GEMINI BIO-PRODUCTS

Certificate of Analysis

Revised July 28, 2017

Product: **Human Serum AB (Off the Clot)**
0.1µm sterile-filtered

Catalog #: 100-318
Lot #: H96S00I
Origin: United States (100%)

Manufacture Date: May 2017
Expiration Date: May 2022

Test	Methodology	Specification	Results
Biological Testing			
Endotoxin	USP<85>	< 10 EU/mL	<0.5 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	2.05mg/dL
Microbiological Testing			
Sterility	USP<71>		
Bacteria		Not Detected	Not Detected
Fungi		Not Detected	Not Detected
Mycoplasma	Barile, MF and Kern, J (1971)	Not Detected	Not Detected
Viral Testing	21 CFR 610.40		
HBsAg		Non-Reactive	Non-Reactive
Anti-HCV		Non-Reactive	Non-Reactive
Anti-HIV-1/HIV-2		Non-Reactive	Non-Reactive
Syphilis		Negative	Negative
HBV-NAT		Not Detected	Not Detected
HIV-NAT		Not Detected	Not Detected
HCV-NAT		Not Detected	Not Detected
Physical Testing			
Osmolality	USP<785>	260-350 mOsm/kg	299 mOsm/kg
pH	USP<791>	Report	7.77

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Biochemical Testing

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Test	Methodology	Specification	Results	
Albumin		Test and Report	3.1	g/dL
ALT (SGPT)		Test and Report	13	U/L
AST (SGOT)		Test and Report	9	U/L
Bilirubin, Total		Test and Report	0.1	mg/dL
BUN		Test and Report	9	mg/dL
Calcium		Test and Report	1.68	mM
Chloride		Test and Report	<80	mM
Cholesterol		Test and Report	97	mg/dL
Creatinine		Test and Report	0.63	mg/dL
Glucose		Test and Report	3.27	mM
Phosphorus		Test and Report	0.71	mM
Potassium		Test and Report	3.2	mM
Protein, Total	Biuret	Test and Report	3.7	g/dL
Sodium		Test and Report	115	mM
Triglycerides		Test and Report	66	mg/dL
Uric Acid		Test and Report	3.8	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. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance.
For further manufacturing or laboratory use. Not for human or animal consumption.

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