

CERTIFICATE OF ANALYSIS

GemCell™ Fetal Bovine Serum

(Catalog Number 100-500) Heat Inactivated*

Lot Number: A63H00L

Date of Manufacture: Nov2020

Product Expiry: Nov2025

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	<1.00 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	11.3 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			
Туре І		≤1:4	< Undiluted
Type II		≤1:4	<undiluted< td=""></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	Tested
Bovine Syncytial Virus		Not Detected	Not Detected
Bovine Rabie Virus		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected



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Cellulose Acetate	Test	Methodology	Specification	Analysis
Display USP<785>, EP 2.2.35 260 – 350 mOsm/kg 315mOsm/kg 260 mosm/kg USP<791> 6.5 – 8.5 7.05 mosm/kg 315mOsm/kg 315	Physical Testing			
Sinchemistry Sinc	Electrophoretic Pattern	Cellulose Acetate	Normal	Normal
Albumin Test and Report 2.2 g/dL Alkaline Phosphatase Test and Report 176 U/L ALT (SGPT) Test and Report 5 U/L ALT (SGOT) Test and Report 27 U/L GGT	Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/ kg	315mOsm/Kg
Albumin Alkaline Phosphatase A	pH	USP<791>	6.5 – 8.5	7.05
Alkaline Phosphatase ALT (SGPT) ALT (SGPT) AST (SGOT) Test and Report AST (Biochemistry			
Test and Report S U/L	Albumin		Test and Report	2.2 g/dL
Test and Report 27 U/L 5	Alkaline Phosphatase		Test and Report	176 U/L
Seg	ALT (SGPT)		Test and Report	5 U/L
Test and Report 15 mg/dl Test and Report 15 mg/dl Test and Report 13.1 mg/dl Test and Report 98 mmol/L Test and Report 28 mg/dl Test and Report 28 mg/dl Test and Report 2.4 mg/dl Test and Report 2.4 mg/dl Test and Report 11.77 pg/ml Test and Report 11.77 pg/ml Test and Report 11.0 mg/dl Test and Report 11.0 mg/dl Test and Report 7.60 ulU/ml Test and Report 166 ug/dl Test and Report 9.7 mg/dl Test and Report 160 ulU/ml Test and Report 10.0 mmol/L Test and Report 10.0 mg/ml Test and Report 10.0 mg/dl Test and Report 10.0 ng/ml	AST (SGOT)		Test and Report	27 U/L
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 28 mg/dL Cortisol Test and Report 2.4 mg/dL Cortisol Test and Report 2.4 mg/dL Cortisol Test and Report 2.4 mg/dL Cortisol Test and Report 11.77 pg/mL Cortisol Test and Report 11.77 pg/mL Cortisol Test and Report 11.0 mg/dL Cortisol Test and Report 7.60 ulU/mL Cortisol Test and Report 166 ug/dL Cortisol Test and Report 9.7 mg/dL Cortisol Test and Report 135 mmol/L Cortisol Test and Report 135 mmol/L Test and Report 101 ng/dL Test and Report 101 ng/dL Test and Report 101 ng/dL Test and Report 12.9 ug/dL Test and Report 71 mg/dL	GGT		<10 U/L	5 U/L
Test and Report 13.1 mg/dL 198 mmol/L 20 mg/dL 20 mg/mL 20 mg/dL 20 mg/dL 20 mg/mL 20 mg/dL 20 mg/mL 20 mg/dL 20 mg/mL 20 mg/dL 20 mg/mL 2	Bilirubin, Total		Test and Report	0.2 mg/dl
Test and Report 98 mmol/L Cholesterol Test and Report 28 mg/dL Cortisol Test and Report 40.2 ug/dL Creatinine Test and Report 41.77 pg/mL Test and Report 410 mg/dL Glucose Test and Report 410 mg/dL Glucose Test and Report 410 mg/dL Glucose Test and Report 40.096 mg/mL Test and Report 40.006 mg/mL Test and Report 40.001 mg/mL Test and Report 40.01 mg/dL Test and Report 40.01 mg/mL Test and Report 40.01 mg/dL Test and Report 40.01 mg/mL Test and Report 40.01 mg/dL Test and Report 40.01 mg/mL Test and Report 40.01 mg/dL Test and Report 40.01 mg/mL Te	BUN		Test and Report	15 mg/dL
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 gG ELISA O.300 mg/mL** O.96 mg/mL ron, Serum Test and Report 7.60 uIU/mL ron, Serum Test and Report 9.7 mg/dL Phosphorus Test and Report 9.7 mg/dL Progesterone Test and Report >10.0 mmol/L Progesterone Test and Report <0.06 ng/mL Sodium Test and Report 135 mmol/L Test and Report 101 ng/dL	Calcium		Test and Report	13.1 mg/dL
Test and Report	Chloride		Test and Report	98 mmol/L
