

Certificate of Analysis

Fetal Bovine Serum, Qualified (Meets USDA import requirements) Performance, Mycoplasma, and Virus and Endotoxin tested **Catalog Number:**

10437

Lot Number:

1799178

Storage Temperature:

-5 to -20C

Country of Origin:

MX

Expiration Date:

2021-05

For in vitro diagnostic use.

Sterile filtered (triple 0.1 um)

EST	SPECIFICATION	RESULT	UNITS
¹ Electrophoretic Pattern	Normal	Normal	
² Endotoxin Testing	>=0 to <=50	1.20	EU/mL
³ Hemoglobin	>=0 to <=25	16.7	mg%
⁴ Mycoplasma, Supplemental (H-Stain)	Negative	Negative	
⁵ Mycoplasma Testing	Negative	Negative	
⁶ Osmolality	>=280 to <=340	311	mOsm/kg
⁷ Performance Testing: Cloning Assay	Check & Record	113	%
⁸ Performance Testing: Growth Assay	Check & Record	87	%
⁹ Performance Testing: Plating Assay	Check & Record	95	%
¹⁰ pH	>=6.9 to <=7.8	7.0	
11 Sterility Testing	Negative	Negative	
¹² Tetracycline	None Detected	None Detected	
¹³ Total Protein	>=3.0 to <=5.0	3.7	g/dL
¹⁴ VT - Bovine Adenovirus FA	Negative	Negative	
15 VT - Bovine Parvovirus FA	Negative	Negative	
16 VT- BRSV Fluorescent Antibody	Negative	Negative	
17 VT - BVDV Fluorescent Antibody	Tested	Tested	
¹⁸ VT - Cytopathogenic Agents	Negative	Negative	



Certificate of Analysis

(Continued)

19 VT - Hemadsorbing Agents	Negative	Negative	
²⁰ VT - Rabies Virus FA	Negative	Negative	
²¹ VT - Reovirus FA	Negative	Negative	
²² VT- USDA Bluetongue Virus	Negative	Negative	

GIBCO brand, Life Technologies cell culture liquid products are prepared by an aseptic process for which each step has been validated to ensure that all products meet the industry standard sterility assurance level of 10\(^2\); i.e. product that demonstrates a contamination level of no more than 1 of 1,000 units during the manufacturing process. The highest level of sterility assurance (equal to or greater than 10\(^2\)-6) cannot be achieved without terminal sterilization which is harmful to the performance of cell culture products.

We certify that all Fetal Bovine Sera meets the USDA requirements for abbatoir-sourced animals, traceability and country of origin.

ABBATOIR-SOURCED ANIMALS: All fetal blood is collected from fetuses derived from healthy dams that have passed pre and post mortem certified veterinary inspection. TRACEABILITY: All Fetal Bovine Sera is traceable by date and location of collection.

COUNTRY OF ORIGIN: Imported Fetal Bovine Serum is collected and processed in countries recognized by the USDA as being free of Foot and Mouth Disease, Rinderpest and Bovine Spongiform Encephalopathy and meets USDA import requirements.

NOTICE: Since our sera are not pre-aged before filtration, turbidity or flocculent debris may develop upon thawing or storage. This condition does not adversely affect performance characteristic of the serum.

Read SDS.

Quality Systems Department

Date: 14-Jun-2016



Certificate of Analysis

(Continued)

REFERENCES:

- 1 Protein Electrophoresis Life Technologies Specifications
- 2 Current United States Pharmacopeia, <85> Bacterial Endotoxins Test.
- 3 Fleming, A.F. and Woolf, A.J. (1965) Clin. Chem. 12, 67.
- 4 Hoechst H Stain Chen, T.R. (1977) Exp. Cell Res., 104, 255 Life Technologies Modified.
- 5 Barile, M.F. and Kern, J. (1971) P.S.E.M.B. 138, 432, Life Technologies Modified.
- 6 Life Technologies Specifications.
- 7 Life Technologies Specifications, Ref.: GIBCO Catalog. Cell Line Used: Sp2/O-Ag14 (ATCC No. CRL-1581) or P3 x 63 Ag8.653 (ATCC No. CRL-1580). The cloning efficiency assay analyzes the ability of each FBS lot to support cloning and growth of murine myeloma cells and derived hybridomas.
- 8 Life Technologies Specifications, Ref.: GIBCO Catalog. Cell Line Used: Human Diploid Lung Fibroblast (WI-38), ATCC No. CCL-75. GIBCO growth promotion assay measures the ability of each FBS lot to support proliferation of fastidious human diploid fibroblasts through multiple subcultures.
- 9 Life Technologies Specifications, Ref.: GIBCO Catalog. Cell Line Used: Human Lung Carcinoma (A549), ATTC No. CCL-185. Analysis of cellular attachment and proliferation of a human transformed cell line.
- 10 Life Technologies Specifications.
- 11 Current edition of USP.
- 12 Life Technologies Specifications. Analysis of tetracycline in fetal bovine serum (FBS). Protein precipitation is performed on the FBS sample followed by a reverse phase HPLC separation of tetracycline from endogenous components of the protein free serum supernatant. The assay detects the presence of tetracycline in FBS at a part per billion level.
- 13 Tietz, Norbert W.: Biuret Method for the Determination of Total Protein in Serum and Exudates. Fundamentals of Clinical Chemistry, 1976, pages 302-304.
- 14 Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
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- 21 Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- 22 Virus Testing (VT) is performed by the sheep inoculation test by the U.S. Department of Agriculture, Animal and Plant Inspection Service, National Veterinary Services Laboratories, Ames, Iowa.