

PRODUCT DATA SHEET

Fetal Bovine Serum

EU-Approved

Catalog #:
S12550
S12595
S12550H
S12595H

Description

Fetal bovine serum (FBS) is the most commonly used media supplement for cells in culture. FBS is the ideal cell growth supplement and generally preferred over other types of cell culture sera. Its high levels of nutrients and optimal combination of growth factors makes FBS the most effective cell growth promoter for virtually any cell culture system. In addition, the significantly lower content of antibodies compared to adult and newborn sera minimizes the risk of antibody cross reaction with cells in culture. R&D Systems, a Bio-Techne brand, offers several grades of Atlanta Biologicals™ FBS, including one approved for use in Europe. Atlanta Biologicals FBS, EU-approved is available in both regular and heat-inactivated formats.

Collection and Processing

Atlanta Biologicals FBS have excellent cell growth characteristics, low endotoxin, and low hemoglobin values. This is achieved 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 for the production of high quality sera and to minimize lot-to-lot variation.

Origin:

Atlanta Biologicals FBS is manufactured under a process that meets EU or USDA requirements for animal products. All FBS is traceable back to the date and location of collection. Both the EU and the USDA restrict the 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). The country of origin for each batch will be stated on the COA.

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 FBS is sourced from an extensive network of serum collection

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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.

Atlanta Biologicals™ Serum and Cell Culture Products are now part of R&D Systems, a Bio-Techne Brand.

sites for FBS. Close partnerships with serum collection sites and use of pioneering collection techniques have resulted in a stable, traceable supply of quality serum for researchers. This network continues to grow even today, allowing for the supply of consistent and high-quality FBS, even as the global supply of serum 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. Monitoring each step of the production process at these critical stages ensures that the raw material meets highest quality standards. The bovine blood is collected using a closed loop system that minimizes bacterial contamination during collection and yields serum with low endotoxin levels. To reduce hemolysis and improve product quality, the whole blood is kept at refrigerated temperatures from the time of collection until it is processed.

Raw Material Processing:

The whole blood is allowed to clot at refrigerated temperatures. Serum is 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 peak levels.

Filtration:

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

Quality Control Testing

Chemical Analyses: (All FBS grades)

The Osmolality 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 amoebocyte lysate (LAL) assay.

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Biochemical Profile:

(FBS grades may vary from the profile shown; full biochemical profile is available on the Certificate of Analysis)

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			

Microbiological Testing: (All FBS grades)

Each lot of serum is tested to confirm the absence of bacterial or fungal contamination using modified methods referenced by European Pharmacopeia (EP) and United States Pharmacopeia (USP).

Each lot of serum is tested to confirm the absence of mycoplasma contamination to the limit of detection using current EP/USP methods.

Biological Performance Testing:

Each lot of serum is tested for biological performance by assessing cell growth in established cell lines, including MDCK, L929, SP2/0-AG14, and MRC-5. Cells are grown in cell culture medium supplemented with serum and are examined for cell growth and, morphological indicators of toxicity as compared to a control.

Virus Testing:

Serum is tested for adventitious agents using modified procedures adapted from the United States 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) 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).

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Virus Name	Testing	Optima S12450, S12450H, S12495, S12495H, S12410, S12410H *Not available for sale in EU	EU-approved S12550, S12550H, S12595, S12595H
Bovine Viral Diarrhea Virus (BVDV)	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	×	

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

Storage and Handling

The FBS is supplied in gamma irradiated, sterile PET 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 in dry ice.

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Heat-inactivation

Heat-inactivation of Atlanta Biologicals FBS, EU-approved, is performed by exposing the FBS to a temperature of 56 °C for 30 minutes under controlled conditions. The objective of heat inactivation is to destroy complement activity in the serum without affecting the growth-promoting characteristics of the product. Removal of complement activity from the serum is not required for most cell cultures, but may be necessary for cultures that are sensitive to the complement activity. Researchers should evaluate the applicability of heat inactivation in regards to their own application.

Defining European (EU) Grade and USDA Grade and FBS

EU Grade FBS is FBS of South American origin that is permitted for importation into the EU under Commission Regulation (EU) No 142/2011. This material is also permitted to be imported into certain countries in Asia. EU Grade is currently not permitted to be imported into the USA.

USDA Grade FBS is of either USA origin or non-USA origin that the United States Department of Agriculture (USDA) considers to be acceptable for importation in the U.S.A. These countries are defined as being free of bovine spongiform encephalopathy (BSE) and foot and mouth disease (FMD).

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