Sterile Fetal Bovine Serum

1. GENERAL INFORMATION

Product code: FEO-500, FEI-500, FEN-500, FE4-000

Packaging: Sterile PET Bottle 500 ml / HDPE Bottle 4000 m

Collected from the source:

- Our vertical production system allows us to be certain of the origins and traceability of our products. Each batch manufactured is rigorously controlled from blood collection, in all stages of production, up to the final packaging in our facilities. Bio Nutrientes Sterile Fetal Bovine Serum is derived from total coagulated blood collected aseptically from the fetus by cardiac puncture.

Sterility: Sterile.

Filtration: Final filter size (pores): 3x0.1 µm or 0.2 µm according to customer's request.

2. QUALITY CONTROL

Bacteria/Fungi: All serums are tested for the absence of aerobic and anaerobic bacteria, fungi, and yeast.

Mycoplasma: Determined by PCR method or culture method.

Endotoxin: Endotoxin levels are detected using the LAL reagent (Limulus amoebocyte lysate).

Virology: Serum is tested for Bovine Viral Diarrhea (BVD), Infectious Bovine Rhinotracheitis (IBR), Blue Tongue Virus (BT), Foot and Mouth Disease (FMDV), and Bovine Leukosis Virus (BLV).

Hemoglobin: The hemoglobin level is measured by spectrophotometry.

pH: Determined by potentiometry.

Osmolality: Determined by calculation performed through the levels of urea, glucose and sodium or Freezing Point Depression Method.

Protein: Determined by Refractometry.

Shelf life: 4 years.

3. TRANSPORTATION CONDITIONS

- Serum is transported frozen and, upon receipt, must be immediately stored at the temperature indicated by the manufacturer. If partial thawing occurs during transport or upon arrival at the destination, the product may be immediately refrozen, provided that the integrity of the packaging is not compromised, and must be kept back at the recommended temperature without affecting its quality.

4. STORAGE CONDITIONS

- Store between -18°C and -40°C to ensure the indicated shelf life;

- Store the serum in an area protected from light.

5. RECOMMENDATIONS FOR USE

5.1 General Recommendations

- Respect the serum storage conditions;

- Do not use the serum after the expiration date;

- Handle the serum under aseptic conditions (e.g., under laminar airflow);

- Use appropriate clothing for handling serum to avoid contamination (e.g., gloves, masks, cap);

- The product should only be used for in vitro research or further manufacturing, and not for use as an Active Pharmaceutical Ingredient or human/animal feed.

5.2 Thawing

- To preserve all serum qualities, it is recommended to thaw the bottle in a refrigerator between +2°C and +8°C, avoiding product degradation. During the thawing process, gently and periodically agitate to resuspend the contents. It is not recommended to use an oven or water bath for thawing, in order to prevent changes in quality;

- Temperatures above 37°C can compromise serum performance by accelerating the degradation of critical serum factors, accelerating the degradation of critical serum factors. To ensure the integrity of the product, these conditions must be strictly avoided during product handling.

5.3 Aliquoting

- To preserve the characteristics of the serum, it is recommended to thaw the original bottle, perform aliquoting, and then refreeze the produced aliquots, avoiding repeated thawing and freezing cycles of the same bottle.

5.4 Storage after thawing

- It is recommended to use the serum immediately after thawing. If this is not possible, the product can be stored between +2°C and +8°C for up to 26 weeks, without significant impact on cell culture performance;

- Thawed serum should be homogenized before being added to the cell culture medium.

5.5 Normal variations during handling

- Turbidity and flocculant material may be present after thawing or after prolonged freezing and/or refrigeration. These changes do not affect the biological performance of the serum.

Some of the precipitates are due to fibrin: Collection and freezing procedures may leave some fibrinogen in the serum. Fibrinogen is the soluble precursor of the clot-forming protein, fibrin. Fibrin

may appear after thawing or heat inactivation. Fibrin does not alter the serum's ability to promote cell growth. It is recommended to use the serum without treatment (filtration or centrifugation).

Some of the precipitates are due to calcium phosphate: Serum incubated at 37°C for long periods will become cloudy and deposits may appear. These are composed of calcium and phosphorus. To the best of our knowledge, this does not alter the performance of the serum in cell cultures.

6. TREATMENT

The Serum can be treated (Inactivated or Irradiated) according to the client's request. To request any type of treatment, please contact Bio Nutrientes.