Fetal Bovine Serum BVDV-free.

CAT N°: S1450.

Collected from the source:
When researchers 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 animal.

Storage conditions:
-18°C to -40°C, protected from light.

Bottles can be stored between -40°C and -80°C for a short period of time but long-term storage below -40°C is not recommended because bottles can become fragile, increasing the risk of breakage.

Shelf life:
5 years.

Filtration:
Final Filter Size: 0.1 µm x 3.

pH:
Determined by Potentiometric, chapter 2.2.3 of the European Pharmacopoeia.
pH specification: 7.4 ± 0.6.

Osmolality:
Determined by a lowered freezing temperature, chapter 2.2.35 of the European Pharmacopoeia.
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 chapter 2.6.14. 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 spectrophotometry.
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 presence of impurities or lower levels of components important for the growth of the cells tested.

Cell Culture Tests:
Cell Growth, Plating Efficiency, Cloning Efficiency.
Cell Lines Tested:
The following cell lines are tested with the serum:
HeLa Human cancer cell.
L929 mouse fibroblasts.
Sp2/0-Ag14 mouse hybridoma.
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 performed according to the chapter 2.6.1. of the European Pharmacopoeia.
The sera are tested for the absence of *Mycoplasma* by standard culture method.

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:
Antibodies against Bovine Viral Diarrhoea virus (BVD) by ELISA method
Specification: Not Detected

Bovine Virology according to 9 CFR 113.47 & 113.53
Specification: Not Detected

Treatments:
Not Applicable.

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 the quality of the serum, repeated freezing and thawing is not recommended. We thus recommend to either:
    - use serum immediately after its thaw out.
    - thaw the bottle once and aliquote it according to the required working volumes.

- If -20°C storage is not possible, the product can be stored at +2°C / +8°C for up to 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 (Heat Inactivated, 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.