

Technical Data Sheet

11/07/2018

Fetal Bovine Serum (FBS) Dialysed

Product code:

FB-1285D FB-1001D FB-1058D FB-1061D FB-1280D FB-1380D

FB-1345D FB-1350D FB-1360D FB-1365D FB-1003D

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: $0.1 \mu m$

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 (Pl3)

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:

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



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.

The endotoxin reagent is standardized against the US reference endotoxin.

Osmolality:

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

Haemoglobin:

The haemoglobin level is measured by spectrophotometer.

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.

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.

Dialysis Treatment:

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 $(0.1\mu\text{m})$.

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

Biosera suggests you to test your cell lines with serum IgG depleted and not in order to define the potential impact of the IgG depletion on your applications.



Country of Origin

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

FB-1058D Uruguay

FB-1345D Central America (USDA approved)

FB-1365D Chile (USDA approved)

FB-1061D Dominican republic

FB-1280D France

FB-1360D Mexico (USDA approved)

FB-1001D South America

FB-1350D USA

FB-1285D Ireland

FB-1003D South Africa

FB-1380D Japan Approved

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.