

Certificate of Analysis

Created October 16, 2019

Product:

GemCell™ Human Serum AB

0.1µm sterile-filtered

Catalog #: 100-512

Lot #: H94X00K

Origin: United States (100%)

Manufacture Date: Aug 2019 Expiration Date: Aug 2024

TEST	M ETHODOLOGY	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	7.5 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	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-1 NAT		Not Detected	Not Detected
HCV-NAT		Not Detected	Not Detected
Physical Testing			
Osmolality	USP<785>	260-350 m0sm/kg	335 m0sm/kg
рН	USP<791>	Report	7.74



Biochemical Testing

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TEST	19	M ETHODOLOGY	SPECIFICATION	RESULT	s
Albumin			Test and Report	3.5	g/dL
ALT (SGPT)			Test and Report	10	U/L
AST (SGOT)			Test and Report	12	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	115	mM
Cholesterol			Test and Report	138	mg/dL
Creatinine			Test and Report	0.94	mg/dL
Glucose			Test and Report	5.5	mM
Phosphorus			Test and Report	0.9	mM
Potassium			Test and Report	3.8	mM
Protein, Total		Biuret	Test and Report	5.2	g/dL
Sodium			Test and Report	>165	mM
Triglycerides			Test and Report	103	mg/dL
Uric Acid			Test and Report	3.6	mg/dL
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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

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