VWR Seradigm LIFE SCIENCE

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:	**311K18**
Total Volume:	**2008.5 Liters**
Date of Manufacture:	**07 November 2018**
Expiration Date:	**December 2023**
Date Released:	**15 December 2018**
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	<0.050
Hemoglobin (Fleming & Woolf)	mg/dL	≤25	14.64
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	7.08
Osmolality (USP 785)	mOsm/KgH20	Test & Report	319
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
Origin Confirmation (Oritain)	N/A	Pass	Pass

Biochemical Assay

Test/Method	Unit of Measure	Result	Test/Method	Unit of Measure	Result
Albumin	g/dL	2.1	Sodium	mEq/L	137
Alkaline Phosphatase	U/L	219	Triglycerides	mg/dL	59
ALT (SGPT)	U/L	6	Urea Nitrogen (BUN)	mg/dL	15
AST (SGOT)	U/L	47	Uric Acid	mg/dL	2.6
Bilirubin – Total	mg/dL	0.3	**Electrophoretic Profile**		
Calcium	mg/dL	12.8	Alpha 1 & 2	g/dL	1.2
Chloride	mEq/L	98	Beta 1 & 2	g/dL	0.2
Cholesterol - Total	mg/dL	27	Gamma 1	N/A	Not Detected
Creatinine	mg/dL	2.9	**Hormone Profile**		
GGT	U/L	5	Cortisol	µg/dL	0.342
Glucose	mg/dL	112	Estradiol	pg/mL	26.6
HDL Cholesterol	mg/dL	9	Insulin	µIU/mL	6.05
IgG (ELISA)	µg/mL	154	Progesterone	ng/mL	<0.06
Iron, Total	µg/dL	170	T3	ng/mL	131
LDL Cholesterol	mg/dL	6	T4	µg/dL	11.9
Phosphorus	mg/dL	10.0	Testosterone	ng/mL	<0.01
Potassium	mEq/L	>10.0			

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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.

Origin Verification with Oritain Global Ltd.: This product has been independently tested by Oritain to verify that the source material has come from animals of United States origin. For additional information visit www.oritain.com.

Statement of Intended Use: For further manufacturing or research use; not for therapeutic applications. 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