PRODUCT DATA SHEET
Fetal Bovine Serum

Description

Fetal bovine serum (FBS) is the most commonly used media supplement for cells in culture. Atlanta Biologicals offers several different FBS grades in order to accommodate even the most demanding cell lines and laboratory applications.

Collection and Processing

Atlanta Biologicals consistently supplies FBS lots with excellent cell growth characteristics, low endotoxin and low hemoglobin values. Our sera are produced by maintaining direct control over every process step from the initial raw material processing at the collection sites, to final filtration, bottling and quality control. This vertical integration allows Atlanta Biologicals to assure production of high quality sera and to minimize lot-to-lot variation.

Origin:

The FBS used in Atlanta Biologicals' manufacturing process meets all of the USDA requirements for animal products. All of our FBS is traceable back to the date and location of collection. The USDA restricts importation of serum from areas that are considered to have or are at high risk for exotic diseases, including foot and mouth disease (FMD) and bovine spongiform encephalopathy (BSE). In addition, all of Atlanta Biologicals' serum used in manufacturing must meet our strict quality requirements for raw material.

Closed System Collection:

Since the beginning of mammalian cell culture back in the 1950s, there has been a constant demand for high quality FBS used to support the growth of cells *in vitro*. Our customers' need for quality and consistency has led Atlanta Biologicals to create an extensive network of serum collection sites for FBS. Atlanta Biologicals' direct control over the serum collection sites and our pioneering collection techniques have resulted in a stable, traceable supply of quality serum for our customers. This network continues to grow even today, allowing us to consistently meet our customers' needs, even as the global supply of FBS fluctuates due to environmental factors such as regional droughts, natural disasters, disease outbreaks and other circumstances that affect our industry.

The quality of FBS is determined primarily at the blood collection site and in the initial serum processing. Atlanta Biologicals closely monitors each step of the production process at these critical stages to assure that the raw material meets our highest quality standards. The bovine blood is collected using a closed loop system that minimizes bacterial contamination during collection and yields serum with low levels of endotoxin. To reduce hemolysis and improve product quality, the whole blood is kept at refrigerated temperatures from the time of collection until it is processed.

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Raw Material Processing:

The whole blood is allowed to clot at refrigerated temperatures. Serum is then carefully removed from the clot after centrifugation at refrigerated temperatures, to avoid contamination by red blood cells. This raw serum product is immediately placed into bottles and frozen for delivery to our manufacturing facility. The product remains frozen throughout the entire shipping and receiving process, from the raw processing site to our manufacturing facility. This rapid processing ensures that endotoxin levels in the serum remain low and that the growth promoting qualities of the serum remain at their peak levels.

Filtration:

Approved lots of raw serum are thawed under controlled conditions and sterile filtered by an in-line process that uses multiple 0.1μm filters for the final filtration step. Filling takes place in a laminar flow hood certified to maintain Class 100 conditions. The filling room is maintained under positive pressure with HEPA-filtered air. The serum is aseptically dispensed into gamma irradiated, sterile PETG or PETE bottles. Filled containers are immediately labeled and frozen, and then maintained at temperatures less than -5°C to preserve the product quality.

Quality Control Testing

Chemical Analyses: *(All FBS grades)*

The Osmolality (vapor pressure method) and pH are measured on instruments that are calibrated daily using reference solutions traceable to National Institute of Standards and Technology Reference Materials.

Hemoglobin content of the serum is measured spectrophotometrically.

Endotoxin content is measured using the Limulus amebocyte lysate (LAL) gel-clotting assay.

Biochemical Profile: *(All FBS grades - different FBS grades may vary from the profile shown)*

Total Protein	Total Bilirubin	Blood Urea Nitrogen (BUN)	Sodium/Potassium Ratio
Albumin	Iron	Creatinine	Chloride
Globulin	UIBC	BUN/Creatinine Ratio	Calcium
A/G ratio	Cholesterol	Uric Acid	Phosphorus
IgG	Triglycerides	Sodium	Magnesium
ALT/SGPT	Glucose	Potassium	Bicarbonate
Alkaline Phosphatase			

Hormone Profile: *(Only lots of FBS - Premium Select grade)*

17-β-Estradiol	Testosterone
Insulin	Thyroxine (T4) - total
Progesterone	

Microbiological Testing: *(All FBS grades)*

Each lot of serum is tested to confirm the absence of bacterial or fungal contamination using modified methods referenced in the U.S. Pharmacopeia (USP).

This product is manufactured for research and development purposes only. It is not intended for any human or animal diagnostic, therapeutic or other clinical uses. It is also not for agricultural, food, drug, cosmetic or household use. The use of these products must be supervised by a person technically qualified to handle potentially hazardous material.

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Each lot of serum is tested to confirm the absence of mycoplasma contamination to the limit of detection with the methods used. The large-volume method of Barile and Kern is used to detect mycoplasma that can be cultivated in media. Three different media are inoculated with the serum sample and grown under both aerobic and anaerobic conditions. Non-cultivatable mycoplasma are detected by passage of the sample on an indicator cell line and staining with a DNA-fluorochrome.

Virus Testing:

Serum is tested for adventitious agents using modified procedures adapted from the Code of Federal Regulations, Title 9, Section 113.53, "Requirements for Ingredients of Animal Origin". Virus susceptible cell cultures previously shown to be free of viral contamination are cultured in medium containing the test serum. During this period, cultures are examined microscopically for evidence of virus-induced morphological changes or cytopathogenic effects. After multiple passages and a minimum of 21 days, the cultures are tested for the presence of specific viral agents (see chart below) by fluorescent antibody staining, for cytopathogenic viral agents such as Infectious Bovine Rhinotracheitis virus (IBRV) by geimsa staining and for hemadsorbing viral agents such as Parainfluenza-3 virus (PI-3V).

Virus Name	Testing	Advantage S110xx	Premium S111xx	Premium Select S115xx	Optima S124xx
Bovine Viral Diarrhea Virus (BVDV)	FL-ab	✕	✕	✕	✕
Infectious Bovine Rhinotracheitis Virus (IBRV)	Geimsa staining	✕	✕	✕	✕
Parainfluenza-3 Virus (PI-3V)	Had	✕	✕	✕	✕
Bluetongue Virus (BTV)	FL-ab			✕	✕
Bovine Respiratory Syncytial Virus (BRSV)	FL-ab or SN			✕	✕
Bovine Parvovirus (BPV)	FL-ab			✕	✕
Bovine Adenovirus, Type 3 (BAV-3)	FL-ab			✕	✕
Bovine Adenovirus, Type 5 (BAV-5)	FL-ab			✕	✕
Reo virus	FL-ab			✕	✕
Rabies virus	FL-ab			✕	✕

FL-ab: fluorescent antibody staining Had: hemadsorption test SN: serum antibody virus neutralization

Storage and Handling

The FBS is supplied in gamma irradiated, sterile PETG or PETE bottles. We recommend that the serum be stored frozen at a temperature of -5°C to -20°C. Multiple freeze-thaw cycles of the serum should be avoided as this may lead to deterioration of the product. If intermittent usage of the product is anticipated, we recommend use of either our smaller package sizes or dividing the serum into smaller aliquots suitable for single use. Always use aseptic techniques when handling the serum and aliquot into sterile containers.

Shipping

Serum is shipped frozen by next day air in insulated containers packed with dry ice.

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