

CERTIFICATE OF ANALYSIS GemCell™ Fetal Bovine Serum

(Catalog Number 100-500)

Lot Number:

A51H00L

Date of Manufacture: Oct2020

Origin:

United States

Product Expiry: Oct2025

For Cell culture, Further Manufacturing or Research

use Only. Not for Direct Therapeutic Use.

Storage Temperature: ≤ -10°C

Product description: Gemcell™ 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 0.500 EU/mL Hemoglobin Fleming, AF and Woolf, AJ (1965) Microbiological Testing Sterility USP<71>, EP 2.6.1 No Growth Fungi No Growth No Detected (1971), EP 2.6.7 Viral Testing 9CFR 113.53c[113.46, 113.47] Cytopathic Agents Not Detected Not Detected Not Detected Not Detected Not Detected No Detected Not Detected No Detected Diarrhea(cytopathic)	Test	Methodology	Specification	Analysis
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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 Extraneous Viruses (FAb) Bluetongue Virus Bovine Parvovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic) Bovine Viral Diarrhea(cytopathic) Bovine Viral Diarrhea(non-cytopathic) Bovine Syncytial Virus Bovine Rabie Virus Not Detected	Hemoglobin		<20.0 mg/dL	7. <mark>3 mg</mark> /dL
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Viral Testing 9CFR 113.53c[113.46, 113.47] Cytopathic Agents Not Detected	Mycop <mark>lasma </mark>	Barile, MF and Kern, J	Not Detected	Not Detected
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Bovine Rabie Virus Not Detected Not Detected	Diarrhea(non-cytopathic)		·	
	Bovine Syncytial Virus		Not Detected	Not Detected
Reovirus Not Detected Not Detected	Bovine Rabie Virus		Not Detected	Not Detected
	Reovirus		Not Detected	Not Detected



Test	Methodology	Specification	Analysis
Physical Testing			
Electrophoretic Pattern	Cellulose Acetate	Normal	
Osmolality	USP<785>, EP 2.2.35	260 - 350 mOsm/ kg	300mOsm/Kg
рН	USP<791>	6.5 – 8.5	7.23
Biochemistry			
Albumin		Test and Report	2.2 g/dL
Alkaline Phosphatase		Test and Report	159 U/L
ALT (SGPT)		Test and Report	4.0 IU/L
AST (SGOT)		Test and Report	36.IU/L
GGT		<10 U/L	4 U/L
Bilirubin, Total		Test and Report	0.2mg/dl
BUN		Test and Report	13 mg/dL
Calcium		Test and Report	12.7 mg/dL
Chloride		Test and Report	97 mmol/L
Cholesterol		Test and Report	29 mg/dL
Cortisol		Test and Report	0.244 ug/dL
Creatinine		Test and Report	2.3 mg/dL
Estradiol		Test and Report	9.85 pg/mL
Glucose		Test and Report	75 mg/dL
IgG	ELISA	<0.300 mg/mL*	0.05 <mark>9 m</mark> g/dL
Insulin		Test and Report	9.0 <mark>1 uIU</mark> /mL
Iron, Serum		Test and Report	1 <mark>58 ug</mark> /dL
Phosphorus		Test and Report	8.9 mg/dL
Potassium		Test and Report	9.7 mmol/L
Progesterone		Test and Report	< 0.06 ng/mL
Protein, <mark>Total</mark>	Biuret	2.5 – 6.0 g/dL	3.3 g/dL
Sodium		Test and Report	136 mmol/L
Testost <mark>eron</mark> e		Test and Report	< 0.01 ng/mL
Т3		Test and Report	95.3 ng/dL
T4		Test and Report	13.2 ug/dL
Trig <mark>lycer</mark> ides		Test and Report	50 mg/dL
Tet <mark>racyc</mark> line		<4 ng/mL	< 1 ng/mL
Uri <mark>c Acid</mark>		Test and Report	1.9 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.

OC Superisor
Title