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Certificate of Analysis

Fetal Bovine Serum, Qualified Performance, Mycoplasma, and Virus and Endotoxin tested

Catalog Number:	10437
Lot Number:	1992275
Storage Temperature:	<= -10C
Country of Origin:	MX
Expiration Date:	2023-04

For research use or further manufacturing use only. Serum and blood proteins are not for direct administration into humans or animals.

Sterile filtered (triple 0.1 um)

TEST	SPECIFICATION	RESULT	UNITS
[1] Electrophoretic Pattern	Normal	Normal	
[2] Endotoxin Testing	>=0 to <=50	4.67	EU/mL
[3] Hemoglobin	>=0 to <=25	14.5	mg%
[4] Mycoplasma, Supplemental (H-Stain)	Negative	Negative	
[5] Mycoplasma Testing	Negative	Negative	
[6] Osmolality	>=280 to <=340	310	mOsm/kg
[7] Performance Testing: Cloning Assay	Check & Record	128	%
[8] Performance Testing: Growth Assay	Check & Record	114	%
[9] Performance Testing: Plating Assay	Check & Record	103	%
[10] pH	>=6.9 to <=7.8	7.2	
[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 - Bluetongue Virus FA *Testing not required for Mexican or Australian origin material.* *Testing required for Canadian origin material.*	Negative	Not Measured	
[15] VT - Bovine Adenovirus FA	Negative	Negative	
[16] VT - Bovine Parvovirus FA	Negative	Negative	

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(Continued)

[17] VT- BRSV Fluorescent Antibody	Negative	Negative
[18] VT - BVDV Fluorescent Antibody	Tested	Tested
[19] VT - Cytopathogenic Agents	Negative	Negative
[20] VT - Hemadsorbing Agents	Negative	Negative
[21] VT - Rabies Virus FA	Negative	Negative
[22] VT - Reovirus FA	Negative	Negative
[23] VT- USDA Bluetongue Virus	Negative	Negative

Testing not required for Canadian origin material.

Testing required for Mexican or Australian origin material.

Notice: For lots manufactured from 28NOV2017, the storage temperature and intended use for this product has changed per ECR1038162 and ECR1038594. These changes will not impact product quality, stability or performance and there are no associated changes in the manufacturing, storage or transport processes. If you have questions regarding this change, please contact Thermo Fisher Scientific Technical Support at 1-800-955-6288 in North America or techsupport@thermofisher.com globally.

Read SDS

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.

GIBCO brand, Thermo Fisher Scientific 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^-3; 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^-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.

Barbara J Schueler

Quality Systems Department Date: 19-Jun-2018

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REFERENCES:

1 Protein Electrophoresis - Thermo Fisher Scientific 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 Thermo Fisher Scientific Modified.

5 Barile, M.F. and Kern, J. (1971) P.S.E.M.B. 138, 432, Thermo Fisher Scientific Modified.

6 Thermo Fisher Scientific Specifications.

7 Thermo Fisher Scientific 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 Thermo Fisher Scientific Specifications, Ref.: Cell Line Used: Human Diploid Normal Lung Fibroblast. GIBCO growth promotion assay measures the ability of each FBS lot to support proliferation of fastidious human diploid fibroblasts through multiple subcultures.

9 Thermo Fisher Scientific 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 Thermo Fisher Scientific Specifications.

11 Current edition of USP.

12 Thermo Fisher Scientific 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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22 Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].

23 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.

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