

Certificate of Analysis

Amended*

Description	Fetal Bovine Serum, USDA Approved Source	Catalog #:	35-010-CF
		Lot #:	35010161
		Manufacture Date:	March 07, 2018
		Expiration Date:	March 31, 2023
Storage	-25 to -15°C	Country of Raw Material Origin:	Nicaragua
		Country of Manufacture:	USA

Notes:

This product was tested in accordance with currently approved Mediatech, Inc. specifications and procedures. Testing procedures are maintained in compliance with the current versions of the USP and/or EP, where applicable.

The Fetal Bovine Serum was obtained from blood that was collected from fetuses whose dams were born in Nicaragua and passed ante – and post mortem veterinary inspection at government approved facility.

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.

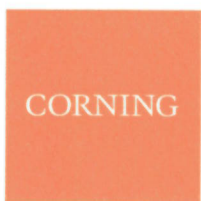
TEST PARAMETERS	SPECIFICATION	RESULT
Appearance (Visual Inspection)	Amber or caramel colored frozen liquid	Pass
Triple 0.1 Micron-Filtered	As Reported	Triple 0.1 µm Filtered
Sterility (USP <71>)	Not Detected	Not Detected
(EP 2.6.1)	Not Detected	Not Detected
Sterility Assurance Level (SAL)	10 ⁻³	10 ⁻³
Endotoxin (USP <85>)	≤ 20EU/mL	< 0.5 EU/mL



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Mycoplasma (Barile, MF and Kern, J (1971)) (Hoechst Fluorochrome Stain)	Not Detected Not Detected	Not Detected Not Detected
pH (USP <791>)	6.8 – 8.4	7.3
Osmolality (USP <785>)	280 – 350 mOsm/kgH ₂ O	331 mOsm/kgH ₂ O
Performance Testing	Passed > 75% to control	Pass
Virus Screening (9 CFR Part 113.53 c [113.46, 113.47])		
Bluetongue Virus	Not Detected	Not Detected
Bovine Adenovirus 1 & 5	Not Detected	Not Detected
Bovine Parvovirus	Not Detected	Not Detected
Bovine Respiratory Syncytial Virus	Not Detected	Not Detected
Bovine Viral Diarrhea Virus	As Reported	Positive
Rabies Virus	Not Detected	Not Detected
Reovirus	Not Detected	Not Detected
Cytopathogenic Agents (e.g. IBR)	Not Detected	Not Detected
Hemadsorbing Agents (e.g. PI3)	Not Detected	Not Detected
Proteins/Other		
Gamma-Glutamyl Transferase (GGT)	As Reported	5 IU/L
Alkaline Phosphatase	As Reported	320 IU/L
Blood Urea Nitrogen (BUN)	As Reported	19 mg/dL
Cholesterol	As Reported	31 mg/dL
Creatinine	As Reported	2.8 mg/dL
Glucose	As Reported	45 mg/dL

Glutamic Oxaloacetic Transaminase (SGOT) (AST)	As Reported	37 IU/L
Glutamic Pyruvic Transaminase (SGPT)(ALT)	As Reported	5 IU/L
Hemoglobin (USP <90> compliant Fleming and Woolf method)	≤ 30 mg/dL	16 mg/dL
High Density Lipoprotein Cholesterol (HDL)	As Reported	10 mg/dL
Immunoglobulin (IgG) (ELISA)	As Reported	97 µg/mL
Low Density Lipo-Protein Cholesterol (LDL)	As Reported	18 mg/dL
Total Bilirubin	As Reported	0.2 mg/dL
Total Protein (Biuret Method)	3.0 -5.0 g/dL	3.5 g/dL
Triglycerides	As Reported	49 mg/dL
Uric Acid	As Reported	1.2 mg/dL
Electrophoretic Profile (Cellulose Acetate Electrophoresis)	Typical OR Normal OR Representative of Fetal Bovine Serum	Typical
Albumin	As Reported	2.3 g/dL
Alpha – 1, 2	Report as Alpha 1,2 OR Report both Alpha 1 and Alpha 2 when applicable	1.2 g/dL
Beta	As Reported	0.2 g/dL
Gamma	As Reported	0.1 g/dL
Trace Metals		
Calcium	As Reported	12.7 mg/dL
Chloride	As Reported	98 mEq/L
Iron	As Reported	156 µg/dL
Magnesium	As Reported	3.1 mg/dL
Phosphorus	As Reported	8.2 mg/dL



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Potassium	As Reported	> 10.0 mEq/L
Sodium	As Reported	136 mEq/L
Hormones		
Cortisol	As Reported	< 0.20 µg/dL
Estradiol	As Reported	27.5 pg/mL
Insulin	As Reported	6.28 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	13.9 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.

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

***Amended to correct the test result of Bovine Viral Diarrhea Virus from “Not Detected” to “Positive”.**

Written By/Date: W 17 JUL 2018

Reviewed By/Date: Paucop Penco / 17 JUL 2018