

## CERTIFICATE OF ANALYSIS

<b>Product:</b>	USDA Approved Origin Fetal Bovine Serum	<b>Origin:</b>	Nicaragua
<b>Catalog no:</b>	04-001-1A-USDA / 04-001-1E-USDA		
<b>Lot number:</b>	1713507	<b>Dated:</b>	March 02, 2017
<b>Expiry date:</b>	March 30, 2022	<b>Storage temperature:</b>	-20°C

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 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	<b>8</b>	u/L
2.	Albumin	1.8 – 3.0	<b>2.2</b>	g/dL
3.	Alkaline Phosphatase	Check & Record	<b>372</b>	u/L
4.	Aspartate Aminotransferase (AST)	Check & Record	<b>60</b>	u/L
5.	Bilirubin- total	Check & Record	<b>0.4</b>	mg/dL
6.	Bilirubin- direct	Check & Record	<b>0.11</b>	mg/dL
7.	Blood Urea Nitrogen (BUN)	Check & Record	<b>21</b>	mg/dL
8.	Calcium	Check & Record	<b>14.1</b>	mg/dL
9.	Chloride	Check & Record	<b>111</b>	MMol/L
10.	Cholesterol	Check & Record	<b>&lt;50</b>	mg/dL
11.	Creatinine	Check & Record	<b>3.1</b>	mg/dL
12.	Creatinine Kinase (CK)	Check & Record	<b>288</b>	u/L
13.	Electrophoretic Pattern	Normal	<b>Normal</b>	
14.	Endotoxin testing	Check & Record	<b>&lt;0.25</b>	EU/mL
15.	Gamma-Glutamyl Transferase (GGT)	Check & Record	<b>11</b>	u/L
16.	Glucose	Check & Record	<b>58</b>	mg/dL
17.	Hemoglobin	0-30	<b>14.8</b>	mg/dL
18.	High Density Lipoproteins (HDL)	Check & Record	<b>15</b>	mg/dL
19.	IgG	Not more than 500	<b>68.4</b>	mg/L
20.	Lactate Dehydrogenase	Check & Record	<b>669</b>	u/L
21.	Low Density Lipoproteins (LDL)	Check & Record	<b>18</b>	mg/dL
22.	Mycoplasma testing	Negative	<b>Negative</b>	
23.	Osmolality	270-345	<b>302</b>	mOsm/kg
24.	Performance testing: Growth assay	>80%	<b>Pass</b>	
25.	Performance testing: Plating assay	>80%	<b>Pass</b>	
26.	pH	7.0-8.0	<b>7.3</b>	
27.	Phosphorous (inorganic)	Check & Record	<b>8.7</b>	mg/dL
28.	Potassium	Check & Record	<b>10.9</b>	MMOL/L
29.	Sodium	Check & Record	<b>136</b>	MMOL/L
30.	Sterility testing	Negative	<b>Negative</b>	
31.	Total protein	3.0-5.0	<b>3.8</b>	g/dL
32.	Triglycerides (TG)	Check & Record	<b>48</b>	mg/dL
33.	Uric acid	Check & Record	<b>1.2</b>	mg/dL
34.	VT-Bluetongue Virus (BTV)	Tested	<b>Not Detected</b>	
35.	VT-Bovine Viral Diarrhea – Cytopathic (BVD)	Tested	<b>Not Detected</b>	
36.	VT-Bovine Viral Diarrhea – Non-cytopathic (BVD)	Tested	<b>Tested</b>	
37.	VT-Parainfluenza Type 3 (PI-3)	Tested	<b>Not Detected</b>	
38.	VT-Bovine Rhinotracheitis (IBR)	Tested	<b>Not Detected</b>	
39.	VT-Bovine Adenovirus	Tested	<b>Not Detected</b>	
40.	VT-Bovine Parvovirus	Tested	<b>Not Detected</b>	
41.	VT-Bovine Respiratory Syncytial Virus (BRSV)	Tested	<b>Not Detected</b>	
42.	VT-Rabies Virus	Tested	<b>Not Detected</b>	
43.	VT-Reovirus	Tested	<b>Not Detected</b>	

