Mediatech, Inc.

A Corning Subsidiary

Certificate of Analysis

Product:

Fetal Bovine Serum

Description:

USDA Approved Origin

Catalog Number:

35-010-CV

Lot Number:

35010165

Date of Manufacture:

06 Jun 2018

Date of Expiration:

2023/06

Country of Raw Material Origin:

Nicaragua

Country of Final Processing:

United States

Triple 0.1 µm Filtered:

10⁻³

Sterility Assurance Level:

Storage:

-25°C to -15°C

| Test | Method | Specification | Populto | Units |
|--|---|------------------------------|--------------|--------------|
| | USP <71> | Specification No Growth | Results | Onits N/A |
| Sterility (Bacteria & Fungi) | EP 2.6.1 | No Growth | No Growth | N/A |
| Endotoxin | USP <85> | ≤ 20 | 4 | EU/mL |
| Mycoplasma | Barile and Kern Hoechst Fluorochrome Stain | Not Detected Not Detected | Not Detected | N/A N/A |
| pH | USP <791> | 6.8 – 8.4 | 7.1 | N/A |
| Osmolality | USP <785> | 280 - 350 | 304 | mOsm/kg H2O |
| 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 | Positive | 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 |
| Hemadsorption Agents (PI3) | | Not Detected | Not Detected | N/A |
| Proteins / Other | | | | |
| Alkaline Phosphatase | | As Reported | 331 | IU/L |
| Blood Urea Nitrogen (BUN) | | As Reported | 19 | mg/dL |
| Cholesterol | | As Reported | 29 | mg/dL |
| Creatinine | | As Reported | 2.9 | mg/dL |
| Gamma-Glutamyl Transferase (GGT) | | As Reported | 5 | IU/L |
| Glucose | | As Reported | 53 | mg/dL |
| Glutamic Oxaloacetic Transaminase (AST) | | As Reported | 38 | IU/L |
| Glutamic Pyruvic Transaminase (ALT) | | As Reported | 5 | IU/L |
| Hemoglobin | Fleming and Woolf | ≤ 30 | 15 | mg/dL |
| High Density Lipoprotein Cholesterol (HDL) | | As Reported | 9 | mg/dL |
| Immunoglobulin G (IgG) | ELISA | As Reported | 87 | µg/mL |
| | | | | |



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| Low Density Lipoprotein Cholesterol (LDL) | | As Reported | 18 | mg/dL | | |
|--|--------------------------------------|-------------|---------|--------|--|--|
| Total Bilirubin | | As Reported | 0.2 | mg/dL | | |
| Total Protein | USP <1057> | 3.0 -5.0 | 3.7 | g/dL | | |
| Triglyceride | | As Reported | 49 | mg/dL | | |
| Uric Acid | | As Reported | 1.2 | mg/dL | | |
| Electrophoretic Profile | Cellulose Acetate Electrophoresis | Normal | Typical | N/A | | |
| Albumin | | As Reported | 2.3 | g/dL | | |
| Alpha 1,2 | | As Reported | 1.2 | g/dL | | |
| Beta 1,2 | | As Reported | 0.2 | g/dL | | |
| Gamma 1,2 | | As Reported | 0.1 | g/dL | | |
| Trace Metals | | | | | | |
| Calcium | | As Reported | 13.1 | mg/dL | | |
| Chloride | | As Reported | 96 | mEq/L | | |
| Iron | | As Reported | 158 | μg/dL | | |
| Magnesium | | As Reported | 3.0 | mg/dL | | |
| Phosphorus | | As Reported | 8.3 | mg/dL | | |
| Potassium | | As Reported | > 10.0 | mEq/L | | |
| Sodium | | As Reported | 135 | mEq/L | | |
| Hormones | | | | | | |
| Cortisol | | As Reported | 0.211 | μg/dL | | |
| Estradiol | | As Reported | 26.0 | pg/mL | | |
| Insulin | | As Reported | 6.12 | μIU/mL | | |
| Progesterone | | As Reported | < 0.05 | ng/mL | | |
| Testosterone | | As Reported | < 0.01 | ng/mL | | |
| T3 | | As Reported | 71.3 | ng/dL | | |
| T4 | | As Reported | 15.0 | 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.

This product was manufactured from fetal bovine blood collected from government approved harvest facilities located in Nicaragua. 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. This material was imported into the United States under a USDA/APHIS issued import permit.

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:

Un 05 SEP 2018

Reviewed By/Date:

George 055572018



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