CERTIFICATE OF ANALYSIS

GemCell™ Plus Xeno-Free Human Serum AB

(Catalog Number 201-223-300mL)

Lot Number: H123001b

Date of Manufacture: Sep2024 **Product Expiry:** Jan2028

Storage Temperature: ≤ -10°C

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

Test	Methodology	Specification	Analysis
Biological Testing			
Endotoxin	USP<85>	< 10.0 EU/mL	<0.250 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	< 20.0 mg/dL	6.5 mg/dL
Microbiological Testing			
Sterility	USP<71>		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Mycoplasma	Barile, MF & Kern, J (1971)	Not Detected	Not Detected
Viral Testing Individual Donor Units	21 CFR 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
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
Anti-HBc IgG		Non-Reactive	Non-Reactive
Anti-HTLV I/II		Non-Reactive	Non-Reactive
Anti-HBc IgM		Non-Reactive	Non-Reactive
West Nile Virus NAT		Non-Reactive	Non-Reactive
Chagas		Non-Reactive	Non-Reactive
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>	260 - 350 mOsm/kg	321 mOsm/kg
pH @ RT	USP<791>	Test and Report	7.88
Biochemistry Testing			
Albumin		Test and Report	3.5 g/dL
ALT (SGPT)		Test and Report	5 U/L
AST (SGOT)		Test and Report	9 U/L

GeminiBio

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(Catalog Number 201-223-300mL)

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Test	Methodology	Specification	Analysis
Bilirubin, Total		Test and Report	0.1 mg/dL
BUN		Test and Report	14 mg/dL
Calcium		Test and Report	>15.0 mg/dL
Chloride		Test and Report	111 mmol/L
Cholesterol		Test and Report	127 mg/dL
Creatinine		Test and Report	0.81 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	81 mg/dL
Uric Acid		Test and Report	4.7 mg/dL

All blood products are collected from stringently screened male donors at FDA-licensed collection centers located in the United States. All viral test methods are FDA approved.

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. This product was manufactured at our West Sacramento, CA U.S.A facility. All final product processes/packaging were also performed at the West Sacramento, CA, U.S.A. facility.

Jacqueline Wilson
Name

QA Specialist
Title

25 OCT 2024
Date