



**CERTIFICATE OF ANALYSIS**  
**GemCell™ Human Serum AB**  
**(Catalog Number 100-512-100, 100-512-005)**

Lot Number: H425016

**Date of Manufacture:** Mar2025

**Product Expiry:** Mar2030

**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™ 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       | <1.25 EU/mL  |
| Hemoglobin                     | Fleming, AF and Woolf, AJ (1965) | <20.0 mg/dL       | 3 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                          | 21 CFR 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 |
| <b>Physical Testing</b>        |                                  |                   |              |
| Osmolality                     | USP<785>, EP 2.2.35              | 260 – 350 mOsm/kg | 332 mOsm/kg  |
| pH                             | USP<791>                         | Test and Report   | 7.69         |
| <b>Biochemistry Testing</b>    |                                  |                   |              |
| Albumin                        |                                  | Test and Report   | 3.7 g/dL     |
| ALT (SGPT)                     |                                  | Test and Report   | 9 U/L        |
| AST (SGOT)                     |                                  | Test and Report   | 11 U/L       |
| Bilirubin, Total               |                                  | Test and Report   | 0.2 mg/dL    |
| BUN                            |                                  | Test and Report   | 13 mg/dL     |
| Calcium                        |                                  | Test and Report   | 15 mg/dL     |
| Chloride                       |                                  | Test and Report   | 116 mmol/L   |



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|----------------|-------------|-----------------|------------|
| Cholesterol    |             | Test and Report | 124 mg/dL  |
| Creatinine     |             | Test and Report | 0.81 mg/dL |
| Glucose        |             | Test and Report | 103 mg/dL  |
| Phosphorus     |             | Test and Report | 2.9 mg/dL  |
| Potassium      |             | Test and Report | 3.9 mmol/L |
| Protein, Total |             | Test and Report | 5.5 g/dL   |
| Sodium         |             | Test and Report | 165 mmol/L |
| Triglycerides  |             | Test and Report | 64 mg/dL   |
| Uric Acid      |             | Test and Report | 3.7 mg/dL  |

*All blood products are collected from stringently screened male donors at FDA-licensed collection centers located in the United States. Viral testing is performed on the individual donor units. All other testing is performed on the final product pool prior to release. 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.*

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.

Alejandra Peña  
Name

26 NOV 2025  
Date

QA Associate II  
Title