

<b>Product:</b>	Fetal Bovine Serum	<b>Description:</b>	Heat Inactivated Gamma Irradiated Premium, New Zealand Origin
<b>Catalog Number:</b>	35-108-CV	<b>Lot Number:</b>	08321001
<b>Date of Heat Inactivation:</b>	24 MAR 2021	<b>Date of Gamma Irradiation:</b>	14 JUL 2020
<b>Heat Inactivation Type:</b>	Individual Bottle Inactivation	<b>Minimum Specified Dose:</b>	25 kGy
<b>Heat Inactivation Temperature:</b>	56°C (±2°C) for 30 minutes	<b>Maximum Specified Dose:</b>	40 kGy
<b>Testing Performed on:</b>	Product Prior to Gamma Irradiation* and Heat Inactivation		

<b>Parent Catalog Number:</b>	35-098-CV	<b>Parent Lot Number:</b>	16020002
<b>Grandparent Catalog Number:</b>	35-078-CV	<b>Grandparent Lot Number:</b>	05020001
<b>Date of Grandparent Lot Manufacture:</b>	AUG 2018	<b>Date of Expiration:</b>	AUG 2024
<b>Country of Raw Material Origin:</b>	New Zealand	<b>Country of Final Processing:</b>	New Zealand
<b>Sterility Assurance Level:</b>	10 <sup>-3</sup> (Triple 0.1 µm Filtered)	<b>Storage:</b>	-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	15	mg/dL
Mycoplasma	Barile and Kern & Hoechst Fluorochrome Stain	Not Detected	Not Detected	N/A
Osmolality	USP <785> & EP 2.2.35	260 – 350	305	mOsm/kg H <sub>2</sub> O
pH	USP <791> & EP 2.2.3	6.5 – 8.5	7.4	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	3.6	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
Cytopathogenic Agents (IBR)		Not Detected	Not Detected	N/A
Hemadsorbing Agents (PI3)		Not Detected	Not Detected	N/A
<b>Biochemical Testing - Proteins &amp; Organic Compounds</b>				
Alkaline Phosphatase		As Reported	199	IU/L
Cholesterol		As Reported	34.8	mg/dL
Creatinine		As Reported	2.1	mg/dL
Glucose		As Reported	75.7	mg/dL
Glutamic Oxaloacetic Transaminase (AST)		As Reported	80	IU/L
Glutamic Pyruvic Transaminase (ALT)		As Reported	15	IU/L
Immunoglobulin G (IgG)	ELISA	As Reported	34.7	µg/mL
Total Bilirubin		As Reported	0.4	mg/dL
Triglyceride		As Reported	53.1	mg/dL
Uric Acid		As Reported	2.0	mg/dL
<b>Biochemical Testing - Electrophoretic Profile</b>				
	Cellulose Acetate Electrophoresis	Normal	Typical	N/A
Albumin		As Reported	2.0	g/dL
Alpha		As Reported	1.2	g/dL
Beta		As Reported	0.4	g/dL
Gamma		As Reported	0.1	g/dL
<b>Biochemical Testing - Trace Metals</b>				
Calcium		As Reported	13.4	mg/dL
Chloride		As Reported	97	mmol/L
Phosphorus		As Reported	37.5	mg/dL
Potassium		As Reported	12.1	mmol/L
Sodium		As Reported	134	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](mailto: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 in MTT Assay: MDBK, MRC-5, Vero and Hybridoma.

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:

*J. He*

02 APR 2021

Reviewed By/Date:

*Michael Murray*

02 APR 2021

