HyClone™

Product: **FetalClone® III**
Bovine Serum Product
Collected and Processed in the USA
Catalog#: **SH30109**
Lot#: **AH29774692**
Filtration: **Triple 0.1 µm Sterile Filtered**

Manufacture Date: **01/MAR/2022**
Expiration Date: **31/MAR/2027**
Total Batch Volume: **2916 L**

CERTIFICATE OF ANALYSIS

Test/(Method)	Specification	Units	Results
General Testing			
Endotoxin	≤ 10	EU/mL	<0.5
Hemoglobin	≤ 25	mg/dL	9
Sterility (Bacteria and Fungi)	No Growth		No Growth
Mycoplasma	Not Detected		Not Detected
Total Protein	Test and Report	g/dL	3.5
pH	Test and Report		6.50
Osmolality	Test and Report	mOsm/kg	363
Growth Promotion	Not Cytotoxic		Not Cytotoxic
Ouchterlony (Double Immunodiffusion)	Positive for Bovine		Positive for Bovine
Gamma Glutamyl Transferase (enzymatic rate method)	Test and Report	U/L	22
Virus Testing			
Bluetongue	Not Detected		Not Detected
Bovine Adenovirus	Not Detected		Not Detected
Bovine Parvo Virus	Not Detected		Not Detected
Bovine Respiratory Syncytial Virus	Not Detected		Not Detected
Bovine Viral Diarrhea	Not Detected		Not Detected
Rabies	Not Detected		Not Detected
Reovirus	Not Detected		Not Detected
Cytopathogenic Agents – e.g. IBR	Not Detected		Not Detected
Hemadsorbing Agents – e.g. PI3	Not Detected		Not Detected
BVDV Beta SN Genotype 1	Test and Report		Undiluted
BVDV Beta SN Genotype 2	Test and Report		Undiluted
Proteins/Other			
Albumin	Test and Report	g/dL	2.4
Alkaline Phosphatase	Test and Report	U/L	90
Blood Urea Nitrogen	Test and Report	mg/dL	10
Creatinine	Test and Report	mg/dL	0.33
Gamma Globulin	Test and Report	% tp	3.66
Glucose	Test and Report	mg/dL	24
Glutamic Oxaloacetic Transaminase (SGOT)	Test and Report	U/L	55
Glutamic Pyruvic Transaminase (SGPT)	Test and Report	U/L	9
IgG – Nephelometer	Test and Report	mg/mL	0.077
Lactate Dehydrogenase	Test and Report	U/L	423
Total Bilirubin	Test and Report	mg/dL	0.2

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Test	Specification	Units	Results
Trace Metals/Iron			
Calcium	Test and Report	mg/dL	>24.0
Chloride	Test and Report	mmol/L	135
Inorganic Phosphorus	Test and Report	mg/dL	7.9
Iron	Test and Report	ug/dL	708
Percent Saturation (Iron)	Test and Report	%	89
Potassium	Test and Report	mmol/L	7.7
Sodium	Test and Report	mmol/L	160
Total Iron Binding Capacity (TIBC)	Test and Report	ug/dL	793
Electrophoretic Profile			
(Cellulose Acetate)			
Albumin		%	67.05
Alpha – 1		%	9.39
Alpha – 2		%	4.47
Beta		%	15.43
Gamma		%	3.66

General Testing References
Endotoxin-Kinetic Turbidimetric USP<85>/Ph. Eur. 2.6.14
Hemoglobin-USP <857> Monograph (Spectrophotometric)
Sterility Testing-Current USP<71>/Ph. Eur. 2.6.1 (Bacteria and Fungi)
Mycoplasma-USP<63>/Ph. Eur. 2.6.7/FDA PTC 1993
Total Protein-USP<1057>Ph. Eur. 2.5.33
pH-USP<791>/Ph. Eur. 2.2.3
Osmolality-USP<785>/Ph. Eur. 2.2.35
Ouchterlony (comparative double diffusion method)-Ph. Eur. 2.7.1

Virus Testing References
Bluetongue, Bovine Adenovirus, Bovine Parvovirus, Bovine Respiratory Syncytial Virus, Bovine Diarrhea Virus, Rabies, Reovirus-9CFR 113.53-Fluorescent Antibody-9CFR113.47 Cytopathic Agents, Hemadsorbing Agents-9CFR 113..53, Beta Serum Neutralization Titer-EMEA/CVMP/743/00 (4.3.3.3) & EMA/CHMP/BWP/457920/2012(7.3.4) BVDV Genotype 1, 2

Cell Lines Used
FOX-NY Hybrid Cells, MRC-5 Cells

This product was manufactured from fetal bovine blood collected in USDA inspected abattoirs located in the United States.

Cytiva Bovine Serum products have been granted a Certificate of Suitability to the European Pharmacopoeia Monograph, Certificate #R1-CEP 2000-185 https://www.cytivalifesciences.com/en/us/support/quality/certificates

The World Organization for Animal Health (O.I.E.) Scientific Commission has recommended the USA be classified 'Negligible Risk' for BSE.

Traceability Certified by the ISIA (International Serum Industry Association) website: https://www.serumindustry.org/

Meets EP2262 Requirements

Lori Aston 21Apr2022
Lori Aston / Date Issued
Quality Department

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