



GEMINI
BIO-PRODUCTS

Certificate of Analysis

Created June 5, 2019

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

Catalog #: 100-612

Lot #: H93S001

Origin: United States (100%)

Manufacture Date: June 2017

Expiration Date: June 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	5.12mg/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 Donor Level			
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
Viral Testing Finished Pool			
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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TEST	METHODOLOGY	SPECIFICATION	RESULTS
Physical Testing			
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

All human blood products are collected from stringently screened male donors at FDA-licensed collection centers in the United States. *Results shown were obtained by carefully performed methods believed to be reliable prior to heat inactivation. As 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. Lot specific samples are available at the customer's request and users are encouraged to evaluate the sample prior to purchase. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance.

CAUTION: For Cell Culture, further Manufacturing and Research use only. Not for direct Therapeutic use. It is the responsibility of the user to undertake verification and testing to determine the suitability of this product's application. The statements herein are offered for informational purposes and are intended to be used solely for your consideration, investigation and verification.

Mark Weber 05 Jun 2019

Created by/ Date

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Verified by/ Date