

Certificate of Analysis

Created September 9, 2019

Product:

GemCell™ Human Serum AB

Heat Inactivated*

0.1µm sterile-filtered

Catalog #: 100-512 Lot #: H68X00K

Origin: United States (100%)

Manufacture Date: Jul 2019 Expiration Date: Jul 2024

T EST	METHODOLOGY	Specification	RESULTS
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Biological Testing			
Endotoxin	USP<85>	< 10 EU/mL	<0.500 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1969		6.4 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
HIV-NAT		Non-Reactive	Non-Reactive
HBV-NAT		Non-Reactive	Non-Reactive
HCV-NAT		Non-Reactive	Non-Reactive
Physical Testing			
Osmolality	USP<785>	260-350 m0sm/kg	317 mOsm/kg
рН	USP<791>	Report	7.69



Biochemical Testing

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TEST	M ETHODOLOGY	Specification	RESULT	S
Albumin		Test and Report	3.2	g/dL
ALT (SGPT)		Test and Report	11	U/L
AST (SGOT)		Test and Report	13	U/L
Bilirubin, Total		Test and Report	0.2	mg/dL
BUN		Test and Report	12	mg/dL
Calcium		Test and Report	>3.75	mM
Chloride		Test and Report	108	mM
Cholesterol		Test and Report	130	mg/dL
Creatinine		Test and Report	0.82	mg/dL
Glucose		Test and Report	5.4	mM
Phosphorus		Test and Report	1.0	mM
Potassium		Test and Report	3.7	mM
Protein, Total	Biuret	Test and Report	5.0	g/dL
Sodium		Test and Report	>165	mM
Triglycerides		Test and Report	110	mg/dL
Uric Acid		Test and Report	2.9	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 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.

Created by/ date

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Verified by/ date