

CERTIFICATE OF ANALYSIS BenchMark™ Fetal Bovine Serum (Catalog Number 100-106)

Lot Number:

A35H74L

Date of Manufacture: Feb2020

Origin:

Nicaragua

Product Expiry: Feb2025

For Cell culture, Further Manufacturing or Research

use Only. Not for Direct Therapeutic Use.

Storage Temperature: ≤ -10°C

Product description: BenchMark™ Fetal Bovine Serum is sterile-filtered through a 0.1 μm filter prior to freezing.

Endotoxin USP<85>, EP 2.6.14 <10.0 EU/mL 0.396 EU/mL Hemoglobin Fleming, AF and Woolf, AJ (1965) Microbiological Testing Sterility USP<71>, EP 2.6.1 Bacteria No Growth No Growth No Growth No Growth Fungi Not Detected (1971), EP 2.6.7 Viral Testing 9CFR 113.53c[113.46, 113.47] Cytopathic Agents Not Detected Diarrhea(cytopathic) Not Detected Not Detected Diarrhea(non-cytopathic) Not Detected Not Detected Diarrhea(non-cytopathic) Not Detected Diarrhea(non-cytopathic) Not Detected	Test	Methodology	Specification	Analysis
Hemoglobin Fleming, AF and Woolf, AJ (1965) Microbiological Testing Sterility USP<71>, EP 2.6.1 Bacteria No Growth No Growth No Growth Fungi Not Detected (1971), EP 2.6.7 Viral Testing 9CFR 113.53c[113.46, 113.47] Cytopathic Agents Not Detected Diarrhea(cytopathic) Not Detected Not Detected Diarrhea(non-cytopathic) Not Detected Not Detected Diarrhea(non-cytopathic) Not Detected Not Detected Not Detected Diarrhea(non-cytopathic) Not Detected Diarrhea(non-cytopathic) Not Detected	Biological Testing			
Microbiological Testing Sterility Bacteria Fungi Mycoplasma Barile, MF and Kern, J (1971), EP 2.6.7 Viral Testing Cytopathic Agents Hemadsorbing Agents Bovine Viral Diarrhea Ab Titer Type I Type II Test and Report Type II Test and Report Bovine Adenovirus Bovine Parvovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic) Bovine Viral Diarrhea(cytopathic) Bovine Viral Diarrhea(non-cytopathic) Bovine Syncytial Virus Bovine Rabies Virus Bovine Rabies Virus Not Detected	Endotoxin	USP<85>, EP 2.6.14	<10.0 EU/mL	0.39 <mark>6 EU</mark> /mL
Sterility USP<71>, EP 2.6.1 Bacteria Fungi Mycoplasma Barile, MF and Kern, J (1971), EP 2.6.7 Viral Testing 9CFR 113.53c[113.46, 113.47] Cytopathic Agents Hemadsorbing Agents Bovine Viral Diarrhea Ab Titer Type I Type I Test and Report Type II Extraneous Viruses (FAb) Bluetongue Virus Bovine Parvovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic) Bovine Viral Diarrhea(non-cytopathic) Bovine Syncytial Virus Bovine Syncytial Virus Bovine Syncytial Virus Bovine Cytopathic Bovine Syncytial Virus Bovine Rabies Virus Not Detected	Hemoglobin	<u> </u>	<20.0 mg/dL	14.5 <mark>6 m</mark> g/dL
Bacteria Fungi Mycoplasma Barile, MF and Kern, J Not Detected	Microbiological Testing			
Fungi No Growth No Growth Mycoplasma Barile, MF and Kern, J Not Detected (1971), EP 2.6.7 Viral Testing 9CFR 113.53c[113.46, 113.47] Cytopathic Agents Not Detected Not Detected Not Detected Hemadsorbing Agents Not Detected Not Detected Not Detected Bovine Viral Diarrhea Ab Titer Type I Test and Report Pending Type II Test and Report Pending Extraneous Viruses (FAb) Bluetongue Virus Not Detected Not Detected Not Detected Bovine Adenovirus Not Detected Not Detected Bovine Parvovirus Not Detected Not Detected Diarrhea(cytopathic) Bovine Viral Test and Report Not Detected Diarrhea(non-cytopathic) Bovine Syncytial Virus Not Detected Not Detected Bovine Rabies Virus Not Detected Not Detected Not Detected Diarrhea(non-cytopathic) Rovine Rabies Virus Not Detected Not Detected Not Detected Rovine Parvovirus Not Detected Not Detected Diarrhea(non-cytopathic) Rovine Syncytial Virus Not Detected Not Detected Not Detected Rovine Rabies Virus Not Detected Not Detected Not Detected Rovine Rabies Virus Not Detected Not Detected Not Detected Rovine Rabies Virus Not Detected Not Detected Not Detected Rovine Rabies Virus Not Detected Not Detected Not Detected Rovine Rabies Virus Not Detected Not Detected Not Detected Rovine Rabies Virus Not Detected Not Detected Not Detected Rovine Rabies Virus Not Detected Not Detected Not Detected Rovine Rabies Virus Not Detected Not Detected Not Detected Rovine Rabies Virus Not Detected Not Detected Not Detected Rovine Rabies Virus Not Detected Rovine Rabies Virus Not Detected Rovine Rabies Virus Rovine Rabies Virus Not Detected Rovine Rabies Virus Rovine Rabi	Sterility	USP<71>, EP 2.6.1		
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Viral Testing (1971), EP 2.6.7 9CFR 113.53c[113.46, 113.47] Cytopathic Agents Hemadsorbing Agents Bovine Viral Diarrhea Ab Titer Type I Type II Test and Report Type II Extraneous Viruses (FAb) Bluetongue Virus Bovine Adenovirus Bovine Adenovirus Not Detected	<u>Fun</u> gi		No Growth	No Growth
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Cytopathic Agents Hemadsorbing Agents Bovine Viral Diarrhea Ab Titer Type I Type II Test and Report Type II Test and Report Pending Extraneous Viruses (FAb) Bluetongue Virus Bovine Adenovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic) Bovine Viral Diarrhea(non-cytopathic) Bovine Syncytial Virus Bovine Rabies Virus Not Detected	Viral <mark>Testing</mark>	9CFR 113.53c[113.46,		
Hemadsorbing Agents Bovine Viral Diarrhea Ab Titer Type I Type II Test and Report Type II Test and Report Pending Extraneous Viruses (FAb) Bluetongue Virus Bovine Adenovirus Bovine Parvovirus Not Detected Not Detected Bovine Viral Diarrhea(cytopathic) Bovine Viral Diarrhea(non-cytopathic) Bovine Syncytial Virus Not Detected		113.47]		
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Type II Test and Report Pending Extraneous Viruses (FAb) Bluetongue Virus Not Detected Not Detected Bovine Adenovirus Not Detected Not Detected Bovine Parvovirus Not Detected Not Detected Bovine Viral Not Detected Tested Diarrhea(cytopathic) Bovine Viral Test and Report Not Detected Diarrhea(non-cytopathic) Bovine Syncytial Virus Not Detected Not Detected Bovine Rabies Virus Not Detected Not Detected	Hemadsorbing Agents		Not Detected	Not Detected
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Extraneous Viruses (FAb) Bluetongue Virus Bovine Adenovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic) Bovine Viral Diarrhea(non-cytopathic) Bovine Syncytial Virus Bovine Rabies Virus Not Detected	Type I		Test and Report	Pending
Bluetongue Virus Bovine Adenovirus Not Detected Tested Diarrhea(cytopathic) Bovine Viral Diarrhea(non-cytopathic) Bovine Syncytial Virus Not Detected	Type II		Test and Report	Pending
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Bovine Viral Test and Report Not Detected Diarrhea(non-cytopathic) Bovine Syncytial Virus Not Detected Not Detected Bovine Rabies Virus Not Detected Not Detected	Bovine Viral		Not Detected	Tested
Diarrhea(non-cytopathic) Bovine Syncytial Virus Bovine Rabies Virus Not Detected Not Detected Not Detected Not Detected	Diarrhea (cytopathic)			
Bovine Syncytial Virus Not Detected Not Detected Bovine Rabies Virus Not Detected Not Detected			Test and Report	Not Detected
Bovine Rabies Virus Not Detected Not Detected			Not Detected	Not Detected
			Not Detected	
	Reovirus		Not Detected	



