



GEMINI
BIO-PRODUCTS

Certificate of Analysis

Created September 29, 2017

Product:

GemCell™ Human Serum AB
0.1µm sterile-filtered

Catalog #: 100-512

Lot #: H97S001

Origin: United States (100%)

Manufacture Date: July 2017

Expiration Date: July 2022

TEST	METHODOLOGY	SPECIFICATION	RESULTS
Biological Testing			
Endotoxin	USP<85>	< 10 EU/mL	<5.0 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	5.42 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			
HBsAg	21 CFR 610.40	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	317 mOsm/kg
pH	USP<791>	Report	7.7



Biochemical Testing

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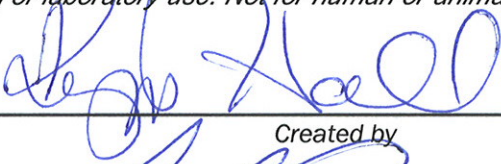
Expiration Date: July 2022


TEST	METHODOLOGY	SPECIFICATION	RESULTS
Albumin		Test and Report	3.2 g/dL
ALT (SGPT)		Test and Report	12 U/L
AST (SGOT)		Test and Report	14 U/L
Bilirubin, Total		Test and Report	0.2 mg/dL
BUN		Test and Report	12 mg/dL
Calcium		Test and Report	>3.75 mM
Chloride		Test and Report	110 mM
Cholesterol		Test and Report	131 mg/dL
Creatinine		Test and Report	0.77 mg/dL
Glucose		Test and Report	5.38 mM
Phosphorus		Test and Report	0.97 mM
Potassium		Test and Report	3.7 mM
Protein, Total	Biuret	Test and Report	4.8 g/dL
Sodium		Test and Report	>165 mM
Triglycerides		Test and Report	81 mg/dL
Uric Acid		Test and Report	2.6 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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