

Table 14-6.05

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

| | | Placebo (N=86) | | Xan. Low (N=84) | | Xan. High (N=84) | | | |
|----------------------------|--------|----------------|-----------|-----------------|-----------|------------------|-----------|----------|-------|
| | | Shift | Normal at | High at | Normal at | High at | Normal at | High at | p- |
| | | [1] | Baseline | Baseline | Baseline | Baseline | Baseline | Baseline | value |
| | | | | | | | | | |
| CHEMISTRY | | | | | | | | | |
| ----- | | | | | | | | | |
| ALANINE AMINOTRANSFERASE | n | | 82 | 2 | 79 | 1 | 80 | 0 | 0.828 |
| | Normal | | 80 (98%) | 0 | 78 (99%) | 0 | 78 (98%) | 0 | |
| | High | | 2 (2%) | 2 (100%) | 1 (1%) | 1 (100%) | 2 (3%) | 0 | |
| ALBUMIN | n | | 84 | 0 | 80 | 0 | 80 | 0 | |
| | Normal | | 84 (100%) | 0 | 80 (100%) | 0 | 80 (100%) | 0 | |
| ALKALINE PHOSPHATASE | n | | 82 | 2 | 79 | 0 | 79 | 1 | 0.611 |
| | Normal | | 81 (99%) | 0 | 78 (99%) | 0 | 79 (100%) | 0 | |
| | High | | 1 (1%) | 2 (100%) | 1 (1%) | 0 | 0 | 1 (100%) | |
| ASPARTATE AMINOTRANSFERASE | n | | 82 | 2 | 79 | 1 | 80 | 0 | 0.770 |
| | Normal | | 79 (96%) | 1 (50%) | 77 (97%) | 1 (100%) | 78 (98%) | 0 | |
| | High | | 3 (4%) | 1 (50%) | 2 (3%) | 0 | 2 (3%) | 0 | |
| BILIRUBIN | n | | 84 | 0 | 80 | 0 | 79 | 1 | 0.353 |
| | Normal | | 83 (99%) | 0 | 80 (100%) | 0 | 77 (97%) | 0 | |

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

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[2] CMH test for general association, controlling for status at baseline.

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|-------------------------------|--------------|-----------------------|---------------------|-----------------------|---------------------|-----------------------|---------------------|--------------------|
| | | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | |
| | High | 1 (1%) | 0 | 0 | 0 | 2 (3%) | 1 (100%) | |
| CALCIUM | n | 84 | 0 | 80 | 0 | 80 | 0 | |
| | Normal | 84 (100%) | 0 | 80 (100%) | 0 | 80 (100%) | 0 | |
| CHLORIDE | n | 84 | 0 | 80 | 0 | 79 | 0 | |
| | Normal | 84 (100%) | 0 | 80 (100%) | 0 | 79 (100%) | 0 | |
| CHOLESTEROL | n | 84 | 0 | 80 | 0 | 80 | 0 | |
| | Normal | 84 (100%) | 0 | 80 (100%) | 0 | 80 (100%) | 0 | |
| CREATINE KINASE | n | 84 | 0 | 79 | 1 | 77 | 3 | 0.811 |
| | Normal | 77 (92%) | 0 | 74 (94%) | 1 (100%) | 72 (94%) | 1 (33%) | |
| | High | 7 (8%) | 0 | 5 (6%) | 0 | 5 (6%) | 2 (67%) | |
| CREATININE | n | 84 | 0 | 80 | 0 | 80 | 0 | |
| | Normal | 84 (100%) | 0 | 80 (100%) | 0 | 80 (100%) | 0 | |
| GAMMA GLUTAMYL TRANSFERASE | n | 82 | 2 | 78 | 2 | 78 | 2 | 0.898 |
| | Normal | 80 (98%) | 0 | 75 (96%) | 1 (50%) | 76 (97%) | 1 (50%) | |

