CORNING

Certificate of Analysis

Product:	Fetal Bovine Serum	**Description:**	Heat Inactivated Premium, United States Origin
Catalog Number:	35-016-CV	**Lot Number:**	11420002
Date of Heat Inactivation:	23 APR 2020	**Heat Inactivation Type:**	Individual Bottle Inactivation
Testing Performed on:	Product Prior to Heat Inactivation	**Heat Inactivation Temperature:**	56°C (±2°C) for 30 minutes
Parent Catalog Number:	35-015-CV	**Parent Lot Number:**	35015169
Date of Parent Lot Manufacture:	19 APR 2019	**Date of Expiration:**	30 APR 2024
Country of Raw Material Origin:	United States	**Country of Final Processing:**	United States
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	<0.1	EU/mL
Hemoglobin	USP <90>	≤ 25	14.24	mg/dL
Mycoplasma	Barile and Kern & Hoechst Fluorochrome Stain	Not Detected	Not Detected	N/A
Osmolality	USP <785> & EP 2.2.35	260 – 350	298	mOsm/kg H_2O
pH	USP <791> & EP 2.2.3	6.5 – 8.5	7.28	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	5	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
BVDV Serum Neutralization	Alpha Antibody Test			
BVDV Antibody Type 1		As Reported	$10^{3.20}$	$TCID_{50}$/mL
BVDV Antibody Type 2		As Reported	No Neutralization	N/A
Biochemical Testing - Proteins & Organic Compounds				
Alkaline Phosphatase		As Reported	284	IU/L
Blood Urea Nitrogen (BUN)		As Reported	15	mg/dL
Cholesterol		As Reported	26	mg/dL
Creatinine		As Reported	2.8	mg/dL

Mediatech, Inc. DBA J R Scientific
1242 Commerce Ave. Woodland, CA 95776
1-800-492-1110 www.corning.com

Glucose		As Reported	154	mg/dL
Glutamic Oxaloacetic Transaminase (AST)		As Reported	57	IU/L
Glutamic Pyruvic Transaminase (ALT)		As Reported	7	IU/L
High Density Lipoprotein Cholesterol (HDL)		As Reported	9	mg/dL
Immunoglobulin G (IgG)	ELISA	As Reported	40.5	µg/mL
Low Density Lipoprotein Cholesterol (LDL)		As Reported	2	mg/dL
Total Bilirubin		As Reported	0.2	mg/dL
Triglyceride		As Reported	73	mg/dL
Uric Acid		As Reported	3.6	mg/dL
Biochemical Testing - Electrophoretic Profile	Cellulose Acetate Electrophoresis	Normal	Normal	N/A
Albumin		As Reported	2.0	g/dL
Alpha		As Reported	1.2	g/dL
Beta		As Reported	0.3	g/dL
Gamma		As Reported	0.1	g/dL
Biochemical Testing - Trace Metals				
Calcium		As Reported	12.8	mg/dL
Chloride		As Reported	97	mmol/L
Iron		As Reported	172	µg/dL
Magnesium		As Reported	3.2	mg/dL
Phosphorus		As Reported	9.9	mg/dL
Potassium		As Reported	>10.0	mmol/L
Sodium		As Reported	137	mmol/L
Biochemical Testing - Hormones				
Cortisol		As Reported	0.299	µg/dL
Estradiol		As Reported	38.5	pg/mL
Insulin		As Reported	6.02	µIU/mL
Progesterone		As Reported	<0.1	ng/mL
Testosterone		As Reported	<0.01	ng/mL
T3		As Reported	189	ng/dL
T4		As Reported	10.0	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, MDBK, 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.

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

Written By/Date: 01 MAY 2020 Reviewed By/Date: 01 MAY 2020

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2018-271-Rev 00

Name of the substance:
FOETAL BOVINE SERUM

Name of holder:
MEDIATECH INC
9345 Discovery Boulevard
United States Am.-20109 Manassas, Virginia

Site(s) of production:
MEDIATECH INC. DBA VACCA BIOLOGICS
994 South Mudline road
United States Am.-62966 Murphysboro, Illinois

MEDIATECH INC. DBA JR SCIENTIFIC
1242 Commerce Avenue
United States Am.-95776 Woodland, California

After examination of the information provided on the origin of raw material(s) and type of tissue(s) used and on the manufacturing process for this substance on the site(s) of production mentioned above, we certify that the substance **FOETAL BOVINE SERUM** meets the criteria described in the current version of the monograph Products with risk of transmitting agents of animal spongiform encephalopathies no. 1483 of the European Pharmacopoeia, current edition including supplements.

- Country of origin of source materials:
  United States of America

- Nature of animal tissues used in manufacture:
  Foetal bovine blood

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance, or that may alter the risk of transmitting animal spongiform encephalopathy agents.

Manufacture of the substance shall take place in accordance with a suitable quality assurance system, and in accordance with the dossier submitted.

Failure to comply with these provisions will render this certificate void.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu

The certificate is valid provided that there has been no deterioration in the TSE status of the country(ies) of origin of the source material.

This certificate is granted within the framework of the procedure established by the European Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from **26 July 2019**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 26 July 2019

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

MEDIATECH INC, as holder of the certificate of suitability

R0-CEP 2018-271-Rev 00 for Foetal Bovine Serum

hereby authorises .....
(*name of the pharmaceutical company*)

to use the above-mentioned certificate of suitability in support of their application(s) for the following Marketing Authorisation(s): (*name of product(s) and marketing number(s), if known*)

The holder also certifies that no significant changes to the operations as described in the CEP dossier have been made since the granting of this version of the certificate.

Date and Signature (*of the CEP holder*):

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu