

Certificate of Analysis

Trade Name: Equalfetal® Bovine Serum
Description: 100% Bovine Neonatal Serum
Lot Number Determined at the time of manufacture
Catalog Numbers: EF-0500-A, EF-0050-A
Country of Origin: United States of America

Expiration Date: Determined at the time of manufacture
Storage Temperature: -10 to -30°C
Manufacture Date:
Country of Final Processing: United States of America
Membrane Filtered: Triple 0.1µm

Product Integrity Analysis*

| Test Description | Specification | Results | Method or Reference |
|------------------------------|-----------------|---------|---|
| Bacteria and Fungi/Sterility | No Growth | | USP <71>/EP 2.6.1/21 CFR |
| Electrophoretic ID | Characteristic | | Gel Electrophoresis |
| Endotoxin | < 10 EU/mL | | USP <85>, Limulus Amebocyte Lysate (LAL) |
| Hemoglobin | < 30 mg/dL | | Three-wavelength Polychromatic Analysis |
| Mycoplasma | Not Detected | | Barile, M.F. and Kern, J., Proc. Soc. Exp. Biol., 1971; 138:432-7 |
| Osmolality | 270-330 mOsm/kg | | USP <785>, Freezing point Depression |
| pH at room temperature | 7.0-8.0 | | USP <791> |
| Total Protein | 3.0-4.5 g/dL | | Spectrophotometry |

Adventitious Agents*

Method: 9 CFR 113.53c with final analysis by 113.46 and 113.47

| Adventitious Agent | Specification | Results | Adventitious Agent | Specification | Results |
|--|---------------------------|---------|---|---------------|---------|
| Blue Tongue Virus | Not Detected | | Cytopathic Agents | Not Detected | |
| Bovine Adenovirus, Group A (type 1 or 3) | Not Detected | | Hemadsorbing Agents | Not Detected | |
| Bovine Adenovirus, Group B (type 5) | Not Detected | | Infectious Bovine Rhinotracheitis (IBR) | Not Detected | |
| Bovine Parvovirus | Not Detected | | Parainfluenza 3 (PI3) | Not Detected | |
| Bovine Respiratory Syncytial Virus | Not Detected | | Rabies Virus | Not Detected | |
| Bovine Viral Diarrhea Virus (BVDV) | Tested | | Reovirus | Not Detected | |
| Serum Antibody Neutralization: | Alpha-SN BVDV Genotype 1: | | Alpha-SN BVDV Genotype 2: | | |

Biochemical Analysis*

Method: 1. Photometric chemical analyzer 2. Ouchterlony double diffusion 3. Protein Electrophoresis 4. LC-MSMS - Listed for informational purposes only.

| Component | Reported Result ¹ | Component | Reported Result ¹ | Electrophoretic Profile ³ | | |
|---------------------------------|------------------------------|---------------------------------------|------------------------------|---|------|------|
| A/G Ratio | Ratio | Iron | µg/dL | Fraction | % TP | g/dL |
| Albumin | g/dL | Magnesium | mg/dL | Albumin | | |
| Alkaline Phosphatase (ALP) | I.U./L | Phosphorus | mg/dL | Alpha 1/2 | | |
| Aspartate Transferase (AST) | I.U./L | Potassium | meq/L | Beta | | |
| Bicarbonate | meq/L | Sodium | meq/L | Gamma | | |
| Bilirubin, Total | mg/dL | Triglyceride | mg/dL | | | |
| Blood Urea Nitrogen (BUN) | mg/dL | Hormone-Tests | | | | |
| Calcium | mg/dL | Testosterone baseline RIA | ng/mL | Tetracycline Antibiotics⁴ | | |
| Chloride | meq/L | Estradiol baseline -Immulite | pg/mL | Chlortetracycline | 3 | |
| Cholesterol | mg/dL | Insulin: Bovine/Rodent - RIA | µIU/mL | Doxycycline | | |
| Creatine Kinase (CK) | I.U./L | Progesterone- RIA- Bovine | ng/mL | Oxytetracycline | | |
| Creatinine | mg/dL | T4 (Thyroxine) - Immulite | µg/dL | Tetracycline | | |
| Gamma-Glutamyltransferase (GGT) | I.U./L | Precipitation-Test² | | | | |
| Globulin | g/dL | Bovine Antibody | | | | |
| Glucose | mg/dL | Equine Antibody | | | | |
| IgG by ELISA, Bovine | µg/mL | Porcine Antibody | | | | |

Intended Use and Affiliations

For further manufacturing use. NOT FOR HUMAN OR ANIMAL CONSUMPTION. Product Meets European Union Requirements for Production of Technical Blood Products. Atlas has been granted a Certificate of Suitability by the European Directorate for the Quality of Medicines and Healthcare (EDQM); certificates are available upon request. Trade Control and Expert System Facility (TRACES) registered by the United States Department of Agriculture (USDA)-APHIS, facility number CO-TEC-0005. Facility is registered with the U.S. Food and Drug Administration.



Independently audited and certified for traceability by the International Serum Industry Association.

Quality Assurance: _____ Date: _____ Issue No. _____

*Results shown were obtained by independent test organizations according to agreed requirements and believed to be reliable. It is suggested that tests which are particularly important to the end user be repeated for validity. Some results may vary depending on methodology and other variables.