

Certificate of Analysis

QC Code: LTI

Fetal Bovine Serum Value FBS Lot Number:2503996Item Number:A52567Manufacturing Date:25APR2022Expiration Date:APR2027Storage Temp:<= -10C</td>Country of Origin:BRAZIL

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 (Liquid)	SOLAPP0066	Satisfactory	Satisfactory		
- Golden yellow to reddish brown liquid					
Batch Volume	VOLWGT0027	Check and Record	2562.0	L	
Country of Origin	COO0016	Check and Record	Brazil		
Documentation	DOC0014	Check and Record	Satisfactory		
Endotoxin	ENDO0068	0.000 - 20.000	0.092	EU/mL	
Haemoglobin/Hemoglobin	HAEMO0045	0.0 - 25.0	16.1	mg/dL	
Health Certificate Number	MISC0493	Check and Record	00498/CC-MET/22		
Identification: Electrophoretic Profile	ELECTR0089	Normal	Normal		
- Normal = Elecrophoretic profile/pattern is consistent with Fetal Bovine Serum					
Mycoplasma	MYCO0065	Not Detected	Not Detected		
Mycoplasma: Supplemental Testing (H-Stain)	MYCO0066	Not Detected	Not Detected		
Osmolality	OSMO0062	280 - 340	310	mOsm/kg H2O	
Performance: Relative Cloning Efficiency(RCE)	CLON0007	Check and Record	100	%	
Performance: Relative Growth Promotion(RGP)	HDFG0003	Check and Record	90	%	
Performance: Relative Plating Efficiency(RPE)	PLATE0011	Check and Record	108	%	
рН	PH0037	7.0 - 8.0	7.4	pH Units	
Protein: Albumin	ELECTR0086	Check and Record	22.7	mg/mL	
Protein: Alpha Globulin	ELECTR0087	Check and Record	13.6	mg/mL	
Protein: Beta Globulin	ELECTR0088	Check and Record	3.1	mg/mL	
Protein: Gamma Globulin	RID0006	0 - 500	33	mg/L	
- <=500mg/L is consistent with Fetal Bovine Serum					
Protein: Total Protein	PROTEI0073	30.0 - 55.0	39.3	mg/mL	
- mg/ml = g/L; mg/ml/10 = g/dL					
Sterility: Bacterial and Fungal Testing	STERI0060	No Growth Detected	No Growth Detected		
Supplier Lot Number	MISC0492	Check and Record	BIO 22/001		
Virus (9CFR): Bovine Adenovirus	VIRUS0623	Not Detected	Not Detected		
Virus (9CFR): Bovine Parvovirus	VIRUS0622	Not Detected	Not Detected		
Virus (9CFR): Bovine Viral Diarrhoea Virus	VIRUS0619	Check and Record	Not Detected		
- Diarrhoea = Diarrhea. Non cytopathogenic.					
Virus (9CFR): BRSV	VIRUS0626	Not Detected	Not Detected		



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Virus (9CFR): Cytopathogenic Agents	VIRUS0621	Not Detected	Not Detected		
- Including Bovine Herpesvirus	1 (BHV-1/IBR)				
Virus (9CFR): Haemadsorbing Agents	VIRUS0620	Not Detected	Not Detected		
- Including Bovine Parainfluenza Virsu (PI-3)					
Virus (9CFR): Reovirus	VIRUS0625	Not Detected	Not Detected		
Virus (EMA): Bluetongue Virus	VIRUS0627	Not Detected	Not Detected		
Virus (EMA): Rabies Virus	VIRUS0624	Not Detected	Not Detected		

QUALITY: Life Technologies Corporation is ISO13485 certified.

ABATTOIR SOURCED ANIMALS: All fetal bovine blood is collected from fetuses 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).

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): 3 Fountain Drive, Inchinnan Business Park, Paisley, PA4 9RF, Scotland.

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

M. Kodger

Quality Systems Department Date: 01-Jun-2022

References

- VOLWGT0027: Batch manufacturing record.
- DOC0014: BMR review carried out Test Reference
- HAEMO0045: Determined Spectrophotometrically.
- ELECTR0089: Protein Electrophoresis.
- OSMO0062: Freezing Point Depression. Current edition of USP <785> and EP 2.2.35.
- ELECTR0086: Protein Electrophoresis.
- ELECTR0087: Protein Electrophoresis.
- ELECTR0088: Protein Electrophoresis.
- RID0006: Radial Immunodiffusion. Current edition of USP <90> modified and EP 2.7.1.
- PROTEI0073: Biuret Method. Current edition of USP <1057> and EP 2.5.33 modified.
- STERI0060: Current edition of USP <71> and EP 2.6.1.
- VIRUS0623: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0622: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.



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- VIRUS0619: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0626: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0621: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0620: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
- VIRUS0625: Code of Federal Regulations, (CFR), Title 9, Part 113.53 (c) [113.46, 113.47]. Detected by fluorescent antibody.
- VIRUS0627: Modified 9CFR testing in compliance with EMA guidelines
- VIRUS0624: Modified 9CFR testing in compliance with EMA guidelines