

# Product Information

## Fetal Bovine Serum Sourced in USA heat inactivated gamma irradiated by SER-TAIN™ Process

CATALOG NO. 12176C

### Description

Animal serum is commonly used to supplement basal media formulations for the optimal growth of many cell types *in vitro*.

Fetal Bovine Serum (FBS) is the most common serum used to supplement cell culture media due to its high nutritional content. Although it is relatively low in protein, FBS is effective in promoting and sustaining growth of vertebrate mammalian and insect cells.

Heat inactivation is commonly used to destroy complement. Heat inactivation is the method of choice of many investigators to insure that cells will not be lysed by antibody binding and complement activation. SAFC Biosciences' validated process consists of raising the temperature of the serum to 56 C for 30 minutes under controlled conditions.

Manufacture of proteins from cell culture systems utilizing products of animal origin is a major regulatory focus. Serum that is gamma irradiated via SAFC Biosciences' validated SER-TAIN™ process minimizes the risks associated with the use of animal-derived components and offers protection against low levels of microbial contaminants. Although all SAFC Biosciences' serum is thoroughly tested according to current 9CFR guidelines, serum may contain undetectable levels of adventitious agents. SER-TAIN™ gamma irradiation has been shown to inactivate up to six logs of many biological contaminants in serum while maintaining growth promotion potential, providing added confidence in the quality and performance of your serum. SAFC Biosciences' standard gamma irradiation of serum includes exposure under controlled conditions to a Cobalt<sup>60</sup> source with a delivered dose of 25 - 35 kGy.

### Raw Serum Process

Animal blood is collected at United States Department of Agriculture (USDA) approved abattoirs located within the USA. Whole fetal blood is aseptically collected via cardiac puncture and allowed to clot under controlled conditions. After centrifugation, the serum is decanted from the clot. The raw serum is then pooled and immediately frozen. Raw serum is pre-tested by SAFC Biosciences according to established criteria, providing a complete awareness of all serum characteristics prior to filtration and further processing.

### Filtration & Packaging

Frozen raw serum is thawed under controlled conditions and then processed through a series of membrane filters in descending pore size. Pooled fetal bovine serum is filtered through three 0.1 µm filters. Integrity tests are conducted on the sterilizing filter pre- and post-filtration by bubble point and diffusive flow methods. The serum filtration process meets the sterility assurance level of 10<sup>-3</sup> as verified by aseptic media fill validation. Serum is dispensed under HEPA filtered, Class 100 conditions. Serum is packaged in sterilized, graduated plastic bottles and sealed with a tamper indicator. Bottles are identified with sequentially numbered labels and frozen at -10 to -40 C.

### Traceability

The material used in this product is collected in the United States. Animals used for collection of serum are USDA inspected and acceptable for slaughter. A Certificate of Analysis indicating the country of origin is available for each lot of serum.

#### United States

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## Precautions

This product is for further manufacturing use. THIS PRODUCT IS NOT INTENDED FOR HUMAN OR THERAPEUTIC USE. For stability and optimal performance, sera should be stored at -10 to -40 C and used prior to the labeled expiration date.

Use aseptic technique when handling serum. Refiltering sterile serum before or after being added to sterile medium is not recommended because the growth promoting capability may be reduced.

## Storage

To effectively preserve the integrity of animal serum, it should be stored frozen and protected from light. For stability and optimal performance, serum should be stored at -10 to -40 C and used prior to the labeled expiration date. Multiple thaw/freezing cycles should be avoided as they will hasten the degradation of serum nutrients and can result in the formation of insoluble precipitates.

## Preparation Instructions

### Thawing

1. Remove the serum bottles from the freezer and allow them to acclimate to room temperature for approximately 10 minutes.
2. Place each container in a 30 to 37 C water bath or incubator. Excessive temperatures will degrade heat labile nutrients. If using a water bath, prevent the bottle caps from being completely submerged.
3. Gently swirl or shake the bottles every 10 - 15 minutes until the serum is completely thawed.
4. After thawing, use the serum promptly. Liquid serum may be stored refrigerated (2 to 8 C) up to four weeks. To avoid thaw/freezing cycles or long periods of refrigeration, it is recommended that any unused serum be immediately dispensed into small, useful aliquots and refrozen for future use.

Periodic agitation is crucial to its optimum performance. If a bottle of serum is not periodically shaken or swirled as it thaws, gradients containing high concentrations of salts, proteins and lipids, will form throughout the liquid portion and lead to the formation of crystalline or flocculent precipitates. These cryoprecipitates are not toxic to cell cultures, but they affect the appearance and consistency of each bottle of serum. Small amounts of cryoprecipitates are not uncommon, and will not affect product performance. Gently warming and mixing the serum will generally allow the material to go back into solution.

## Characteristics

### Adventitious Viral Agents (AVA) (9CFR 113.53)

None detected

### Electrophoretic Profile

Normal pattern

### Endotoxin

≤ 10.0 EU/mL

### Hemoglobin

≤ 20 mg/dL

### Mycoplasma (9CFR 113.28)

None detected

### Osmolality

260 - 330 mOsm/kg H<sub>2</sub>O

### pH (at 25 C)

6.8 - 8.1

### Sterility (Current USP)

No microbial growth detected

### Total Protein

3.0 - 4.3 g/dL

Test results are recorded For Information Only on the following: Chemical Profile, Growth Promotion, Cloning Efficiency, Plating Efficiency and Virus Antibody.

#### Warranty, Limitation of Remedies

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Issued December 2006 P12176  
1103 0805 0905 0406 0906

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