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|--|--|---------------------------------------|--|
| Product: | Fetal Bovine Serum | Description: | Heat Inactivated Premium, United States Origin |
| Catalog Number: | 35-016-CV | Lot Number: | 23022002 |
| Date of Heat Inactivation: | 24 AUG 2022 | 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: | 05422001 |
| Date of Parent Lot Manufacture: | 11 FEB 2022 | Date of Expiration: | FEB 2027 |
| 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 | <1 | EU/mL |
| Hemoglobin | USP <90> | ≤ 25 | 7.07 | mg/dL |
| Mycoplasma | Barile and Kern & Hoechst Fluorochrome Stain | Not Detected | Not Detected | N/A |
| Osmolality | USP <785> & EP 2.2.35 | 260 – 350 | 309 | mOsm/kg H ₂ O |
| pH | USP <791> & EP 2.2.3 | 6.5 – 8.5 | 7.17 | 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 | 3.5 | 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 ^{2.45} | TCID ₅₀ /mL |
| BVDV Antibody Type 2 | | As Reported | No Neutralization | N/A |
| Biochemical Testing - Proteins & Organic Compounds | | | | |
| Alkaline Phosphatase | | As Reported | 187 | IU/L |
| Blood Urea Nitrogen (BUN) | | As Reported | 14 | mg/dL |
| Cholesterol | | As Reported | 28 | mg/dL |
| Creatinine | | As Reported | 2.9 | mg/dL |

| | | | | |
|---|-----------------------------------|-------------|--------|--------|
| Glucose | | As Reported | 131 | mg/dL |
| Glutamic Oxaloacetic Transaminase (AST) | | As Reported | 43 | IU/L |
| Glutamic Pyruvic Transaminase (ALT) | | As Reported | 5 | IU/L |
| High Density Lipoprotein Cholesterol (HDL) | | As Reported | 8 | mg/dL |
| Immunoglobulin G (IgG) | ELISA | As Reported | 67.3 | µg/mL |
| Low Density Lipoprotein Cholesterol (LDL) | | As Reported | 6 | mg/dL |
| Total Bilirubin | | As Reported | 0.2 | mg/dL |
| Triglyceride | | As Reported | 68 | mg/dL |
| Uric Acid | | As Reported | 3.2 | 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 | 13.2 | mg/dL |
| Chloride | | As Reported | 97 | mmol/L |
| Iron | | As Reported | 193 | µg/dL |
| Magnesium | | As Reported | 3.0 | mg/dL |
| Phosphorus | | As Reported | 10.3 | mg/dL |
| Potassium | | As Reported | >10.0 | mmol/L |
| Sodium | | As Reported | 136 | mmol/L |
| Biochemical Testing - Hormones | | | | |
| Cortisol | | As Reported | <0.20 | µg/dL |
| Insulin | | As Reported | 6.68 | µIU/mL |
| Progesterone | | As Reported | <0.1 | ng/mL |
| Testosterone | | As Reported | 0.01 | ng/mL |
| T3 | | As Reported | 192 | ng/dL |
| T4 | | As Reported | 18.4 | 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, MDCK 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: *Michael Maurer* 14-Sep-2022

DocuSigned by:
Michael Maurer 14-Sep-2022

Signer Name: Michael Maurer
Signing Reason: I am the author of this document
Signing Time: 14-Sep-2022 | 11:21:15 AM EDT
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Reviewed By/Date: *La Her* 14-Sep-2022

DocuSigned by:
La Her 14-Sep-2022

Signer Name: La Her
Signing Reason: I have reviewed this document
Signing Time: 14-Sep-2022 | 10:43:56 AM EDT
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