

**CERTIFICATE OF ANALYSIS**

Product:	<i>European Grade Foetal Bovine Serum H.I</i>	Origin:	<i>BRAZIL</i>
Catalog no:	<i>04-127-1</i>	Raw material certificate no:	<i>FR4909 000799</i>
Lot number:	<i>416637</i>	Dated:	<i>SEPTEMBER 3, 2009</i>
Expiry date:	<i>MAY 30, 2013</i>	Storage temperature:	<i>-20°C</i>

Triple 0.1 micron filtered

For In Vitro Diagnostic use (not for human or animal therapeutic use)

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.	Albumin	1.8 – 3.0	1.82	g/dL
2.	Alkaline Phosphatase	Check & Record	1175	u/L
3.	Bilirubin- total	Check & Record	0.3	mg/dL
4.	Bilirubin- direct	Check & Record	0.3	mg/dL
5.	Calcium	Check & Record	14.5	mg/dL
6.	Chloride	Check & Record	102	MMol/L
7.	Cholesterol	Check & Record	30	mg/dL
8.	Creatinine	Check & Record	3.5	mg/dL
9.	Electrophoretic Pattern	Normal	Normal	
10.	Endotoxin testing	Check & Record	0.32	EU/mL
11.	Gamma-Glutamyl Transferase (GGT)	Check & Record	7	u/L
12.	Glucose	Check & Record	57	mg/dL
13.	Hemoglobin	0-25	15.4	mg/dL
14.	IgG	Not more than 500	154	mg/L
15.	Lactate Dehydrogenase	Check & Record	1558	u/L
16.	Mycoplasma testing	Negative	Negative	
17.	Osmolality	270-345	320	mOsm/kg
18.	Performance testing: Growth assay	>80%	Pass	
19.	Performance testing: Hybridoma growth	>80%	Pass	
20.	Performance testing: Plating assay	>80%	Pass	
21.	pH	7.0-8.0	7.42	
22.	Phosphorous (inorganic)	Check & Record	9.2	mg/dL
23.	Potassium	Check & Record	11.6	MMOL/L
24.	Sodium	Check & Record	141	MMOL/L
25.	Sterility testing	Negative	Negative	
26.	Total protein	3.0-5.0	3.83	g/dL
27.	Triglycerides (TG)	Check & Record	59	mg/dL
28.	Uric acid	Check & Record	1.5	mg/dL
29.	VT- Bovine Viral Diarrhea (BVD)	Tested	Negative	
30.	VT- Parainfluenza Type 3 (PI-3)	Tested	Negative	
31.	VT- Bovine Rhinotracheitis (IBR)	Tested	Negative	


A. HERMAN
 Quality Control Department

September 13, 2009

Date:



BIOLOGICAL INDUSTRIES



Quality Control Tests: - Certified FBS

1. **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
2. **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
3. **Bilirubin- total** Sodium nitrite/ biliverdin. Colorimetric determination.
4. **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.
5. **Calcium** Arsenazo III dye. Tietz NW, editor. *Fundamentals of clinical chemistry*, Philadelphia PA: WB Saunders: 1970: 638
6. **Chloride** Ion selective electrode.
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. Roeschlaue 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, Ertlingshausen 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. **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
12. **Glucose** Hexokinase/Glucose-6-phosphate dehydrogenase. Colorimetric determination.
13. **Hemoglobin** Average absorbance value. Fleming AF, Woolf AJ. *Clin Chem* 1965: 12: 67
14. **IgG** Radial Immunodiffusion method, Mancini et al, *Immunochemistry*, vol 2, Page 255-262, 1965
15. **Lactate dehydrogenase** 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
16. **Mycoplasma testing** Detection of mycoplasma contamination of bovine serum by the large volume method, ASTM: E 1536-00
17. **Osmolality** Freeze-point depression assay.
18. **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.
19. **Performance testing: Hybridoma growth** Biological Industries specifications. Cell line used: Sp2/0-Ag14 myeloma-derived hybridoma. Hybridoma growth test analyzes the ability of each FBS lot to support growth of hybridoma cells.
20. **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.
21. **pH** Potentiometric determination.
22. **Phosphorous (inorganic)** Phosphomolybdate: Inorganic phosphate reacts with ammonium molybdate to form a heteropolyacid complex.
23. **Potassium** Ion selective electrode.
24. **Sodium** Ion selective electrode.
25. **Sterility testing** Current edition of USP.
26. **Total protein** Biuret method. Biuret method for the determination of total protein in serum and exudates, *Fundamentals of Clinical Chemistry* 1976: 302-304
27. **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
28. **Uric acid** 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-aminoantipyrine chromogen, *Clin Chem* 1973: 19: 522.
29. **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].
30. **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].
31. **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].