

Certificate of Analysis

Revised October 25, 2019

Product:

GemCell™ Fetal Bovine Serum Heat Inactivated*

Triple 0.1µm sterile-filtered

Catalog #: 100-500 Lot #: A14H00K

Origin: United States (100%)

Manufacture Date: Sep 2019 Expiration Date: Sep 2024

TEST	M ETHODOLOGY	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
Microbiological Testing	4		
Sterility	USP<71>		Đ
Bacteria		Not Detected	Not Detected
Fungi	a _c	Not Detected	Not Detected
Mycoplasma	Barile, MF and Kern, J (1971)	Not Detected	Not Detected
Viral Testing	9 CFR 113.53c [113.46, 113.47]		
Cytopathic Agents		Not Detected	Not Detected
Hemadsorbing Agents	e	Not Detected	Not Detected
Bovine Viral Diarrhea Ab Titer			
Type I		Test and Report	1:4
Type II		Test and Report	1:1
Extraneous Viruses (FAb)			
Bluetongue Virus		Not Detected	Not Detected
Bovine Adenovirus		Not Detected	Not Detected
Bovine Parvovirus		Not Detected	Not Detected
Bovine Viral Diarrhea (cy	topathic)	Not Detected	Not Detected
Bovine Viral Diarrhea (no	n-cytopathic)	Test and Report	Negative
Bovine Syncytial Virus		Not Detected	Not Detected
Bovine Rabies Virus	2	Not Detected	Not Detected
Reovirus	į.	Not Detected	Not Detected
Physical Testing			
Electrophoretic Pattern	Cellulose Acetate	Normal	Normal
Osmolality	USP<785>	260-350 mOsm/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	12	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 pM
Glucose		Test and Report	6.27 mM
lgG	ELISA	<0.300 mg/mL**	0.214 mg/mL
Insulin		Test and Report	57 pM
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
T 4		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
		. cot and mopore	2.0 1116/42

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

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. WMM 250C47011

CREATED BY/ DATE

250012019 **VERIFIED BY/ DATE**

^{*}Results shown were obtained by carefully performed methods believed to be reliable prior to Heat Inactivation, 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.