

FetalPURE™ Bovine Serum
Triple 0.1µm Sterile Filtered
Origin: 100% USA, Collected and Processed in USA
Storage Temperature: -10° to -30°C

Catalog Number: 25-525, 25-525H
Lot Number: P093156
Manufacture Date: 04/2020
Expiration Date: 03/2025

TEST	METHOD	SPECIFICATION	RESULT
Endotoxin	Current USP <85>, LAL	<10 EU/mL	<0.149 EU/mL
Hemoglobin	Three-wavelength Polychromatic Analysis	<30 mg/dL	10.2 mg/dL

Microbiological Testing

TEST	METHOD	SPECIFICATION	RESULT
Sterility (Bacteria & Fungi)	USP <71>/ EP 2.6.1/21 CFR	Not Detected	Not Detected
Mycoplasma	Barile, M.F. and Kern, J.	Not Detected	Not Detected

Virus Testing

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 (FAB)			
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
Rabies (Rabdovirus)		Not Detected	Not Detected
Reovirus		Not Detected	Not Detected
BVDV		Tested	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 ^{5.30} Alpha-SN BVDV Genotype 1: 10 ^{4.91}		No Neutralization

Physical Analyses

TEST	METHOD	SPECIFICATION	UNITS	RESULT
Protein electrophoresis	Cellulose acetate			
Alpha 1 + 2		Check & Record	g/dL	1.33
Beta		Check & Record	g/dL	0.42
Gamma		Check & Record	g/dL	0.07
Osmolality	USP<785>	Check & Record	mOsm/Kg	292
pH	USP<791>	Check & Record	N/A	7.7
Precipitation	Ouchterlony Double Diffusion			
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	g/dL	2.33
Albumin	Check & Record	g/dL	2.8
Alkaline Phosphatase (ALP)	Check & Record	IU/L	113
Bicarbonate	Check & Record	mEq/L	22.6
Blood Urea Nitrogen (BUN)	Check & Record	mg/dL	11
Creatinine	Check & Record	mg/dL	1.4
Creatinine Kinase	Check & Record	IU/L	496
Cholesterol	Check & Record	mg/dL	25
Glucose	Check & Record	mg/dL	85
Aspartate Transferase (AST)	Check & Record	IU/L	55
IgG (ELISA)	Check & Record	µg/mL	130
GGT	Check & Record	IU/L	9
Globulin	Check & Record	g/dL	1.2
Total Bilirubin	Check & Record	mg/dL	0.9
Total Protein	Check & Record	g/dL	4.0
Triglycerides	Check & Record	mg/dL	16
Calcium	Check & Record	mg/dL	10.6
Chloride	Check & Record	mEq/L	99.6
Magnesium	Check & Record	mq/dL	2.1
Inorganic Phosphorus	Check & Record	mg/dL	6.9
Iron	Check & Record	µg/dL	80
Potassium	Check & Record	mEq/L	5.52
Sodium	Check & Record	mEq/L	144

Hormone Profile

	SPECIFICATION	UNITS	RESULT
Insulin	Check & Record	µIU/mL	<2.36
Progesterone	Check & Record	ng/mL	<0.06
Testosterone	Check & Record	ng/mL	<0.01
T4	Check & Record	µg/dL	11.9

For further manufacturing use. Not for human consumption. Product meets EU requirements for Production of Technical Blood Products. Results shown were obtained by independent test organizations according to the 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 the methodology and other variables.

Reviewed by *Kathryn Maisch*
Product Marketing Manager

Date: 03/25/2020