CERTIFICATE OF ANALYSIS

Human Serum AB

Off-the-Clot

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

Lot Number: H425044

Date of Manufacture: Jul2025

Product Expiry: Jul2030

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	<10.0EU/mL	<5.00 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	2 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	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
HIV p24 Ag		Non-Reactive	Non-Reactive
HBV-NAT	ROCHE NAT/ PCR	Non-Reactive	Non-Reactive
HIV-NAT	ROCHE NAT/ PCR	Non-Reactive	Non-Reactive
HCV-NAT	ROCHE NAT/ PCR	Non-Reactive	Non-Reactive
Anti-HTLV I/II		Non-Reactive	Non-Reactive
Anti-HBc IgM		Non-Reactive	Non-Reactive
Anti-HBc IgG		Non-Reactive	Non-Reactive
Parvo B19 DNA NAT		Non-Reactive	Non-Reactive
HAV RNA NAT		Non-Reactive	Non-Reactive
Zika RNA NAT		Non-Reactive	Non-Reactive
West Nile Virus NAT		Non-Reactive	Non-Reactive
Chagas		Non-Reactive	Non-Reactive

GeminiBio

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

Lot Number: H425044

Test	Methodology	Specification	Analysis
Physical Testing			
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/kg	292 mOsm/kg
pH	USP<791>	Test and Report	7.41
Biochemistry Testing			
Albumin		Test and Report	4.2 g/dL
ALT (SGPT)		Test and Report	9 U/L
AST (SGOT)		Test and Report	19 U/L
Bilirubin, Total		Test and Report	0.2 mg/dL
BUN		Test and Report	12 mg/dL
Calcium		Test and Report	8.9 mg/dL
Chloride		Test and Report	103 mmol/L
Cholesterol		Test and Report	144 mg/dL
Creatinine		Test and Report	0.96 mg/dL
Glucose		Test and Report	94 mg/dL
Phosphorus		Test and Report	3.6 mg/dL
Potassium		Test and Report	4.2 mmol/L
Protein, Total		Test and Report	7.2 g/dL
Sodium		Test and Report	140 mmol/L
Triglycerides		Test and Report	64 mg/dL
Uric Acid		Test and Report	5.2 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. 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.

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

13AUG2025
Date

QA Associate II
Title