Test	Methodology	Specification	Analysis
Physical Testing			
Electrophoretic Pattern	Cellulose Acetate	Normal	Pending
Osmolality	USP<785>, EP 2.2.35	260 - 350 mOsm/ kg	304 mOsm/Kg
pH@RT	USP<791>	6.5 – 8.5	7.31
Biochemistry			
Albumin		Test and Report	16.7 g/L
Alkaline Phosphatase		Test and Report	336 U/L
ALT (SGPT)		Test and Report	6 U/L
AST (SGOT)		Test and Report	45 U/L
GGT		<10 U/L	6 U/L
Bilirubin, Total		Test and Report	0.2 mg/dL
BUN		Test and Report	Pending
Calcium		Test and Report	13.5 mg/dL
Chloride		Test and Report	102 mEq/L
Cholesterol		Test and Report	36 mg/dL
Cortisol		Test and Report	Pending
Creatinine		Test and Report	2.7 mg/dL
Estradiol		Test and Report	Pending
Glucose		Test and Report	45 mg/dL
lgG	ELISA	<0.300 mg/mL*	0.13 <mark>8 mg</mark> /mL
Insulin		Test and Report	Pending
Iron, Serum		Test and Report	1 <mark>74 u</mark> g/dL
Phosphorus		Test and Report	8.3 mg/dL
Potassium		Test and Report	10.5 mEq/L
Progesterone		Test and Report	Pending
Protein, Total	Biuret	2.5 – 6.0 g/dL	3.68 g/dL
Sodium		Test and Report	137 mEq/L
Testosterone		Test and Report	Pending
T3		Test and Report	Pending
T4		Test and Report	Pending
Trigl <mark>ycerid</mark> es		Test and Report	47 mg/dL
Tet <mark>racycl</mark> ine		<4 ng/mL	Pass
Uric Acid Our fotal boying sorum mosts all		Test and Report	1.0 mg/dL

Our fetal bovine serum meets all USDA requirements and has passed ante and post-mortem inspection by a licensed veterinarian. It is collected in countries recognized as being free of foot-and-mouth disease and rinderpest. The origin of all fetal bovine serum is traceable by lot number, date and country of collection. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance. *Some geographic regions may test higher than 0.300 mg/mL. If this be the case, refer to GGT results less than 10 U/L to ensure FBS purity.

The testing that has been performed as part of this lot release has been reviewed by Quality Assurance personnel and has confirmed that the testing meets the specifications presented on this Certificate of Analysis.

Megha Khalayi	OA Associate III
Name 05 May 2020	Title
Date	