



CERTIFICATE OF ANALYSIS
GemCell™ Human Serum AB
(Catalog Number 100-512)

Lot Number: H42X00K

Date of Manufacture: Apr2019

Origin: United States

Product Expiry: Apr2024

For Cell culture, Further Manufacturing or Research use Only. Not for Direct Therapeutic Use.

Storage Temperature: ≤ -10°C

Product description: GemCell™ 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™ 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	<0.500 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1985)	<20.0 mg/ dL	7.3 mg/dL
Microbiological Testing			
Sterility	USP<71>, EP 2.6.1		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Mycoplasma	Barile, MF and Kern, J (1971), EP 2.6.7	Not Detected	Not Detected
Viral Testing			
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
Physical Testing			
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/ kg	313 mOsm/kg
pH	USP<791>	Test and Report	8.0
Biochemistry			
Albumin		Test and Report	3.2
ALT (SGPT)		Test and Report	13
AST (SGOT)		Test and Report	14
Bilirubin, Total		Test and Report	0.2



Test	Methodology	Specification	Analysis
BUN		Test and Report	13
Calcium		Test and Report	>3.75
Chloride		Test and Report	109
Cholesterol		Test and Report	126
Creatinine		Test and Report	0.78
Glucose		Test and Report	5.4
Phosphorus		Test and Report	1.0
Potassium		Test and Report	3.8
Protein, Total	Biuret	Test and Report	5.3
Sodium		Test and Report	>165
Triglycerides		Test and Report	70
Uric Acid		Test and Report	2.9

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. The purified thrombin undergoes a pasteurization process where it is treated at 62°C ± 2°C for a period of 10 hours. This pasteurization process is validated by the vendor. Material is derived from human blood and should be considered biohazardous. Universal precautions should be used when handling this material.

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.

Megha Khalasi
Name

QA Associate III
Title

01 May 2020
Date