

## **Certificate of Analysis**

Created October 25, 2019

**Product:** 

## GemCell™ Fetal Bovine Serum

Triple 0.1µm sterile-filtered

Catalog #: 100-500 Lot #: A14H00K

**Origin: United States (100%)** 

Manufacture Date: Sep 2019 Expiration Date: Sep 2024

ТЕЅТ	METHODOLOGY	SPECIFICATION	RESULTS
Biological Testing			
Endotoxin	USP<85>	<10.0 EU/mL	<0.500 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	10.1 mg/dL
	- 4		_
Microbiological Testing			
Sterility	USP<71>		
Bacteria		Not Detected	Not Detected
Fungi		Not Detected	Not Detected
Mycoplasma	Barile, MF and Kern, J (1971)	Not Detected	Not Detected
Viral Teeting	0.050.440.50.440.40.40		
Viral Testing	9 CFR 113.53c [113.46, 113.47]		Net Detected
Cytopathic Agents		Not Detected	Not Detected
Hemadsorbing Agents Bovine Viral Diarrhea Ab Titer		Not Detected	Not Detected
			4.4
Type I	<u>'</u>	Test and Report	1:4
Type II		Test and Report	1:1
Extraneous Viruses (FAb)			Net Detected
Bluetongue Virus Bovine Adenovirus		Not Detected	Not Detected
Bovine Parvovirus		Not Detected	Not Detected
		Not Detected	Not Detected
Bovine Viral Diarrhea (cytopathic		Not Detected	Not Detected
Bovine Viral Diarrhea (non-cytop	atnic)	Test and Report	Negative
Bovine Syncytial Virus  Bovine Rabies Virus		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected
Physical Testing			
Electrophoretic Pattern	Cellulose Acetate	Normal	Normal
Osmolality	USP<785>	260-350 m0sm/kg	319 m0sm/kg
pH @ RT	USP<791>	6.5 – 8.5	7.11



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Test	METHODOLOGY	Specification		RESULTS	
Albumin		Test and Report	2.4	g/dL	
Alkaline Phosphatase		Test and Report	185	U/L	
ALT (SGPT)		Test and Report	6	U/L	
AST (SGOT)		Test and Report	40	U/L	
GGT		<10 U/L	5	U/L	
Bilirubin, Total		Test and Report	0.3	mg/dL	
BUN		Test and Report	16	mg/dL	
Calcium		Test and Report	3.33	mM	
Chloride		Test and Report	102	mM	
Cholesterol		Test and Report	30	mg/dL	
Cortisol		Test and Report	10.7	nM	
Creatinine		Test and Report	2.9	mg/dL	
Estradiol		Test and Report	159	pМ	
Glucose		Test and Report	6.27	mM	
lgG	ELISA	<0.300 mg/mL*	0.214	mg/mL	
Insulin		Test and Report	57	pΜ	
Iron, Serum		Test and Report	191	ug/dL	
Phosphorus		Test and Report	3.1	mM	
Potassium		Test and Report	>10.0	mM	
Progesterone		Test and Report	<0.19	nM	
Protein, Total	Biuret	2.5-6.0 g/dL	3.6	g/dL	
Sodium		Test and Report	138	mM	
Testosterone		Test and Report	<0.03	nM =	
T3		Test and Report	1.57	nM	
T4		Test and Report	167	nM	
Triglycerides		Test and Report	61	mg/dL	
Tetracycline		<4 ng/mL		Pass	
Uric Acid		Test and Report	2.5	mg/dL	

For Cell Culture, further Manufacturing and Research use only. Not for direct Therapeutic use.

Results shown were obtained by carefully performed methods believed to be reliable. However, since some results may vary by methodology, it is suggested that tests for which results are particularly critical be repeated by the end user. 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.

CREATED BY/ DATE

**VERIFIED BY/ DATE**