



**GEMINI**  
BIO-PRODUCTS

# Certificate of Analysis

Created February 20, 2018

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

**Catalog #: 100-612G**

**Lot #: H93S001**

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

**Manufacture Date: June 2017**

**Expiration Date: June 2022**

TEST	METHODOLOGY	SPECIFICATION	RESULTS
<b>Biological Testing</b>			
Endotoxin	USP<85>	< 10 EU/mL	<0.5 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	5.12mg/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 Donor Level</b>			
HBsAg	21 CFR 610.40	Non-Reactive	Non-Reactive
Anti-HCV		Non-Reactive	Non-Reactive
Anti-HIV-1/HIV-2		Non-Reactive	Non-Reactive
HIV-NAT		Not Detected	Not Detected
HCV-NAT		Not Detected	Not Detected
Syphilis		Negative	Negative
Anti-HBc IgG		Non-Reactive	Non-Reactive
Anti-HTLV I/II		Non-Reactive	Non-Reactive
Anti-HBc IgM		Non-Reactive	Non-Reactive
West Nile Virus NAT		Not Detected	Not Detected
HBV NAT		Non-Reactive	Non-Reactive
Chagas		Non-Reactive	Non-Reactive
<b>Viral Testing Finished Pool</b>			
HBcAB		Non-Reactive	Non-Reactive
HTLV-I&II		Non-Reactive	Non-Reactive
West Nile Virus		Not Detected	Not Detected
Chagas		Non-Reactive	Non-Reactive



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# Biochemical Testing

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TEST	METHODOLOGY	SPECIFICATION	RESULTS
<b>Physical Testing</b>			
Osmolality	USP<785>	260-350 mOsm/kg	320 mOsm/kg
pH @ RT	USP<791>	Test and Report	7.59
Albumin		Test and Report	3.3 g/dL
ALT (SGPT)		Test and Report	11 U/L
AST (SGOT)		Test and Report	17 U/L
Bilirubin, Total		Test and Report	0.3 mg/dL
BUN		Test and Report	12 mg/dL
Calcium		Test and Report	>3.75 mM
Chloride		Test and Report	112 mM
Cholesterol		Test and Report	130 mg/dL
Creatinine		Test and Report	0.79 mg/dL
Glucose		Test and Report	5.77 mM
Phosphorus		Test and Report	0.97 mM
Potassium		Test and Report	3.8 mM
Protein, Total	Biuret	Test and Report	5.1 g/dL
Sodium		Test and Report	>165 mM
Triglycerides		Test and Report	77 mg/dL
Uric Acid		Test and Report	3.2 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.*

  
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Created by

  
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Verified by