



## CERTIFICATE OF ANALYSIS

### **GemCell™ Plus Human Serum AB (Catalog Number 100-612)Heat Inactivated\*\***

Lot Number: H121042-A Rev.1 27SEP2021

**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
<b>Biological Testing</b>			
Endotoxin	USP<85>, EP 2.6.14	< 10.0 EU/ mL	<0.750 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1985)	<20.0 mg/ dL	5.1 mg/dL
<b>Microbiological Testing</b>			
Sterility	USP<71>, EP 2.6.1		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Mycoplasma	USP<63>	Not Detected	Not Detected
<b>Viral Testing</b>			
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	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
<b>Viral Testing Finished Pool Level</b>			
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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Test	Methodology	Specification	Analysis
<b>Physical Testing</b>			
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/ kg	327 mOsm/kg
pH @RT	USP<791>	Test and Report	7.87
<b>Biochemistry</b>			
Albumin		Test and Report	3.4 g/dL
ALT (SGPT)		Test and Report	12 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	114 mmol/L
Cholesterol		Test and Report	151 mg/dL
Creatinine		Test and Report	0.84 mg/dL
Glucose		Test and Report	99 mg/dL
Phosphorus		Test and Report	3.1 mg/dL
Potassium		Test and Report	3.9 mmol/L
Protein, Total	Biuret	Test and Report	5.0 g/dL
Sodium		Test and Report	>165 mmol/L
Triglycerides		Test and Report	109 mg/dL
Uric Acid		Test and Report	3.2 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. \*Some Individual donor units in this lot had Anti-HBc IgG results that were Reactive. This can happen if donors are vaccinated or indicates a past infection with HBV. All units had Non-Reactive Anti-HBc IgM results which indicates that there was no HBV infection within the past 6 months All individual units were tested for HBV NAT and HBsAg and had Not-Detected, Non-Reactive results. The final pool was tested for HBcAB Total and was Non-Reactive. \*\* Results shown were obtained by carefully performed methods believed to be reliable prior to heat inactivation.*



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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.

Jacqueline Wilson / 13 OCT 2021  
Name/Date

QA Associate II  
Title

