

Certificate of Analysis

Product: Delipidated, Double Charcoal Stripped, Human Serum
Lot#: 190CM
Bulk: 1200 Liters
Filled in: 3.5 Liters/Bottle
Preservative: As required
Bioburden: <10cfu/mL or no growth
Shelf Life: Five years at -20°C from date of manufactured
Filtration: Filtered through a 0.22micron absolute membrane filter prior to bottling
Storage: -20°C
Bleed testing: Donors used in this pool were tested negative or non-reactive for: HIV-1/2, HCV, HBsAg, HIV1-Ag, (HCV/HIV-1/HBV by NAT testing) and ALT within acceptable range by FDA approved method.

Analyte	Normal Range
Calcium	5.0 – 10 mg/dl
Phosphorus	2.5 – 4.5 mg/dl
Uric Acid	1.9 – 8.4 mg/dl
Alkaline Phosphatase	30 – 130 IU/L
LDH	60 – 225 IU/ml
SGOT/AST	0.0 – 48 U/L
Total Bilirubin	0.1 – 1.4 mg/dl
SGTP/ALT	0.0 – 52 U/L
GGTP	0.0 – 65 IU/L
Total Protein	5.0 – 8.0 gm/dl
Albumin	3.0 – 5.0 gm/dl
Globulin	2.0 – 4.0 gm/dl
A/G Ratio	1.0 – 2.2
BUN	8.0 – 26 gm/dl
Creatinin	0.7 – 1.4 mg/dl
Glucose	65 – 114 mg/dl
Total Iron	34 – 185 µg/dl
Cholride	95 – 110 mEQ/L
Sodium	130 – 150 mEQ/L
Potasium	1.0 – 5.5 mEQ/L
Triglycerides	< 15 mg/dl
Cholesterol	< 15 mg/dl
Ionized Calcium	1 – 4.7 mg/dl
Serum Osmolality	260 – 310 mOSM/Kg
Ammonia	< 300 µmol/L
T3 Value	0.0 ng/dl
T4 Value	0.0 µg/ml
Cortisol	0.0 µg/ml

Caution: Not for use in products subject to license under section 351 of the public health safety acts. For use in research or manufacturing into non-injectable products only.