GeminiBio

CERTIFICATE OF ANALYSIS

GemCell™ Plus Xeno-Free, World Grade Human Serum AB

(Catalog Number 100-916-100, 100-916-005)

Lot Number: H425032

Date of Manufacture: May2025

Product Expiry: May2030

Origin: United States

Storage Temperature: ≤ -10°C

For Cell Culture, further Manufacturing or Research use only. Not for direct Therapeutic use.

Product Description: *GemCell™ Plus Xeno-Free, World Grade Human Serum AB is collected from a maximum of sixteen (16) 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. GemCell™ Plus Xeno-Free, World Grade Human Serum AB is converted to serum from human plasma using recombinant human thrombin and sterile-filtered through a 0.1 µm filter prior to freeze.*

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	3 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		Non-Reactive	Non-Reactive
Anti-HCV		Non-Reactive	Non-Reactive
Anti-HIV-1/ HIV-2		Non-Reactive	Non-Reactive
Syphilis		Negative	Negative
HIV p24 Ag		Non-Reactive	Non-Reactive
HBV-NAT		Non-Reactive	Non-Reactive
HIV-NAT		Non-Reactive	Non-Reactive
HCV-NAT		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

CERTIFICATE OF ANALYSIS

GemCell™ Plus Xeno-Free, World Grade Human Serum AB

(Catalog Number 100-916-100, 100-916-005)

Lot Number: H425032

Test	Methodology	Specification	Analysis
Viral Testing Finished Pool Level			
HBcAB		Non-Reactive	Non-Reactive
HTLV-I/II		Non-Reactive	Non-Reactive
West Nile Virus		Not Detected	Not Detected
Chagas		Non-Reactive	Non-Reactive
Physical Testing			
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/kg	319 mOsm/kg
pH	USP<791>	Test and Report	7.74
Biochemistry Testing			
Albumin		Test and Report	3.3 g/dL
ALT (SGPT)		Test and Report	7 U/L
AST (SGOT)		Test and Report	10 U/L
Bilirubin, Total		Test and Report	0.1 mg/dL
BUN		Test and Report	15 mg/dL
Calcium		Test and Report	>15.0 mg/dL
Chloride		Test and Report	111 mmol/L
Cholesterol		Test and Report	124 mg/dL
Creatinine		Test and Report	0.76 mg/dL
Glucose		Test and Report	90 mg/dL
Phosphorus		Test and Report	3.3 mg/dL
Potassium		Test and Report	3.8 mmol/L
Protein, Total		Test and Report	5.0 g/dL
Sodium		Test and Report	>165 mmol/L
Triglycerides		Test and Report	68 mg/dL
Uric Acid		Test and Report	3.3 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.

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.

Jacqueline Wilson
Name

02 SEP 2025
Date

QA Specialist
Title