



CERTIFICATE OF ANALYSIS

Addendum

GemCell™ Fetal Bovine Serum

(Catalog Number 100-500)

Lot Number: A122057

Date of Manufacture: JUN2022

Product Expiry: JUN2027

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	<0.1 EU/mL
Hemoglobin	USP<90>	<20.0 mg/dL	5.06 mg/dL
Microbiological Testing			
Sterility	USP<71>, EP 2.6.1		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Mycoplasma	Barile and Kern & Hoechst Fluorochrome Stain	Not Detected	Not Detected
Viral Testing	9CFR 113.53c [113.46, 113.47]		
Cytopathic Agents		Not Detected	Not Detected
Hemadsorbing Agents		Not Detected	Not Detected
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 Respiratory Syncytial Virus		Not Detected	Not Detected
Bovine Rabies Virus		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected
BVDV Serum Neutralization	Alpha Antibody Test		
BVDV Antibody Type 1		As Reported	No Neutralization
BVDV Antibody Type 2		As Reported	No Neutralization
Physical Testing			
Electrophoretic Pattern	Cellulose Acetate Electrophoresis	Normal	Normal
Osmolality	USP<785>, EP2.2.35	260 – 350 mOsm/ kg	281 mOsm/kg
pH	USP<791>, EP 2.2.3	6.5 – 8.5	7.16



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Biochemistry			
Albumin		Test and Report	2.1 g/dL
Alkaline Phosphatase		Test and Report	247 IU/L
ALT (SGPT)		Test and Report	5 IU/L
AST (SGOT)		Test and Report	36 IU/L
GGT	Chemistry Analyzer	<10 U/L	5 IU/L
Bilirubin, Total		Test and Report	0.2 mg/dL
BUN		Test and Report	14 mg/dL
Calcium		Test and Report	13.1 mg/dL
Chloride		Test and Report	98 mmol/L
Cholesterol		Test and Report	26 mg/dL
Cortisol		Test and Report	<0.20 µg/dL
Creatinine		Test and Report	2.9 mg/dL
Glucose		Test and Report	119 mg/dL
IgG	ELISA	<0.300 mg/mL*	0.0622 mg/mL
Insulin		Test and Report	4.08 µIU/mL
Iron, Serum		Test and Report	192 µg/dL
Phosphorus		Test and Report	9.7 mg/dL
Potassium		Test and Report	11.9 mmol/L
Progesterone		Test and Report	<0.1 ng/mL
Protein, Total	USP<1057>, EP 2.5.33	2.5 – 6.0 g/dL	3.6 g/dL
Sodium		Test and Report	137 mmol/L
Testosterone		Test and Report	<0.01 ng/mL
T3		Test and Report	185 ng/dL
T4		Test and Report	89.0 µg/dL
Triglycerides		Test and Report	61 mg/dL
Tetracycline		<4 ng/mL	<4.0 ng/mL
Uric Acid		Test and Report	3.5 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.



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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 Khatri
Name

QA Doc. Control Supervisor
Title

24 AUG 2023
Date