



CERTIFICATE OF ANALYSIS

GemCell™ Fetal Bovine Serum Gamma Irradiated** (Catalog Number 100-500)

Lot Number: A424055

Date of Manufacture: Aug2024

Product Expiry: Aug2029

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	9.21 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
Rabies Virus		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected
Physical Testing			
Electrophoretic Pattern	Cellulose Acetate Electrophoresis	Normal	Normal
Osmolality	USP <785> & EP 2.2.35	260 – 350 mOsm/kg	317 mOsm/kg
pH	USP <791> & EP 2.2.3	6.5 – 8.5	7.05
Biochemistry Testing			
Albumin		Test and Report	2.1 g/dL
Alkaline Phosphatase		Test and Report	231 IU/L
ALT (SGPT)		Test and Report	7 IU/L
AST (SGOT)		Test and Report	50 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



CERTIFICATE OF ANALYSIS

GemCell™ Fetal Bovine Serum Gamma Irradiated** **(Catalog Number 100-500)**

Lot Number: A424055

Test	Methodology	Specification	Analysis
Calcium	ELISA	Test and Report	13.6 mg/dL
Chloride		Test and Report	99 mmol/L
Cholesterol		Test and Report	28 mg/dL
Cortisol		Test and Report	0.300 µg/dL
Creatinine		Test and Report	3.0 mg/dL
Glucose		Test and Report	157 mg/dL
IgG		<0.300 mg/mL*	0.0938 mg/mL
Insulin		Test and Report	6.80 µU/mL
Iron, Serum		Test and Report	195 µg/dL
Phosphorus		Test and Report	10.9 mg/dL
Potassium		Test and Report	13.1 mmol/L
Progesterone		Test and Report	<0.1 ng/mL
Protein, Total		2.5 – 6.0 g/dL	3.6 g/dL
Sodium		Test and Report	140 mmol/L
Testosterone	USP <1057> & EP 2.5.33	Test and Report	<0.01 ng/mL
T3		Test and Report	254.0 ng/dL
T4		Test and Report	8.9 µg/dL
Triglycerides		Test and Report	78 mg/dL
Uric Acid		Test and Report	3.6 mg/dL

Our fetal bovine serum meets all USDA requirements and has passed ante and post-mortem. 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. **Results shown were obtained by carefully performed methods believed to be reliable prior to gamma irradiation.

Jaqueline Wilson
Name
QA Specialist
Title

14 APR 2025
Date