

### **CERTIFICATE OF ANALYSIS**

### GemCell™ Fetal Bovine Serum

(Catalog Number 100-500)

Lot Number: A121032

Date of Manufacture: DEC2021

**Product Expiry: DEC2026** 

**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.

Endotoxin USP<85>, EP 2.6.14 <10.0 EU/mL 0.267 EU/mL Hemoglobin Fleming, AF and Woolf, AJ (1965)  Microbiological Testing Sterility USP<71>, EP 2.6.1 No Growth Fungi No Growth No Growth No Growth No Growth No Growth No Growth No Detected (1971), EP 2.6.7/PCR  Viral Testing 9CFR 113.53c[113.46, 113.47]  Cytopathic Agents Not Detected Not Dete	Test	Methodology	Specification	Analysis
Hemoglobin Fleming, AF and Woolf, AJ (1965)  Microbiological Testing Sterility USP<71>, EP 2.6.1  Bacteria No Growth No Detected (1971), EP 2.6.7/PCR  Viral Testing 9CFR 113.53c[113.46, 113.47]  Cytopathic Agents Not Detected Diarrhea(cytopathic)  Bovine Syncytial Virus Not Detected No	Biological Testing			
AJ (1965)  Microbiological Testing Sterility  Bacteria Fungi  Mycoplasma  Barile, MF and Kern, J Mytoplasma  Barile, MF and Kern, J Mytoplasma  Wiral Testing  Cytral Testing  Cytopathic Agents  Hemadsorbing Agents  Extraneous Viruses (FAb)  Bluetongue Virus Bovine Adenovirus Bovine Parvovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic)  Bovine Syncytial Virus Bovine Rabies Virus  Bovine Rabies Virus  Bovine Rabies Virus  Bovine Rabies Virus  Bovine Rabies Virus  Not Detected	Endotoxin	USP<85>, EP 2.6.14	<10.0 EU/mL	0.267 EU/mL
Sterility USP<71>, EP 2.6.1  Bacteria Fungi No Growth No Detected Not Detected	Hemoglobin	Fleming, AF and Woolf,	<20.0 mg/dL	12.42 mg/dL
Sterility USP<71>, EP 2.6.1  Bacteria Fungi Mycoplasma Barile, MF and Kern, J (1971), EP 2.6.7/PCR Viral Testing Octopathic Agents Hemadsorbing Agents  Extraneous Viruses (FAb) Bluetongue Virus Bovine Adenovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic)  Bovine Syncytial Virus Bovine Rabies Virus  Bovine Rabies Virus  Bock and a company of the company of		AJ (1965)		
Bacteria Fungi No Growth No Detected Not Detected (1971), EP 2.6.7/PCR Viral Testing 9CFR 113.53c[113.46, 113.47]  Cytopathic Agents Hemadsorbing Agents Not Detected	Microbiological Testing			
Fungi No Growth No Growth Mycoplasma Barile, MF and Kern, J Not Detected Not Detected (1971), EP 2.6.7/PCR  Viral Testing 9CFR 113.53c[113.46, 113.47]  Cytopathic Agents Not Detected Detected Not Detected Not Detected Not Detected Detected Not Detected Not Detected Not Detected Detected Diarrhea(cytopathic)  Bovine Syncytial Virus Not Detected Not Detected Detected Detected Detected Detected Not Detected Not Detected Dete	Sterility	USP<71>, EP 2.6.1		
Mycoplasma  Barile, MF and Kern, J (1971), EP 2.6.7/PCR  Viral Testing  9CFR 113.53c[113.46, 113.47]  Cytopathic Agents Hemadsorbing Agents  Not Detected	Bacteria		No Growth	No Growth
Viral Testing  (1971), EP 2.6.7/PCR 9CFR 113.53c[113.46, 113.47]  Cytopathic Agents Hemadsorbing Agents  Not Detected	Fungi		No Growth	No Growth
Viral Testing  9CFR 113.53c[113.46, 113.47]  Cytopathic Agents  Hemadsorbing Agents  Not Detected	Mycoplasma	Barile, MF and Kern, J	Not Detected	Not Detected
Cytopathic Agents Hemadsorbing Agents  Extraneous Viruses (FAb) Bluetongue Virus Bovine Adenovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic)  Bovine Syncytial Virus Bovine Rabies Virus Not Detected		(1971), EP 2.6.7/PCR		
Cytopathic Agents Hemadsorbing Agents  Extraneous Viruses (FAb) Bluetongue Virus Bovine Adenovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic)  Bovine Syncytial Virus Bovine Rabies Virus  Not Detected	Viral Testing	9CFR 113.53c[113.46,		
Extraneous Viruses (FAb) Bluetongue Virus Bovine Adenovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic)  Bovine Syncytial Virus Bovine Rabies Virus  Not Detected		113.47]		
Extraneous Viruses (FAb)  Bluetongue Virus Bovine Adenovirus Bovine Parvovirus Bovine Viral Diarrhea(cytopathic)  Bovine Syncytial Virus Bovine Rabies Virus Not Detected	Cytopathic Agents		Not Detected	Not Detected
Extraneous Viruses (FAb)  Bluetongue Virus  Bovine Adenovirus  Bovine Parvovirus  Bovine Viral  Diarrhea(cytopathic)  Bovine Syncytial Virus  Bovine Rabies Virus  Not Detected			Not Detected	Not Detected
Bluetongue Virus  Bovine Adenovirus  Bovine Parvovirus  Bovine Parvovirus  Bovine Viral  Diarrhea(cytopathic)  Bovine Syncytial Virus  Bovine Rabies Virus  Not Detected				
Bluetongue Virus  Bovine Adenovirus  Bovine Parvovirus  Bovine Parvovirus  Bovine Viral  Diarrhea(cytopathic)  Bovine Syncytial Virus  Bovine Rabies Virus  Not Detected				
Bluetongue Virus  Bovine Adenovirus  Bovine Parvovirus  Bovine Parvovirus  Bovine Viral  Diarrhea(cytopathic)  Bovine Syncytial Virus  Bovine Rabies Virus  Not Detected				
Bovine Adenovirus  Bovine Parvovirus  Bovine Viral  Diarrhea(cytopathic)  Bovine Syncytial Virus  Bovine Rabies Virus  Not Detected	Extraneous Viruses (FAb)			
Bovine Parvovirus Bovine Viral Diarrhea(cytopathic)  Bovine Syncytial Virus Bovine Rabies Virus Not Detected	Bluetongue Virus		Not Detected	Not Detected
Bovine Viral Not Detected Not Detected Diarrhea(cytopathic)  Bovine Syncytial Virus Not Detected Not Detected Bovine Rabies Virus Not Detected Not Detected	Bovine Adenovirus		Not Detected	Not Detected
Diarrhea(cytopathic)  Bovine Syncytial Virus  Bovine Rabies Virus  Not Detected  Not Detected  Not Detected	Bovine Parvovirus		Not Detected	Not Detected
Bovine Syncytial Virus  Bovine Rabies Virus  Not Detected  Not Detected  Not Detected	Bovine Viral		Not Detected	Not Detected
Bovine Rabies Virus Not Detected Not Detected	Diarrhea(cytopathic)			
Bovine Rabies Virus Not Detected Not Detected				
Bovine Rabies Virus Not Detected Not Detected	<b>Bovine Syncytial Virus</b>		Not Detected	Not Detected
Reovirus Not Detected Not Detected			Not Detected	Not Detected
	Reovirus		Not Detected	Not Detected



