

|                                   |                                       |                                       |  |
|-----------------------------------|---------------------------------------|---------------------------------------|--|
| <b>Product:</b>                   | Fetal Bovine Serum                    | <b>Description:</b>                   | Heat Inactivated<br>Premium,<br>United States Origin |
| <b>Catalog Number:</b>            | 35-016-CV                             | <b>Lot Number:</b>                    | 27019002   |
| <b>Date of Heat Inactivation:</b> | 30 SEP 2019                           | <b>Heat Inactivation Type:</b>        | Individual Bottle<br>Inactivation                    |
| <b>Testing Performed on:</b>      | Product Prior to Heat<br>Inactivation | <b>Heat Inactivation Temperature:</b> | 56°C (±2°C) for 30<br>minutes                        |

|  |  |                                     |                |
|--|--|-------------------------------------|----------------|
| <b>Parent Catalog Number:</b>          | 35-015-CV                                    | <b>Parent Lot Number:</b>           | 35015171       |
| <b>Date of Parent Lot Manufacture:</b> | 31 JAN 2018                                  | <b>Date of Expiration:</b>          | JAN 2023       |
| <b>Country of Raw Material Origin:</b> | United States                                | <b>Country of Final Processing:</b> | United States  |
| <b>Sterility Assurance Level:</b>      | 10 <sup>-3</sup> (Triple 0.1 µm<br>Filtered) | <b>Storage:</b>                     | -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          | 16.46              | mg/dL                    |
| Mycoplasma   | Barile and Kern &<br>Hoechst Fluorochrome Stain | Not Detected  | Not Detected       | N/A                      |
| Osmolality   | USP <785> & EP 2.2.35                           | 260 – 350     | 301                | mOsm/kg H <sub>2</sub> O |
| pH   | USP <791> & EP 2.2.3                            | 6.5 – 8.5     | 7.22               | 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     | 3.4                | g/dL                     |
| Gamma-Glutamyl Transferase (GGT)                   | Chemistry Analyzer                              | ≤ 10          | 4                  | 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   | 1.0                | TCID <sub>50</sub> /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                      |
| Hemadsorbing Agents (PI3)                          |   | Not Detected  | Not Detected       | N/A                      |
| BVDV Serum Neutralization                          | Alpha Antibody Test                             |               |                    |                          |
| BVDV Antibody Type 1                               |   | As Reported   | 10 <sup>2.70</sup> | TCID <sub>50</sub> /mL   |
| BVDV Antibody Type 2                               |   | As Reported   | No Neutralization  | N/A                      |
| Biochemical Testing - Proteins & Organic Compounds |   |               |                    |                          |
| Alkaline Phosphatase                               |   | As Reported   | 210                | IU/L                     |
| Blood Urea Nitrogen (BUN)                          |   | As Reported   | 14                 | mg/dL                    |
| Cholesterol  |   | As Reported   | 30                 | mg/dL                    |
| Creatinine   |   | As Reported   | 2.4                | mg/dL                    |

|   |                                   |             |        |        |
|---|-----------------------------------|-------------|--------|--------|
| Glucose                                       |                                   | As Reported | 109    | mg/dL  |
| Glutamic Oxaloacetic Transaminase (AST)       |                                   | As Reported | 82     | IU/L   |
| Glutamic Pyruvic Transaminase (ALT)           |                                   | As Reported | 9      | IU/L   |
| High Density Lipoprotein Cholesterol (HDL)    |                                   | As Reported | 8      | mg/dL  |
| Immunoglobulin G (IgG)                        | ELISA                             | As Reported | 118.8  | µg/mL  |
| Low Density Lipoprotein Cholesterol (LDL)     |                                   | As Reported | 8      | mg/dL  |
| Total Bilirubin                               |                                   | As Reported | 0.3    | mg/dL  |
| Triglyceride                                  |                                   | As Reported | 70     | mg/dL  |
| Uric Acid                                     |                                   | As Reported | 2.4    | mg/dL  |
| Biochemical Testing - Electrophoretic Profile | Cellulose Acetate Electrophoresis | Normal      | Normal | N/A    |
| Albumin                                       |                                   | As Reported | 1.9    | 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 | 13.0   | mg/dL  |
| Chloride                                      |                                   | As Reported | 96     | mmol/L |
| Iron  |                                   | As Reported | 187    | µg/dL  |
| Magnesium                                     |                                   | As Reported | 3.2    | mg/dL  |
| Phosphorus                                    |                                   | As Reported | 10.3   | mg/dL  |
| Potassium                                     |                                   | As Reported | >10.0  | mmol/L |
| Sodium  |                                   | As Reported | 134    | mmol/L |
| Biochemical Testing - Hormones                |                                   |             |        |        |
| Cortisol                                      |                                   | As Reported | <0.2   | µg/dL  |
| Estradiol                                     |                                   | As Reported | 42.0   | pg/mL  |
| Insulin                                       |                                   | As Reported | 7.03   | µIU/mL |
| Progesterone                                  |                                   | As Reported | <0.1   | ng/mL  |
| Testosterone                                  |                                   | As Reported | <0.01  | ng/mL  |
| T3  |                                   | As Reported | 128    | ng/dL  |
| T4  |                                   | As Reported | 9.0    | µg/dL  |

#### Notes:

For additional information on this Mediatech product, please contact our Technical Services department at (800) 235-5476 or via email at [MTTechServ@corning.com](mailto:MTTechServ@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: BT 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: *J. Hu* 08 OCT 2019

Reviewed By/Date: *Dorah Fogarty* 08 OCT 2019



**Certification of Substances Department**

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

1 *Name of the substance:*

2 **FOETAL BOVINE SERUM**

3 *Name of holder:*

4 **MEDIATECH INC**

5 9345 Discovery Boulevard

6 United States Am.-20109 Manassas, Virginia

7 *Site(s) of production:*

8 **MEDIATECH INC. DBA VACCA BIOLOGICS**

9 994 South Mudline road

10 United States Am.-62966 Murphysboro, Illinois

11 **MEDIATECH INC. DBA JR SCIENTIFIC**

12 1242 Commerce Avenue

13 United States Am.-95776 Woodland, California

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

20 – Country of origin of source materials:

21 United States of America

22 – Nature of animal tissues used in manufacture:

23 Foetal bovine blood

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

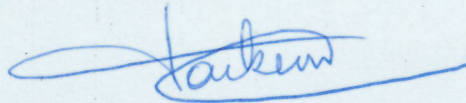
27 Manufacture of the substance shall take place in accordance with a suitable quality assurance  
28 system, and in accordance with the dossier submitted.

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

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

32 This certificate is granted within the framework of the procedure established by the European  
33 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from  
34 **26 July 2019**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and  
35 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

36 This certificate has:  
37 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)*: