PRODUCT DATA SHEET
Donor Goat Serum

Description

Donor goat serum (DGS) is collected from selected donor herds that receive regular veterinary inspection and care. It is commonly used as a blocking agent in immunochemistry applications and as a medium supplement in specialized cell culture applications.

Collection and Processing

Origin:

The donor goat serum used in Atlanta Biologicals' manufacturing process meets all of the USDA requirements for donor animal products. Every lot of donor goat serum is traceable back to the date and location of collection. In addition, all of Atlanta Biologicals' serum used in manufacturing must meet strict quality requirements for raw material to ensure a consistent high quality product.

Raw Material Processing:

*A*nimal blood is aseptically collected from prescreened donor animals that are maintained in controlled herds. 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.

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, in a filling room maintained under positive pressure with HEPA-filtered air. The serum is aseptically dispensed into gamma irradiated 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

Each individual lot of serum manufactured is subjected to a series of quality control testing procedures and must comply with set specifications and acceptance criteria before release for distribution.
Key quality assessment criteria and results are documented in a certificate of analysis specific to the serum lot tested.

Address: 4172 Industry Way, Flowery Branch, GA 30542
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Physical and Chemical Analysis:

pH
The pH is measured on an instrument that is calibrated daily using reference solutions that are traceable to National Institute of Standards and Technology Reference Materials. Each lot of serum is tested and must show a pH value within the physiological range.

Osmolality
Osmolality is measured by vapor pressure using instruments which are calibrated using reference solutions that are traceable to the National Bureau of Standards. Each lot is tested and values must fall within the physiological range.

Hemoglobin
The hemoglobin content of each serum lot is measured spectrophotometrically. Hemoglobin levels are reported in mg/dl.

Endotoxin
The Limulus Amoebocyte Lysate (LAL) gel clot assay is used to quantify endotoxin. The endotoxin content in each serum lot is reported in Endotoxin Units (EU).

Biochemical Profile:

Concentrations of many biochemical constituents are measured and reported. The certificate of analysis of every serum lot lists the specific serum components tested.

Bacterial, Fungal and Mycoplasma 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 further tested to confirm the absence of mycoplasma contamination to the limit of detection with the methods used. Screening lots for absence of mycoplasma organisms is routinely accomplished via direct cultivation of serum samples in agar and broth media capable of detecting mycoplasma both under aerobic and anaerobic conditions. To facilitate detection of low concentrations of mycoplasma, this test is performed with large sample volumes, following the procedure of Barile and Kern.
A supplemental indirect DNA staining assay for mycoplasma is utilized to detect mycoplama strains that cannot be cultivated in media. Non-cultivatable mycoplasma are detected by passage of the sample on an indicator cell line and staining with a DNA-fluorochrome.

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Storage and Handling

The donor goat serum is supplied in gamma irradiated PETG or PETE bottles. It is recommended 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, either the smaller package sizes should be purchased or the serum should be divided 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 insulated containers packed with dry ice.

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