



CERTIFICATE OF ANALYSIS
GemCell™ Fetal Bovine Serum
(Catalog Number 100-500)

Lot Number: A020013 Rev.2

Date of Manufacture: Oct2020

Product Expiry: Oct2025

Origin: United States

Storage Temperature: ≤ -10°C

For Cell culture, Further Manufacturing or Research use Only. Not for Direct Therapeutic Use

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

Test	Methodology	Specification	Analysis
Biological Testing			
Endotoxin	USP<85>, EP 2.6.14	<10.0 EU/mL	<1 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	4.91 mg/dL
Microbiological Testing			
Sterility	USP<71>, EP 2.6.1		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Mycoplasma	Barile, MF and Kern, J (1971), EP 2.6.7	Not Detected	Not Detected
Viral Testing			
Cytopathic Agents		Not Detected	Not Detected
Hemadsorbing Agents		Not Detected	Not Detected
Bovine Viral Diarrhea Ab Titer*	9CFR 113.53c[113.46, 113.47]		
Type I		≤1:4	No Neutralization
Type II		≤1:4	No Neutralization
Extraneous Viruses (FAb)			
Bluetongue Virus		Not Detected	Not Detected
Bovine Adenovirus		Not Detected	Not Detected
Bovine Parvovirus		Not Detected	Not Detected
Bovine Viral Diarrhea(cytopathic)		Not Detected	Not Detected
Bovine Viral Diarrhea(non-cytopathic)		Test and Report	Not Detected
Bovine Syncytial Virus		Not Detected	Not Detected
Bovine Rabies Virus		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected



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Physical Testing			
Electrophoretic Pattern	Cellulose Acetate	Normal	Normal
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/ kg	306 mOsm/kg
pH	USP<791>	6.5 – 8.5	7.15
Biochemistry			
Albumin		Test and Report	2.0 g/dL
Alkaline Phosphatase		Test and Report	203 IU/L
ALT (SGPT)		Test and Report	6 IU/L
AST (SGOT)		Test and Report	47 IU/L
GGT		<10 U/L	5 IU/L
Bilirubin, Total		Test and Report	0.2 mg/dL
BUN		Test and Report	15 mg/dL
Calcium		Test and Report	12.9 mg/dL
Chloride		Test and Report	98 mmol/L
Cholesterol		Test and Report	27 mg/dL
Cortisol		Test and Report	<0.2 µg/dL
Creatinine		Test and Report	2.8 mg/dL
Glucose		Test and Report	129 mg/dL
IgG	ELISA	<0.300 mg/mL**	0.085 mg/mL
Insulin		Test and Report	7.79 µIU/mL
Iron, Serum		Test and Report	190 µg/dL
Phosphorus		Test and Report	10.0 mg/dL
Potassium		Test and Report	>10.0 mmol/L
Progesterone		Test and Report	<0.1 ng/mL
Protein, Total	Biuret	2.5 – 6.0 g/dL	3.5 g/dL
Sodium		Test and Report	137 mmol/L
Testosterone		Test and Report	<0.01 ng/mL
T3		Test and Report	160 ng/dL
T4		Test and Report	16.0 µg/dL
Triglycerides		Test and Report	72 mg/dL
Tetracycline		<4 ng/mL	<0.001 mg/dL
Uric Acid		Test and Report	3.2 mg/dL



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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. * Testing not required if Bovine Viral Diarrhea(cytopathic) and Bovine Viral Diarrhea (non – cytopathic) is not detected. **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.

Karen Zuniga

Name 05 APR 2023

Date

QA Associate I

Title