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# (Catalog Number 100-500)

Lot Number: A121032

Test	Methodology	Specification	Analysis
Physical Testing			
Electrophoretic Pattern	Cellulose Acetate	Normal	Normal
Osmolality	USP<785>, EP 2.2.35	260 - 350 mOsm/ kg	312 mOsm/kg
pH	USP<791>	6.5 - 8.5	7.1
Biochemistry			
Albumin		Test and Report	1.6 g/dL
Alkaline Phosphatase		Test and Report	257 IU/L
ALT (SGPT)		Test and Report	13 IU/L
AST (SGOT)		Test and Report	55 IU/L
GGT		<10 U/L	3.0 IU/L
Bilirubin, Total		Test and Report	0.1 mg/dL
BUN		Test and Report	14.0 mg/dL
Calcium		Test and Report	14.2 mg/dL
Chloride		Test and Report	96.0 mEq/L
Cholesterol		Test and Report	30.0 mg/dL
Cortisol		Test and Report	0.200 µg/dL
Creatinine		Test and Report	2.7 mg/dL
Glucose		Test and Report	131.0 mg/dL
lgG	ELISA	<0.300 mg/mL*	0.098 mg/mL
Insulin		Test and Report	8.12 μIU/mL
Iron, Serum		Test and Report	174.0 μg/dL
Phosphorus		Test and Report	10.1 mg/dL
Potassium		Test and Report	12.4 mEq/L
Progesterone		Test and Report	<0.06 ng/mL
Protein, Total	Biuret	2.5 - 6.0 g/dL	3.7 g/dL
Sodium		Test and Report	136.0 mEq/L
Testosterone		Test and Report	<0.01 ng/mL
Т3		Test and Report	203.0 ng/dL
T4		Test and Report	12.2 μg/dL
Trig <mark>lycerid</mark> es		Test and Report	71.0 mg/dL
Tetracycline		<4 ng/mL	1.40 ng/mL
Uric Acid		Test and Report	2.6 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. \*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.

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