CERTIFICATE OF ANALYSIS

GemCell™ Plus Xeno-Free Human Serum AB

(Catalog Number 100-912-100, 100-912-005)

Lot Number: H426032

Date of Manufacture: Jul2026

Product Expiry: Jul2031

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 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. GemCell™ Plus Xeno-Free 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	3.4 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	21 CFR 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	Negative
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-HBc IgG	Immunoassay	Negative / Non-Reactive	Non-Reactive
Anti-HBc 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	311 mOsm/kg
pH	USP<791>	Test and Report	7.65
Biochemistry Testing			
Albumin		Test and Report	3.3 g/dL
ALT (SGPT)		Test and Report	9 U/L
AST (SGOT)		Test and Report	10 U/L
Bilirubin, Total		Test and Report	0.2 mg/dL
BUN		Test and Report	13 mg/dL
Calcium		Test and Report	>15.0 mg/dL
Chloride		Test and Report	110 mmol/L
Cholesterol		Test and Report	132 mg/dL
Creatinine		Test and Report	0.86 mg/dL
Glucose		Test and Report	98 mg/dL
Phosphorus		Test and Report	3.2 mg/dL
Potassium		Test and Report	3.7 mmol/L
Protein, Total		Test and Report	5.1 g/dL
Sodium		Test and Report	165 mmol/L
Triglycerides		Test and Report	93 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.

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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.

Karen Zuniga
Name

12OCT2024
Date

QC Associate Scientist
Title