

Certificate of Analysis

Description: Fetal Bovine Serum (Heat Inactivated)	Catalog #	35-011-CV
	Lot #	35011134
	Parent Part #:	35-010-CV
Storage: -25 to -15°C	Parent Lot #:	35010156
	Date of Manufacture:	21 Jun 2017
	Expiration Date:	2022/07
	Country of Raw Material Origin:	Mexico
	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.

This is to certify that the raw bovine serum used to manufacture Fetal Bovine Serum was collected from cattle of Mexico origin and were manufactured in the United States of America. 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.

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	Caramel colored frozen liquid
Triple 0.1 Micron-Filtered	As Reported	Triple 0.1 µm Filtered
Sterility (USP <71>) (EP 2.6.1)	Not Detected Not Detected	Not Detected Not Detected
Sterility Assurance Level (SAL)	10 ⁻³	10 ⁻³



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Endotoxin (USP <85>)	≤ 20EU/mL	0.96 EU/mL
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	7.02
Osmolality (USP <785>)	280 – 350 mOsm/kgH ₂ O	315 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	Not Detected
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	248 IU/L
Blood Urea Nitrogen (BUN)	As Reported	15 mg/dL
Cholesterol	As Reported	30 mg/dL
Creatinine	As Reported	2.8 mg/dL

Glucose	As Reported	111 mg/dL
Glutamic Oxaloacetic Transaminase (SGOT) (AST)	As Reported	45 IU/L
Glutamic Pyruvic Transaminase (SGPT)(ALT)	As Reported	7 IU/L
Hemoglobin (USP <90> compliant Fleming and Woolf method)	≤ 30 mg/dL	15.42 mg/dL
High Density Lipoprotein Cholesterol (HDL)	As Reported	9 mg/dL
Immunoglobulin (IgG) (ELISA)	As Reported	254 µg/mL
Low Density Lipo-Protein Cholesterol (LDL)	As Reported	19 mg/dL
Total Bilirubin	As Reported	0.2 mg/dL
Total Protein (Biuret Method)	3.0 -5.0 g/dL	3.6 g/dL
Triglycerides	As Reported	67 mg/dL
Uric Acid	As Reported	3.0 mg/dL
Electrophoretic Profile (Cellulose Acetate Electrophoresis)	Typical OR Normal OR Representative of Fetal Bovine Serum	Typical
Albumin	As Reported	2.2 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	0.3 g/dL
Gamma	As Reported	Not Detected
Trace Metals		
Calcium	As Reported	13.4 mg/dL
Chloride	As Reported	96 mEq/L
Iron	As Reported	179 µg/dL
Magnesium	As Reported	3.3 mg/dL
Phosphorus	As Reported	9.9 mg/dL
Potassium	As Reported	> 10.0 mEq/L
Sodium	As Reported	134 mEq/L



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Hormones		
Cortisol	As Reported	0.351 µg/dL
Estradiol	As Reported	23.2 pg/mL
Insulin	As Reported	6.81 µIU/mL
Progesterone	As Reported	< 0.05 ng/mL
Testosterone	As Reported	< 0.01 ng/mL
T3	As Reported	147 ng/dL
T4	As Reported	13.2 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.

Written By/Date: Janice Taylor 20 Aug 2018

Reviewed By/Date: Macampster / YZ 20 Aug 2018



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