	0	31 (100%)	0
	24	n	57	0	24	0	29	0
		Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
	26	n	55	0	24	0	26	0
		Normal	55 (100%)	0	24 (100%)	0	26 (100%)	0
	2	n	82	0	77	0	77	0
		Normal	82 (100%)	0	77 (100%)	0	77 (100%)	0
	4	n	78	0	69	0	69	0
		Normal	78 (100%)	0	69 (100%)	0	69 (100%)	0
	6	n	72	0	59	0	63	0
		Normal	72 (100%)	0	59 (100%)	0	63 (100%)	0
	8	n	71	0	56	0	55	0
		Normal	71 (100%)	0	56 (100%)	0	55 (100%)	0

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

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
HEMATOCRIT	12	n	65	0	48	0	49	0
		Normal	65 (100%)	0	48 (100%)	0	49 (100%)	0
	16	n	67	0	39	0	36	0
		Normal	67 (100%)	0	39 (100%)	0	36 (100%)	0
	20	n	64	0	29	0	31	0
		Normal	64 (100%)	0	29 (100%)	0	31 (100%)	0
	24	n	57	0	24	0	29	0
		Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
	26	n	56	0	24	0	26	0
		Normal	56 (100%)	0	24 (100%)	0	26 (100%)	0
	2	n	82	0	76	0	76	0
		Normal	82 (100%)	0	76 (100%)	0	76 (100%)	0
	4	n	76	0	67	0	67	0
		Normal	76 (100%)	0	67 (100%)	0	67 (100%)	0
	6	n	71	0	57	0	63	0
		Normal	71 (100%)	0	57 (100%)	0	63 (100%)	0
	8	n	70	0	53	0	55	0
		Normal	70 (100%)	0	53 (100%)	0	55 (100%)	0

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

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
HEMOGLOBIN	12	n	64	0	47	0	49	0
		Normal	64 (100%)	0	47 (100%)	0	49 (100%)	0
	16	n	67	0	39	0	36	0
		Normal	67 (100%)	0	39 (100%)	0	36 (100%)	0
	20	n	63	0	29	0	31	0
		Normal	63 (100%)	0	29 (100%)	0	31 (100%)	0
	24	n	57	0	24	0	29	0
		Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
	26	n	55	0	24	0	26	0
		Normal	55 (100%)	0	24 (100%)	0	26 (100%)	0
	2	n	82	0	77	0	77	0
		Normal	82 (100%)	0	77 (100%)	0	77 (100%)	0
	4	n	78	0	69	0	69	0
		Normal	78 (100%)	0	69 (100%)	0	69 (100%)	0
	6	n	72	0	59	0	63	0
		Normal	72 (100%)	0	59 (100%)	0	63 (100%)	0
	8	n	71	0	56	0	55	0
		Normal	71 (100%)	0	56 (100%)	0	55 (100%)	0

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

There were no subjects with abnormal low values at baseline.

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\rt_labshiftweek.sas

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Table 14-6.04

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
LEUKOCYTES	12	n	65	0	48	0	49	0
		Normal	65 (100%)	0	48 (100%)	0	49 (100%)	0
	16	n	67	0	39	0	36	0
		Normal	67 (100%)	0	39 (100%)	0	36 (100%)	0
	20	n	64	0	29	0	31	0
		Normal	64 (100%)	0	29 (100%)	0	31 (100%)	0
	24	n	57	0	24	0	29	0
		Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
	26	n	56	0	24	0	26	0
		Normal	56 (100%)	0	24 (100%)	0	26 (100%)	0
	2	n	82	0	77	0	77	0
		Normal	82 (100%)	0	77 (100%)	0	77 (100%)	0
	4	n	78	0	69	0	69	0
		Normal	78 (100%)	0	69 (100%)	0	69 (100%)	0
	6	n	72	0	59	0	63	0
		Normal	72 (100%)	0	59 (100%)	0	63 (100%)	0
	8	n	71	0	56	0	55	0
		Normal	71 (100%)	0	56 (100%)	0	55 (100%)	0

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

There were no subjects with abnormal low values at baseline.