A. Herman  
Quality Control Department

July 02, 2017  
Date

## Quality Control Tests

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. **Alkaline Phosphatase** Para-nitrophenyl phosphate. Bowers GN, McComb RB. A continuous spectrophotometric method for measuring the activity of serum alkaline phosphatase, *Clin Chem* 1966:12 (2): 70-89 Tietz NW, Burtis CA, Duncan P, et al ; A reference method for measurement of alkaline phosphatase activity in human serum, *Clin Chem* 1983: 29 (5): 751-756
4. **Aspartate aminotransferase (AST)** Malate dehydrogenase/NADH, colorimetric determination at 340nm.
5. **Bilirubin- total** Solubilized Bilirubin+ diazotized sulfanilic acid. Red Chromophore or Sodium nitrite/ biliverdin. Colorimetric determination.
6. **Bilirubin- direct** Diazo reaction based on the reaction of bilirubin with a diazotized sulfanilic acid, Burtis CA, Ashwood ER, editors. *Tietz Textbook of Clinical Chemistry*, 3<sup>rd</sup> ed. Philadelphia, PA: WB Saunders: 1999: 1136.
7. **Blood urea nitrogen (BUN)** Urease /glutamate dehydrogenase coupled enzymatic technique or Urease hydrolysis to ammonia and carbon dioxide. Colorimetric determination. Talke H, Schubert GE. *Klinische Wochenschrift* 1965: 43: 174
8. **Calcium + OCPC** (at pH 9.7) Ca-OCPC complex measured using bichromatic endpoint or Arsenazo III dye. Tietz NW, editor. *Fundamentals of clinical chemistry*, Philadelphia PA: WB Saunders: 1970: 638
9. **Chloride** Ion selective electrode.
10. **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
11. **Creatinine** Alkaline Picrate. Modified kinetic Jaffe using Picrate and NaOH or Reflectance spectrophotometry at 500nm. Fabiny DL, Erlingshausen 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
12. **Creatinine kinase (CK)** Enzymatic reaction: N-acetyl-L-cysteine as an enzyme reactivator. The rate of formation of NADPH is measured by reflectance spectrophotometry at 340nm and is proportional to the activity of CK in the sample.
13. **Electrophoretic Pattern** Agarose Gel or Cellulose Acetate
14. **Endotoxin testing** Guideline on Validation of the Limulus Amebocyte Lysate test as an End Product Endotoxin in Test for Human and Animal Parenterals Drugs, Biological Products and Medical Devices- U.S. Department of Health and Human Services, FDA, December 1987
15. **Gamma-Glutamyl Transferase (GGT)** L-Gamma-glutamyl-3-carboxy-4-nitroanilide substrate/glycylglycine Theodorsen L, Stromme JH, Gamma-Glutamyl-3-carboxy-14-nitroanilide: the substrate of choice for routine determinations of GGT activity in serum, *Clin Chem Acta* 1976: 72: 205
16. **Glucose** Hexokinase/Glucose-6-phosphate dehydrogenase. Colorimetric determination.
17. **Hemoglobin** Average absorbance value. Fleming AF, Woolf AJ. *Clin Chem* 1965: 12: 67
18. **High Density Lipoproteins (HDL)** Accelerator Selective Detergent Methodology or Enzymatic reaction: Cholesterol esterase-cholesterol oxidase-peroxidase-chromogen. Warnick GR, Nauck M, Rifai N, Evaluation of methods for measurement of HDL-Cholesterol: from ultracentrifugation to homogeneous assays, *Clin Chem* 2001, 47 (9): 1579-1596
19. **IgG** Radial Immunodiffusion method, Mancini et al, *Immunochemistry*, vol 2, Page 255-262, 1965
20. **Lactate dehydrogenase** Measured as a rate reaction at 340 & 700 nm with substrate in presence of NAD<sup>+</sup> or Pyruvate to lactate, NADH oxidation measured by reflectance spectrophotometry at 340nm. Recommendation of the German Society for Clinical Chemistry, *Z. Klin Chem Klin Biochem* 1970: 8: 658, 1972:10: 182
21. **Low Density Lipoproteins (LDL)** Direct measurement using a 2 reagent format or LDL= Cholesterol - HDL - Triglycerides/5
22. **Mycoplasma testing** Detection of mycoplasma contamination of bovine serum by the large volume method, ASTM: E 1536-00
23. **Osmolality** Freeze-point depression assay.
24. **Performance testing: Growth assay** Biological Industries specifications. Cell line used: human diploid lung fibroblast cells (MRC-5), ATCC CCL-171. Biological Industries growth promotion assay measures the ability of each FBS lot to support proliferation of fastidious human diploid fibroblasts through multiple subcultures.
25. **Performance testing: Plating assay** Biological Industries specifications. Cell line used: African green monkey kidney cells (Vero), ATCC CRL-81. Analysis of cellular attachment and proliferation of Vero cells.
26. **pH** Potentiometric determination.
27. **Phosphorous (inorganic)** Phosphomolybdate: Inorganic phosphate reacts with ammonium molybdate to form a heteropolyacid complex.
28. **Potassium** Ion selective electrode.
29. **Sodium** Ion selective electrode.
30. **Sterility testing** Current edition of USP.
31. **Total protein** Modified Biuret or Biuret method. Biuret method for the determination of total protein in serum and exudates, *Fundamentals of Clinical Chemistry* 1976: 302-304
32. **Triglycerides** Enzymatic assay (Glycerol Phosphate Oxidase). Fossati P, Prencipe L, Serum triglycerides determined colorimetrically with an enzyme that produces hydrogen peroxide, *Clin Chem* 1982: 28: 2077-2080; McGowan MW, Artiss JD, Strandbergh DR, et al, A peroxidase-coupled method for the colorimetric determination of serum triglycerides, *Clin Chem* 1983: 29: 538-542
33. **Uric acid** Uricase/Allantoin at 293nm or Uricase/Allantoin. Trivedi R, Berta E, Rebar L, Enzymatic uric acid determination at 500nm by Trinder method, *Clin Chem* 1976: 22: 1223; Kabasakalian P, Kalliney S, Wescott A, Determination of uric acid in serum, with use of uricase and tribromophenol-aminopyrine chromogen, *Clin Chem* 1973: 19: 522.
34. **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].
35. **VT- Bovine Viral Diarrhea (BVD) Cytopathogenic agents.** Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46].
36. **VT- Bovine Viral Diarrhea (BVD) Detection of extraneous viruses.** Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.47].
37. **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].
38. **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].
39. **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].
40. **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].
41. **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].
42. **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].
43. **VT-Reovirus.** Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 113.47].