

Fetal Bovine Serum, Embryonic Stem Cells tested

Product Codes

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

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 : 0.1µm 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.

The endotoxin reagent is standardized against the US reference endotoxin.

Haemoglobin :

The haemoglobin level is measured by spectrophotometer.

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.

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 :

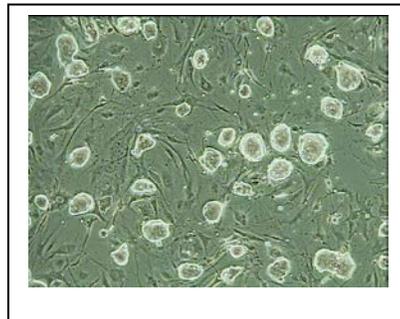
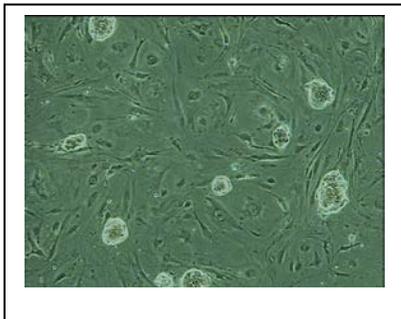
Determined by Biuret Colorimetry.

Embryonic Stem Cells tests :

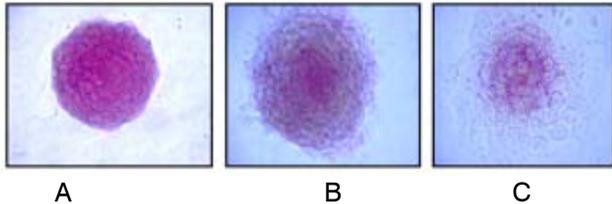
BioSera delegates this test to an external laboratory.

The cell growth is studied during two passages with mouse embryonic stem cell E14 cell line.

The validation criteria are the cell growth and the morphology of the cells (see below photos of embryonic stem cells grown up on a BioSera fetal Bovine serum).



A validation of the cell growth test is made with the use of an Alkaline Phosphatase Detection kit. The Kit is a specific and sensitive tool for the phenotypic assessment of ES cell differentiation by the determination of the AP activity



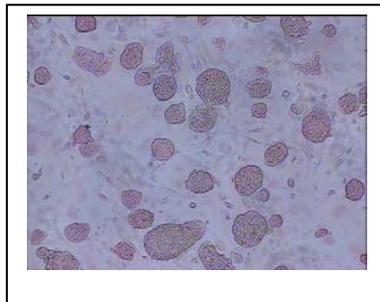
Alkaline Phosphatase staining of ES cells.
High magnification revealed :

-(A) Undifferentiated ES cells (mouse MBL.5 cell line)

-(B) Differentiated ES cells

-(C) Differentiated ES cells

See below a photo of embryonic stem cells grown up on a BioSera fetal Bovine serum and revealed by the Alkaline Phosphatase Detection Kit.



A toxicity test is also performed with the serum at 30%.

Country of Origin :

Biosera FBS is sourced from the following Countries

FB-1058S Uruguay

FB-1345S Central America

FB-1365S Chile

FB-1061S Dominican republic

FB-1280S France

FB-1360S Mexico

FB-1001S South America

FB-1350S USA

FB-1285S Ireland

FB-1003S South Africa

FB-1380S 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°C / +8°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.