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Technical Data Sheet

20/07/2017

Fetal Bovine Serum (South America), Premium

Product Code:

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

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 Premium is derived from clotted whole blood aseptically collected from fetus via cardiac puncture.

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

Filtration :

Final Filter Size : 0.1µm, x 3

Sterility :

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 Tested :

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 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 carries out a chromokinetic quantitative test, according to the method D of the European Pharmacopoeia.

2 rue du Vieux Bourg 49340 Nuaillé Tel +33 (0)5 61 97 69 69 info@biosera.com www.biosera.com L'unité de production pour BIOSERA à Nuaillé est certifiée ISO 9001

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The endotoxin reagent is standardized against the US reference endotoxin. Biosera Fetal Bovine serum has an endotoxin level lower than 5 EU/ml

Haemoglobin :

The haemoglobin level is measured by spectrophotometer. Biosera Fetal Bovine serum has an haemoglobin level lower than 25 mg/100ml.

Osmolality:

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

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.

Biosera Fetal Bovine serum has a cell growth promotion higher than 80% after the day 6, compared to a serum of reference.

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.

Country of Origin :

The country in which the serum was taken from the donor/animal. Biosera sera are sourced from following countries :

FB-1058B Uruguay

FB-1345B Central America

FB-1365B Chile

FB-1061B Dominican republic

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- FB-1280B France
- FB-1360B Mexico
- FB-1001B South America
- FB-1350B USA
- FB-1285B Ireland
- FB-1003B South Africa
- FB-1380B Japan

Storage conditions : Store at -20°C

Shelf life : 5 years

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 (all the serum intended for the Chinese market is gamma irradiated at minimum 25kGy)

- Technical or quality aspects.

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