



GEMINI
BIO-PRODUCTS

Certificate of Analysis

Revised April 4, 2018

Product: **GemCell™ Human Serum AB**
Heat Inactivated*
0.1µm sterile-filtered

Catalog #: 100-512

Lot #: H77P00F

Origin: United States (100%)

Manufacture Date: Jun 2014

Expiration Date: Jun 2019

<i>TEST</i>	<i>METHODOLOGY</i>	<i>SPECIFICATION</i>	<i>RESULTS</i>
Biological Testing			
Endotoxin	USP<85>	< 10 EU/mL	<0.5 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	3.42 mg/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	326 mOsm/kg
pH @ RT	USP<791>	Report	7.95



Biochemical Testing

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TEST	METHODOLOGY	SPECIFICATION	RESULTS
Albumin			3.3 g/dL
ALT (SGPT)			11 U/L
AST (SGOT)			15 U/L
Bilirubin, Total			0.3 mg/dL
BUN			11 mg/dL
Calcium			>3.75 mM
Chloride			110 mM
Cholesterol			128 mg/dL
Creatinine			0.77 mg/dL
Glucose			5.55 mM
Phosphorus			0.94 mM
Potassium			3.8 mM
Protein, Total	Biuret		5.1 g/dL
Sodium			168 mM
Triglycerides			82 mg/dL
Uric Acid			3.8 mg/dL

**Results shown were obtained by carefully performed methods believed to be reliable prior to heat inactivation at 56°C for 25 minutes. 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.

QUALITY ASSURANCE