



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

**Lot Number:** A63H00L

**Date of Manufacture:** Nov2020

**Origin:** United States

**Product Expiry:** Nov2025

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.

Test	Methodology	Specification	Analysis
<b>Biological Testing</b>			
Endotoxin	USP<85>, EP 2.6.14	<10.0 EU/mL	<1.00 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	11.3 mg/dL
<b>Microbiological Testing</b>			
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
<b>Viral Testing</b>			
	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		Test and Report	< Undiluted
Type II		Test and Report	<Undiluted
<b>Extraneous Viruses (FAB)</b>			
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	Tested
Bovine Syncytial Virus		Not Detected	Not Detected
Bovine Rabies Virus		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected



Test	Methodology	Specification	Analysis
<b>Physical Testing</b>			
Electrophoretic Pattern	Cellulose Acetate	Normal	Normal
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/ kg	315mOsm/Kg
pH	USP<791>	6.5 – 8.5	7.05
<b>Biochemistry</b>			
Albumin		Test and Report	2.2 g/dL
Alkaline Phosphatase		Test and Report	176 U/L
ALT (SGPT)		Test and Report	5 U/L
AST (SGOT)		Test and Report	27 U/L
GGT		<10 U/L	5 U/L
Bilirubin, Total		Test and Report	0.2 mg/dl
BUN		Test and Report	15 mg/dL
Calcium		Test and Report	13.1 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	2.4 mg/dL
Estradiol		Test and Report	11.77 pg/mL
Glucose		Test and Report	110 mg/dL
IgG	ELISA	<0.300 mg/mL*	0.096 mg/mL
Insulin		Test and Report	7.60 uIU/mL
Iron, Serum		Test and Report	166 ug/dL
Phosphorus		Test and Report	9.7 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	135 mmol/L
Testosterone		Test and Report	<0.01 ng/mL
T3		Test and Report	101 ng/dL
T4		Test and Report	12.9 ug/dL
Triglycerides		Test and Report	71 mg/dL
Tetracycline		<4 ng/mL	<1.0 ng/mL
Uric Acid		Test and Report	2.0 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 Khalasi

Name

08 JAN 2021

Date

QC Supervisor

Title