



**GEMINI**  
BIO-PRODUCTS

# Certificate of Analysis

Created July 19, 2019

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

**Catalog #: 100-712b**  
**Lot #: H55X00K**  
**Origin: United States (100%)**

**Manufacture Date: Jun 2019**  
**Expiration Date: May 2024**

TEST	METHODOLOGY	SPECIFICATION	RESULTS
<b>Biological Testing</b>			
Endotoxin	USP<85>	< 10 EU/mL	<0.500 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	8.3 mg/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</b>			
	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
<b>Physical Testing</b>			
Osmolality	USP<785>	260-350 mOsm/kg	331 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	3.3 g/dL
ALT (SGPT)		Test and Report	13 U/L
AST (SGOT)		Test and Report	14 U/L
Bilirubin, Total		Test and Report	0.3 mg/dL
BUN		Test and Report	13 mg/dL
Calcium		Test and Report	>3.75 mM
Chloride		Test and Report	111 mM
Cholesterol		Test and Report	145 mg/dL
Creatinine		Test and Report	0.86 mg/dL
Glucose		Test and Report	5.3 mM
Phosphorus		Test and Report	1.1 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	128 mg/dL
Uric Acid		Test and Report	3.0 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.

*[Signature]* 19 Jun 2019

Created by/ date

*[Signature]* 19 Jun 2019

Verified by/ date