Fetal Bovine Serum Heat Inactivated

CAT N°: SxxxH

Collected from the source:
When searchers choose their serum an important factor that should be taken into consideration is the source, which also emphasises the traceability of the serum.
Our system of vertical integration allows us to be certain of the origins and traceability of our FBS.
Each manufactured batch is rigorously controlled, from the collection of serum and throughout all stages of its treatment and production through to final packaging on our premises.
BioWest Fetal Bovine Serum is derived from clotted whole blood aseptically collected from foetus via cardiac puncture.
The serum is collected or imported and treated in agreement with the European regulations.

Country of Origin:
The country in which the serum was taken from the donor/animal.
To see the countries of origin we can offer, please refer to the technical data sheet for the standard Fetal Bovine Serum (ref. FT.FBSan).

To order the treated serum, please replace the last number of the Cat N° of standard serum (written on the FT.FBSan) by the letter H.

Storage conditions:
- 18°C to - 40°C, protected from light.
Bottles can be stored between -40°C and -80°C for a short period (few days).

Shelf life:
5 years

Filtration:
Final Filter Size: 0.1µm, x 3

pH:
pH specification: 7,4 ± 0,6

Osmolality:
Determined by a lowered freezing temperature. The osmometer is calibrated against standard solutions.
Osmolality specification: 322,5 ± 42,5 mOsm/kg

Endotoxin:
All sera are tested to determine the levels of endotoxins. BioWest carries out a chromokinetic quantitative test, according to the method D of the European Pharmacopoeia.
The endotoxin reagent is standardized against the US reference endotoxin.
Specifications available on Certificate of Analysis

Haemoglobin:
The haemoglobin level is measured by spectrophotometer.
Specifications available on Certificate of Analysis

Cell Culture:
Biological performance is assessed using cell culture medium supplemented with the serum being tested. During the test period, cultures are examined microscopically for any morphological abnormalities that may indicate toxic components in the serum.

Cell Culture Tests:

Cell Growth, Plating Efficiency, Cloning Efficiency.

Cell Lines Tested:

The following cell lines are tested with the serum:

HELA -Cancer Cell/Human.
L929 -Fibroblast-Mouse/ As Macrophage
SP2/O-AG14 -Mouse/Lymphoma
MRC- 5 -Human/Lung.

Total Protein:
Determined by Biuret Colorimetry.
Total protein specification: 40 ± 15 g/l

Sterility tests:
All sera are tested for the absence of aerobic and anaerobic bacteria, fungi, yeast and *Mycoplasma*.
The sterility test is based on the European Pharmacopoeia requirements.
The sera are tested for the absence of *Mycoplasma* by culture.

Virus test:
All of our sera are tested for:
- Bovine Viral Diarrhoea (BVD)
- Cytopathogenic agents e.g. Infectious Bovine Rhinotracheitis (IBR) / BHV-1
- Hemadsorbing agents e.g. Parainfluenza Type 3 (Pl3)

Sera are tested by inoculation to permissive cells. The revelation is made by immunofluorescence for pestiviruses. Cytopathogenic agents and hemadsorbing agents are detected by microscopic observations.

Other tests:
Not Applicable

Treatments:
Sera are heat inactivated to inactivate complement. The complement can lead to complement-mediated cell lysis. Immunological studies justify the need to heat inactivate the serum. The treatment is a heating of the serum at 56°C during 30 minutes.

This treatment can modify the colour of the serum. This is normal and it does not compromise the quality of the product for the cell culture.

Note: To heat the serum during a long period can reduce or destroy the growth factors. It can also increase the build of precipitates that are frequently confounded with contamination.

Effects of the heat inactivation:

- Destruction of proteins
- Precipitation of fibrin
- Destruction of fibrinogen
- Deterioration total or partial of vitamins
- Decrease of the growth factors concentration
- Destruction of the LDH
- Decrease of the amylase concentration
- Destruction of the alkaline phosphatase
- Deterioration of the IgG, IgE, IgM
- Inactivation of viruses
- Inactivation of T4 Phage
- Inactivation of mycoplasma
- Increase of oxidation and catalysis reactions.

The chemical composition of the serum is not altered.

Recommended use:
- Respect storage conditions of the serum
- Do not use the serum after its expiry date
- Store serum in an area protected from light
- Manipulate serum in aseptic conditions (e.g.: under laminar air flow)
- Wear clothes adapted to the manipulation of serum to avoid contamination (e.g.: gloves, mask, hygiene cap, overall…)
- In order to preserve all serum qualities, it is recommended to thaw out the flask, to aliquote, then to re-freeze the produced flasks rather than to thaw out and re-freeze the flask at each use.
- It is recommended to use the serum immediately after its thaw out. However, if it is not useful, it is possible to store thaw out serum, at +2°C / +8°C, until 26 weeks without significant decrease of its performances in cell culture.

The product is intended to be used in vitro for research or further manufacturing only and not for use as an Active Pharmaceutical Ingredient or food or animal feed.

Remarks:
The raw serum may be treated (Gamma Irradiated, pH modified) before filtration for different reasons:
- Importation regulation
- Exportation necessity
- Technical or quality aspects.

To be informed if your batch is concerned by treatment before filtration, please contact Biowest.