CORNING

Certificate of Analysis

Product:	Fetal Bovine Serum	**Description:**	Heat Inactivated Premium, United States Origin
Catalog Number:	35-016-CF, 35-016-CV	**Lot Number:**	16621001
Date of Heat Inactivation:	10 JUN 2021	**Heat Inactivation Type:**	Bulk Tank Inactivation
Testing Performed on:	Heat Inactivated Product	**Heat Inactivation Temperature:**	56°C (±2°C) for 30 minutes
Parent Catalog Number:	N/A	**Parent Lot Number:**	N/A
Date of Manufacture:	11 JUN 2021	**Date of Expiration:**	JUN 2026
Country of Raw Material Origin:	United States	**Country of Final Processing:**	United States
Sterility Assurance Level:	10^{-3} (Triple 0.1 µm Filtered)	**Storage:**	-40°C to -10°C

Test	Method	Specification	Results	Units
Endotoxin	USP <85> & EP 2.6.14	≤ 5.0	<1	EU/mL
Hemoglobin	USP <90>	≤ 25	5.08	mg/dL
Mycoplasma	Barile and Kern & Hoechst Fluorochrome Stain	Not Detected	Not Detected	N/A
Osmolality	USP <785> & EP 2.2.35	260 – 350	311	mOsm/kg H_2O
pH	USP <791> & EP 2.2.3	6.5 – 8.5	7.07	N/A
Sterility (Bacteria & Fungi)	USP <71> & EP 2.6.1	No Growth	No Growth	N/A
Total Protein	USP <1057> & EP 2.5.33	3.0 – 4.5	3.4	g/dL
Gamma-Glutamyl Transferase (GGT)	Chemistry Analyzer	≤ 10	5	IU/L
Cell Growth Performance Testing	MTT Assay	Passed	Passed	N/A
Identification (Species ID)	EP 2.7.1	Bovine	Bovine	N/A
Virus Testing	9 CFR Part 113.53c			
Bluetongue Virus		Not Detected	Not Detected	N/A
Bovine Adenovirus 1 & 5		Not Detected	Not Detected	N/A
Bovine Parvovirus		Not Detected	Not Detected	N/A
Bovine Respiratory Syncytial Virus		Not Detected	Not Detected	N/A
Bovine Viral Diarrhea Virus		As Reported	Not Detected	N/A
Rabies Virus		Not Detected	Not Detected	N/A
Reovirus		Not Detected	Not Detected	N/A
Cytopathogenic Agents (IBR)		Not Detected	Not Detected	N/A
Hemadsorbing Agents (PI3)		Not Detected	Not Detected	N/A
BVDV Serum Neutralization	Alpha Antibody Test			
BVDV Antibody Type 1		As Reported	$10^{4.30}$	$TCID_{50}$/mL
BVDV Antibody Type 2		As Reported	No Neutralization	N/A
Biochemical Testing - Proteins & Organic Compounds				
Alkaline Phosphatase		As Reported	6	IU/L
Blood Urea Nitrogen (BUN)		As Reported	14	mg/dL
Cholesterol		As Reported	29	mg/dL
Creatinine		As Reported	2.4	mg/dL

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1-800-492-1110 www.corning.com

Glucose		As Reported	94	mg/dL
Glutamic Oxaloacetic Transaminase (AST)		As Reported	45	IU/L
Glutamic Pyruvic Transaminase (ALT)		As Reported	6	IU/L
High Density Lipoprotein Cholesterol (HDL)		As Reported	8	mg/dL
Immunoglobulin G (IgG)	ELISA	As Reported	53.6	µg/mL
Low Density Lipoprotein Cholesterol (LDL)		As Reported	7	mg/dL
Total Bilirubin		As Reported	0.2	mg/dL
Triglyceride		As Reported	72	mg/dL
Uric Acid		As Reported	2.5	mg/dL
Biochemical Testing - Electrophoretic Profile	Cellulose Acetate Electrophoresis	Normal	Normal	N/A
Albumin		As Reported	1.9	g/dL
Alpha		As Reported	1.2	g/dL
Beta		As Reported	0.2	g/dL
Gamma		As Reported	0.1	g/dL
Biochemical Testing - Trace Metals				
Calcium		As Reported	13.0	mg/dL
Chloride		As Reported	97	mmol/L
Iron		As Reported	204	µg/dL
Magnesium		As Reported	3.0	mg/dL
Phosphorus		As Reported	9.9	mg/dL
Potassium		As Reported	>10.0	mmol/L
Sodium		As Reported	136	mmol/L
Biochemical Testing - Hormones				
Cortisol		As Reported	<0.20	µg/dL
Insulin		As Reported	3.31	µIU/mL
Progesterone		As Reported	<0.1	ng/mL
Testosterone		As Reported	<0.01	ng/mL
T3		As Reported	106	ng/dL
T4		As Reported	19.0	µg/dL

Notes:

For additional information on this Mediatech product, please contact our Technical Services department at (800) 492-1110 or via email at scientificsupport@corning.com.

This product was tested in accordance with Mediatech, Inc. specifications and procedures current as of date of manufacture. Testing procedures are maintained in compliance with the current versions of the USP and/or EP, where applicable.

Cell lines used in MTT Assay: 3T3, L929, MDCK and Vero. Cell lines used in 9CFR Part 113.53c virus testing: MDBK and Vero.

For research or further manufacturing uses only. Not for use as an excipient. Not for therapeutic or diagnostic uses. Not for human or animal consumption. Utilization of this product apart from the labeled intended use may be a violation of local and/or Federal Law.

Product meets European Union requirements for the production of technical blood products.

This product has been granted a Certificate of Suitability, R0-CEP 2018-271, by the European Directorate for the Quality of Medicines (EDQM) certifying that the product meets the criteria described in the current version of the monograph no. 1483 of the European Pharmacopoeia “Product with risk of transmitting agent of animal spongiform encephalopathies”

Origin and BSE/TSE Statements:

The aforementioned lot was manufactured from fetal bovine blood collected from government approved harvest facilities located in the United States, a country recognized by the United States Department of Agriculture - Animal and Plant Health Inspection Service (USDA-APHIS) and the World Organization for Animal Health (OIE) as having a negligible risk of Bovine Spongiform Encephalopathy (BSE), a bovine-specific Transmissible Spongiform Encephalopathy (TSE). All fetal bovine serum is derived from fetuses collected from healthy bovine cows and heifers that have passed ante and post mortem inspection and were found free of contagious diseases.

The following signatures indicate the above material has met all quality specifications and has been reviewed by a Quality representative.

Written By/Date: 29 JUL 2021 Reviewed By/Date: 29 JUL 2021