

Fetal Bovine Serum, Qualified

Lot Number: A2932148CP
Item Number: 10099C
Manufacturing Date: 30 APR 24
Expiration Date: 2029-04
Storage Temp: <= -10C
Country of Origin: Australia

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.	SOLAPP0191	Pass	Pass	
Batch Volume	VOLWGT0025	Check and Record	1746.5	L
Biochemical Profile: Alkaline Phosphatase	BP0109	Check and Record	235	U/L
Biochemical Profile: ALT - ALT: Serum Alanine Transaminase.	BP0110	Check and Record	9	U/L
Biochemical Profile: AST - AST: Serum Aspartate Transaminase.	BP0111	Check and Record	44	U/L
Biochemical Profile: Bicarbonate	BP0112	Check and Record	15	mmol/L
Biochemical Profile: Bilirubin (Total)	BP0113	Check and Record	0.2	mg/dL
Biochemical Profile: BUN - BUN: Blood Urea Nitrogen.	BP0114	Check and Record	16	mg/dL
Biochemical Profile: BUN/Creatinine Ratio	BP0115	Check and Record	6.2	
Biochemical Profile: Calcium	BP0116	Check and Record	13.9	mg/dL
Biochemical Profile: Chloride	BP0117	Check and Record	98	mmol/L
Biochemical Profile: Cholesterol	BP0118	Check and Record	35	mg/dL
Biochemical Profile: Creatinine	BP0119	Check and Record	2.6	mg/dL
Biochemical Profile: GGPT - GGPT: Gamma Glutamyl Transpeptidase.	BP0120	Check and Record	5	U/L
Biochemical Profile: Glucose	BP0121	Check and Record	123	mg/dL
Biochemical Profile: HDL - HDL: High Density Lipoproteins.	BP0122	Check and Record	12	mg/dL
Biochemical Profile: Iron	BP0123	Check and Record	204	ug/dL
Biochemical Profile: Iron Saturation	BP0124	Check and Record	75	%
Biochemical Profile: LDH - LDH: Lactic Dehydrogenase.	BP0125	Check and Record	530	U/L
Biochemical Profile: LDL - LDL: Low Density Lipoproteins.	BP0126	Check and Record	8	mg/dL
Biochemical Profile: Phosphorous (Inorganic)	BP0127	Check and Record	10.1	mg/dL
Biochemical Profile: Potassium	BP0128	Check and Record	12.0	mmol/L
Biochemical Profile: Sodium	BP0129	Check and Record	140	mmol/L
Biochemical Profile: TIBC - TIBC: Total Iron Binding Capacity.	BP0130	Check and Record	272	ug/dL

