



## Certificate of Analysis

**Trade Name:** Equafetal® Bovine Serum  
**Description:** 100% Bovine Serum  
**Lot Number**  
**Catalog Numbers:** EF-0500-A, EF-0050-A  
**Country of Origin:** United States of America

**Expiration Date:**  
**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
Electrophoretic ID	Characteristic		Gel Electrophoresis
Endotoxin	< 10 E.U./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 gm/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: 10		Alpha-SN BVDV Genotype 2: 10		

### 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 <sup>1</sup>	Component	Reported Result <sup>1</sup>	Electrophoretic Profile <sup>3</sup>		
A/G Ratio	Ratio	Iron	µg/dL	Fraction	% TP	gm/dL
Albumin	gm/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			
Calcium	mg/dL	<b>Hormone-Tests</b>				
Chloride	meq/L	Testosterone baseline RIA	ng/mL	<b>Tetracycline Antibiotics<sup>4</sup></b>		
Cholesterol	mg/dL	Estradiol baseline -Immulite	pg/mL	Chlortetracycline	ppb	
Creatine Kinase (CK)	I.U./L	Insulin: Bovine/Rodent - RIA	µIU/mL	Doxycycline	ppb	
Creatinine	mg/dL	Progesterone- RIA- Bovine	ng/mL	Oxytetracycline	ppb	
Gamma-Glutamyltransferase (GGT)	I.U./L	T4 (Thyroxine) - Immulite	µg/dL	Tetracycline	ppb	
Globulin	gm/dL	<b>Precipitation-Test<sup>2</sup></b>				
Glucose	mg/dL	Bovine Antibody				
IgG by ELISA, Bovine	µg/mL	Equine Antibody				
		Porcine Antibody				

### Performance Testing

Test Description	Specification	Results	Method: Atlas Biologicals Specifications
Growth Assay	>75% of Control		Cell line: . Growth promotion assay measures the ability of the lot to support proliferation.
Cloning Assay	>70% of Control		Cell line: . Cloning Efficiency measures the ability of the lot to support cloning and growth.

### 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. 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.

2649 East Mulberry St., Unit A-3  
 Fort Collins, CO 80524

Phone: 970.494.2051  
 Fax: 970.494.2052

www.atlasbio.com  
 Toll Free: 866.222.8988  
 06Mar2018 COA-V11