

CERTIFICATE OF ANALYSIS

Product:	<i>Fetal Bovine Serum (FBS) Qualified for Human Mesenchymal Stem Cells</i>	Origin:	<i>United States of America</i>
Catalog no:	<i>04-400-1A-US / 04-400-1E-US</i>		
Lot number:	<i>1604339</i>	Dated:	<i>January 01, 2016</i>
Expiry date:	<i>January 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	7	u/L
2.	Albumin	1.8 – 3.0	2.1	g/dL
3.	Alkaline Phosphatase	Check & Record	132	u/L
4.	Aspartate Aminotransferase (AST)	Check & Record	69.0	u/L
5.	Bilirubin- total	Check & Record	0.2	mg/dL
6.	Bilirubin- direct	Check & Record	0.11	mg/dL
7.	Blood Urea Nitrogen (BUN)	Check & Record	15.0	mg/dL
8.	Calcium	Check & Record	13.4	mg/dL
9.	Chloride	Check & Record	98	MMol/L
10.	Cholesterol	Check & Record	36	mg/dL
11.	Creatinine	Check & Record	2.6	mg/dL
12.	Creatinine Kinase (CK)	Check & Record	206	u/L
13.	Electrophoretic Pattern	Normal	Normal	
14.	Endotoxin testing	Check & Record	<0.05	EU/mL
15.	Gamma-Glutamyl Transferase (GGT)	Check & Record	4	u/L
16.	Glucose	Check & Record	97	mg/dL
17.	Hemoglobin	0-30	15.3	mg/dL
18.	High Density Lipoproteins (HDL)	Check & Record	8	mg/dL
19.	IgG	Not more than 500	134	mg/L
20.	Lactate Dehydrogenase	Check & Record	336.87	u/L
21.	Low Density Lipoproteins (LDL)	Check & Record	16.2	mg/dL
22.	Mycoplasma testing	Negative	Negative	
23.	Osmolality	270-345	295	mOsm/kg
24.	Performance testing: Growth assay	>80%	Pass	
25.	Performance testing: Plating assay	>80%	Pass	
26.	Human Mesenchymal Stem Cells Proliferation test	Pass Test	Pass Test	
27.	pH	7.0-8.0	7.4	
28.	Phosphorous (inorganic)	Check & Record	10.8	mg/dL
29.	Potassium	Check & Record	>10.0	MMOL/L
30.	Sodium	Check & Record	141	MMOL/L
31.	Sterility testing	Negative	Negative	
32.	Total protein	3.0-5.0	3.4	g/dL
33.	Triglycerides (TG)	Check & Record	59	mg/dL
34.	Uric acid	Check & Record	1.9	mg/dL
35.	VT-Bluetongue Virus (BTV)	Tested	Not Detected	
36.	VT-Bovine Viral Diarrhea – Cytopathic (BVD)	Tested	Not Detected	
37.	VT-Bovine Viral Diarrhea – Non-cytopathic (BVD)	Tested	Tested	
38.	VT-Parainfluenza Type 3 (PI-3)	Tested	Not Detected	
39.	VT-Bovine Rhinotracheitis (IBR)	Tested	Not Detected	
40.	VT-Bovine Adenovirus	Tested	Not Detected	
41.	VT-Bovine Parvovirus	Tested	Not Detected	
42.	VT-Bovine Respiratory Syncytial Virus (BRSV)	Tested	Not Detected	
43.	VT-Rabies Virus	Tested	Not Detected	
44.	VT-Reovirus	Tested	Not Detected	

A. Herman
Quality Control Department

June 06, 2017
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. **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*, 3rd 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, 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
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 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⁺ 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. **Performance testing: FBS Qualification** to support proliferation of hMSC by growth, phenotypic and functional assays over the course of 3 passages.
27. **pH** Potentiometric determination.
28. **Phosphorous (inorganic)** Phosphomolybdate: Inorganic phosphate reacts with ammonium molybdate to form a heteropolyacid complex.
29. **Potassium** Ion selective electrode.
30. **Sodium** Ion selective electrode.
31. **Sterility testing** Current edition of USP.
32. **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
33. **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
34. **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-aminoantipyrene chromogen, *Clin Chem* 1973: 19: 522.
35. **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].
36. **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].
37. **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].
38. **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].
39. **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].
40. **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].
41. **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].
42. **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].
43. **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].
44. **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].