CORNING

Certificate of Analysis

Product:	Fetal Bovine Serum	**Description:**	Heat Inactivated Gamma Irradiated Premium, New Zealand Origin
Catalog Number:	35-108-CV	**Lot Number:**	10221003
Date of Heat Inactivation:	12 APR 2021	**Date of Gamma Irradiation:**	14 JUL 2021
Heat Inactivation Type:	Individual Bottle Inactivation	**Minimum Specified Dose:**	25 kGy
Heat Inactivation Temperature:	56°C (±2°C) for 30 minutes	**Maximum Specified Dose:**	40 kGy
Testing Performed on:	Product Prior to Gamma Irradiation* and Heat Inactivation		

Parent Catalog Number:	35-098-CV	**Parent Lot Number:**	16720009
Grandparent Catalog Number:	35-078-CV	**Grandparent Lot Number:**	35078001
Date of Grandparent Lot Manufacture:	NOV 2018	**Date of Expiration:**	NOV 2024
Country of Raw Material Origin:	New Zealand	**Country of Final Processing:**	New Zealand
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	<1.00	EU/mL
Hemoglobin	USP <90>	≤ 25	11	mg/dL
Mycoplasma	Barile and Kern & Hoechst Fluorochrome Stain	Not Detected	Not Detected	N/A
Osmolality	USP <785> & EP 2.2.35	260 – 350	313	mOsm/kg H_2O
pH	USP <791> & EP 2.2.3	6.5 – 8.5	7.15	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	4	g/dL
Gamma-Glutamyl Transferase (GGT)	Chemistry Analyzer	≤ 10	9	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

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Cytopathogenic Agents (IBR)		Not Detected	Not Detected	N/A
Hemadsorbing Agents (PI3)		Not Detected	Not Detected	N/A
Biochemical Testing - Proteins & Organic Compounds				
Alkaline Phosphatase		As Reported	238	IU/L
Cholesterol		As Reported	27.07	mg/dL
Creatinine		As Reported	3.0	mg/dL
Glucose		As Reported	151.3	mg/dL
Glutamic Oxaloacetic Transaminase (AST)		As Reported	46	IU/L
Glutamic Pyruvic Transaminase (ALT)		As Reported	11	IU/L
Immunoglobulin G (IgG)	ELISA	As Reported	64.6	µg/mL
Total Bilirubin		As Reported	0.35	mg/dL
Triglyceride		As Reported	44.29	mg/dL
Biochemical Testing - Electrophoretic Profile	Cellulose Acetate Electrophoresis	Normal	Normal	N/A
Albumin		As Reported	2.28	g/dL
Alpha 1, 2		As Reported	1.30	g/dL
Beta		As Reported	0.36	g/dL
Gamma		As Reported	0.05	g/dL
Biochemical Testing - Trace Metals				
Calcium		As Reported	13.43	mg/dL
Chloride		As Reported	98	mmol/L
Potassium		As Reported	11.1	mmol/L
Sodium		As Reported	138	mmol/L

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.

Minimum gamma irradiation dose delivered: 25.5 kGy. Maximum gamma irradiation dose delivered: 33.7 kGy.

*Testing above was performed prior to gamma irradiation and heat inactivation; however, if BVD virus was detected prior to irradiation the results reported are post-irradiation.

Cell lines used: MDBK, MRC-5 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 treated technical blood products. Treatment: Irradiation at a minimum of 25 kGy by gamma rays.

Origin and BSE/TSE Statements:

The aforementioned lot was manufactured from fetal bovine blood collected from government approved harvest facilities located in New Zealand, 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. This material was imported into the United States under a USDA/APHIS issued import permit.

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

Written By/Date: 30 APR 2021 Reviewed By/Date: 04 MAY 2021