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Fetal Bovine Serum Gamma Irradiated

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.
Serox 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 (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.
The antibodies are tested by an Elisa method.

Endotoxin :
All sera are tested to determine the levels of endotoxins. Serox 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.

Gamma irradiation :
Viral clearance is a major concern for manufacturers of both human and animal biological products. The first step in viral clearance is to reduce the potential risks associated with the animal-derived raw materials used in the manufacturing process.
The viruses were significantly reduced at a radiation dose range between 25 - 35 kGy.
That is why the European authorities request an irradiation for importation of risky material in Europe at 25kGy.
Serox offers this irradiation at minimum 25kGy for its products. This kind of irradiation allows making a viral clearance without significantly damaging the quality and properties of the product.

Effects of the gamma irradiation :

- Destruction of viruses
- No significant effect on hormones, osmolality, pH, endotoxin level and electrophoretic pattern
- Reduction of haemoglobin level
- Decrease of serum metabolites (ALP, ALT, AST, LDH)
- Breakdown of some proteins
- Increase of the amount and size of particulate matter
- Slight discoloration of the product
- Slight coloration of the bottle
- Possible decrease of growth promotion, plating efficiency and cloning efficiency with some cell lines
- Modification of serum odour

Serox suggests you to test your cell lines with serum gamma irradiated and not in order to define the potential impact of the gamma irradiation on your applications.

Country of Origin :
The country in which the serum was taken from the donor/animal.
Serox sera are sourced from the following countries

Canada	USA Approved et USA	Chile
Central America	Mexico	Australia
Denmark	EU Approved	South America
France		

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.