

Certificate of Analysis

Created September 30, 2019

Product:

Statis™ Stem cell Qualified Fetal Bovine Serum

Triple 0.1µm sterile-filtered

Catalog #: 100-525 Lot #: A12H00K

Origin: United States (100%)

Manufacture Date: Jan 2019 Expiration Date: Jan 2024

T EST	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	12.4 mg/dL
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 Testing	9 CFR 113.53c [113.46, 113.47]		
Cytopathic Agents		Not Detected	Not Detected
Hemadsorbing Agents		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 (cytopathic)		Not Detected	Not Detected
Bovine Viral Diarrhea (non-cytopathic)		Test and Report	Not Detected
Bovine Syncytial Virus		Not Detected	Not Detected
Bovine Rabies Virus		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected
Physical Testing			
Electrophoretic Pattern	Cellulose Acetate	Normal	Normal
Osmolality	USP<785>	260-350 m0sm/kg	303 m0sm/kg
pH @ RT	USP<791>	6.5 - 8.5	7.15



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Albumin		Test and Report	2.1	g/dL
Alkaline Phosphatase		Test and Report	207	U/L
ALT (SGPT)		Test and Report	6	U/L
AST (SGOT)		Test and Report	49	U/L
GGT		<10 U/L	3	U/L
Bilirubin, Total		Test and Report	0.3	mg/dL
BUN		Test and Report	13	mg/dL
Calcium		Test and Report	3.2	mM
Chloride		Test and Report	96	mM
Cholesterol		Test and Report	28	mg/dL
Cortisol		Test and Report	9.52	nM
Creatinine		Test and Report	2.2	mg/dL
Estradiol		Test and Report	171	pM
Glucose		Test and Report	4.4	mM
IgG	ELISA	<0.300 mg/mL*	0.106	mg/mL
Insulin		Test and Report	63.8	pM
Iron, Serum		Test and Report	173	ug/dL
Phosphorus		Test and Report	2.9	mM
Potassium		Test and Report	>10.0	mM
Progesterone		Test and Report	<0.19	nM
Protein, Total	Biuret	2.5-6.0 g/dL	3.3	g/dL
Sodium		Test and Report	134	mM
Testosterone		Test and Report	< 0.03	nM
T3		Test and Report	1.56	nM
T4		Test and Report	147	nM
Triglycerides		Test and Report	60	mg/dL
Tetracycline		<4 ng/mL	Pass	
Uric Acid		Test and Report	1.9	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.

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