



Certificate of Analysis

QC Code: GIBCO

Fetal Bovine Serum, Premium FBS

Lot Number: U2924321RP
Item Number: A56707
Manufacturing Date: MAR 2024
Expiration Date: 2029-03
Storage Temp: <= -10C
Country of Origin: United States

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 - Golden yellow to reddish brown liquid.	SOLAPP0014	Pass	Pass	
Batch Volume	VOLWGT0009	Check and Record	1560.5	L
Biochemical Profile: Alkaline Phosphatase	BP0026	Check and Record	279	u/L
Biochemical Profile: ALT - ALT: Serum Alanine Transaminase.	BP0047	Check and Record	12	u/L
Biochemical Profile: AST - AST: Serum Aspartate Transaminase.	BP0042	Check and Record	71	u/L
Biochemical Profile: Bicarbonate	BP0027	Check and Record	13	MMOL/L
Biochemical Profile: Bilirubin (Total)	BP0028	Check and Record	0.2	mg/dL
Biochemical Profile: BUN - BUN: Blood Urea Nitrogen.	BP0029	Check and Record	14	mg/dL
Biochemical Profile: BUN/Creatinine Ratio	BP0030	Check and Record	5.2	
Biochemical Profile: Calcium	BP0031	Check and Record	14.1	mg/dL
Biochemical Profile: Chloride	BP0032	Check and Record	95	MMOL/L
Biochemical Profile: Cholesterol	BP0033	Check and Record	32	mg/dL
Biochemical Profile: Creatinine	BP0034	Check and Record	2.7	mg/dL
Biochemical Profile: GGPT - GGPT: Gamma Glutamyl Transpeptidase.	BP0035	Check and Record	3	u/L
Biochemical Profile: Glucose	BP0036	Check and Record	124	mg/dL
Biochemical Profile: HDL - HDL: High Density Lipoproteins.	BP0037	Check and Record	12	mg/dL
Biochemical Profile: Iron	BP0048	Check and Record	183	ug/dL
Biochemical Profile: Iron Saturation	BP0049	Check and Record	72	%
Biochemical Profile: LDH - LDH: Lactic Dehydrogenase.	BP0038	Check and Record	571	u/L
Biochemical Profile: LDL - LDL: Low Density Lipoproteins.	BP0039	Check and Record	5	mg/dL
Biochemical Profile: Phosphorous (Inorganic)	BP0040	Check and Record	10.4	mg/dL
Biochemical Profile: Potassium	BP0041	Check and Record	13.1	MMOL/L
Biochemical Profile: Sodium	BP0043	Check and Record	135	MMOL/L
Biochemical Profile: TIBC - TIBC: Total Iron Binding Capacity.	BP0044	Check and Record	253	ug/dL
Biochemical Profile: Triglycerides (TG)	BP0045	Check and Record	78	mg/dL

Biochemical Profile: Uric Acid	BP0046	Check and Record	3.6	mg/dL
Endotoxin	ENDO0028	<=10.00	0.05	EU/mL
Haemoglobin/Hemoglobin	HAEMO0009	<=25.0	14.5	mg/dL
Hormone Profile: Estradiol	HORMON0011	Check and Record	62.70	pg/mL
Hormone Profile: Insulin	HORMON0012	Check and Record	7.99	uIU/mL
Hormone Profile: Progesterone	HORMON0013	Check and Record	<0.06	ng/mL
Hormone Profile: Testosterone	HORMON0014	Check and Record	<0.10	ng/mL
Hormone Profile: Thyroxine (T4)	HORMON0015	Check and Record	12.60	ug/dL
Identification: Bovine Gamma Globulin	RID0001	Bovine	Bovine	
Identification: Electrophoretic Profile	ELECTR0016	Normal	Normal	
<i>- Normal = Electrophoretic profile/pattern is consistent with Fetal Bovine Serum.</i>				
Mycoplasma	MYCO0062	Not Detected	Not Detected	
Mycoplasma: Supplemental Testing (H-Stain)	MYCO0063	Not Detected	Not Detected	
Origin Confirmation	ORICNF0001	Pass	Pass	
<i>- Pass = U.S. or Canadian origin.</i>				
Osmolality	OSMO0020	280 - 340	311	mOsm/kg H2O
Performance: Relative Cloning Efficiency(RCE)	CLON0001	Check and Record	99	%
Performance: Relative Growth Promotion(RGP)	WI380002	Check and Record	103	%
Performance: Relative Plating Efficiency(RPE)	PLATE0004	Check and Record	102	%
pH	PH0024	7.0 - 8.0	7.1	
Protein: Albumin	ELECTR0017	Check and Record	22.3	mg/mL
Protein: Alpha Globulin	ELECTR0018	Check and Record	9.1	mg/mL
Protein: Beta Globulin	ELECTR0019	Check and Record	3.3	mg/mL
Protein: Gamma Globulin	RID0002	<=500	213	mg/L
<i>- <=500mg/L is consistent with Fetal Bovine Serum.</i>				
Protein: Total Protein	PROTEI0005	30.0 - 45.0	36.0	mg/mL
<i>- mg/mL= g/L; mg/mL/10= g/dL.</i>				
Serology: BVDV Serum Neutralisation Titre(Ab)	VIRUS0003	Check and Record	4	
<i>- Neutralisation Titre = Neutralization Titer.</i>				
Sterility: Bacterial and Fungal Testing	STERI0010	No Growth Detected	No Growth Detected	
TSE CEP R1-CEP 2000-089 Revision	DOC0009	Check and Record	Rev. 03	
Virus (9CFR): Bluetongue Virus	VIRUS0016	Not Detected	Not Detected	
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	Not Detected	
<i>- Diarrhoea = Diarrhea.Non Cytopathogenic.</i>				
Virus (9CFR): BRSV	VIRUS0019	Not Detected	Not Detected	
<i>- BRSV: Bovine Respiratory Syncytial Virus.</i>				
Virus (9CFR): Cytopathogenic Agents	VIRUS0022	Not Detected	Not Detected	
<i>- Including Bovine Herpesvirus 1 (BHV-1/IBR).</i>				

