

CERTIFICATE OF ANALYSIS

Fetal Bovine Serum

Premium

(Catalog Number S11150, S11195)

Lot Number: M23263

Date of Manufacture: Dec2023

Product Expiry: Dec2028

Origin: Central America

Storage Temperature: ≤-10°C

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

Product Description: Fetal Bovine Serum Premium is a triple 0.1 µm filter processed serum.

<u>Notice</u>: The serum was collected and processed rapidly at cold temperatures to yield the highest quality serum with excellent cell growth properties. This cold processing leaves some fibrinogen in the serum which may convert to fibrin upon storage, thawing, or heat-inactivation. Fibrin can cause the serum to look slightly turbid or may be visible as a flocculent material. This material does not adversely affect the growth performance characteristics of the serum.

| Test | Mathadalage | Consideration | Aughusta |
|-----------------------------------|-----------------------------------|-------------------------|--------------|
| Bacterial and Fungal Testing | U.S.P. Modified | Specification | Analysis |
| | | Not Detected | Not Detected |
| Mycoplasma Testing | Large Volume Barile Method | Not Detected | Not Detected |
| Mycoplasma Testing, Supplemental | DNA Fluorochrome Stain | Not Detected | Not Detected |
| Viral Testing | Modified 9CFR | | |
| BVDV - Fluorescent Antibody | | Test | Tested |
| Cytopathogenic Agents - e.g. IBRV | | Test and Report | Not Detected |
| Hemadsorbing Agents - e.g. PI-3V | | Test and Report | Not Detected |
| BTV | | Not Detected | Not Detected |
| Cell Culture Testing | | Pass | Pass |
| pH | | 6.8 - 7.8 | 7.4 |
| Osmolality | Vapor Pressure | 280 – 335 mOsm | 309 mOsm |
| Endotoxin | Limulus Amebocyte Lysate Gel Clot | ≤ 50.0 EU/mL | 1.92 EU/mL |
| Hemoglobin | Spectrophotometric | ≤ 25 mg/dL | 10.7 mg/dL |
| B <mark>iochemical Profile</mark> | | • | 3, |
| Total Protein | | 3.0 - 4.6 g/dL | 3.5 g/dL |
| Albumin | | Check and Record | 2.4 g/dL |
| Globulin | | Check and Record | < 2.6 g/dL |
| A/G ratio | | Check and Record | 2.2 |
| IgG | | Check and Record | 25.0 mg/dL |
| ALT/SGPT | | Check and Record | 6.0 IU/L |
| GGT | | Check and Record | 2.0 IU/L |
| Alkaline Phosphatase | | Check and Record | 223.0 IU/L |
| | | | |



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| Test | Methodology | Specification | Analysis |
|-----------------------------|-------------|-------------------------|--------------|
| Biochemical Profile (cont.) | | Was six | |
| Total Bilirubin | | Check and Record | 0.1 mg/dL |
| Iron | | Check and Record | 180.0 μg/dL |
| UIBC | | Check and Record | 86.0 μg/dL |
| Cholesterol | | Check and Record | 38.0 mg/dL |
| Triglycerides | | Check and Record | 78.0 mg/dL |
| Glucose | | Check and Record | 71.0 mg/dL |
| Blood Urea Nitrogen (BUN) | | Check and Record | 19.0 mg/dL |
| Creatinine | | Check and Record | 2.5 mg/dL |
| BUN/Creatinine Ratio | | Check and Record | 8.0 |
| Uric Acid | | Check and Record | 1.9 mg/dL |
| Sodium | | Check and Record | 139.0 mEq/L |
| Potassium | | Check and Record | > 10.0 mEq/L |
| Sodium/Potassium Ratio | | Check and Record | 13.9 |
| Chloride | | Check and Record | 103.0 mEq/L |
| Calcium | | Check and Record | 13.2 mg/dL |
| Phosphorus | | Check and Record | 10.1 mg/dL |
| Magnesium | | Check and Record | 3.0 mg/dL |
| Bicarbonate | | Check and Record | 22.0 mmol/L |

The fetal bovine serum used in the manufacturing process is certified as meeting all USDA requirements for donor animal health, country of origin, and traceability of the product.

Origin: The fetal bovine serum is collected in USDA approved slaughterhouses or in countries certified by the USDA to be free of Foot and Mouth Disease (FMD) and other exotic disease agents. All imported serum used for manufacturing purposes is Safety tested and approved by the USDA for distribution in the United States.

TSE/BSE Statement: Product-specific validated virus removal studies have not been conducted for the majority of offered items. Statements to confirm that a product is "free of TSE/BSE" are not scientifically possible; consequently, we cannot state definitively that a material is TSE/BSE free. This product does contain animal-derived raw materials and GeminiBio maintains information confirming these materials are sourced from countries considered as negligible or controlled (Canada) risk for BSE by the World Organisation for Animal Health.

Donor Animals: All fetal blood is collected from fetuses derived from healthy animals. The donor dams must pass both ante- and post-mortem certified veterinary inspections before collection of the fetal blood.



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Traceability: The serum has been imported into the United States in full compliance with all USDA import regulations. Final processing of the serum took place in a processing facility located in the United States. All fetal bovine serum is traceable to the date and location of collection.

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.

| Korrina Nicewonger | 05 FEB 2025 | | |
|--------------------|-------------|--|--|
| Name | Date | | |
| QA Associate 11 | | | |
| Title | | | |