



Technical data sheet Serum

Ref : FT.SxxxDan
Page : 1/3

Version date : 05/08/2022

Fetal Bovine Serum Dialysed

CAT N°: SxxxD

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. TDS.FBS).

To order the treated serum, please replace the last number of the Cat N° of standard serum (written on the TDS.FBS) by the letter D.

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

pH:

pH specification: Not applicable

Osmolality:

Determined by a lowered freezing temperature. The osmometer is calibrated against standard solutions

Osmolality specification: Not applicable

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.

Endotoxin specification: As low as possible

Haemoglobin:

The haemoglobin level is measured by spectrophotometer.

Haemoglobin specification: As low as possible

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.



Technical data sheet Serum

Ref : FT.SxxxDan
Page : 2/3

Version date : 05/08/2022

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: Not applicable

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 (PI3)

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:

The serum can be dialysed for technical or quality aspects. The sterile serum is dialysed by a tangential flow filtration at 10kDa MWCO, against a 0.15M NaCl solution. Glucose levels are tested prior and after dialyse to check the efficiency of the treatment, and to ensure a rate of glucose < 5 mg/dl. The serum treated is finally sterile filtered (0.1µm).

Effects of dialysis:

- No significant effect on osmolality, pH and endotoxin level
- Slight decrease of some proteins
- Increase of the amount and size of particulate matter
- Possible decrease of growth promotion, plating efficiency and cloning efficiency with some cell lines

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.



Technical data sheet Serum

Ref : FT.SxxxDan
Page : 3/3

Version date : 05/08/2022

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.