



CERTIFICATE OF ANALYSIS

GemCell™ Fetal Bovine Serum

(Catalog Number 100-500) Heat Inactivated*

Lot Number: A64H00L

Date of Manufacture: Dec2020

Product Expiry: Dec2025

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	< 0.500 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	12.3 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			
	9CFR 113.53c[113.46, 113.47]		
Cytopathic Agents		Not Detected	Not Detected
Hemadsorbing Agents		Not Detected	Not Detected
Bovine Viral Diarrhea Ab Titer			
Type I		≤1:4	Undiluted
Type II		≤1:4	< Undiluted
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 Rabie 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	309 mOsm/Kg
pH	USP<791>	6.5 – 8.5	7.1
Biochemistry			
Albumin		Test and Report	2.1 g/dL
Alkaline Phosphatase		Test and Report	162 U/L
ALT (SGPT)		Test and Report	4 U/L
AST (SGOT)		Test and Report	28 U/L
GGT		<10 U/L	5 U/L
Bilirubin, Total		Test and Report	0.3 mg/dL
BUN		Test and Report	14 mg/dL
Calcium		Test and Report	13.0 mg/dL
Chloride		Test and Report	98 mmol/L
Cholesterol		Test and Report	28 mg/dL
Cortisol		Test and Report	< 0.2 ug/dL
Creatinine		Test and Report	2.3 mg/dL
Estradiol		Test and Report	12.17 pg/mL
Glucose		Test and Report	103 mg/dL
IgG	ELISA	<0.300 mg/mL**	0.102 g/mL
Insulin		Test and Report	8.27 uIU/mL
Iron, Serum		Test and Report	160 g/dL
Phosphorus		Test and Report	9.4 mg/dL
Potassium		Test and Report	>10.0 mmol/L
Progesterone		Test and Report	< 0.06 ng/mL
Protein, Total	Biuret	2.5 – 6.0 g/dL	3.3 g/dL
Sodium		Test and Report	136 mmol/L
Testosterone		Test and Report	< 0.01 ng/mL
T3		Test and Report	96.7 ng/mL
T4		Test and Report	11.4 ug/dL
Triglycerides		Test and Report	71 mg/dL
Tetracycline		<4 ng/mL	< 1 ng/mL
Uric Acid		Test and Report	2.1gm/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. **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. *Results shown were obtained prior to heat inactivation by carefully performed methods believed to be reliable prior to heat inactivation

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 Khatala

Name

08 FEB 2021

Date

QC Supervisor

Title