Biochemical Profile: Triglycerides (TG)	BP0132	Check and Record	76	mg/dL
Biochemical Profile: Uric Acid	BP0133	Check and Record	2.3	mg/dL
Endotoxin	ENDO0102	<=5.00	<0.50	EU/mL
Haemoglobin/Hemoglobin	HAEMO0037	<=30.0	7.4	mg/dL
Hormone Profile: Estradiol	HORMON0027	Check and Record	8.02	pg/mL
Hormone Profile: Insulin	HORMON0028	Check and Record	8.11	uIU/mL
Hormone Profile: Progesterone	HORMON0029	Check and Record	<0.06	ng/mL
Hormone Profile: Testosterone	HORMON0030	Check and Record	<0.01	ng/mL
Hormone Profile: Thyroxine (T4)	HORMON0031	Check and Record	13.80	ug/dL
Identification: Bovine Gamma Globulin	RID0005	Bovine	Bovine	
Identification: Electrophoretic Profile	ELECTR0064	Normal	Normal	
<i>- Normal = Electrophoretic profile/pattern is consistent with Fetal Bovine Serum.</i>				
Mycoplasma	MYCO0059	Not Detected	Not Detected	
Mycoplasma: Supplemental Testing(H-Stain)	MYCO0058	Not Detected	Not Detected	
Origin Confirmation	ORICNF0003	Pass	Pass	
<i>- Pass = Australia origin.</i>				
Osmolality	OSMO0055	280 - 340	317	mOsm/kg H2O
Performance: Relative Cloning Efficiency(RCE)	NZCC0009	Check and Record	82	%
Performance: Relative Growth Promotion(RGP)	NZCC0007	Check and Record	91	%
Performance: Relative Plating Efficiency(RPE)	NZCC0011	Check and Record	94	%
pH	PH0119	7.0 - 8.0	7.3	
Protein: Albumin	ELECTR0058	Check and Record	21.5	mg/mL
Protein: Alpha Globulin	ELECTR0054	Check and Record	12.6	mg/mL
Protein: Beta Globulin	ELECTR0062	Check and Record	3.7	mg/mL
Protein: Gamma Globulin	RID0003	<=500	106	mg/L
<i>- <=500mg/L is consistent with Fetal Bovine Serum.</i>				
Protein: Total Protein	PROTEI0059	30.0 - 45.0	37.8	mg/mL
<i>- mg/mL= g/L; mg/mL/10= g/dL.</i>				
Serology: BVDV Serum Neutralisation Titre(Ab)	VIRUS0382	Check and Record	16	
<i>- Neutralisation Titre = Neutralization Titer.</i>				
Sterility: Bacterial and Fungal Testing	STERI0057	No Growth Detected	No Growth Detected	
TSE CEP R1-CEP 2001-024 Revision	CEP0011	Check and Record	Rev. 03	
Virus (9CFR): Bluetongue Virus	VIRUS0433	Not Detected	Not Detected	
Virus (9CFR): Bovine Adenovirus	VIRUS0428	Not Detected	Not Detected	
Virus (9CFR): Bovine Parvovirus	VIRUS0427	Not Detected	Not Detected	
Virus (9CFR): Bovine Viral Diarrhoea Virus	VIRUS0425	Check and Record	Not Detected	
<i>- Diarrhoea = Diarrhea.Non Cytopathogenic.</i>				
Virus (9CFR): BRSV	VIRUS0434	Not Detected	Not Detected	
<i>- BRSV: Bovine Respiratory Syncytial Virus.</i>				

Virus (9CFR): Cytopathogenic Agents	VIRUS0431	Not Detected	Not Detected
- Including Bovine Herpesvirus 1 (BHV-1/IBR).			
Virus (9CFR): Haemadsorbing Agents	VIRUS0432	Not Detected	Not Detected
- Including Bovine Parainfluenza Virus 3 (PI-3).			
Virus (9CFR): Rabies Virus	VIRUS0429	Not Detected	Not Detected
Virus (9CFR): Reovirus	VIRUS0430	Not Detected	Not Detected

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): 11 Sandringham Ave, Thornton, NSW 2322, Australia.

QUALITY: Thermo Fisher Scientific Australia Pty Ltd is ISO9001 certified.

REGULATORY: Thermo Fisher Scientific Australia Pty Ltd is approved by the Department of Agriculture, Water and the Environment (DAWE) to process inedible products and export to multiple overseas markets including Europe, USA and China.

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.

Notice: Effective 01MAR2019, the specification for this product has changed as per ECR1044965. 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.

Notice: Effective 01JUN2020, the testing method for this product has changed as per ECR1063790. Our approved contract laboratory has updated the method for testing hormone: Estradiol. 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.

Notice: Effective 03NOV2021, a new testing contractor and product test method has been qualified to perform Estradiol testing per ECR1074975. This change will not impact the customer's ability to utilize the purchased product as product form, fit and function will not be affected. All finished products will continue to meet the same specifications established prior to the changes. 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.



Quality Systems Department

Date: 20-Jun-2024

References

- SOLAPP0191: Visual and Physical Inspection.
- VOLWGT0025: Batch Manufacturing Record.
- BP0109: Biochemical Profile testing performed by approved contract laboratory.
- BP0110: Biochemical Profile testing performed by approved contract laboratory.
- BP0111: Biochemical Profile testing performed by approved contract laboratory.

