



CERTIFICATE OF ANALYSIS

Fetal Bovine Serum

Premium Select

(Catalog Number S11550, S11595)

Lot Number: L23249

Date of Manufacture: Nov2023

Product Expiry: Nov2028

Origin: Central America

Storage Temperature: $\leq -10^{\circ}\text{C}$

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

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

Notice: 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	Methodology	Specification	Analysis
Bacterial and Fungal Testing	U.S.P. Modified	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	Full 9CFR		
BVDV – Fluorescent Antibody		Test	Tested
Cytopathogenic Agents - e.g. IBRV		Not Detected	Not Detected
Hemadsorbing Agents - e.g. PI-3V		Not Detected	Not Detected
BTV		Not Detected	Not Detected
BRSV		Not Detected	Not Detected
Bovine Parvo		Not Detected	Not Detected
Bovine Adeno 1		Not Detected	Not Detected
Bovine Adeno 5		Not Detected	Not Detected
Reo Virus		Not Detected	Not Detected
Rabies Virus		Not Detected	Not Detected
Cell Culture Testing		Pass	Pass
pH		6.8 – 7.8	7.4
Osmolality	Vapor Pressure	280 – 335 mOsm	307 mOsm
Endotoxin	Limulus Amebocyte	≤ 15.0 EU/mL	0.06 EU/mL
	Lysate Gel Clot		
Hemoglobin	Spectrophotometric	≤ 15 mg/dL	10.1 mg/dL



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Hormone Profile			
Estradiol		Check and Record	5.4 pg/mL
Insulin		Check and Record	10.2 µIU/mL
Progesterone		Check and Record	< 0.19 nmol/L
Testosterone		Check and Record	1.0 ng/dL
Thyroxine (T4) - total		Check and Record	162.2 nmol/L
Biochemical Profile			
Total Protein		3.0 – 4.6 g/dL	3.5 g/dL
Albumin		Check and Record	2.4 g/dL
Globulin		Check and Record	1.1 g/dL
A/G ratio		Check and Record	2.2
IgG		Check and Record	25.0 mg/dL
ALT/SGPT		Check and Record	9.0 IU/L
GGT		Check and Record	5.0 IU/L
Alkaline Phosphatase		Check and Record	281.0 IU/L
Total Bilirubin		Check and Record	0.10 mg/dL
Iron		Check and Record	174.0 µg/dL
UIBC		Check and Record	91.0 µg/dL
Cholesterol		Check and Record	35.0 mg/dL
Triglycerides		Check and Record	61.0 mg/dL
Glucose		Check and Record	59.0 mg/dL
Blood Urea Nitrogen (BUN)		Check and Record	17.0 mg/dL
Creatinine		Check and Record	2.8 mg/dL
BUN/Creatinine Ratio		Check and Record	6.0
Uric Acid		Check and Record	1.4 mg/dL
Sodium		Check and Record	142.0 mEq/L
Potassium		Check and Record	10.4 mEq/L
Sodium/Potassium Ratio		Check and Record	13.7
Chloride		Check and Record	104.0 mEq/L
Calcium		Check and Record	13.8 mg/dL
Phosphorus		Check and Record	9.7 mg/dL
Magnesium		Check and Record	3.2 mg/dL
Bicarbonate		Check and Record	20.0 mmol/L



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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 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.

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.

Karen Zuniga

Name

13JAN2025

Date

QA Associate II

Title