## CORNING

## **Certificate of Analysis**

**Product:** 

Fetal Bovine Serum

Description:

Charcoal Dextran Stripped

Premium,

United States Origin

**Catalog Number:** 

35-072-CF, 35-072-CV

Lot Number:

35072109

**Date of Manufacture:** 

29 JUN 2019

Date of Expiration:

JUN 2024

**Country of Raw Material** 

Origin:

**United States** 

Country of Final Processing:

**United States** 

**Sterility Assurance** 

Level:

 $10^{-3}$  (Triple 0.1  $\mu m$ 

Filtered)

Storage:

-40°C to -10°C

Test	Method	Specification	Results	Units
Endotoxin	USP <85>	≤ 5.0	<0.1	EU/mL
Hemoglobin	Fleming and Woolf	≤ 25	6.49	mg/dL
Mycoplasma	Barile and Kern & Hoechst Fluorochrome Stain	Not Detected	Not Detected	N/A
Osmolality	USP <785>	260 - 350	289	mOsm/kg H₂O
pH	USP <791>	6.5 - 8.5	7.42	N/A
Sterility (Bacteria & Fungi)	USP <71> & EP 2.6.1	No Growth	No Growth	N/A
Total Protein	USP <1057>	3.0 - 4.5	3.2	g/dL
Gamma-Glutamyl Transferase (GGT)	Chemistry Analyzer	≤ 10	3	IU/L
Cell Growth Performance Testing	MTT Assay	Passed	Passed	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	No Neutralization	N/A
BVDV Antibody Type 2		As Reported	No Neutralization	N/A
Biochemical Testing - Proteins & Organic Compou	nds			
Alkaline Phosphatase		As Reported	180	IU/L
Blood Urea Nitrogen (BUN)		As Reported	16	mg/dL
Cholesterol		As Reported	31	mg/dL
Creatinine		As Reported	0.0	mg/dL
Glucose		As Reported	77	mg/dL
Glutamic Oxaloacetic Transaminase (AST)		As Reported	28	IU/L
Glutamic Pyruvic Transaminase (ALT)		As Reported	5	IU/L
High Density Lipoprotein Cholesterol (HDL)		As Reported	8	mg/dL
Immunoglobulin G (IgG)	ELISA	As Reported	56.6	µg/mL
Low Density Lipoprotein Cholesterol (LDL)		As Reported	12	mg/dL
Total Bilirubin		As Reported	0.0	mg/dL
Triglyceride		As Reported	57	mg/dL
Uric Acid		As Reported	0.0	mg/dL

Biochemical Testing - Electrophoretic Profile	Cellulose Acetate Electrophoresis	Normal	Normal	N/A
Albumin		As Reported	1.7	g/dL
Alpha 1, 2		As Reported	1.1	g/dL
Beta		As Reported	0.3	g/dL
Gamma		As Reported	0.1	g/dL
Biochemical Testing - Trace Metals				
Calcium		As Reported	11.6	mg/dL
Chloride		As Reported	97	mmol/L
Iron		As Reported	147	μg/dL
Magnesium		As Reported	2.8	mg/dL
Phosphorus		As Reported	9.0	mg/dL
Potassium		As Reported	9.9	mmol/L
Sodium		As Reported	135	mmol/L
Biochemical Testing - Hormones				
Cortisol		As Reported	<0.20	μg/dL
Estradiol		As Reported	22.2	pg/mL
Insulin		As Reported	<2.36	μIU/mL
Progesterone		As Reported	<0.1	ng/mL
Testosterone		As Reported	<0.01	ng/mL
Т3		As Reported	<10.0	ng/dL
T4		As Reported	7.0	μg/dL

## Notes:

For additional information on this Mediatech product, please contact our Technical Services department at (800) 235-5476 or via email at MTTechServ@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, MDBK 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.

## 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:

144467019

Reviewed By/Date:



Lot Number: 35072109