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- BP0112: Biochemical Profile testing performed by approved contract laboratory.
 - BP0113: Biochemical Profile testing performed by approved contract laboratory.
 - BP0114: Biochemical Profile testing performed by approved contract laboratory.
 - BP0115: Biochemical Profile testing performed by approved contract laboratory.
 - BP0116: Biochemical Profile testing performed by approved contract laboratory.
 - BP0117: Biochemical Profile testing performed by approved contract laboratory.
 - BP0118: Biochemical Profile testing performed by approved contract laboratory.
 - BP0119: Biochemical Profile testing performed by approved contract laboratory.
 - BP0120: Biochemical Profile testing performed by approved contract laboratory.
 - BP0121: Biochemical Profile testing performed by approved contract laboratory.
 - BP0122: Biochemical Profile testing performed by approved contract laboratory.
 - BP0123: Biochemical Profile testing performed by approved contract laboratory.
 - BP0124: Biochemical Profile testing performed by approved contract laboratory.
 - BP0125: Biochemical Profile testing performed by approved contract laboratory.
 - BP0126: Biochemical Profile testing performed by approved contract laboratory.
 - BP0127: Biochemical Profile testing performed by approved contract laboratory.
 - BP0128: Biochemical Profile testing performed by approved contract laboratory.
 - BP0129: Biochemical Profile testing performed by approved contract laboratory.
 - BP0130: Biochemical Profile testing performed by approved contract laboratory.
 - BP0132: Biochemical Profile testing performed by approved contract laboratory.
 - BP0133: Biochemical Profile testing performed by approved contract laboratory.
 - ENDO0102: Current edition of USP <85> and EP 2.6.14.
 - HAEMO0037: Determined Spectrophotometrically. Current edition of USP <90>.
 - HORMON0027: Hormone Profile testing performed by approved contract laboratory.
 - HORMON0028: Hormone Profile testing performed by approved contract laboratory.
 - HORMON0029: Hormone Profile testing performed by approved contract laboratory.
 - HORMON0030: Hormone Profile testing performed by approved contract laboratory.
 - HORMON0031: Hormone Profile testing performed by approved contract laboratory.
 - RID0005: Radial Immunodiffusion. Current edition of USP <90> modified and EP 2.7.1.
 - ELECTR0064: Protein Electrophoresis.
 - MYCO0059: Direct Culture. Current edition of USP <63> and EP 2.6.7.
 - MYCO0058: Hoescht Stain. Current edition of USP <63> and EP 2.6.7.
 - ORICNF0003: Acid digestion, ICP-MS and statistical modelling.
 - OSMO0055: Freezing Point Depression. Current edition of USP <785> and EP 2.2.35.
 - NZCC0009: 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.

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- NZCC0007: 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.
 - NZCC0011: Cell Line Used: Human Carcinoma (A549), ATCC No. CCL-185. Analysis of cellular attachment and proliferation of a human transformed cell line.
 - PH0119: Combined Electrode. Current edition of USP <791>.
 - ELECTR0058: Protein Electrophoresis.
 - ELECTR0054: Protein Electrophoresis.
 - ELECTR0062: Protein Electrophoresis.
 - RID0003: Radial Immunodiffusion. Current edition of USP <90> modified and EP 2.7.1.
 - PROTEI0059: Biuret Method. Current edition of USP <1057> and EP 2.5.33.
 - VIRUS0382: Serum Neutralisation/Neutralization testing performed by approved contract laboratory.
 - STERI0057: Current edition of USP <71> and EP 2.6.1.
 - CEP0011: EDQM Certificate of Suitability for Transmissible Spongiform Encephalopathy Risk. Current edition of EP 5.2.8.
 - VIRUS0433: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
 - VIRUS0428: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
 - VIRUS0427: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
 - VIRUS0425: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
 - VIRUS0434: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
 - VIRUS0431: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
 - VIRUS0432: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
 - VIRUS0429: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
 - VIRUS0430: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.