PRODUCT DATA SHEET
Newborn Calf Serum

Description

Newborn calf serum (NBC) is collected from healthy, inspected calves that are less than 14 days old. NBC provides many of the same nutrients as fetal bovine serum (FBS) with slightly higher protein levels. For many cell lines, NBC can be used as an alternative to the more costly FBS.

Collection and Processing

Atlanta Biologicals consistently supplies NBC lots with excellent cell growth characteristics, low endotoxin and low hemoglobin values.

Origin:

The NBC used in Atlanta Biologicals' manufacturing process meets all of the USDA requirements for animal products. All of our NBC is traceable back to the date and location of collection. In addition, all of Atlanta Biologicals' serum used in manufacturing must meet our strict quality requirements for raw material.

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 a series of filters in descending pore size, utilizing 0.2μm 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:

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.

Address: 4172 Industry Way, Flowery Branch, GA 30542 **Phone:** (800) 780-7788, (770) 446-3336 **Fax:** (800) 780-7374, (770) 446-3332

Biochemical Profile:

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:

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).

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).

Storage and Handling

The NBS 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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