

CERTIFICATE OF ANALYSIS

Product:	<i>Certified Fetal Bovine Serum</i>	Origin:	<i>United States of America</i>
Catalog no:	<i>04-0011-1A-US/04-0011-1C-US/04-0011-1C-US</i>		
Lot number:	<i>1613594</i>	Dated:	<i>March 30, 2016</i>
Expiry date:	<i>March 30 , 2021</i>	Storage temperature:	<i>-20°C</i>

Triple 0.1 micron filtered

For research use only (not for human or animal therapeutic use).

We certify that this lot of Fetal Bovine Serum is produced from raw material originating in the United States. The raw serum was collected and initially processed in USDA-APHIS approved facilities. The serum was processed, filtered, filled and tested in the United States.

The United States of America is recognized as having negligible BSE/TSE risk by the World Organization for Animal Health (OIE)

Note: Since our sera are not pre-aged before filtration, turbidity or flocculent debris may develop upon thawing or storage of the serum. This condition does not adversely affect performance characteristics of the serum.

Reference	Test	Specification	Result	Units
1.	Alanine Transaminase (ALT)	Check & Record	6	u/L
2.	Albumin	1.8 – 3.0	2.2	g/dL
3.	Aspartate Aminotransferase (AST)	Check & Record	39	u/L
4.	Bilirubin- total	Check & Record	0.3	mg/dL
5.	Blood Urea Nitrogen (BUN)	Check & Record	15	mg/dL
6.	Calcium	Check & Record	13.6	mg/dL
7.	Cholesterol	Check & Record	27	mg/dL
8.	Creatinine	Check & Record	2.6	mg/dL
9.	Electrophoretic Pattern	Normal	Normal	
10.	Endotoxin testing	Check & Record	<0.2	EU/mL
11.	Glucose	Check & Record	108	mg/dL
12.	Hemoglobin	0-30	11.6	mg/dL
13.	IgG	Not more than 500	102	mg/L
14.	Mycoplasma testing	Negative	Not Detected	
15.	Osmolality	270-345	298	mOsm/kg
15.	pH	7.0-8.0	7.2	
17.	Phosphorous (inorganic)	Check & Record	9.8	mg/dL
18.	Potassium	Check & Record	>10	MMOL/L
19.	Sodium	Check & Record	136	MMOL/L
20.	Sterility testing	Negative	Negative	
21.	Total protein	3.0-5.0	3.5	g/dL
22.	VT-Bluetongue Virus (BTV)	Tested	Not Detected	
23.	VT- Bovine Viral Diarrhea (BVD)	Tested	Not Detected	
24.	VT- Parainfluenza Type 3 (PI-3)	Tested	Not Detected	
25.	VT- Bovine Rhinotracheitis (IBR)	Tested	Not Detected	
26.	VT-Bovine Adenovirus	Tested	Not Detected	
27.	VT-Bovine Parvovirus	Tested	Not Detected	
28.	VT-Bovine Respiratory Syncytial Virus (BRSV)	Tested	Not Detected	
29.	VT-Rabies Virus	Tested	Not Detected	
30.	VT-Reovirus	Tested	Not Detected	

A. Herman
Quality Control Department

August 10, 2016
Date

Quality Control Tests: US Origin - FBS

1. **Alanine Transaminase (ALT)** Lactate dehydrogenase/NADH, colorimetric determination at 340nm.
2. **Albumin** Bromocresol Green (BCG). Gustafsson JEC. Improved specificity of serum albumin determination and estimation of "acute phase reactants" by use of the bromocresol green reaction, *Clin Chem* 1977: 22, 616
3. **Aspartate aminotransferase (AST)** Malate dehydrogenase/NADH, colorimetric determination at 340nm.
4. **Bilirubin- total** Sodium nitrite/ biliverdin. Colorimetric determination.
5. **Blood urea nitrogen (BUN)** Urease hydrolysis to ammonia and carbon dioxide. Colorimetric determination. Talke H, Schubert GE. *Klinische Wochenschrift* 1965: 43: 174
6. **Calcium** Arsenazo III dye. Tietz NW, editor. *Fundamentals of clinical chemistry*, Philadelphia PA: WB Saunders: 1970: 638
7. **Cholesterol** Enzymatic (cholesterol esterase/oxidase/peroxidase). Allain CC, Poon LS, Chan CS, et al, Enzymatic determination of total serum cholesterol, *Clin Chem* 1974: 20 (4): 470-475. Roeschlau P, Bernt E, Gruber WA. Enzymatic determination of total cholesterol in serum, *Z Klin Chem Klin Biochem* 1974: 12: 226
8. **Creatinine** Alkaline Picrate. Reflectance spectrophotometry at 500nm. Fabiny DL, Ertingshausen G, Automated reaction-rate method for determination of serum creatinine with the centrifichem, *Clin Chem* 1971: 17: 696-700; Soldin S, Henderson L, Hill G, The effect of bilirubin and ketones on reaction rate methods for the measurement of creatinine, *Clin Biochem* 1978: 82-6
9. **Electrophoretic Pattern** Cellulose Acetate
10. **Endotoxin testing** Guideline on Validation of the Limulus Amebocyte Lysate test as an End Product Endotoxin Test for Human and Animal Parenterals Drugs, Biological Products and Medical Devices- U.S. Department of Health and Human Services, FDA, December 1987
11. **Glucose** Hexokinase/Glucose-6-phosphate dehydrogenase. Colorimetric determination.
12. **Hemoglobin** Average absorbance value. Fleming AF, Woolf AJ. *Clin Chem* 1965: 12: 67
13. **IgG** Elisa.
14. **Mycoplasma testing** Detection of mycoplasma contamination of bovine serum by the large volume method, ASTM: E 1536-00
15. **Osmolality** Freeze-point depression assay.
16. **pH** Potentiometric determination.
17. **Phosphorous (inorganic)** Phosphomolybdate: Inorganic phosphate reacts with ammonium molybdate to form a heteropolyacid complex.
18. **Potassium** Ion selective electrode.
19. **Sodium** Ion selective electrode.
20. **Sterility testing** Current edition of USP.
21. **Total protein** Biuret method. Biuret method for the determination of total protein in serum and exudates, *Fundamentals of Clinical Chemistry* 1976: 302-304
22. **VT-Bluetongue Virus (BTV)** Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
23. **VT- Bovine Viral Diarrhea (BVD)** Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
24. **VT- Parainfluenza Type 3 (PI-3)** Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
25. **VT- Bovine Rhinotracheitis (IBR)** Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
26. **VT-Bovine Adenovirus (BAV3, BAV5)**. Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
27. **VT-Bovine Parvovirus (BPV)**. Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
28. **VT-Bovine Respiratory Syncytial Virus (BRSV)**. Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
29. **VT-Rabies Virus** . Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].
30. **VT-Reovirus Virus**. Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].