

Certificate of Analysis

Product: Defibrinated, Charcoal Stripped, Non-Lipid Stripped Human Serum
Lot#: 099CM-01K04
Bulk: 800 Liters
Sample: 200mL
Filled in: 3.5 Liters/Bottle
Preservative: None
Bioburden: <10cfu/mL or no growth
Date of Manufacture: 11-01-2004
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	Result	Method
Calcium	6.1 mg/dL	SMAC
Phosphorus	1.5mg/dL	SMAC
Uric Acid	<0.2 mg/dL	SMAC
Alkaline Phosphatase	10 IU/L	SMAC
LDH	39 IU/L	SMAC
SGOT/AST	4 U/L	SMAC
Total Bilirubin	<0.1 mg/dL	SMAC
SGPT/ALT	<4 U/L	SMAC
GGTP	13 IU/L	SMAC
Total Protein	5.2 g/dL	SMAC
Albumin	3.2 g/dL	SMAC
Globulin	2. g/dL	SMAC
A/G Ratio	1.6	SMAC
BUN	4 mg/dL	SMAC
Creatinine	<0.1 mg/dL	SMAC
Glucose	2 mg/dL	SMAC
Total Iron	77 µg/dL	SMAC
Chloride	101 meq/L	SMAC
Sodium	132 meq/L	SMAC
Potassium	1.6 meq/L	SMAC
Triglycerides	54 mg/dL	SMAC
Cholesterol	116 mg/dL	SMAC
Ionized Calcium	3.1 mg/dL	SMAC
Serum Osmolality	266 mOSM/Kg	SMAC

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.