

Certificate of Analysis

Created October 24, 2018

Product:

GemCell™ Human Serum AB

Heat Inactivated*

0.1µm sterile-filtered

Catalog #: 100-512

Lot #: H97S00I

Origin: United States (100%)

Manufacture Date: July 2017 Expiration Date: July 2022

Test	М ЕТНОDOLOGY	SPECIFICATION	RESULTS
Biological Testing			
Endotoxin	USP<85>	< 10 EU/mL	<5.0 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965) <20.0 mg/dL	5.42 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-NAT		Not Detected	Not Detected
HCV-NAT		Not Detected	Not Detected
Physical Testing			
Osmolality	USP<785>	260-350 m0sm/kg	317 m0sm/kg
рН	USP<791>	Report	7.7



Biochemical Testing

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TEST	M ETHODOLOGY	SPECIFICATION	RESULTS	
Albumin		Test and Report	3.2 g/dL	
ALT (SGPT)		Test and Report	12 U/L	
AST (SGOT)		Test and Report	14 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	110 mM	
Cholesterol		Test and Report	131 mg/dL	
Creatinine		Test and Report	0.77 mg/dL	
Glucose		Test and Report	5.38 mM	
Phosphorus		Test and Report	0.97 mM	
Potassium		Test and Report	3.7 mM	
Protein, Total	Biuret	Test and Report	4.8 g/dL	
Sodium		Test and Report	>165 mM	
Triglycerides		Test and Report	81 mg/dL	
Uric Acid		Test and Report	2.6 mg/dL	

For Cell Culture, further Manufacturing and Research use only. Not for direct Therapeutic use.

*Results shown were obtained by carefully performed methods believed to be reliable prior to heat inactivation.

However, since 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.

All human blood products are collected from stringently screened donors at FDA-licensed collection centers in the United States. All donors are tested and found to be negative for Indirect Antiglobulin. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance.

For further manufacturing or laboratory use. Not for human or animal consumption.

Created by/ Date

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