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

			Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
	Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
LYMPHOCYTES	12	n	65	0	48	0	49	0
		Normal	65 (100%)	0	48 (100%)	0	49 (100%)	0
	16	n	67	0	39	0	36	0
		Normal	67 (100%)	0	39 (100%)	0	36 (100%)	0
	20	n	64	0	29	0	31	0
		Normal	64 (100%)	0	29 (100%)	0	31 (100%)	0
	24	n	57	0	24	0	29	0
		Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
	26	n	56	0	24	0	26	0
		Normal	56 (100%)	0	24 (100%)	0	26 (100%)	0
	2	n	82	0	77	0	77	0
		Normal	82 (100%)	0	77 (100%)	0	77 (100%)	0
	4	n	78	0	69	0	69	0
		Normal	78 (100%)	0	69 (100%)	0	69 (100%)	0
	6	n	72	0	59	0	62	0
		Normal	72 (100%)	0	59 (100%)	0	62 (100%)	0
	8	n	71	0	56	0	55	0
		Normal	70 (99%)	0	56 (100%)	0	55 (100%)	0
		High	1 (1%)	0	0	0	0	0

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

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Table 14-6.04

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

		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
MONOCYTES	12 n	65	0	48	0	49	0
	Normal	64 (98%)	0	48 (100%)	0	49 (100%)	0
	High	1 (2%)	0	0	0	0	0
	16 n	67	0	39	0	36	0
	Normal	67 (100%)	0	39 (100%)	0	36 (100%)	0
	20 n	64	0	29	0	31	0
	Normal	64 (100%)	0	29 (100%)	0	31 (100%)	0
	24 n	57	0	24	0	29	0
	Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
	26 n	56	0	24	0	26	0
	Normal	56 (100%)	0	24 (100%)	0	26 (100%)	0
	2 n	82	0	77	0	77	0
	Normal	82 (100%)	0	77 (100%)	0	77 (100%)	0
	4 n	78	0	69	0	69	0
	Normal	78 (100%)	0	69 (100%)	0	69 (100%)	0
	6 n	72	0	59	0	62	0
	Normal	71 (99%)	0	59 (100%)	0	62 (100%)	0
	Low	1 (1%)	0	0	0	0	0

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

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

		Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
Week	Shift to	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
8	n	71	0	56	0	55	0
	Normal	71 (100%)	0	56 (100%)	0	55 (100%)	0
12	n	65	0	48	0	49	0
	Normal	65 (100%)	0	48 (100%)	0	49 (100%)	0
16	n	67	0	39	0	36	0
	Normal	66 (99%)	0	39 (100%)	0	36 (100%)	0
	Low	1 (1%)	0	0	0	0	0
20	n	64	0	29	0	31	0
	Normal	64 (100%)	0	29 (100%)	0	31 (100%)	0
24	n	57	0	24	0	29	0
	Normal	57 (100%)	0	24 (100%)	0	29 (100%)	0
26	n	56	0	24	0	26	0
	Normal	56 (100%)	0	24 (100%)	0	26 (100%)	0
PLATELET	n	82	0	74	0	77	0
	Normal	82 (100%)	0	74 (100%)	0	77 (100%)	0
4	n	77	0	67	0	68	0
	Normal	77 (100%)	0	67 (100%)	0	68 (100%)	0
6	n	72	0	57	0	61	0
	Normal	72 (100%)	0	57 (100%)	0	61 (100%)	0

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

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Week	Shift to	Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
		Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
8	n	71	0	55	0	54	0
	Normal	71 (100%)	0	55 (100%)	0	54 (100%)	0
12	n	64	0	47	0	48	0
	Normal	64 (100%)	0	47 (100%)	0	48 (100%)	0
16	n	67	0	37	0	36	0
	Normal	67 (100%)	0	37 (100%)	0	36 (100%)	0
20	n	64	0	28	0	30	0
	Normal	64 (100%)	0	28 (100%)	0	30 (100%)	0
24	n	56	0	22	0	28	0
	Normal	56 (100%)	0	22 (100%)	0	28 (100%)	0
26	n	55	0	23	0	26	0
	Normal	55 (100%)	0	23 (100%)	0	26 (100%)	0

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

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