

	<b>Catalog Number:</b>	<b>Size:</b>
Donor Bovine Serum	S11350	500 mL
	S11310	100 mL
	S11395	50 mL
Donor Bovine Serum, Heat Inactivated	S11350H	500 mL
	S11310H	100 mL
	S11395H	50 mL

### PRODUCT DESCRIPTION

Donor Bovine Serum is frequently used in applications where serum sero-negative to IBR and BVD is required. Donor Bovine Serum is collected from US-origin healthy, live animals greater 12 months of age or older. The donor cattle are carefully selected and maintained in closed herds ensuring complete control of their care, diet and health. Before acceptance into the segregated herd, all cattle must test sero-negative to Infectious Bovine Rhinotracheitis (IBR) and Bovine Viral Diarrhea (BVD). The animals are used exclusively for the production of donor bovine products such as bovine serum and are not medicated or fed sub-therapeutic levels of antibiotics. Donor Bovine Serum is manufactured in our ISO 9001:2015 certified facility.

### STORAGE AND HANDLING

Donor Bovine 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.

### PRECAUTION

When handling bio-hazardous materials such as human cells, safe laboratory procedures should be followed, and personal protective equipment should be worn.

### LIMITATIONS

- FOR LABORATORY RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.
- The safety and efficacy of this product in diagnostic or other clinical uses has not been established.
- Results may vary due to variations among tissue/cells derived from different donors or sources.

### 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 0.2 µm 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.

### 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/mL).

### 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.

### 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.

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-cultivable 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 Table 1) 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).

### HEAT-INACTIVATION

Donor Bovine Serum is available in a heat-inactivated format. The most common objective of heat inactivation is to destroy heat-labile components such as complement that may adversely affect the growth performance of some cell cultures. Serum is inactivated by raising the temperature to 56 °C for 30 minutes under controlled conditions. Researchers should evaluate the applicability of heat inactivation as it pertains to their cell culture requirements.