



GEMINI
BIO-PRODUCTS

Certificate of Analysis

Created July 25, 2019

Product: **Human Serum AB (Off the Clot)**
Heat Inactivated*
0.1µm sterile-filtered

Catalog #: 100-318

Lot #: H59X00K

Origin: United States (100%)

Manufacture Date: Jun 2019

Expiration Date: Jun 2024

TEST	METHODOLOGY	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	2.3 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 per donor unit			
HBsAg	21 CFR 610.40	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
Chagas		Not Detected	Not Detected
WNV RNA		Not Detected	Not Detected
Zika RNA	Investigational NAT	Not Detected	Not Detected
Physical Testing			
Osmolality	USP<785>	260-350 mOsm/kg	294 mOsm/kg
pH	USP<791>	Report	7.97



Biochemical Testing

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Albumin		Test and Report	4.2 g/dL
ALT (SGPT)		Test and Report	6 U/L
AST (SGOT)		Test and Report	5 U/L
Bilirubin, Total		Test and Report	0.1 mg/dL
BUN		Test and Report	14 mg/dL
Calcium		Test and Report	2.3 mM
Chloride		Test and Report	105 mM
Cholesterol		Test and Report	158 mg/dL
Creatinine		Test and Report	1.07 mg/dL
Glucose		Test and Report	5.83 mM
Phosphorus		Test and Report	1.45 mM
Potassium		Test and Report	4.2 mM
Protein, Total	Biuret	Test and Report	7.2 g/dL
Sodium		Test and Report	141 mM
Triglycerides		Test and Report	118 mg/dL
Uric Acid		Test and Report	5.5 mg/dL

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.

Oliver 25 JUL 2019

Created by/date

Mark Weber 25 JUL 2019

Verified by/date