

Appendix 3

Listing of Limits for Markedly Abnormal Laboratory Values

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Reference values and criteria for markedly abnormal values are presented below: (Source: EOT Table 22, 2001133-134addendum.pdf, pp 99-100)

| Laboratory Test (Units) | Reference Range | Markedly Abnormal Criteria ^a | |
|------------------------------|---|--|----------------|
| | | Limits | Percent Change |
| Albumin (g/dL) | Age ≤ 65: 3.5-5.3 Age ≥ 66: 3.2-4.6 | None | None |
| ALT (U/L) | 6-37 | ≥ 3X ULN | > 30% ↑ |
| AST (U/L) | 10-36 | ≥ 3X ULN | > 30% ↑ |
| Total bilirubin (mg/dL) | 0.2-1.2 | ≥ 2.0 mg/dL | > 50% ↑ |
| Alkaline phosphatase (U/L) | Age ≤ 65: 31-121 Age ≥ 66: 53-141 | ≥ 3X ULN | > 20% ↑ |
| Calcium (mg/dL) | Age ≤ 65: 8.4-10.3 Age ≥ 66: 8.8-10.2 | > 1.1X ULN < 0.9X LLN | > 10% ↑/↓ |
| Chloride (mEq/L) | Age ≤ 65: 94-111 Age ≥ 66: 95-109 | > 1.05X ULN < 0.95X LLN | > 5% ↑/↓ |
| Creatinine (mg/dL) | 0.4-1.2 | ≥ 2.0 mg/dL | > 25% ↑ |
| Phosphorus (mg/dL) | Age ≤ 65: 2.3-5.1 Age ≥ 66: 2.8-4.0 | > 1.25X ULN < 0.75X LLN | > 25% ↑/↓ |
| Potassium (mEq/L) | Age ≤ 65: 3.3-5.5 Age ≥ 66: 3.6-5.5 | > 1.25X ULN < 0.75X LLN | > 25% ↑/↓ |
| Sodium (mEq/L) | Age ≤ 65: 132-147 Age ≥ 66: 135-148 | > 1.05X ULN < 0.95X LLN | > 5% ↑/↓ |
| Hemoglobin A1C (%) | 4.3-6.1 | > 6.1% | > 30% ↑ |
| Insulin (μIU/mL) | 3-16 | > 25 μIU/mL | > 30% ↑ |
| Glucose ^b (mg/dL) | Fasting (Age ≤ 65): 68-118 Fasting (Age ≥ 66): 82-115 Non-fasting: 68-169 | Fasting: > 140 mg/dL Non-fasting: > 200 mg/dL Fasting: < 50 mg/dL Non-fasting: < 50 mg/dL | > 15% ↑/↓ |
| Total Cholesterol (mg/dL) | 130-200 | > 280 mg/dL | > 30% ↑ |
| HDL (mg/dL) | 40-80 | < 34 mg/dL | > 30% ↓ |
| LDL (mg/dL) | 0-130 | > 160 mg/dL | > 30% ↑ |
| Triglycerides (mg/dL) | 45-250 | > 250 mg/dL | > 30% ↑ |

^a A value was defined as markedly abnormal if it was outside the limits *and* in excess of the allowed percent change from baseline.

^b Application of the markedly abnormal criteria was based on the fasting criteria for all samples. The criteria for non-fasting are presented only to show what was initially planned.

^c Although markedly abnormal criteria were pre-specified for neutrophils and eosinophils, no markedly abnormal summaries were created as these laboratory tests were not run on all patients.

| Laboratory Test (Units) | Reference Range | Markedly Abnormal Criteria ^a | |
|--------------------------------|--|---|----------------|
| | | Limits | Percent Change |
| RBC (10 ⁶ μL) | Age ≤ 65: 3.8-5.5 Age ≥ 66: 3.8-5.4 | None | None |
| Hematocrit (%) | Age ≤ 65: 35.0-47.0 Age ≥ 66: 33.0-46.0 | ≤ 32% | > 30% ↓ |
| Hemoglobin (g/dL) | Age ≤ 65: 11.6-16.2 Age ≥ 66: 11.0-16.1 | ≤ 9.5 G·DL | > 30% ↓ |
| Platelets (10 ³ μL) | 140-450 | ≤ 75 10 ⁹ L ≥ 700 10 ⁹ L | > 30% ↑/↓ |
| WBC (10 ³ μL) | 4.1-12.3 | ≤ 2.8 x 10 ⁹ L ≥ 16.0 x 10 ⁹ L | > 25% ↑/↓ |
| Neutrophils ^c (%) | 40.9-77.0 | ≤ 15% | > 30% ↓ |
| Eosinophils ^c (%) | 0.0-6.0 | ≥ 10% | > 50% ↑ |
| Lymphocytes (%) | 15.5-46.6 | None | None |
| Monocytes (%) | 4.0-9.4 | None | None |
| Basophils (%) | 0.0-2.4 | None | None |
| Bands (%) | 0.0-10.0 | None | None |
| Fibrinogen (mg/dL) | 184-514 | < 100 mg·dL > 600 mg·dL | > 0% ↑/↓ |
| PT (sec) | 10.0-13.0 | > ULN < LLN | > 30% ↑/↓ |
| APTT (sec) | 20.6-39.9 | > ULN < LLN | > 30% ↑/↓ |
| Antithrombin III (%) | 87.0-127.0 | None | None |
| PAI-1 Antigen (ng mL) | Age ≤ 65: 4.0-43.0 Age ≥ 66: None | None | None |
| PAI-1 Activity (μmL) | Age ≤ 65: 0.0-31.0 Age ≥ 66: None | None | None |
| t-PA Antigen (ng mL) | Age ≤ 65: 0.5-14.0 Age ≥ 66: None | None | None |

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^c Although markedly abnormal criteria were pre-specified for neutrophils and eosinophils, no markedly abnormal summaries were created as these laboratory tests were not run on all patients.