

Certificate of Analysis

Description:	Fetal Bovine Serum (Heat Inactivated)	Catalog #	35-011-CV
		Lot #	35011132
		Parent Part #:	N/A
Storage:	-25 to -15°C	Parent Lot #:	N/A
		Date of Manufacture:	June 8, 2018
		Expiration Date:	2023/06
		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 product was manufactured from fetal bovine blood collected from government approved harvest facilities located in Mexico. 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.

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>)	Not Detected	Not Detected
(EP 2.6.1)	Not Detected	Not Detected
Sterility Assurance Level (SAL)	10 ⁻³	10 ⁻³



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Endotoxin (USP <85>)	≤ 20 EU/mL	< 0.1 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	7.2
Osmolality (USP <785>)	280 – 350 mOsm/kgH ₂ O	306 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	4 IU/L
Blood Urea Nitrogen (BUN)	As Reported	17 mg/dL
Cholesterol	As Reported	33 mg/dL
Creatinine	As Reported	2.8 mg/dL

Glucose	As Reported	70 mg/dL
Glutamic Oxaloacetic Transaminase (SGOT) (AST)	As Reported	21 IU/L
Glutamic Pyruvic Transaminase (SGPT)(ALT)	As Reported	4 IU/L
Hemoglobin (USP <90> compliant Fleming and Woolf method)	≤ 30 mg/dL	7 mg/dL
High Density Lipoprotein Cholesterol (HDL)	As Reported	9 mg/dL
Immunoglobulin (IgG) (ELISA)	As Reported	137.2 µg/mL
Low Density Lipo-Protein Cholesterol (LDL)	As Reported	10 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	68 mg/dL
Uric Acid	As Reported	2.1 mg/dL
Electrophoretic Profile (Cellulose Acetate Electrophoresis)	Typical OR Normal OR Representative of Fetal Bovine Serum	Normal
Albumin	As Reported	2.0 g/dL
Alpha – 1, 2	Report as Alpha 1,2 OR Report both Alpha 1 and Alpha 2 when applicable	1.3 g/dL
Beta	As Reported	0.2 g/dL
Gamma	As Reported	0.1 g/dL
Trace Metals		
Calcium	As Reported	13.4 mg/dL
Chloride	As Reported	97 mEq/L
Iron	As Reported	185 µg/dL
Magnesium	As Reported	3.1 mg/dL
Phosphorus	As Reported	9.3 mg/dL
Potassium	As Reported	> 10.0 mEq/L
Sodium	As Reported	137 mEq/L



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