

FetalPURE™ Bovine Serum
Triple 0.1µm Sterile Filtered
Origin: 100% USA, Collected and Processed in USA
Expiration Date: 06/2023

Catalog Number: 25-525, 25-525H
Lot Number: GS180621
Manufacture Date: 06/2018
Storage Temperature: -10 to -30°C

TEST	METHOD	SPECIFICATION	RESULT
Endotoxin	USP <85>, LAL	<10 EU/mL	1.04 EU/mL
Hemoglobin	Three-wavelength Polychromatic Analysis	<30 mg/dL	21.5 mg/dL

Microbiological Testing

TEST	METHOD	SPECIFICATION	RESULT
Sterility (Bacteria & Fungi)	USP <71>/EP 2.6.1	No Growth	No Growth
Mycoplasma	Barile, M.F. and Kern, J.	Not Detected	Not Detected
Electrophoretic ID	Gel Electrophoresis	Characteristic	Characteristic

Virus Testing

TEST	METHOD	SPECIFICATION	RESULT
9 CFR 113.53c with final analysis by 113.46 and 113.47			
Cytopathic Agents		Not Detected	Not Detected
Hemadsorbing Agents		Not Detected	Not Detected
Extraneous Virus			
Bluetongue Virus		Not Detected	Not Detected
Bovine Adenovirus		Not Detected	Not Detected
Bovine Parvovirus		Not Detected	Not Detected
Bovine Respiratory Syncytial Virus		Not Detected	Not Detected
Bovine Viral Diarrhea Virus (BVDV)		Tested	Not Detected
Rabies (Rabdovirus)		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected
Infectious Bovine Rhinotracheitis		Not Detected	Not Detected
Parainfluenza 3 (PI3)		Not Detected	Not Detected

Serum Antibody Neutralization: Alpha-SN BVDV Genotype 1: 10^{5.70} Alpha-SN BVDV Genotype 2: 10^{5.95}

Physical Analyses

TEST	METHOD	SPECIFICATION	UNITS	RESULT
Protein electrophoresis	Cellulose acetate			
Albumin		Check & Record	gm/dL	2.41
Alpha 1/2		Check & Record	gm/dL	1.14
Beta		Check & Record	gm/dL	0.46
Gamma		Check & Record	gm/dL	0.10
Osmolality	USP<785>, Freezing point Depression	Check & Record	mOsm/Kg	296
pH at room temperature	USP<791>	Check & Record	N/A	7.7
Precipitation	Ouchterlony double fusion			
Bovine Antibody		Check & Record	N/A	Positive
Equine Antibody		Check & Record	N/A	Negative
Porcine Antibody		Check & Record	N/A	Negative

Certificate of Analysis

Tetracycline Antibiotics

	SPECIFICATION	UNITS	RESULT
Chlortetracycline	Check & Record	ppb	<10
Doxycycline	Check & Record	ppb	<20
Oxytetracycline	Check & Record	ppb	<10
Tetracycline	Check & Record	ppb	<10

Biochemical Assay

	SPECIFICATION	UNITS	RESULT
A/G Ratio	Check & Record	Ratio	2.2
Albumin	Check & Record	gm/dL	2.8
Alkaline Phosphatase (ALP)	Check & Record	IU/L	130
Bicarbonate	Check & Record	mEq/L	22.5
Creatine Kinase (CK)	Check & Record	IU/L	650
Creatinine	Check & Record	mg/dL	1.4
Cholesterol	Check & Record	mg/dL	29
Gamma-Glutamyltransferase (GGT)	Check & Record	IU/L	13
Globulin	Check & Record	gm/dL	1.3
Glucose	Check & Record	mg/dL	91
Aspartate Transferase (AST)	Check & Record	IU/L	62
IgG by ELISA, Bovine	Check & Record	µg/mL	214
Total Bilirubin	Check & Record	mg/dL	0.9
Total Protein	Check & Record	gm/dL	4.1
Triglycerides	Check & Record	mg/dL	20
Calcium	Check & Record	mg/dL	10.5
Chloride	Check & Record	mEq/L	97.1
Iron	Check & Record	µg/dL	92
Potassium	Check & Record	mEq/L	6.29
Sodium	Check & Record	mEq/L	144
Magnesium	Check & Record	mq/dL	2.3
Phosphorous	Check & Record	mg/dL	7.2

Hormone Profile

	SPECIFICATION	UNITS	RESULT
Estradiol baseline - Immulite	Check & Record	pg/mL	32.3
Insulin: Bovine/Rodent - RIA	Check & Record	µIU/mL	2.96
Progesterone- RIA - Bovine	Check & Record	ng/mL	<0.05
Testosterone baseline - RIA	Check & Record	ng/mL	<0.01
T4 (Thyroxine) - Immuliate	Check & Record	µg/dL	>10.0

Performance Testing Assays

Growth (Ability of lot to support proliferation)	>75% of Control	Cell Line: Vero, CHO-K1	Pass
Cloning (Ability of lot to support cloning & growth)	>70% of Control	Cell Line: Vero, CHO-K1	Pass

For further manufacturing use. Not for human or animal consumption. Product meets EU requirements for Production of Technical Blood Products. Results shown were obtained by independent test organizations according to agreed requirements and believed to be reliable. It is suggested that tests which are particularly important to the end user be repeated for validity. Some results may vary depending on methodology and other variables.