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|-----------|--------------|-----------------------|---------------------|-----------------------|---------------------|-----------------------|---------------------|----------------|
| | Shift [1] | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | |
| | High | 2 (2%) | 2 (100%) | 3 (4%) | 1 (50%) | 2 (3%) | 1 (50%) | |
| GLUCOSE | n | 83 | 1 | 80 | 0 | 80 | 0 | 0.354 |
| | Normal | 83 (100%) | 1 (100%) | 79 (99%) | 0 | 78 (98%) | 0 | |
| | High | 0 | 0 | 1 (1%) | 0 | 2 (3%) | 0 | |
| PHOSPHATE | n | 84 | 0 | 79 | 0 | 80 | 0 | |
| | Normal | 84 (100%) | 0 | 79 (100%) | 0 | 80 (100%) | 0 | |
| POTASSIUM | n | 84 | 0 | 79 | 0 | 79 | 0 | |
| | Normal | 84 (100%) | 0 | 79 (100%) | 0 | 79 (100%) | 0 | |
| PROTEIN | n | 84 | 0 | 80 | 0 | 80 | 0 | |
| | Normal | 84 (100%) | 0 | 80 (100%) | 0 | 80 (100%) | 0 | |
| SODIUM | n | 84 | 0 | 80 | 0 | 79 | 0 | |
| | Normal | 84 (100%) | 0 | 80 (100%) | 0 | 79 (100%) | 0 | |
| URATE | n | 84 | 0 | 80 | 0 | 80 | 0 | |
| | Normal | 84 (100%) | 0 | 80 (100%) | 0 | 80 (100%) | 0 | |

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|---|--------------|-----------------------|---------------------|-----------------------|---------------------|-----------------------|---------------------|--------------------|
| | Shift [1] | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | |
| UREA NITROGEN | n | 84 | 0 | 78 | 2 | 80 | 0 | 0.363 |
| | Normal | 84 (100%) | 0 | 78 (100%) | 2 (100%) | 79 (99%) | 0 | |
| | High | 0 | 0 | 0 | 0 | 1 (1%) | 0 | |
| HEMATOLOGY | | | | | | | | |
| ----- | | | | | | | | |
| BASOPHILS | n | 83 | 0 | 79 | 0 | 78 | 0 | 0.044 |
| | Normal | 83 (100%) | 0 | 79 (100%) | 0 | 78 (100%) | 0 | |
| EOSINOPHILS | n | 83 | 0 | 78 | 1 | 78 | 0 | |
| | Normal | 83 (100%) | 0 | 73 (94%) | 1 (100%) | 72 (92%) | 0 | |
| | High | 0 | 0 | 5 (6%) | 0 | 6 (8%) | 0 | |
| ERY. MEAN CORPUSCULAR Hb CONCENTRATION | n | 82 | 0 | 78 | 0 | 77 | 0 | |
| | Normal | 82 (100%) | 0 | 78 (100%) | 0 | 77 (100%) | 0 | |
| ERY. MEAN CORPUSCULAR HEMOGLOBIN | n | 83 | 0 | 79 | 0 | 78 | 0 | |
| | Normal | 83 (100%) | 0 | 79 (100%) | 0 | 78 (100%) | 0 | |

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|---------------------------------|--------------|-----------------------|---------------------|-----------------------|---------------------|-----------------------|---------------------|----------------|
| | Shift [1] | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | |
| ERY. MEAN CORPUSCULAR VOLUME | n | 82 | 0 | 78 | 0 | 77 | 0 | 0.388 |
| | Normal | 82 (100%) | 0 | 78 (100%) | 0 | 77 (100%) | 0 | |
| ERYTHROCYTES | n | 83 | 0 | 79 | 0 | 78 | 0 | |
| | Normal | 83 (100%) | 0 | 79 (100%) | 0 | 78 (100%) | 0 | |
| HEMATOCRIT | n | 82 | 0 | 78 | 0 | 77 | 0 | |
| | Normal | 82 (100%) | 0 | 78 (100%) | 0 | 77 (100%) | 0 | |
| HEMOGLOBIN | n | 83 | 0 | 79 | 0 | 78 | 0 | |
| | Normal | 83 (100%) | 0 | 79 (100%) | 0 | 78 (100%) | 0 | |
| LEUKOCYTES | n | 83 | 0 | 79 | 0 | 78 | 0 | |
| | Normal | 83 (100%) | 0 | 79 (100%) | 0 | 78 (100%) | 0 | |
| LYMPHOCYTES | n | 83 | 0 | 79 | 0 | 78 | 0 | |
| | Normal | 82 (99%) | 0 | 79 (100%) | 0 | 78 (100%) | 0 | |
| | High | 1 (1%) | 0 | 0 | 0 | 0 | 0 | |

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|-----------|--------------|-----------------------|---------------------|-----------------------|---------------------|-----------------------|---------------------|----------------|
| | Shift [1] | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | Normal at Baseline | High at Baseline | |
| MONOCYTES | n | 83 | 0 | 79 | 0 | 78 | 0 | 0.150 |
| | Normal | 81 (98%) | 0 | 79 (100%) | 0 | 78 (100%) | 0 | |
| | Low | 2 (2%) | 0 | 0 | 0 | 0 | 0 | |
| PLATELET | n | 83 | 0 | 77 | 0 | 78 | 0 | |
| | Normal | 83 (100%) | 0 | 77 (100%) | 0 | 78 (100%) | 0 | |

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