



BIOLOGICAL INDUSTRIES



No. R1-CEP-2000-112

CERTIFICATE OF ANALYSIS

Product:	<i>Certified Foetal Bovine Serum H.I</i>	Origin:	<i>AUSTRALIA</i>
Catalog no:	<i>04-121AUS-1A</i>	Raw material certificate no:	<i>17836</i>
Lot number:	<i>212485</i>	Dated:	<i>NOVEMBER 20, 2007</i>
Expiry date:	<i>NOVEMBER 30, 2011</i>	Storage temperature:	<i>-20°C</i>

Triple 0.1 micron filtered

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

We certify that all lots of Biological Industries' Foetal Bovine Serum are produced from raw materials originating in countries completely free of both BSE and FMD diseases. Therefore, they are certified for use by the European Directorate for the Quality of Medicines (EDQM).

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	2.95	g/dL
3.	Alkaline Phosphatase	Check & Record	253	u/L
4.	Aspartate Aminotransferase (AST)	Check & Record	51	u/L
5.	Bilirubin- total	Check & Record	0.2	mg/dL
6.	Bilirubin- direct	Check & Record	0.1	mg/dL
7.	Blood Urea Nitrogen (BUN)	Check & Record	16	mg/dL
8.	Calcium	Check & Record	13	mg/dL
9.	Chloride	Check & Record	102	MMol/L
10.	Cholesterol	Check & Record	41	mg/dL
11.	Creatinine	Check & Record	2.66	mg/dL
12.	Creatinine Kinase (CK)	Check & Record	127	u/L
13.	Electrophoretic Pattern	Normal	Normal	
14.	Endotoxin testing	Check & Record	3	EU/mL
15.	Gamma-Glutamyl Transferase (GGT)	Check & Record	9	u/L
16.	Glucose	Check & Record	170	mg/dL
17.	Hemoglobin	0-25	24.0	mg/dL
18.	High Density Lipoproteins (HDL)	Check & Record	13	mg/dL
19.	IgG	Not more than 500	183	mg/L
20.	Lactate Dehydrogenase	Check & Record	1080	u/L
21.	Low Density Lipoproteins (LDL)	Check & Record	15	mg/dL
22.	Mycoplasma testing	Negative	Negative	
23.	Osmolality	270-345	306	mOsm/kg
24.	Performance testing: Growth assay	>80%	Pass	
25.	Performance testing: Hybridoma growth	>80%	Pass	
26.	Performance testing: Plating assay	>80%	Pass	
27.	pH	7.0-8.0	7.6	
28.	Phosphorous (inorganic)	Check & Record	9.6	mg/dL
29.	Potassium	Check & Record	10	MMOL/L
30.	Sodium	Check & Record	138	MMOL/L
31.	Sterility testing	Negative	Negative	
32.	Total protein	3.0-5.0	3.60	g/dL
33.	Triglycerides (TG)	Check & Record	65	mg/dL
34.	Uric acid	Check & Record	3.2	mg/dL
35.	VT-Bluetongue Virus (BTV)	Negative	Negative	
36.	VT- Bovine Viral Diarrhea (BVD)	Negative	Negative	
37.	VT- Parainfluenza Type 3 (PI-3)	Negative	Negative	
38.	VT- Bovine Rhinotracheitis (IBR)	Negative	negative	

Quality Control Department

June 11, 2009

Date:

**Quality Control Tests: - Certified 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** 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 hydrolysis to ammonia and carbon dioxide. Colorimetric determination. Talke H, Schubert GE. *Klinische Wochenschrift* 1965: 43: 174
8. **Calcium** 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. 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** 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)** 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** 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)** 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: Hybridoma growth** Biological Industries specifications. Cell line used: Sp2/O-Ag14 myeloma-derived hybridoma. Hybridoma growth test analyzes the ability of each FBS lot to support growth of hybridoma cells.
26. **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.
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** 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. 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.
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)** Virus testing is performed according to the Code of Federal Regulations (CFR), Title 9, Part 113.53 (c) [113.46, 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].