Certificate of Analysis and Origin

Catalog Number:	**89510-194, 97068-085**	**Gamma Irradiated:**	**97068-086**
Heat Inactivated:	**89510-196, 97068-091**	**Heat Inactivated, Gamma Irradiated:**	**97068-088**

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

Material description:	**Fetal Bovine Serum**
Grade:	**Premium Grade**
Lot Number:	**249B17**
Total Volume:	**2034.7 Liters**
Date of Manufacture:	**06 September 2017**
Expiration Date:	**October 2022**
Date Released:	**14 October 2017**
Origin:	**Collected 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	≤20	<0.020
Hemoglobin (Fleming & Woolf)	mg/dL	≤25	11.89
Total Protein	g/dL	3.0 to 4.5	3.4
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	7.21
Osmolality (USP 785)	mOsm/KgH20	Test & Report	297
Virus Testing (9 CFR 113.53c)			
Bluetongue	N/A	Not Detected	Not Detected
Bovine Adenovirus	N/A	Not Detected	Not Detected
Bovine Parvovirus	N/A	Not Detected	Not Detected
Bovine Respiratory Syncytial Virus	N/A	Not Detected	Not Detected
Bovine Viral Diarrhea Virus	N/A	Tested	Not Detected
Rabies	N/A	Not Detected	Not Detected
Reovirus	N/A	Not Detected	Not Detected
Cytopathogenic Agents (IBR)	N/A	Not Detected	Not Detected
Hemadsorbing Agents (PI3)	N/A	Not Detected	Not Detected

Biochemical Assay

Test/Method	Unit of Measure	Result	Test/Method	Unit of Measure	Result
Albumin	g/dL	2.2	Sodium	mEq/L	133
Alkaline Phosphatase	U/L	212	Triglycerides	mg/dL	60
ALT (SGPT)	U/L	6	Urea Nitrogen (BUN)	mg/dL	14
AST (SGOT)	U/L	61	Uric Acid	mg/dL	2.8
Bilirubin – Total	mg/dL	0.3	**Electrophoretic Profile**		
Calcium	mg/dL	13.0	Alpha 1 & 2	g/dL	1.1
Chloride	mEq/L	96	Beta 1 & 2	g/dL	0.3
Cholesterol - Total	mg/dL	29	Gamma 1	N/A	Not Detected
Creatinine	mg/dL	2.6	**Hormone Profile**		
GGT	U/L	5	Cortisol	µg/dL	0.271
Glucose	mg/dL	123	Estradiol	pg/mL	31.7
HDL Cholesterol	mg/dL	9	Insulin	µIU/mL	7.25
IgG (ELISA)	µg/mL	120	Progesterone	ng/mL	<0.05
Iron, Total	µg/dL	180	T3	ng/mL	174
LDL Cholesterol	mg/dL	20	T4	µg/dL	12.5
Phosphorus	mg/dL	10.0	Testosterone	ng/mL	<0.01
Potassium	mEq/L	>10.0			

Certificate of Analysis and Origin

Statements

Statement of Origin: This product was manufactured from fetal bovine blood collected exclusively from approved harvest facilities. All fetal bovine serum used in this product is derived from fetuses collected from cows that are United States origin and have passed ante- and post-mortem inspection. All harvest facilities are USDA inspected and approved and located within the continental United States of America. All collection and processing activities are performed under the strict guidance of standard operating procedures. This product meets European Union requirements for production of technical blood products.

Statement of Intended Use: This product is intended for further manufacturing or research use. This product is not intended for human or therapeutic use. Not for human or animal consumption.

ISIA Certified Traceability: All raw serum is certified by the International Serum Industry Association (ISIA) to be sourced in accordance with their strict traceability guidelines (www.serumindustry.org).

ISIA Compliant Documentation: This document complies with all documentation standards issued by the ISIA regarding the definition, quality control, country of origin and certified analysis of fetal bovine serum (www.serumindustry.org).

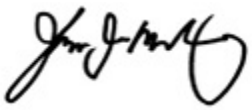
BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) STATEMENT

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”. Material from the US is now Category A (formerly GBR I) which is the lowest risk category for BSE.

Signed on behalf of VWR:



John Manley
Quality Manager