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

QUALITY: ISO13485 certified.

REGULATORY: Our manufacturing facilities are regularly inspected and approved by the in-country Competent Authority for the handling, processing, and exporting, of inedible blood products for technical purposes outside of the food chain, to multiple overseas markets.

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).

New Zealand, Australia and USA 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): 3175 Staley Rd, Grand Island, NY 14072. USA

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



Quality Systems Department

Date: 16-May-2024

References

- SOLAPP0014: Visual and physical inspection.
- VOLWGT0009: Batch manufacturing record.
- BP0026: Biochemical Profile testing performed by approved contract laboratory.
- BP0047: Biochemical Profile testing performed by approved contract laboratory.
- BP0042: Biochemical Profile testing performed by approved contract laboratory.
- BP0027: Biochemical Profile testing performed by approved contract laboratory.
- BP0028: Biochemical Profile testing performed by approved contract laboratory.
- BP0029: Biochemical Profile testing performed by approved contract laboratory.
- BP0030: Biochemical Profile testing performed by approved contract laboratory.
- BP0031: Biochemical Profile testing performed by approved contract laboratory.
- BP0032: Biochemical Profile testing performed by approved contract laboratory.
- BP0033: Biochemical Profile testing performed by approved contract laboratory.
- BP0034: Biochemical Profile testing performed by approved contract laboratory.
- BP0035: Biochemical Profile testing performed by approved contract laboratory.
- BP0036: Biochemical Profile testing performed by approved contract laboratory.
- BP0037: Biochemical Profile testing performed by approved contract laboratory.

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- BP0048: Biochemical Profile testing performed by approved contract laboratory.
 - BP0049: Biochemical Profile testing performed by approved contract laboratory.
 - BP0038: Biochemical Profile testing performed by approved contract laboratory.
 - BP0039: Biochemical Profile testing performed by approved contract laboratory.
 - BP0040: Biochemical Profile testing performed by approved contract laboratory.
 - BP0041: Biochemical Profile testing performed by approved contract laboratory.
 - BP0043: Biochemical Profile testing performed by approved contract laboratory.
 - BP0044: Biochemical Profile testing performed by approved contract laboratory.
 - BP0045: Biochemical Profile testing performed by approved contract laboratory.
 - BP0046: Biochemical Profile testing performed by approved contract laboratory.
 - ENDO0028: Current edition of USP <85> and EP 2.6.14.
 - HAEMO0009: Determined Spectrophotometrically. Current addition of USP <90>.
 - HORMON0011: Hormone profile testing performed by approved contract laboratory.
 - HORMON0012: Hormone profile testing performed by approved contract laboratory.
 - HORMON0013: Hormone profile testing performed by approved contract laboratory.
 - HORMON0014: Hormone profile testing performed by approved contract laboratory.
 - HORMON0015: Hormone profile testing performed by approved contract laboratory.
 - RID0001: Radial Immunodiffusion. Current edition of USP <90> modified and EP 2.7.1.
 - ELECTR0016: Protein Electrophoresis.
 - ORICNF0001: Acid digestion, ICP-MS and statistical modelling.
 - 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 Fibroblast (MRC-5), ATCC No. CCL-171 or Human Diploid Lung Fibroblast (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.
 - VIRUS0003: Serum Neutralisation/Neutralization testing performed by approved contract laboratory.
 - STERI0010: Current edition of USP <71> and EP 2.6.1.
 - DOC0009: EDQM Certificate of Suitability for Transmissible Spongiform Encephalopathy Risk. Current edition of EP 5.2.8.
 - VIRUS0016: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.

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- 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.