Mediatech, Inc.

A Corning Subsidiary

Certificate of Analysis

Product: Fetal Bovine Serum

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Description: Premium, United Sta

United States Origin Tetracycline Negative

Catalog Number:

35-075-CV

35075108

Date of Manufacture:

28 FEB 2018

Date of Expiration: 28 FEB 2023

Country of Raw

United States

Country of Final Processing:

Lot Number:

United States

Material Origin: Triple 0.1 µm Filtered:

Sterility Assurance Level:

Storage:

-25°C to -15°C

Test	Method	Specification	Results	Units
Sterility (Bacteria & Fungi)	USP <71> EP 2.6.1	No Growth No Growth	No Growth	N/A N/A
Endotoxin	USP <85>	≤ 5	< 0.1	EU/mL
Mycoplasma	Barile and Kern Hoechst Fluorochrome Stain	Not Detected Not Detected	Not Detected	N/A N/A
pH	USP <791>	7.0 - 8.0	7.3	N/A
Osmolality	USP <785>	280 - 350	303	mOsm/kg H2C
Tetracycline	AOAC 995.09	Not Detected	Not Detected	N/A
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	1.59	TCID ₅₀ /mL
Rabies Virus		Not Detected	Not Detected	N/A
Reovirus		Not Detected	Not Detected	N/A
Cytopathogenic Agents (IBR)		Not Detected	Not Detected	N/A
Hemadsorption Agents (PI3)		Not Detected	Not Detected	N/A
BVDV Serum Neutralization	Alpha Antibody Test			
BVDV Antibody Type 1		As Reported	10 ^{2.30}	TCID ₅₀ /mL
BVDV Antibody Type 2		As Reported	No Neutralization	TCID ₅₀ /mL
Proteins / Other Alkaline Phosphatase		As Reported	256	IU/L
Blood Urea Nitrogen (BUN)		As Reported	13	mg/dL
Cholesterol		As Reported	29	mg/dL
Creatinine		As Reported	2.2	mg/dL
Gamma-Glutamyl Transferase (GGT)		As Reported	4	IU/L
Glucose		As Reported	89	mg/dL
Glutamic Oxaloacetic Transaminase (AST)		As Reported	71	IU/L
Glutamic Pyruvic Transaminase (ALT)		As Reported	7	IU/L



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	High Density Lipoprotein Cholesterol (HDL) Immunoglobulin G (IgG) Low Density Lipoprotein Cholesterol (LDL) Total Bilirubin Total Protein Triglyceride Uric Acid	ELISA USP <1057>	As Reported As Reported As Reported As Reported 3.0 -5.0 As Reported As Reported	8 68.1 7 0.3 3.2 71 2.3	mg/dL µg/mL mg/dL mg/dL g/dL mg/dL mg/dL
Elec	ctrophoretic Profile	Cellulose Acetate Electrophoresis	Normal	Normal	N/A
	Albumin	•	As Reported	1.8	g/dL
	Alpha 1,2		As Reported	1.1	g/dL
	Beta 1,2		As Reported	0.2	g/dL
	Gamma 1,2		As Reported	0.1	g/dL
Trac	ce Metals		1	• • • • • • • • • • • • • • • • • • • •	3
	Calcium		As Reported	12.6	mg/dL
	Chloride		As Reported	94	mEq/L
	Iron		As Reported	193	μg/dL
	Magnesium		As Reported	3.0	mg/dL
	Phosphorus		As Reported	10.1	mg/dL
	Potassium		As Reported	> 10.0	mEg/L
	Sodium		As Reported	130	mEq/L
Hor	mones				•
	Cortisol		As Reported	< 0.20	μg/dL
	Estradiol		As Reported	< 15	pg/mL
	Insulin		As Reported	< 2.36	μlU/mL
	Progesterone		As Reported	< 0.2	ng/mL
	Testosterone		As Reported	< 0.01	ng/mL
	T3		As Reported	77.8	ng/dL
	T4		As Reported	10.0	μg/dL

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

Notes:

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. 0.001 mg/dL is the detection limit for the AOAC 995.09 tetracycline test used.

This product was manufactured from fetal bovine whole blood collected from USDA approved harvest facilities. 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. All harvest facilities are USDA Inspected and located within the continental United States.

For research and further manufacturing use only. Not for use as an excipient. Not for therapeutic or diagnostic use. 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.

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

Written By/Date:

12 01 NOV 2018

Reviewed By/Date:

0100 × 2016



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