

Catalog Number: 89510-182, 89510-186  
Heat Inactivated: 89510-184, 89510-188

When additional processing is requested, original catalog # will appear on product along with heat inactivation sticker. VWR product # will be amended to reflect processing.

Material description: Fetal Bovine Serum  
Grade: USDA Approved Origin  
Lot Number: 015B20  
Total Volume: 978.0 Liters  
Date of Manufacture: 15 January 2020  
Expiration Date: February 2025  
Date Released: 09 March 2020  
Origin: Collected in Mexico and Processed in USA  
Filtration: Triple 0.1µm Sterile Filtered  
Storage: -10° to -20°C

## Certified Analysis

Test/Method	Unit of Measure	Specification	Result
Endotoxin (USP 85)	EU/mL	≤10	<0.025
Hemoglobin (Fleming & Woolf)	mg/dL	≤25	19.51
Sterility (Current USP and EP 2.6.1 for Bacteria & Fungi)	N/A	No Growth	No Growth
Mycoplasma (Barile & Kern; Large Volume, Direct Culture)	N/A	Not Detected	Not Detected
pH (USP 791)	N/A	Test & Report	7.28
Osmolality (USP 785)	mOsm/KgH2O	Test & Report	322
<b>Virus Testing</b> (9 CFR 113.53c)			
Bluetongue	N/A	Tested	Not Detected
Bovine Adenovirus	N/A	Tested	Not Detected
Bovine Parvovirus	N/A	Tested	Not Detected
Bovine Respiratory Syncytial Virus	N/A	Tested	Not Detected
Bovine Viral Diarrhea Virus	N/A	Tested	Not Detected
Rabies	N/A	Tested	Not Detected
Reovirus	N/A	Tested	Not Detected
Cytopathogenic Agents (IBR)	N/A	Tested	Not Detected
Hemadsorbing Agents (PI3)	N/A	Tested	Not Detected

## Biochemical Assay

Test/Method	Unit of Measure	Result	Test/Method	Unit of Measure	Result
Albumin	g/dL	2.2	Phosphorus	mg/dL	9.5
Alkaline Phosphatase	U/L	214	Potassium	mEq/L	>10.0
ALT (SGPT)	U/L	8	Protein, Total	g/dL	3.4
AST (SGOT)	U/L	62	Sodium	mEq/L	132
Bilirubin – Total	mg/dL	0.2	Triglycerides	mg/dL	63
Calcium	mg/dL	13.2	Urea Nitrogen (BUN)	mg/dL	16
Chloride	mEq/L	96	Uric Acid	mg/dL	2.6
Cholesterol - Total	mg/dL	26	<b>Electrophoretic Profile</b>		
Creatinine	mg/dL	2.5	Alpha 1 & 2	g/dL	1.2
GGT	U/L	4	Beta 1 & 2	g/dL	0.2
Glucose	mg/dL	114	Gamma 1	N/A	Not Detected
HDL Cholesterol	mg/dL	9			
IgG (ELISA)	µg/mL	263			
Iron, Total	ug/dL	164			
LDL Cholesterol	mg/dL	4			

## Statements

**Statement of Origin:** This product was manufactured from fetal bovine whole blood collected exclusively from USDA approved countries of origin. All fetal bovine serum used in this product is derived from fetuses collected from cows that are of Mexico origin and have passed ante- and post-mortem inspection. All collection and processing activities are performed under strict guidance of standard operating procedures

**Statement of Intended Use:** For further manufacturing or research use; not for therapeutic applications. NOT FOR HUMAN OR ANIMAL CONSUMPTION.


### **BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) STATEMENT**

Seradigm certifies that this product does not contain, and is not derived from, specified risk material as defined in Commission Decision 97/534/EC. The Commission Decision defines specified risk material of bovine origin as: the skull, including the brain and eyes, tonsils and spinal cord of bovine animals aged over 12 months.

Bovine spongiform encephalopathy cannot be removed using collection or filtration methods. No assays are available to detect prions in blood products, there preventing any inactivation processes from being performed that would guarantee bovine blood to be prion-free. The European Pharmacopeia (Ph.Eur. 2002, 5.2.8 Minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products) and the World Health Organization both assign fetal bovine serum a Category iV "no detectable infectivity" classification, a designation of least amount of risk.

OIE Resolution No. 20, issued May 2013, upgraded the United States' risk status classification for BSE to "negligible risk".

Signed on behalf of VWR:



John Manley  
Quality Manager