

## **Certificate of Analysis**

Created August 16, 2019

**Product:** 

GemCell™ Human Serum AB

0.1µm sterile-filtered

Catalog #: 100-512

Lot #: H61X00K

Origin: United States (100%)

Manufacture Date: Jun 2019 Expiration Date: Jun 2024

1	Test	<b>М</b> ЕТНОDOLOGY	SPECIFICATION	RESULTS
	Biological Testing			
	Endotoxin	USP<85>	< 10 EU/mL	<0.500 EU/mL
	Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	7.00 mg/dL
			9	
	Microbiological Testing	pl.		
	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		
5,	HBsAg	21 0111 010.10	Non-Reactive	Non-Reactive
	Anti-HCV	4	Non-Reactive	Non-Reactive
	Anti-HIV-1/HIV-2		Non-Reactive	Non-Reactive
	Syphilis		Negative	Negative
	HBV-DNA		Not Detected	Not Detected
	HIV-1 RNA		Not Detected	Not Detected
	HCV-RNA		Not Detected	Not Detected
	Physical Testing		8	
	Osmolality	USP<785>	260-350 m0sm/kg	321 m0sm/kg
	pH	USP<791>	Report	7.84



## **Biochemical Testing**

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<b>T</b> EST	METHODOLOGY	SPECIFICATION		RESULTS	
Albumin		Test and Report		3.2	g/dL
ALT (SGPT)		Test and Report		7	U/L
AST (SGOT)		Test and Report		11	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		115	mM
Cholesterol		Test and Report		134	mg/dL
Creatinine		Test and Report		0.83	mg/dL
Glucose		Test and Report		4.9	mM
Phosphorus		Test and Report		1.0	mM
Potassium		Test and Report	3	3.8	mM
Protein, Total	Biuret	Test and Report		5.2	g/dL
Sodium		Test and Report		165	mM
Triglycerides		Test and Report		66	mg/dL
Uric Acid	* 12	Test and Report		3.2	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. 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.

Created by/ date

Verified by/ date