



FETAL BOVINE SERUM (FBS)

USDA Origin: FB5002, FB5002-H

US Origin: FB5001, FB5001-H

HISTORY

For decades, Fetal Bovine Serum has been the first choice for supplementing cell culture media for the purpose of culturing cells. FBS is a complex mixture of defined and unknown growth factors, hormones, proteins, lipids, and minerals that are necessary for successful in vitro cell culture.

COLLECTION AND TRACEABILITY

Fetal blood is collected from USDA approved abattoirs in the United States, Australia, New Zealand, Canada, Mexico, or Central America. Whole fetal blood is collected via cardiac puncture in 1L – 2L bags using a closed system. The blood is allowed to clot at a refrigerated temperature. Red blood cells are removed by refrigerated centrifugation. The raw serum is then pooled into batches of 500L – 2,000L and frozen. Each lot is pre-tested for endotoxin and hemoglobin levels to ensure that stringent quality specifications are met.

Each lot of FBS comes with a Certificate of Origin. The Certificate of Origin ensures that each lot is traceable back to the abattoir in the country of origin.

PROCESSING

All lots from Denville Scientific are manufactured according to current Good Manufacturing Practices (cGMP). Lots are triple 0.1 micron filtered, a process that has been validated to remove mycoplasma and adventitious agents. Serum is aseptically dispensed into gamma irradiated sterile bottles in a HEPA filtered Class 100 cleanroom.

STORAGE

FBS should be stored between - 10°C and - 80°C. Product stability is guaranteed for 5 years from the date of manufacture if stored properly. Denville does NOT recommend storage in an auto-defrost or frost-free freezer in which the FBS undergoes multiple freeze/thaw cycles.

THAWING

Remove the bottle(s) from the freezer and allow it (them) to acclimate to room temperature for 10 minutes. Place each bottle into a water bath at 37°C and allow the material to completely thaw. Swirl the bottle(s) every 5 – 10 minutes to ensure complete thawing. After thawing, the FBS can be stored in a refrigerator for up to 3 weeks. Denville recommends that the FBS does not undergo multiple freeze/thaw cycles, additional aliquots should be made.

Turbidity or flocculent material may be observed upon thawing or prolonged storage in a refrigerator. This can be minimized by periodic swirling while the product is thawing. The precipitate or flocculent material is normal, non-toxic, and not detrimental to the performance of the FBS.

LOT VARIABILITY

FBS is a biological product and there is inherent variability between each lot. Denville performs cell culture assays on each lot that must meet or exceed stringent quality standards, however no lot of FBS will work for every type of cell. Omega provides free samples upon request so that each end user can test the lot on their cells of interest before making a purchase.



PRODUCT PROFILE

Sterility

FBS is tested for the absence of aerobic and anaerobic bacteria, molds, and fungi according to US Code of Federal Regulations (CFR Title 9, Part 113, 1990).

Endotoxin Testing

Endotoxin levels in FBS are determined by Gel-Clot LAL method.

Hemoglobin Testing

Hemoglobin concentration in FBS is determined by a colorimetric assay that measures the peroxidase activity of hemoglobin.

Mycoplasma Testing

FBS is tested for mycoplasma by the large batch Barile method for 28 days. Positive controls are inoculated and grown in parallel.

Viral Testing

FBS is tested for the absence of viruses according to US Code of Federal Regulations (CFR Title 9, Part 113, 1990). Virus testing includes, but is not limited to Bovine Viral Diarrhea (BVD), Infectious Bovine Rhinotracheitis (IBR), and Parainfluenza Type 3 (PI3). Additionally, all FBS imported from Canada, Mexico, and Central America must undergo USDA safety testing prior to release. USDA test screens for Bluetongue Virus and Akabane Disease.

Bovine Spongiform Encephelopathy (BSE)

The USDA considers the USA to be a BSE-Free country. The USDA also recognizes Australia, New Zealand, Mexico, Canada, and parts of Central America to be free of BSE. Raw blood is deemed to be free of BSE and FMD and eligible for importation into the USA for final processing and distribution.

ADDITIONAL TREATMENTS

Heat Inactivation

FBS is thawed and then heated in a water bath at 56°C for 30 minutes. The bottle is continuously swirled to ensure complete inactivation of complement proteins.

Gamma Irradiation

Serum is exposed to 2.5 – 3.5 mRads (25-35 kGy) of radiation. A Certificate of Irradiation accompanies each lot that undergoes gamma irradiation.

Dialysis

Dialysis reduces the concentrations of low molecular weight components using a molecular weight cut-off of 10,000. FBS is dialyzed against 0.15M NaCl.

Charcoal Dextran

Steroid and hormone concentrations in FBS are reduced using charcoal, dextran, and NaCl until progesterone concentration is less than 0.2 ng/ml. A hormone panel is performed pre and post-treatment.