



CERTIFICATE OF ANALYSIS
Stasis™ Fetal Bovine Serum
(Catalog Number 100-125)

Lot Number: A65H02K

Date of Manufacture: Oct2019

Origin: United States

Product Expiry: Oct2024

For Cell culture, Further Manufacturing or Research use Only. Not for Direct Therapeutic Use.

Storage Temperature: ≤ -10°C

Product description: *Stasis™ 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	<0.1 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	9.25 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			
Type I		Test and Report	1:1
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 Rabie Virus		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected



Test	Methodology	Specification	Analysis
Physical Testing			
Electrophoretic Pattern	Cellulose Acetate	Normal	Normal
Osmolality	USP<785>, EP 2.2.35	260 – 350 mOsm/ kg	293 mOsm/kg
pH	USP<791>	6.5 – 8.5	7.32
Biochemistry			
Albumin		Test and Report	2.0 g/dL
Alkaline Phosphatase		Test and Report	207 U/L
ALT (SGPT)		Test and Report	6 U/L
AST (SGOT)		Test and Report	53 U/L
GGT		<10 U/L	5 U/L
Bilirubin, Total		Test and Report	0.2 mg/dL
BUN		Test and Report	14 mg/dL
Calcium		Test and Report	3.3 mM
Chloride		Test and Report	98 mM
Cholesterol		Test and Report	29 mg/dL
Cortisol		Test and Report	9.1nM
Creatinine		Test and Report	2.6 mg/dL
Estradiol		Test and Report	142pM
Glucose		Test and Report	6.3mM
IgG	ELISA	<0.300 mg/mL*	0.118 mg/mL
Insulin		Test and Report	22.9pM
Iron, Serum		Test and Report	192 ug/dL
Phosphorus		Test and Report	3.1mM
Potassium		Test and Report	>10.0 mmol/L
Progesterone		Test and Report	<0.3nM
Protein, Total	Biuret	2.5 – 6.0 g/dL	3.5 g/dL
Sodium		Test and Report	137 mmol/L
Testosterone		Test and Report	<0.03nM
T3		Test and Report	1.53nM
T4		Test and Report	206nM
Triglycerides		Test and Report	61 mg/dL
Tetracycline		<4 ng/mL	Pass
Uric Acid		Test and Report	2.7 mg/dL

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.

Megha Khatalasi

Name

03 DEC 2020

Date

QA Associate III

Title