



**CERTIFICATE OF ANALYSIS**  
**GemCell™ Plus Human Serum AB**  
**(Catalog Number 100-612)**

Lot Number: H121016

**Date of Manufacture:** Mar2021

**Product Expiry:** Mar2026

**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	21CFR 610.40 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
<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

