



Certificate of Analysis

Revised April 7, 2016

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

Catalog #: 100-512

Lot #: H12Q03F

Origin: United States (100%)

Manufacture Date: Dec 2014

Expiration Date: Dec 2019

TEST	METHODOLOGY	SPECIFICATION	RESULTS
Biological Testing			
Endotoxin	USP<85>	< 10 EU/mL	1.0 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	3.3 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 mOsm/kg	284 mOsm/kg
pH	USP<791>	Report	7.6



Biochemical Testing

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Albumin			3.4 g/dL
ALT (SGPT)			11 U/L
AST (SGOT)			12 U/L
Bilirubin, Total			0.3 mg/dL
BUN			2 mg/dL
Calcium			2.13 mM
Chloride			119 mM
Cholesterol			136 mg/dL
Creatinine			<0.2 mg/dL
Glucose			5.11 mM
Phosphorus			0.84 mM
Potassium			3.8 mM
Protein, Total	Biuret		5.1 g/dL
Sodium			139 mM
Triglycerides			105 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.

QUALITY ASSURANCE