## CORNING

## **Certificate of Analysis**

Heat Inactivated Product: Fetal Bovine Serum **Description:** 

Premium,

**United States Origin** 

**Catalog Number:** 35-016-CF, 35-016-CV Lot Number: 29921001

Date of Heat **Heat Inactivation** 12 OCT 2021 Inactivation:

Type:

**Bulk Tank Inactivation** 

**United States** 

Heat Inactivated **Heat Inactivation** 56°C (±2°C) for 30 **Testing Performed on:** 

Product **Temperature:** minutes

**Parent Catalog Number:** N/A Parent Lot Number: N/A

**Date of Manufacture:** 13 OCT 2021 **Date of Expiration: OCT 2026** 

**Country of Raw Material Country of Final United States** Origin:

**Processing:** 

**Sterility Assurance** 10<sup>-3</sup> (Triple 0.1 μm -40°C to -10°C Storage: Level: Filtered)

Test Method **Specification** Results Units Endotoxin USP <85> & EP 2.6.14 ≤ 5.0 EU/mL <1 ≤ 25 Hemoglobin USP <90> 6.76 mg/dL Barile and Kern & Mycoplasma Not Detected Not Detected N/A Hoechst Fluorochrome Stain 260 - 350300 Osmolality USP <785> & EP 2.2.35 mOsm/kg H<sub>2</sub>O USP <791> & EP 2.2.3 6.5 - 8.57.16 pΗ N/A Sterility (Bacteria & Fungi) No Growth USP <71> & EP 2.6.1 No Growth N/A **Total Protein** USP <1057> & EP 2.5.33 3.0 - 4.53.5 g/dL Gamma-Glutamyl Transferase (GGT) Chemistry Analyzer ≤ 10 5 IU/L Cell Growth Performance Testing Passed N/A MTT Assay Passed EP 2.7.1 Bovine Bovine N/A Identification (Species ID) 9 CFR Part 113.53c Virus Testing 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 Not Detected N/A As Reported Rabies Virus Not Detected Not Detected N/A Reovirus Not Detected N/A Not Detected Cytopathogenic Agents (IBR) Not Detected Not Detected N/A Hemadsorbing Agents (PI3) Not Detected N/A Not Detected **BVDV Serum Neutralization** Alpha Antibody Test **BVDV Antibody Type 1** As Reported  $10^{2.95}$ TCID<sub>50</sub>/mL **BVDV** Antibody Type 2 As Reported No Neutralization N/A Biochemical Testing - Proteins & Organic Compounds IU/L Alkaline Phosphatase As Reported 5 Blood Urea Nitrogen (BUN) As Reported mg/dL 14 Cholesterol As Reported mg/dL 29 Creatinine mg/dL As Reported 2.7

Glucose		As Reported	92	mg/dL
Glutamic Oxaloacetic Transaminase (AST)		As Reported	37	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	57.6	μg/mL
Low Density Lipoprotein Cholesterol (LDL)		As Reported	8	mg/dL
Total Bilirubin		As Reported	0.2	mg/dL
Triglyceride		As Reported	67	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	1.3	g/dL
Beta		As Reported	0.2	g/dL
Gamma		As Reported	0.1	g/dL
Biochemical Testing - Trace Metals				
Calcium		As Reported	13.2	mg/dL
Chloride		As Reported	99	mmol/L
Iron		As Reported	196	μg/dL
Magnesium		As Reported	3.1	mg/dL
Phosphorus		As Reported	9.7	mg/dL
Potassium		As Reported	>10.0	mmol/L
Sodium		As Reported	137	mmol/L
Biochemical Testing - Hormones				
Cortisol		As Reported	<0.20	μg/dL
Insulin		As Reported	3.65	μIU/mL
Progesterone		As Reported	<0.1	ng/mL
Testosterone		As Reported	<0.01	ng/mL
T3		As Reported	108	ng/dL
T4		As Reported	18.0	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.

Lot Number: 29921001

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



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