



**GEMINI**  
BIO-PRODUCTS

# Certificate of Analysis

Created November 7, 2018

**Product:** **GemCell™ Human Serum AB**  
**Heat Inactivated\***  
0.1µm sterile-filtered

**Catalog #: 100-512**

**Lot #: H48W00J**

**Origin: United States (100%)**

**Manufacture Date: Sep 2018**

**Expiration Date: Sep 2023**

| TEST                           | METHODOLOGY                      | SPECIFICATION   | RESULTS      |
|--------------------------------|----------------------------------|-----------------|--------------|
| <b>Biological Testing</b>      |                                  |                 |              |
| Endotoxin                      | USP<85>                          | < 10 EU/mL      | <0.500 EU/mL |
| Hemoglobin                     | Fleming, AF and Woolf, AJ (1965) | <20.0 mg/dL     | 6.0 mg/dL    |
| <b>Microbiological Testing</b> |                                  |                 |              |
| Sterility                      | USP<71>                          |                 |              |
| Bacteria                       |                                  | Not Detected    | Not Detected |
| Fungi                          |                                  | Not Detected    | Not Detected |
| Mycoplasma                     | Barile, MF and Kern, J (1971)    | Not Detected    | Not Detected |
| <b>Viral Testing</b>           |                                  |                 |              |
|                                | 21 CFR 610.40                    |                 |              |
| HBsAg                          |                                  | Non-Reactive    | Non-Reactive |
| Anti-HCV                       |                                  | Non-Reactive    | Non-Reactive |
| Anti-HIV-1/HIV-2               |                                  | Non-Reactive    | Non-Reactive |
| Syphilis                       |                                  | Negative        | Negative     |
| HBV-NAT                        |                                  | Not Detected    | Not Detected |
| HIV-NAT                        |                                  | Not Detected    | Not Detected |
| HCV-NAT                        |                                  | Not Detected    | Not Detected |
| <b>Physical Testing</b>        |                                  |                 |              |
| Osmolality                     | USP<785>                         | 260-350 mOsm/kg | 314 mOsm/kg  |
| pH                             | USP<791>                         | Report          | 7.76         |



# Biochemical Testing

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| TEST             | METHODOLOGY | SPECIFICATION   | RESULTS    |
|------------------|-------------|-----------------|------------|
| Albumin          |             | Test and Report | 3.3 g/dL   |
| ALT (SGPT)       |             | Test and Report | 5 U/L      |
| AST (SGOT)       |             | Test and Report | 18 U/L     |
| Bilirubin, Total |             | Test and Report | 0.2 mg/dL  |
| BUN              |             | Test and Report | 12 mg/dL   |
| Calcium          |             | Test and Report | >3.75 mM   |
| Chloride         |             | Test and Report | 113 mM     |
| Cholesterol      |             | Test and Report | 140 mg/dL  |
| Creatinine       |             | Test and Report | 0.89 mg/dL |
| Glucose          |             | Test and Report | 5.0 mM     |
| Phosphorus       |             | Test and Report | 0.969 mM   |
| Potassium        |             | Test and Report | 3.7 mM     |
| Protein, Total   | Biuret      | Test and Report | 5.3 g/dL   |
| Sodium           |             | Test and Report | 165 mM     |
| Triglycerides    |             | Test and Report | 62 mg/dL   |
| Uric Acid        |             | Test and Report | 4.2 mg/dL  |

All human blood products are collected from stringently screened male donors at FDA-licensed collection centers in the United States. \*Results shown were obtained by carefully performed methods believed to be reliable prior to heat inactivation. As some results may vary for specific tests depending upon methodology and other variables, it is suggested that tests for which results are particularly important be repeated by the user of this product. Lot specific samples are available at the customer's request and users are encouraged to evaluate the sample prior to purchase. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance.

**CAUTION:** For Cell Culture, further Manufacturing and Research use only. Not for direct Therapeutic use. It is the responsibility of the user to undertake verification and testing to determine the suitability of this product's application. The statements herein are offered for informational purposes and are intended to be used solely for your consideration, investigation and verification.

Mark Weber 11072018

Created by/ date

Mark Weber 11072018

Verified by/ date