biosera

Technical Data Sheet

20/07/2017

Fetal Bovine Serum (FBS)

Product Codes

FB-1285	FB-1001	FB-1058	FB-1061	FB-1280	FB-1380
FB-1345	FB-1350	FB-1360	FB-1365	FB-1003	

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.

Biosera Fetal Bovine Serum is derived from clotted whole blood aseptically collected from fetus via cardiac puncture.

The serum is collected or imported and treated in agreement with the European regulations.

Filtration:

Final Filter Size: $0.1 \,\mu\text{m} \ge 3$

Sterility:

All sera are tested for the absence of aerobic and anaerobic bacteria and 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 tested:

All of our sera are tested for:

- Bovine Viral Diarrhoea (BVD)
- Cytopathogenic agents e.g. Infectious Bovine Rhinotracheitis (IBR) / BHV-1

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- Hemadsorbing agents e.g. Parainfluenza Type 3 (PI3)

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

Endotoxin:

All sera are tested to determine the levels of endotoxins. Biosera FBS has 2 tests carried out.

- 1) Turbidimetric, a qualitative test
- 2) Chromokinetic, a quantitative test

The endotoxin reagent is standardized against the US reference endotoxin. The method is based on "the bacterial endotoxins test", US pharmacopoeia 23rd revision.

Endotoxin specification: < 30 EU/mI

Osmolality:

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: < 30 EU/ml

Total Protein :

Determined by Biuret Colorimetry. Protein specification: 30 to 45 g/l

Haemoglobin:

The haemoglobin level is measured by spectrophotometer.

Haemoglobin specification: <30 mg/100ml

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

HELA – Cancer Cell/Human L929 – Fibroblast mouse/ As macrophage SP2/0-AG14 – Mouse Lymphoma MRC-5 – Human Lung

Country of Origin

The country in which the serum was taken from the donor/animal. Biosera FBS is sourced from the following Countries

FB-1058 Uruguay **Central America** FB-1345 FB-1365 Chile FB-1061 Dominican republic FB-1280 France FB-1360 Mexico FB-1001 South America FB-1350 USA FB-1285 Ireland FBS-1003 South Africa FBS-1380 Japan

Storage conditions

Store at -20°C

Shelf Life

5 years

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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 $+2^{\circ}C$ / $+8^{\circ}C$, until 26 weeks without significant decrease of its performances in cell culture.

The product is intended to be used in vitro, in laboratory only. Do not use it in therapy, human or veterinary applications.

Note:

The raw serum may be gamma irradiated before filtration for different reasons:

- Importation regulation
- Exportation necessity
- Technical or quality aspects.

To be informed if your batch is concerned by the gamma irradiation before filtration, please contact BIOSERA.