Test and Report 2.4 mg/dL Estradiol Test and Report 11.77 pg/mL Test and Report 11.0 mg/dL gG ELISA <0.300 mg/mL** 0.096 mg/mL ron, Serum Test and Report 7.60 uIU/mL ron, Serum Test and Report 166 ug/dL Phosphorus Test and Report 9.7 mg/dL Progesterone Test and Report >10.0 mmol/L Progesterone Test and Report <0.06 ng/mL Test and Report 135 mmol/L Test and Report 135 mmol/L Test and Report 101 ng/dL Test and Report 101 ng/dL Test and Report 102.9 ug/dL Test and Report 102.9 ug/dL Test and Report 103 mg/dL Test and Report 104 mg/dL Test and Report 105 mg/dL Test and Report 105 mg/dL Test and Report 105 ng/mL	Cholesterol		Test and Report	28 mg/dL
Test and Report 11.77 pg/mL Glucose gG ELISA	Cortisol		Test and Report	<0.2 ug/dL
Test and Report 110 mg/dL Squared Squ	Creatinine		Test and Report	2.4 mg/dL
gG ELISA <0.300 mg/mL** 0.096 mg/mL nsulin Test and Report 7.60 uIU/mL ron, Serum Test and Report 166 ug/dL Phosphorus Test and Report 9.7 mg/dL Protessium Test and Report >10.0 mmol/L Protein, Total Biuret 2.5 – 6.0 g/dL 3.3 g/dL Sodium Test and Report 135 mmol/L Test and Report 101 ng/mL Test and Report 101 ng/dL Test and Report 101 ng/dL Test and Report 102.9 ug/dL Test and Report 71 mg/dL	Estradiol		Test and Report	11.77 pg/mL
Test and Report 7.60 uIU/mL ron, Serum Test and Report 166 ug/dL Phosphorus Test and Report 9.7 mg/dL Protessium Test and Report 9.7 mg/dL Protein, Total Protein, Total Biuret 2.5 – 6.0 g/dL 3.3 g/dL Test and Report 135 mmol/L Test and Report 40.01 ng/mL Test and Report 101 ng/dL Test and Report 101 ng/dL Test and Report 101 ng/dL Test and Report 12.9 ug/dL Test and Report 71 mg/dL	Glucose		Test and Report	110 mg/dL
Test and Report 166 ug/dL Phosphorus Test and Report 9.7 mg/dL Protassium Progesterone Test and Report >10.0 mmol/L Protein, Total Biuret 2.5 – 6.0 g/dL 3.3 g/dL Test and Report 135 mmol/L Test and Report <0.01 ng/mL Test and Report 101 ng/dL Test and Report 101 ng/dL Test and Report 12.9 ug/dL Test and Report 71 mg/dL	lgG	ELISA	<0.300 mg/mL**	0.096 mg/mL
Phosphorus Potassium Potassium Progesterone Progesterone Protein, Total Protein, Total Potassium Protein, Total	Insulin		Test and Report	7.60 uIU/mL
Potassium Progesterone Progesterone Protein, Total Biuret Signature Fest and Report Fest and	Iron, Serum		Test and Report	166 ug/dL
Progesterone Protein, Total Biuret 2.5 – 6.0 g/dL 3.3 g/dL 3.3 g/dL 5odium Test and Report	Phosphorus		Test and Report	9.7 mg/dL
Protein, Total Biuret 2.5 – 6.0 g/dL 3.3 g/dL Godium Test and Report 135 mmol/L Testosterone Test and Report <0.01 ng/mL Test and Report 101 ng/dL Test and Report 12.9 ug/dL Triglycerides Test and Report 71 mg/dL Tetracycline <4 ng/mL <1.0 ng/mL	Potassium		Test and Report	>10.0 mmol/L
GodiumTest and Report135 mmol/LTestosteroneTest and Report<0.01 ng/mL	Progesterone		Test and Report	<0.06 ng/mL
Test and Report <0.01 ng/mL Test and Report 101 ng/dL Test and Report 12.9 ug/dL Triglycerides Test and Report 71 mg/dL Tetracycline <4 ng/mL <1.0 ng/mL	Protein, Total	Biuret	2.5 – 6.0 g/dL	3.3 g/dL
Test and Report 101 ng/dL Test and Report 12.9 ug/dL Triglycerides Test and Report 71 mg/dL Tetracycline <4 ng/mL <1.0 ng/mL	Sodium		Test and Report	135 mmol/L
T4Test and Report12.9 ug/dLFriglyceridesTest and Report71 mg/dLFetracycline<4 ng/mL	Testosterone		Test and Report	<0.01 ng/mL
Friglycerides Test and Report 71 mg/dL Fetracycline <4 ng/mL <1.0 ng/mL	Т3		Test and Report	101 ng/dL
Tetracycline <4 ng/mL <1.0 ng/mL	T4		Test and Report	12.9 ug/dL
•	Triglycerides		Test and Report	71 mg/dL
Jric Acid Test and Report 2.0 mg/dL	Tetracycline		<4 ng/mL	<1.0 ng/mL
	Uric Acid		Test and Report	2.0 mg/dL



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(Catalog Number 100-500) Heat Inactivated*

Lot Number: A63H00L

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 Kharasi	OC supervisor
Name	Title
12 FEB 2021	
Date	