GeminiBio

CERTIFICATE OF ANALYSIS

GemCell™ Plus Human Serum AB

(Catalog Number 100-612)

Lot Number: H121042

Date of Manufacture: JUN2021 **Product Expiry:** JUN2026

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 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 Human serum AB is converted to serum from human plasma using bovine 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	<0.893 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1985)	<20.0 mg/ dL	5.8 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
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		Non-Reactive	Non-Reactive
Chagas		Non-Reactive	Non-Reactive

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(Catalog Number 100-612)

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Test	Methodology	Specification	Analysis
Physical Testing			
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/ kg	328 mOsm/kg
pH @RT	USP<791>	Test and Report	7.98
Biochemistry			
Albumin		Test and Report	3.4 g/dL
ALT (SGPT)		Test and Report	14 U/L
AST (SGOT)		Test and Report	14 U/L
Bilirubin, Total		Test and Report	0.3 mg/dL
BUN		Test and Report	13 mg/dL
Calcium		Test and Report	>15.0 mg/dL
Chloride		Test and Report	117 mmol/L
Cholesterol		Test and Report	147 mg/dL
Creatinine		Test and Report	0.83 mg/dL
Glucose		Test and Report	97 mg/dL
Phosphorus		Test and Report	3.0 mg/dL
Potassium		Test and Report	4.0 mmol/L
Protein, Total	Biuret	Test and Report	5.3 g/dL
Sodium		Test and Report	>165 mmol/L
Triglycerides		Test and Report	114 mg/dL
Uric Acid		Test and Report	3.1 mg/dL

All blood products are collected from stringently screened male donors at FDA-licensed collection centers located in the United States. This product is a pool of > 100 donor units and the viral testing is performed on the individual donor units. All other testing is performed on the final product pool prior to release. The bovine thrombin that is used as part of the conversion to serum is sourced from controlled herds located in the United States and the source cattle are ante and post-mortem inspected by a U.S. Veterinary Service Inspector where they were deemed free of infectious and contagious diseases. All animals used in the production of the thrombin were from a natural beef program in accordance with FDA regulations. 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.

Hina Z Khan
Name

QC Associate I
Title

10 SEP 2021
Date