



# Certificate of Analysis

Created January 12, 2017

**Product:** **GemCell™ Human Serum AB**  
0.1µm sterile-filtered

**Catalog #: 100-512**

**Lot #: H14S03H**

**Origin: United States (100%)**

**Manufacture Date: Nov 2016**

**Expiration Date: Oct 2019**

<i>TEST</i>	<i>METHODOLOGY</i>	<i>SPECIFICATION</i>	<i>RESULTS</i>
<b>Biological Testing</b>			
Endotoxin	LAL	< 10 EU/mL	0.9 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	6.1 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	290 mOsm/kg
pH	USP<791>	Report	7.7



# Biochemical Testing

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TEST	METHODOLOGY	SPECIFICATION	RESULTS
Albumin			3.5 g/dL
ALT (SGPT)			11 U/L
AST (SGOT)			13 U/L
Bilirubin, Total			0.3 mg/dL
BUN			3 mg/dL
Calcium			2.48 mM
Chloride			121 mM
Cholesterol			147 mg/dL
Creatinine			<0.20 mg/dL
Glucose			5.27 mM
Phosphorus			0.94 mM
Potassium			3.8 mM
Protein, Total	Biuret		5.4 g/dL
Sodium			142 mM
Triglycerides			89 mg/dL
Uric Acid			<1.5 mg/dL

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

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**QUALITY ASSURANCE**