CERTIFICATE OF ANALYSIS

GemCell™ Plus Human Serum AB Xeno-Free

(Catalog Number 100-912) Gamma-Irradiated*

Lot Number: H122020

Date of Manufacture: Jun2022 **Product Expiry:** Jun2027

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 Xeno-Free 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 Xeno-Free is converted to serum from human plasma using 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	< 10.0EU/ mL	<0.750 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1985)	<20.0 mg/ dL	5.5 mg/dL
Microbiological Testing			
Sterility	USP<71>, EP 2.6.1		
Bacteria		Not Detected	Not Detected
Fungi		Not Detected	Not Detected
Mycoplasma	Barile, MF & Kern, J (1971)	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
Antibody Screen		Negative	Negative
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

GeminiBio

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GemCell™ Plus Human Serum AB Xeno-Free

(Catalog Number 100-912) Gamma-Irradiated*

Lot Number: H122020

Test	Methodology	Specification	Analysis
Physical Testing			
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/ kg	317 mOsm/kg
pH @RT	USP<791>	Test and Report	7.85
Biochemistry			
Albumin		Test and Report	3.4 g/dL
ALT (SGPT)		Test and Report	9 U/L
AST (SGOT)		Test and Report	14 U/L
Bilirubin, Total		Test and Report	0.2 mg/dL
BUN		Test and Report	12 mg/dL
Calcium		Test and Report	>15.0 mg/dL
Chloride		Test and Report	113 mmol/L
Cholesterol		Test and Report	139 mg/dL
Creatinine		Test and Report	0.79 mg/dL
Glucose		Test and Report	93 mg/dL
Phosphorus		Test and Report	3.1 mg/dL
Potassium		Test and Report	3.8 mmol/L
Protein, Total	Biuret	Test and Report	5.2 g/dL
Sodium		Test and Report	164 mmol/L
Triglycerides		Test and Report	81 mg/dL
Uric Acid		Test and Report	4.4 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. 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. *Results shown were obtained by carefully performed methods believed to be reliable prior to gamma-irradiation.*

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

QA Associate I

Title

09MAR2023

Date