# biosera

# **Technical Data Sheet**

26/11/2019

# Foetal Bovine Serum, Tetracycline free

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

# 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:  $0.1 \,\mu m \times 3$ 

# 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
- 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.

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### 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. 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.

#### Tetracycline test:

Biosera delegate this test to an independent laboratory. The laboratory uses a liquid chromatography electrospray ionisation tandem mass spectrometry method to detect the Tetatrycline.

This method allows also the detection of the Chlortetracycline and the Oxytetracycline in the same time. The limit de detection is 0.05 mg/l.

#### **Country of Origin:**

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

FB-1058T Uruguay FB-1345T Central America

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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FB-1365T Chile FB-1061T Dominican Republic FB-1280T France FB-1360T Mexico FB-1001T South America FB-1350T USA FB-1285T Ireland FBS-1003T South Africa FBS-1380T Japan

# Storage conditions:

Store at -20°C in the dark

# 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.