Certificate of Analysis

QC Code: GIBCO

ES Cell Qualified Fetal Bovine Serum

Lot Number:	2754089RP
Item Number:	10439
Expiration Date:	2027-05
Storage Temp:	<= -10C
Country of Origin:	Mexico
Originated From:	2707016RP

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	TEST ID	SPECIFICATION	RESULT	UNITS
Electrophoretic Pattern	ELECTR0001	Normal	Normal	
Endotoxin Testing	ENDO0007	0.00 - 50.00	0.15	EU/mL
ES Cell Qualification Colony Forming Assay	ESCELL0014	Acceptable	Acceptable	
Hemoglobin	HAEMO0002	0.0 - 25.0	12.9	mg%
Mycoplasma Testing	MYCO0013	Negative	Negative	
Mycoplasma, Supplemental (H-Stain)	MYCO0016	Negative	Negative	
Osmolality	OSMO0002	280 - 340	317	mOsm/kg
Performance Testing: Growth Assay	WI380001	Check and Record	104	%
Performance Testing: Plating Assay	PLATE0003	Check and Record	105	%
Performance: Relative Cloning Efficiency(RCE)	CLON0001	Check and Record	100	%
pH	PH0003	6.9 - 7.4	7.2	
Sterility Testing	STERI0006	Negative	Negative	
Total Protein	PROTEI0001	3.0 - 5.0	3.7	g/dL
VT - Bovine Adenovirus FA	VIRUS0029	Negative	Negative	
VT - Bovine Parvovirus FA	VIRUS0028	Negative	Negative	
VT - BVDV Fluorescent Antibody	VIRUS0005	Tested	Tested	
VT - Cytopathogenic Agents	VIRUS0032	Negative	Negative	
VT - Hemadsorbing Agents	VIRUS0033	Negative	Negative	
VT - Rabies Virus FA	VIRUS0030	Negative	Negative	
VT - Reovirus FA	VIRUS0031	Negative	Negative	
VT- BRSV Fluorescent Antibody	VIRUS0041	Negative	Negative	
VT- USDA Bluetongue Virus	VIRUS0040	Negative	Negative	

Read SDS.

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.

ABATTOIR-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. Thermo Fisher Scientific serum processes are traceability certified by the International Serum Industry Association (ISIA).
COUNTRY OF ORIGIN: 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.

NOTE: GIBCO brand Embryonic Stem Cell Qualified Sera, Media, and Reagents from GIBCO are tested for their ability to sustain undifferentiated cellular morphology of ES cells in culture. GIBCO does not guarantee the successful outcome of complex applications such as targeted gene mutation experiments.

NOTE: For optimal performance, we recommend the serum be heat inactivated prior to use. Heat inactivation of FBS is performed by placing the thawed, room temperature FBS bottle(s) into a 56C waterbath for 30 minutes. Periodic swirling of the FBS during the inactivation step is recommended to aid in uniform inactivation. If multiple bottles are being inactivated at once, or the serum is not at room temperature, the temperature of the waterbath may drop below the desired inactivation temperature. If this happens, leave the bottle(s) in the waterbath and allow the temperature to return to 56C before beginning the 30 minute inactivation step. After inactivation, remove the serum from the waterbath. There needs to be a sufficient amount of water in the waterbath to allow full volume of FBS to be heat inactivated.

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.

NOTICE: Effective 16DEC2022, per ECR1096567, the expiration date for this product has increased from 4 years to 5 years. If you have any questions regarding this change, please contact Thermo Fisher Scientific Technical Support at 1-800-955-6288 in North America or techsupport@thermofisher.com globally.

ECR1081634 - 15DEC2021 - the expiration date for this product has increased from 2 years to 3 years, product description was revised as well as the USDA requirements note.
ECR1041705 - 30MAR2018, the specification for this product has changed. The ES Cell Qualification Assay has been replaced with the ES Cell Qualification Colony Forming Assay and the shelf life has increased to 2 years from the time of manufacture.
ECR1038162 and ECR1038594 - 28NOV2017 - the storage temperature and intended use for this product have changed.
Parent Lot Number is 2707016RP

Quality Systems Department Date: 29-Jun-2023

References

- ELECTR0001: Protein Electrophoresis.
- ENDO0007: Current United States Pharmacopeia, <85> Bacterial Endotoxins Test.
- ESCELL0014: Each lot of serum is qualified by thawing mESCs, culturing them in control media and media supplemented with test lot FBS. After 7 days the cells are stained for the pluripotency marker alkaline phosphatase, then with the non-specific cellular marker Methylene Blue. Pluripotent colonies are counted. Test serum and ES Qualified FBS Control must meet ES Cell Qualification Colony Forming Assay specifications for test serum to be ES Cell Qualified.
- HAEMO0002: Fleming, A.F. and Woolf, A.J. (1965) Clin. Chem. 12, 67.
- MYCO0013: Barile, M.F. and Kern, J. (1971) P.S.E.M.B. 138, 432, Thermo Fisher Scientific Modified.
- MYCO0016: Hoechst H Stain Chen, T.R. (1977) Exp. Cell Res., 104, 255 Thermo Fisher Scientific Modified.
- OSMO0002: Thermo Fisher Scientific Specifications.

- WI380001: 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.
- PLATE0003: 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.
- CLON0001: 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.
- PH0003: Thermo Fisher Scientific Specifications.
- STERI0006: Current edition of USP.
- PROTEI0001: Tietz, Norbert W. : Biuret Method for the Determination of Total Protein in Serum and Exudates. Fundamentals of Clinical Chemistry, 1976, pages 302-304.
- VIRUS0029: Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0028: Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0005: Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0032: Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0033: Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0030: Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0031: Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0041: Virus Testing (VT) is performed according to the Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0040: 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.