



# Certificate of Analysis

Created October 14, 2013

**Product:** **Defibrinated Human Serum**  
0.1µm sterile-filtered

**Catalog #: 900-311**

**Lot #: H32P00E**

**Origin: United States (100%)**

**Manufacture Date: May 2013**

**Expiration Date: May 2018**

TEST	METHODOLOGY	SPECIFICATION	RESULTS
<b>Biological Testing</b>			
Endotoxin	USP<85>	< 10 EU/mL	<0.50 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	5.2 mg/dL
<b>Microbiological Testing</b>			
Sterility	USP<71>		
Bacteria		Not Detected	Not Detected
Fungi		Not Detected	Not Detected
Mycoplasma	Barile, MF and Kern, J (1971)	Not Detected	Not Detected
<b>Viral Testing</b>			
	21 CFR 610.40		
HBsAg		Non-Reactive	Non-Reactive
Anti-HCV		Non-Reactive	Non-Reactive
Anti-HIV-1/HIV-2		Non-Reactive	Non-Reactive
HIV-2		Non-Reactive	Non-Reactive
ALT		Pass	Pass
Syphilis		Negative	Negative
HIV-NAT		Not Detected	Not Detected
HCV-NAT		Not Detected	Not Detected
<b>Physical Testing</b>			
Osmolality	USP<785>	260-350 mOsm/kg	305 mOsm/kg
pH @ RT	USP<791>	Report	7.77



# Biochemical Testing

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TEST	METHODOLOGY	SPECIFICATION	RESULTS
Albumin			3.1 g/dL
ALT (SGPT)			9 U/L
AST (SGOT)			14 U/L
Bilirubin, Total			0.3 mg/dL
BUN			12 mg/dL
Calcium			34.3 mM
Chloride			107 mM
Cholesterol			115 mg/dL
Creatinine			0.68 mg/dL
Glucose			5.05 mM
Phosphorus			0.84 mM
Potassium			3.6 mM
Protein, Total	Biuret		4.8 g/dL
Sodium			164 mM
Triglycerides			58 mg/dL
Uric Acid			2.3 mg/dL

Results shown were obtained by carefully performed methods believed to be reliable. However, since some results may vary for specific tests depending upon methodology and other variables, it is suggested that tests for which results are particularly important be repeated by the user of this product.

*All human blood products are collected from stringently screened donors at FDA-licensed collection centers in the United States. All donors are tested and found to be negative for Indirect Antiglobulin.*

**QUALITY ASSURANCE**