



Technical data sheet Serum

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Fetal Bovine Serum Gamma Irradiated

CAT N°: SxxxG

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 G.

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.



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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
- SP2/0-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 (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:

Viral clearance is a major concern for manufacturers of both human and animal biological products. The first step in viral clearance is to reduce the potential risks associated with the animal-derived raw materials used in the manufacturing process.

The viruses were significantly reduced at a radiation dose range between 25 - 35 kGy.

That is why the European authorities request an irradiation for importation of risky material in Europe at 25kGy.

Biowest offers this irradiation at minimum 25kGy for its products. This kind of irradiation allows making a viral clearance without significantly damaging the quality and properties of the product.

Effects of the gamma irradiation:

- Destruction of viruses
- No significant effect on hormones, osmolality, pH, endotoxin level and electrophoretic pattern
- Reduction of haemoglobin level
- Decrease of serum metabolites (ALP, ALT, AST, LDH)
- Breakdown of some proteins
- Increase of the amount and size of particulate matter
- Slight discoloration of the product
- Slight coloration of the bottle
- Possible decrease of growth promotion, plating efficiency and cloning efficiency with some cell lines
- Modification of serum odour

Biowest suggests you to test your cell lines with serum gamma irradiated and not in order to define the potential impact of the gamma irradiation on your applications.



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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 (Heat Inactivated, 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.