SAFC Biosciences™
Accelerate Success™

Product Information

Porcine Serum Sourced in USA gamma irradiated by SER-TAIN™ Process

CATALOG NO. 12737C

Description

Animal serum and/or the protein products derived from sera are essential supplements required for the growth of most cells *in vitro.*

Porcine Serum is commonly used as a media supplement in virus and mycoplasma production applications, as well as certain specialized applications.

Manufacture of proteins from cell culture systems utilizing products of an 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 $Cobalt^{60}$ 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 blood is aseptically collected 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 serum is filtered through 0.2 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^{-3} 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.

Precautions

This product is for further manufacturing use. THIS PRODUCT IS NOT INTENDED FOR HUMAN OR THERAPEUTIC USE. For stability and optimal performance, serum 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.

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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/freeze cycles should be avoided as they will hasten the degradation of serum nutrients and can result in the formation of insoluble precipitates

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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/freeze 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
≤ 50.0 EU/mL

Hemoglobin
≤ 50 mg/dL

Mycoplasma (9CFR 113.28)
None detected

Osmolality
260 - 330 mOsm/kg H_2O

pH (at 25 C)
6.8 - 8.1

Sterility (Current USP)
No microbial growth detected

Test results are recorded For Information Only on the following: Chemical Profile and Total Protein.

Warranty, Limitation of Remedies

SAFC Biosciences warrants to the purchaser for a period of one year from date of delivery that this product conforms to its specifications. Other terms and conditions of this warranty are contained in SAFC Biosciences' written warranty, a copy of which is available upon request. ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXCLUDED. In no case will SAFC Biosciences be liable for any special, incidental, or consequential damages arising out of this product or the use of this product by the customer or any third party based upon breach of warranty, breach of contract, negligence, strict tort, or any other legal theory. SAFC Biosciences expressly disclaims any warranty against claims by any third party by way of infringement or the like. THIS PRODUCT IS INTENDED FOR PURPOSES DESCRIBED ONLY AND IS NOT INTENDED FOR ANY HUMAN OR THERAPEUTIC USE.

Additional Terms and Conditions are contained in the product Catalog, a copy of which is available upon request.

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