

Product:	Fetal Bovine Serum	Description:	Heat Inactivated Gamma Irradiated Premium, New Zealand Origin
Catalog Number:	35-108-CV	Lot Number:	32519006
Date of Heat Inactivation:	26 NOV 2019	Date of Gamma Irradiation:	10 DEC 2019
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:	35-081-CV	Parent Lot Number:	35081005
Grandparent Catalog Number:	N/A	Grandparent Lot Number:	N/A
Date of Parent Lot Manufacture:	AUG 2018	Date of Expiration:	AUG 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	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 ₂ 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		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 ^{3.30}	TCID ₅₀ /mL
BVDV Antibody Type 2		As Reported	No Neutralization	N/A
Biochemical Testing - Proteins & Organic Compounds				
Alkaline Phosphatase		As Reported	199	IU/L
Blood Urea Nitrogen (BUN)		As Reported	19.4	mg/dL
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
High Density Lipoprotein Cholesterol (HDL)		As Reported	10	mg/dL
Immunoglobulin G (IgG)	ELISA	As Reported	34.7	µg/mL
Low Density Lipoprotein Cholesterol (LDL)		As Reported	9	mg/dL
Total Bilirubin		As Reported	0.4	mg/dL
Triglyceride		As Reported	53.1	mg/dL
Uric Acid		As Reported	2.0	mg/dL
Biochemical Testing - Electrophoretic Profile	Agarose Gel Electrophoresis	Normal	Normal	N/A
Albumin		As Reported	2.01	g/dL
Alpha		As Reported	1.18	g/dL
Beta		As Reported	0.36	g/dL
Gamma		As Reported	0.05	g/dL
Biochemical Testing - Trace Metals				
Calcium		As Reported	13.4	mg/dL
Chloride		As Reported	97	mmol/L
Iron		As Reported	239	µg/dL
Magnesium		As Reported	3.3	mg/dL
Phosphorus		As Reported	10.1	mg/dL
Potassium		As Reported	12.1	mmol/L
Sodium		As Reported	134	mmol/L
Biochemical Testing - Hormones				
Cortisol		As Reported	< 0.2	µg/dL
Estradiol		As Reported	37.6	pg/mL
Insulin		As Reported	5.99	µIU/mL
Progesterone		As Reported	< 0.1	ng/mL
Testosterone		As Reported	< 0.01	ng/mL
T3		As Reported	112	ng/dL
T4		As Reported	13.0	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.

Minimum gamma irradiation dose delivered: 26.1 kGy. Maximum gamma irradiation dose delivered: 34.0 kGy. Testing above was performed prior to gamma irradiation and heat inactivation. Additional testing performed after gamma irradiation is available upon request and will be recorded on a separate manufacturer declaration.

Cell lines used in MTT Assay: 3T3, L-929, 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.

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.

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

Written By/Date: *Daniel Hu* 17DEC2019 Reviewed By/Date: *Dorothy Fogearley* 17DEC2019

