



CERTIFICATE OF ANALYSIS
GemCell™ Fetal Bovine Serum
(Catalog Number 100-500)

Lot Number: A51H00L

Date of Manufacture: Oct2020

Origin: United States

Product Expiry: Oct2025

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

Storage Temperature: ≤ -10°C

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 | 0.500 EU/mL |
| Hemoglobin | Fleming, AF and Woolf, AJ (1965) | <20.0 mg/dL | 7.3 mg/dL |
| Microbiological Testing | | | |
| Sterility | USP<71>, EP 2.6.1 | | |
| Bacteria | | No Growth | No Growth |
| Fungi | | No Growth | No Growth |
| Mycoplasma | Barile, MF and Kern, J (1971), EP 2.6.7 | Not Detected | Not Detected |
| Viral Testing | | | |
| | 9CFR 113.53c[113.46, 113.47] | | |
| Cytopathic Agents | | Not Detected | Not Detected |
| Hemadsorbing Agents | | Not Detected | Not Detected |
| Bovine Viral Diarrhea Ab Titer | | | |
| Type I | | Test and Report | < Undiluted |
| Type II | | Test and Report | < Undiluted |
| Extraneous Viruses (FAb) | | | |
| Bluetongue Virus | | Not Detected | Not Detected |
| Bovine Adenovirus | | Not Detected | Not Detected |
| Bovine Parvovirus | | Not Detected | Not Detected |
| Bovine Viral Diarrhea(cytopathic) | | Not Detected | Not Detected |
| Bovine Viral Diarrhea(non-cytopathic) | | Test and Report | Not Detected |
| Bovine Syncytial Virus | | Not Detected | Not Detected |
| Bovine Rabie Virus | | Not Detected | Not Detected |
| Reovirus | | Not Detected | Not Detected |



| Test | Methodology | Specification | Analysis |
|-------------------------|---------------------|--------------------|--------------|
| Physical Testing | | | |
| Electrophoretic Pattern | Cellulose Acetate | Normal | |
| Osmolality | USP<785>, EP 2.2.35 | 260 – 350 mOsm/ kg | 300mOsm/Kg |
| pH | USP<791> | 6.5 – 8.5 | 7.23 |
| Biochemistry | | | |
| Albumin | | Test and Report | 2.2 g/dL |
| Alkaline Phosphatase | | Test and Report | 159 U/L |
| ALT (SGPT) | | Test and Report | 4.0 IU/L |
| AST (SGOT) | | Test and Report | 36.IU/L |
| GGT | | <10 U/L | 4 U/L |
| Bilirubin, Total | | Test and Report | 0.2mg/dl |
| BUN | | Test and Report | 13 mg/dL |
| Calcium | | Test and Report | 12.7 mg/dL |
| Chloride | | Test and Report | 97 mmol/L |
| Cholesterol | | Test and Report | 29 mg/dL |
| Cortisol | | Test and Report | 0.244 ug/dL |
| Creatinine | | Test and Report | 2.3 mg/dL |
| Estradiol | | Test and Report | 9.85 pg/mL |
| Glucose | | Test and Report | 75 mg/dL |
| IgG | ELISA | <0.300 mg/mL* | 0.059 mg/dL |
| Insulin | | Test and Report | 9.01 uIU/mL |
| Iron, Serum | | Test and Report | 158 ug/dL |
| Phosphorus | | Test and Report | 8.9 mg/dL |
| Potassium | | Test and Report | 9.7 mmol/L |
| Progesterone | | Test and Report | < 0.06 ng/mL |
| Protein, Total | Biuret | 2.5 – 6.0 g/dL | 3.3 g/dL |
| Sodium | | Test and Report | 136 mmol/L |
| Testosterone | | Test and Report | < 0.01 ng/mL |
| T3 | | Test and Report | 95.3 ng/dL |
| T4 | | Test and Report | 13.2 ug/dL |
| Triglycerides | | Test and Report | 50 mg/dL |
| Tetracycline | | <4 ng/mL | < 1 ng/mL |
| Uric Acid | | Test and Report | 1.9 mg/dL |

Our fetal bovine serum meets all USDA requirements and has passed ante and post-mortem inspection by a licensed veterinarian. 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.

Megha Khalaji
 Name
28 DEC 2020
 Date

QC Supervisor
 Title