GeminiBio

CERTIFICATE OF ANALYSIS

Fetal Bovine Serum

Premium

(Catalog Number S11195)

Lot Number: A325020-R1

Date of Manufacture: Feb2026

Product Expiry: Nov2030

Origin: Mexico

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.

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	Modified 9CFR		
BVDV – Fluorescent Antibody		Test	Not Detected
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	MTT Assay	Pass	Pass
pH	USP<791> & EP 2.2.3	6.8 – 7.8	7.06
Osmolality	USP<785> & EP 2.2.35	280 – 335 mOsm	306 mOsm/kg H_2O
Endotoxin*	USP<85> & EP 2.6.14	≤ 50.0 EU/mL	<0.1 EU/mL
Hemoglobin	USP<90>	≤ 25 mg/dL	11.33 mg/dL
Biochemical Profile			
Total Protein	USP<1057> & EP 2.5.33	3.0 – 4.6 g/dL	3.8 g/dL
Albumin		Check and Record	2.1 g/dL
Globulin		Check and Record	1.6 g/dL
A/G ratio		Check and Record	1.28
IgG	ELISA	Check and Record	0.208 mg/mL
ALT/SGPT		Check and Record	6 IU/L
GGT		Check and Record	5 IU/L
Alkaline Phosphatase		Check and Record	282 IU/L

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Biochemical Profile (cont.)			
Total Bilirubin		Check and Record	0.3 mg/dL
Iron		Check and Record	139 µg/dL
UIBC		Check and Record	105 µg/dL
Cholesterol		Check and Record	34 mg/dL
Triglycerides		Check and Record	70 mg/dL
Glucose		Check and Record	92 mg/dL
Blood Urea Nitrogen (BUN)		Check and Record	17 mg/dL
Creatinine		Check and Record	3.0 mg/dL
BUN/Creatinine Ratio		Check and Record	5.67
Uric Acid		Check and Record	2.6 mg/dL
Sodium		Check and Record	139 mmol/L
Potassium		Check and Record	12.4 mmol/L
Sodium/Potassium Ratio		Check and Record	11.21
Chloride		Check and Record	101 mmol/L
Calcium		Check and Record	14.1 mg/dL
Phosphorus		Check and Record	9.8 mg/dL
Magnesium		Check and Record	3.3 mg/dL
Bicarbonate		Check and Record	16 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. **Testing was performed after redispense to confirm test result meets final product specification. The test result reported is obtained from parent lot (prior to redispense).*

Karen Zuniga
Name

03MAR2024
Date

QA Associate II
Title