

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

	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		
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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			Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
			Normal	n	1 (100%)	1 (100%)	29 (100%)	0
ALBUMIN	24	Normal	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	Normal	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
	2	Normal	83	0	78	0	78	0
		Normal	83 (100%)	0	78 (100%)	0	78 (100%)	0
	4	Normal	79	0	70	0	72	0
		Normal	79 (100%)	0	70 (100%)	0	72 (100%)	0
	6	Normal	73	0	60	0	66	0
		Normal	73 (100%)	0	60 (100%)	0	66 (100%)	0
	8	Normal	72	0	58	0	56	0
		Normal	72 (100%)	0	58 (100%)	0	56 (100%)	0
	12	Normal	67	0	50	0	50	0
		Normal	67 (100%)	0	50 (100%)	0	50 (100%)	0
	16	Normal	68	0	40	0	37	0
		Normal	68 (100%)	0	40 (100%)	0	37 (100%)	0

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			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
		n	57	0	25	0	30	0
	24	Normal	57 (100%)	0	25 (100%)	0	30 (100%)	0
		n	57	0	24	0	27	0
	26	Normal	57 (100%)	0	24 (100%)	0	27 (100%)	0
		n	82	2	78	0	77	1
		Normal	82 (100%)	0	78 (100%)	0	77 (100%)	0
	4	High	0	2 (100%)	0	0	0	1 (100%)
		n	80	2	69	0	71	1
		Normal	80 (100%)	0	69 (100%)	0	71 (100%)	0
	6	High	0	2 (100%)	0	0	0	1 (100%)
		n	75	0	62	0	66	1
		Normal	75 (100%)	0	62 (100%)	0	66 (100%)	0
	8	High	0	0	0	0	0	1 (100%)
		n	72	1	58	0	55	1
		Normal	72 (100%)	0	57 (98%)	0	55 (100%)	0
	12	High	0	1 (100%)	1 (2%)	0	0	1 (100%)
		n	66	1	50	0	49	1

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		Shift to	Placebo (N=86)		Xan. Low (N=84)		Xan. High (N=84)	
			Week	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal 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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		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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			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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			Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline	Normal at Baseline	High at Baseline
			Normal	n	57(100%)	0	25(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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			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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			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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			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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			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%)
	4	High	0	1 (50%)	1 (1%)	1 (50%)	1 (1%)	1 (50%)
		n	80	2	68	2	70	2
	6	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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		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	n	82	1	78	0	78	0
	Normal	82 (100%)	1 (100%)	78 (100%)	0	77 (99%)	0

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		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

21:05 Monday, June 26, 2006

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

	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
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

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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
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

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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
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

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

	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
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

	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
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

	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
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

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

	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
		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
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

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

	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
EOSINOPHILS	24	n	57	0	24	0	29	0
		Normal	57(100%)	0	24(100%)	0	29(100%)	0
		n	56	0	24	0	26	0
	26	Normal	56(100%)	0	24(100%)	0	26(100%)	0
		n	82	0	76	1	77	0
		Normal	82(100%)	0	74 (97%)	1(100%)	77(100%)	0
	4	High	0	0	2 (3%)	0	0	0
		n	78	0	69	0	69	0
		Normal	78(100%)	0	69(100%)	0	68 (99%)	0
	6	High	0	0	0	0	1 (1%)	0
		n	72	0	59	0	62	0
		Normal	72(100%)	0	59(100%)	0	58 (94%)	0
	8	High	0	0	0	0	4 (6%)	0
		n	71	0	56	0	55	0
		Normal	71(100%)	0	53 (95%)	0	52 (95%)	0
	12	High	0	0	3 (5%)	0	3 (5%)	0
		n	65	0	48	0	49	0
		Normal	65(100%)	0	46 (96%)	0	49(100%)	0
	16	High	0	0	2 (4%)	0	0	0
		n	67	0	39	0	36	0

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

	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
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

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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
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

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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
		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
ERY. MEAN CORPUSCULAR VOLUME	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

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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
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
	ERYTHROCYTES	n	82	0	77	0	77	0
		Normal	82 (100%)	0	77 (100%)	0	77 (100%)	0
		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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	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
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
BILIRUBIN	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

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

	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
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
	8	n	82	0	77	0	77	0
		Normal	82 (100%)	0	77 (100%)	0	77 (100%)	0
		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

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

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

	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
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.

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

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

	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	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	2	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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