

Certificate of Analysis

QC Code: GIBCOCB

Fetal Bovine Serum Value FBS One Shot™ Value Lot Number:C3177231RPItem Number:A52094Manufacturing Date:MAR 2025Expiration Date:2030-03Storage Temp:<= -10C</td>Country of Origin:CanadaOriginated From:C3177231RP

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

Triple 0.1um filtered

TEST	TEST ID	SPECIFICATION	RESULT	UNITS	
Appearance	SOLAPP0014	Pass	Pass		
- Golden yellow to reddish brown liquid.					
Batch Volume	VOLWGT0009	Check and Record	1062.5	L	
Endotoxin	ENDO0028	<=20.00	<0.10	EU/mL	
Haemoglobin/Hemoglobin	HAEMO0009	<=25.0	16.5	mg/dL	
- Testing performed post heat inactivation.					
Identification: Electrophoretic Profile	ELECTR0016	Normal	Normal		
- Normal = Electrophoretic profile/pattern is consistent with Fetal Bovine Serum.					
Mycoplasma	MYCO0062	Not Detected	Not Detected		
Mycoplasma: Supplemental Testing (H-Stain)	MYCO0063	Not Detected	Not Detected		
Osmolality	OSMO0020	280 - 340	314	mOsm/kg H2O	
Performance: Relative Cloning Efficiency(RCE)	CLON0001	Check and Record	95	%	
Performance: Relative Growth Promotion(RGP)	WI380002	Check and Record	106	%	
Performance: Relative Plating Efficiency(RPE)	PLATE0004	Check and Record	99	%	
pH	PH0024	7.0 - 8.0	7.3		
Protein: Albumin	ELECTR0017	Check and Record	20.4	mg/mL	
Protein: Alpha Globulin	ELECTR0018	Check and Record	10.5	mg/mL	
Protein: Beta Globulin	ELECTR0019	Check and Record	3.1	mg/mL	
Protein: Gamma Globulin	RID0002	<=500	226	mg/L	
- =500mg/L is consistent with</td <td>h Fetal Bovine S</td> <td>Serum.</td> <td></td> <td></td>	h Fetal Bovine S	Serum.			
Protein: Total Protein	PROTEI0005	30.0 - 55.0	35.0	mg/mL	
- mg/mL= g/L; mg/mL/10= g/dL.					
Sterility: Bacterial and Fungal Testing	STERI0010	No Growth Detected	No Growth Detected		
Virus (9CFR): Bluetongue Virus	VIRUS0662	Not Detected	Not Detected		
- If Mexican or Australian raw material origin is used, testing not required. If United States, New Zealand, or Canadian raw material origin is used, testing required.					
Virus (9CFR): Bovine Adenovirus	VIRUS0017	Not Detected	Not Detected		
Virus (9CFR): Bovine Parvovirus	VIRUS0018	Not Detected	Not Detected		
Virus (9CFR): Bovine Viral Diarrhoea Virus	VIRUS0020	Check and Record	Detected		
- Diarrhoea = Diarrhea.Non Cyt	opathogenic.				
Virus (9CFR): BRSV	VIRUS0019	Not Detected	Not Detected		
- BRSV: Bovine Respiratory Syncytial Virus.					



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Virus (9CFR): Cytopathogenic Agents	VIRUS0022	Not Detected	Not Detected		
- Including Bovine Herpesvirus 1 (BHV-1/IBR).					
Virus (9CFR): Haemadsorbing Agents	VIRUS0023	Not Detected	Not Detected		
- Including Bovine Parainfluenza Virus 3 (PI-3).					
Virus (9CFR): Rabies Virus	VIRUS0024	Not Detected	Not Detected		
Virus (9CFR): Reovirus	VIRUS0025	Not Detected	Not Detected		
Virus (USDA): Akabane Virus	VIRUS0027	Negative	Not Measured		
- If Mexican, United States, New Zealand or Canadian raw material origin is used, testing not required. If Australian raw material origin is used, testing required.					
Virus (USDA): Bluetongue Virus	VIRUS0026	Negative	Not Measured		
- If Mexican or Australian raw material origin is used, testing required. If United States, Candian or New Zealand sourced raw material is used, testing not required.					
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QUALITY: Life Technologies Corporation is ISO13485 certified.

REGULATORY: Life Technologies Corporation export blood products to multiple overseas markets and is approved by the United States Department of Agriculture (USDA) for export to the EU of blood products for technical purposes outside the food chain. ABATTOIR SOURCED ANIMALS: All fetal bovine blood is collected from fetuses derived from healthy dams that have passed pre and post-mortem verified 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).

Australia, Canada, Mexico, New Zealand and United States are recognised as being free of Foot and Mouth Disease, Rinderpest and negligible risk for Bovine Spongiform Encephalopathy.

GIBCO brand 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 1000 units during the manufacturing process. The highest level of sterility assurance (equal to or greater than 10-6) cannot be achieved without terminal sterilisation.

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.

Manufacturing address (Filtration): United States.

Batch Volume = Original bottled volume at the time of manufacturing and delivered to storage of the parent (original) lot.

Notice: Effective 16DEC2022, per ECR1095870, 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.

NOTICE: Effective 18OCT2022 the specification has been updated based on ECR1094977. 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.



Quality Systems Department Date: 11-Apr-2025

References

- SOLAPP0014: Visual and physical inspection.
- VOLWGT0009: Batch manufacturing record.
- ENDO0028: Current edition of USP <85> and EP 2.6.14.
- HAEMO0009: Determined Spectrophotometrically. Current addition of USP <90>.



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- ELECTR0016: Protein Electrophoresis.
- OSMO0020: Freezing Point Depression. Current edition of USP <785> and EP 2.2.35.
- 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.
- WI380002: Cell Line Used Human Diploid Lung Fibroplast (MRC-5), ATCC No. CCL-171 or Human Diploid Lung Fibroplast (WI-38), ATCC No. CCL-75. The growth promotion assay measures the ability of each FBS lot to support proliferation of fastidious human diploid fibroblasts through multiple subcultures.
- PLATE0004: Cell Line Used: Human Carcinoma (A549), ATCC No. CCL-185. Analysis of cellular attachment and proliferation of a human transformed cell line.
- PH0024: Combined Electrode. Current edition of USP <791>.
- ELECTR0017: Protein Electrophoresis.
- ELECTR0018: Protein Electrophoresis.
- ELECTR0019: Protein Electrophoresis.
- RID0002: Radial Immunodiffusion. Current edition of USP <90> modified and EP 2.7.1.
- PROTEI0005: Biuret Method. Current edition of USP <1057> and EP 2.5.33 modified.
- STERI0010: Current edition of USP <71> and EP 2.6.1.
- VIRUS0662: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0017: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0018: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0020: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0019: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0022: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0023: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0024: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0025: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0027: Virus Testing 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.
- VIRUS0026: Virus Testing 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.