

## **CERTIFICATE OF ANALYSIS**

## GemCell™ Fetal Bovine Serum

(Catalog Number 100-500)

Lot Number: A424055

Date of Manufacture: Aug2024 Product Expiry: Aug2029

Origin: United States Storage Temperature: ≤ -10°C

For cell culture, further manufacturing or research use only. Not for direct therapeutic use.

Product Description: GemCell™ Fetal Bovine Serum is sterile-filtered through a 0.1 μm filter prior to freezing.

| Test                               | Methodology               | Specification     | Analysis     |
|------------------------------------|---------------------------|-------------------|--------------|
| Biological Testing                 |                           |                   |              |
| Endotoxin                          | USP <85> & EP 2.6.14      | <10.0 EU/mL       | <0.1 EU/mL   |
| -lemoglobin                        | USP <90>                  | <20.0 mg/dL       | 9.21 mg/dL   |
| Microbiological Testing            |                           |                   |              |
| Sterility                          | USP <71> & EP 2.6.1       |                   |              |
| Bacteria                           |                           | No Growth         | No Growth    |
| Fungi                              |                           | No Growth         | No Growth    |
| Mycoplasma                         | Barile and Kern & Hoechst | Not Detected      | Not Detected |
|                                    | Fluorochrome Stain        |                   |              |
| /iral Testing                      | 9 CFR Part 113.53c        |                   |              |
| Cytopathic Agents                  |                           | Not Detected      | Not Detected |
| lemadsorbing Agents                |                           | Not Detected      | Not Detected |
| extraneous Viruses (FAb)           |                           |                   |              |
| Bluetongue Virus                   |                           | Not Detected      | Not Detected |
| Bovine Adenovirus                  |                           | Not Detected      | Not Detected |
| <b>Bovine Parvovirus</b>           |                           | Not Detected      | Not Detected |
| Bovine Viral Diarrhea (Cytopathic) |                           | Not Detected      | Not Detected |
| Bovine Respiratory Syncytial Virus |                           | Not Detected      | Not Detected |
| Rabies Virus                       |                           | Not Detected      | Not Detected |
| Reovirus                           |                           | Not Detected      | Not Detected |
| Physical Testing                   |                           |                   |              |
| Electrophoretic Pattern            | Cellulose Acetate         | Normal            | Normal       |
|                                    | Electrophoresis           |                   |              |
| Osmolality                         | USP <785> & EP 2.2.35     | 260 - 350 mOsm/kg | 317 mOsm/kg  |
| oH                                 | USP <791> & EP 2.2.3      | 6.5 - 8.5         | 7.05         |
| Biochemistry Testing               |                           |                   |              |
| Albumin                            |                           | Test and Report   | 2.1 g/dL     |
| Alkaline Phosphatase               |                           | Test and Report   | 231 IU/L     |
| ALT (SGPT)                         |                           | Test and Report   | 7 IU/L       |
| AST (SGOT)                         |                           | Test and Report   | 50 IU/L      |
| GGT                                | Chemistry Analyzer        | <10 U/L           | 5 IU/L       |
| Bilirubin, Total                   |                           | Test and Report   | 0.2 mg/dL    |
| BUN                                |                           | Test and Report   | 15 mg/dL     |



## CERTIFICATE OF ANALYSIS

## GemCell™ Fetal Bovine Serum

(Catalog Number 100-500)

Lot Number: A424055

| Test           | Methodology            | Specification   | Analysis     |
|----------------|------------------------|-----------------|--------------|
| Calcium        |                        | Test and Report | 13.6 mg/dL   |
| Chloride       |                        | Test and Report | 99 mmol/L    |
| Cholesterol    |                        | Test and Report | 28 mg/dL     |
| Cortisol       |                        | Test and Report | 0.300 µg/dL  |
| Creatinine     |                        | Test and Report | 3.0 mg/dL    |
| Glucose        |                        | Test and Report | 157 mg/dL    |
| gG             | ELISA                  | <0.300 mg/mL*   | 0.0938 mg/ml |
| nsulin         |                        | Test and Report | 6.80 μIU/mL  |
| ron, Serum     |                        | Test and Report | 195 µg/dL    |
| Phosphorus     |                        | Test and Report | 10.9 mg/dL   |
| otassium       |                        | Test and Report | 13.1 mmol/L  |
| Progesterone   |                        | Test and Report | <0.1 ng/mL   |
| Protein, Total | USP <1057> & EP 2.5.33 | 2.5 - 6.0 g/dL  | 3.6 g/dL     |
| Sodium         |                        | Test and Report | 140 mmol/L   |
| Testosterone   |                        | Test and Report | <0.01 ng/mL  |
| Г3             |                        | Test and Report | 254.0 ng/dL  |
| Γ4             |                        | Test and Report | 8.9 µg/dL    |
| riglycerides   |                        | Test and Report | 78 mg/dL     |
| Jric Acid      |                        | Test and Report | 3.6 mg/dL    |

Our fetal bovine serum meets all USDA requirements and has passed ante and post-mortem. It is collected in countries recognized as being free of foot-and-mouth disease and rinderpest. The origin of all fetal bovine serum is traceable by lot number, date, and country of collection. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance. \*Some geographic regions may test higher than 0.300 mg/mL. If this be the case, refer to GGT results less than 10 U/L to ensure FBS purity.

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.

| Levi Tmmoos  | O6NOV2024 |  |
|--------------|-----------|--|
| Name         | Date      |  |
| QC Associate |           |  |
| Title        |           |  |