CERTIFICATE OF ANALYSIS

Human Serum AB

Off-the-Clot

(Catalog Number 100-318-100, 100-318-005)

Lot Number: H426041

Date of Manufacture: Sep2026 **Product Expiry:** Sep2031

Origin: United States **Storage Temperature:** ≤ -10°C

For cell culture, further manufacturing or research use only. Not for direct therapeutic use.

Product Description: Human Serum AB Off-the-Clot 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
Biological Testing			
Endotoxin	USP<85>, EP 2.6.14	<10.0 EU/mL	<0.750 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	<0.1 mg/dL
Microbiological Testing			
Sterility	USP<71>, EP 2.6.1		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Mycoplasma	USP<63>	Not Detected	Not Detected
Viral Testing	21CFR 610.40		
HBsAg	Immunoassay	Negative / Non-Reactive	Non-Reactive
Anti-HCV	Immunoassay	Negative / Non-Reactive	Non-Reactive
Anti-HIV-1/ HIV-2	Immunoassay	Negative / Non-Reactive	Non-Reactive
Syphilis	RPR	Negative / Non-Reactive	Non-Reactive
HBV-NAT	PCR / NAT	Negative / Non-Reactive	Non-Reactive
HIV-NAT	PCR / NAT	Negative / Non-Reactive	Non-Reactive
HCV-NAT	PCR / NAT	Negative / Non-Reactive	Non-Reactive
HAV RNA NAT	PCR / NAT	Negative / Non-Reactive	Non-Reactive
Parvo B19 DNA NAT	PCR / NAT	Negative / Non-Reactive	Non-Reactive
West Nile Virus NAT	PCR / NAT	Negative / Non-Reactive	Non-Reactive
Zika RNA NAT	PCR / NAT	Negative / Non-Reactive	Non-Reactive
Anti-HTLV I/II	Immunoassay	Negative / Non-Reactive	Non-Reactive
Anti-H8c IgG	Immunoassay	Negative / Non-Reactive	Non-Reactive
Anti-H8c IgM	Immunoassay	Negative / Non-Reactive	Non-Reactive
HIV p24 Ag	Immunoassay	Negative / Non-Reactive	Non-Reactive
Chagas	Immunoassay	Negative / Non-Reactive	Non-Reactive

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Viral Testing Finished Pool Level			
HBcAB	Immunoassay	Non-Reactive	Non-Reactive
HTLV-I/II	Immunoassay	Non-Reactive	Non-Reactive
West Nile Virus	Immunoassay	Not Detected	Not Detected
Chagas	Immunoassay	Non-Reactive	Non-Reactive
Physical Testing			
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/kg	291 mOsm/kg
pH	USP<791>	Test and Report	7.78
Biochemistry Testing			
Albumin		Test and Report	4.3 g/dL
ALT (SGPT)		Test and Report	12 U/L
AST (SGOT)		Test and Report	19 U/L
Bilirubin, Total		Test and Report	0.2 mg/dL
BUN		Test and Report	15 mg/dL
Calcium		Test and Report	9.0 mg/dL
Chloride		Test and Report	105 mmol/L
Cholesterol		Test and Report	166 mg/dL
Creatinine		Test and Report	0.92 mg/dL
Glucose		Test and Report	101 mg/dL
Phosphorus		Test and Report	3.3 mg/dL
Potassium		Test and Report	6.7 mmol/L
Protein, Total		Test and Report	6.8 g/dL
Sodium		Test and Report	139 mmol/L
Triglycerides		Test and Report	109 mg/dL
Uric Acid		Test and Report	5.5 mg/dL

All blood products are collected from stringently screened male donors at FDA-licensed collection centers located in the United States. Viral testing is performed on the individual donor units. All other testing is performed on the final product pool prior to release. Material is derived from human blood and should be considered biohazardous. 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.

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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.

Alejandra Peña
Name

10 Nov 2026
Date

QA Associate II
Title