



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

Lot Number: H122016

Date of Manufacture: May2022

Product Expiry: May2027

Origin: United States

Storage Temperature: ≤ -10°C

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

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 | <0.750 EU/mL |
| Hemoglobin | Fleming, AF and Woolf, AJ (1985) | <20.0 mg/ dL | 4.7 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 | | | |
| HBsAg | 21CFR 610.40 | | |
| 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 | 316 mOsm/kg |
| pH | USP<791> | Test and Report | 7.74 |
| Biochemistry | | | |
| Albumin | | Test and Report | 3.3g/dL |
| ALT (SGPT) | | Test and Report | 11 U/L |
| AST (SGOT) | | Test and Report | 13 U/L |



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|------------------|-------------|-----------------|-------------|
| 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 | 109 mmol/L |
| Cholesterol | | Test and Report | 144 mg/dL |
| Creatinine | | Test and Report | 0.88 mg/dL |
| Glucose | | Test and Report | 101 mg/dL |
| Phosphorus | | Test and Report | 2.8 mg/dL |
| Potassium | | Test and Report | 3.7 mmol/L |
| Protein, Total | Biuret | Test and Report | 5.1 g/dL |
| Sodium | | Test and Report | >165 mmol/L |
| Triglycerides | | Test and Report | 113 mg/dL |
| Uric Acid | | Test and Report | 3.5 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. *Results shown were obtained by carefully performed methods believed to be reliable prior to heat inactivation.*

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

02 MAY 2023

Date