Fetal Bovine Serum - Dialyzed 12-14 kD

Standard and Heat-inactivated

	Catalog Number:	Size:
FBS - Dialyzed 12-14 kD	S12850	500 mL
	S12810	100 mL
	S12895	50 mL
FBS - Dialyzed 12-14 kD	S12850H	500 mL
	S12810H	100 mL
	S12895H	50 mL

PRODUCT DESCRIPTION

Fetal Bovine Serum (FBS) - Dialyzed 12-14 kD is used in cell culture systems requiring a more defined environment of small molecules. Dialysis reduces the concentration of low molecular weight components such as nucleotides, amino acids, hormones, salts and various small proteins in serum. Pre-selected FBS is dialyzed against physiological saline using a 12,000 to 14,000 Dalton cutoff membrane. The process is controlled by precisely monitoring the glucose concentration throughout the procedure. Exhaustive dialysis is not performed in order to prevent precipitation and inactivation of serum peptides. All lots of FBS-Dialyzed 12-14 kD are manufactured in our ISO 9001:2015 certified facility.

STORAGE AND HANDLING

FBS – Dialyzed 12-14 kD 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.

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.

Global bio-techne.com info@bio-techne.com TEL +1 612 379 2956 **USA** TEL 800 343 7475 **Canada** TEL 855 668 8722
Europe | Middle East | Africa TEL +44 (0)1235 529449 **China** TEL +86 (21) 52380373

COLLECTION AND PROCESSING

R&D Systems® FBS has 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 for the minimization of lot-to-lot variation.

ORIGIN:

R&D Systems FBS is manufactured under a process that 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 sera 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*. R&D Systems customers need for quality and consistency has led our FBS to be sourced from an extensive network of serum collection sites. This direct control over the serum collection sites and our pioneering collection techniques have resulted in a stable, traceable supply of quality serum for researchers. 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. R&D Systems 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.

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 0.1 µm 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.

BIOCHEMICAL PROFILE:

All grades of FBS from R&D Systems undergo a biochemical profiling. The specific biochemical profile may differ between FBS grades.

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 Phosphate	Gamma Glutamyl Transferase		

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-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 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

FBS – Dialyzed 12-14 kD 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.