



## CERTIFICATE OF ANALYSIS

### Human Serum AB

**(Off the Clot)**

**(Catalog Number 100-318)**

**Lot Number:** H41X00K

**Date of Manufacture:** Mar2019

**Origin:** United States

**Product Expiry:** Mar2024

For Cell culture, Further Manufacturing or Research use Only. Not for Direct Therapeutic Use.

**Storage Temperature:** ≤ -10°C

**Product description:** Human Serum AB is collected from healthy male donors of the AB serotype at FDA-licensed facilities located in the United States. Donor units are tested for infectious disease markers prior to processing and found to be non-reactive. Human Serum AB (Off the clot) is sterile-filtered through a 0.1 µm filter prior to freezing.

Test	Methodology	Specification	Analysis
<b>Biological Testing</b>			
Endotoxin	USP<85>, EP 2.6.14	<10.0 EU/mL	<0.500 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1985)	<20.0 mg/dL	2.2 mg/dL
<b>Microbiological Testing</b>			
Sterility	USP<71>, EP 2.6.1		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Mycoplasma	Barile, MF and Kern, J (1971), EP 2.6.7	Not Detected	Not Detected
<b>Viral Testing</b>			
HBsAg	ABBOTT ChLIA	Non-Reactive	Non-Reactive
Anti-HCV	ABBOTT ChLIA	Non-Reactive	Non-Reactive
Anti-HIV-1/ HIV-2	ABBOTT ChLIA	Non-Reactive	Non-Reactive
Syphilis	ASI RPR	Negative	Negative
HBV-NAT	ROCHE NAT/ PCR	Not Detected	Not Detected
HIV-NAT	ROCHE NAT/ PCR	Not Detected	Not Detected
HCV-NAT	ROCHE NAT/ PCR	Not Detected	Not Detected
Zika	Investigational NAT	Not Detected	Not Detected
WNV RNA		Not Detected	Not Detected
Chagas		Not Detected	Not Detected
<b>Physical Testing</b>			
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/ kg	292 mOsm/kg
pH	USP<791>	Test and Report	7.92



Test	Methodology	Specification	Analysis
<b>Biochemistry</b>			
Albumin		Test and Report	>6.0 g/dL
ALT (SGPT)		Test and Report	23 U/L
AST (SGOT)		Test and Report	13 U/L
Bilirubin, Total		Test and Report	0.3 mg/dL
BUN		Test and Report	25 mg/dL
Calcium		Test and Report	>3.75 mM
Chloride		Test and Report	>140 mM
Cholesterol		Test and Report	295 mg/dL
Creatinine		Test and Report	1.78 mg/dL
Glucose		Test and Report	10.6 mM
Phosphorus		Test and Report	2.4 mM
Potassium		Test and Report	7.4 mM
Protein, Total	Biuret	Test and Report	14.0 g/dL
Sodium		Test and Report	>165 mM
Triglycerides		Test and Report	242 mg/dL
Uric Acid		Test and Report	9.7 mg/dL

*All blood products are collected from stringently screened male donors at FDA-licensed collection centers located in the United States. This product is a pool of > 100 donor units and the viral testing is performed on the individual donor units. All other testing is performed on the final product pool prior to release. Universal precautions should be used when handling this material. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance.*

The testing that has been performed as part of this lot release has been reviewed by Quality Assurance personnel and has confirmed that the testing meets the specifications presented on this Certificate of Analysis.

Meghee Khator  
Name

QA Associate III  
Title

23 NOV 2020  
Date