

Fetal Bovine Serum (FBS)

Fetal Bovine Serum (FBS) is the most applied supplement (2–20 % in medium) in cell culture systems and where applicable also in the production of therapeutic proteins. FBS is a byproduct of the meat industry and can be extracted as such in sufficient quantity only in regions, where enough bovine fetuses are accumulated at the slaughtering. This is only given in regions with extensive cattle husbandry.

FBS provided by Biochrom AG principally comes from South America and Australia. FBS from Biochrom AG is tested for endotoxins, mycoplasma, viral contamination and viral antibodies (against BVD-MD, BHV-1, PI3).

Which cells do you like to cultivate? Furthermore we offer pretested FBS lots suitable for different mammalian cells, amniotic fluid cells, and hybridoma cells. Australian FBS (some current batches)

was tested as suitable for murine embryonal stem cells.

Biochrom AG additionally offers FBS with specific pre-treatment:

- γ -irradiated FBS
On request, γ -irradiation is available for improved viral safety (irradiation dose ≥ 30 kGray)
- charcoal-stripped FBS, hormone-free (cat. no. S 3113, 100 ml)
- on request, heat-inactivated or dialyzed sera (exclusion limit 10 kDa or 12 – 14 kDa) (please enquire for conditions and prices)
- tetracyclin-free FBS

Do you need a new FBS sample?

Please fill in the form to request samples (see appendix) and send it to us via fax.

Or request samples online: fill in the form www.biochrom.de/products/sera/sample-order-fbs.

Product	Cat. No.	Unit
FBS, origin: EU-approved countries (South America) virus tested Storage temperature: -20 °C	S 0113	100 ml
	S 0115	500 ml
FBS, origin: EU-approved countries (Argentina) (with Certificate of Suitability, CoS; R1-CEP 2001-030), virus tested acc. to EMEA guidelines Storage temperature: -20 °C	S 0213	100 ml
	S 0215	500 ml
	S 0210	1000 ml
FBS, origin: Australia (with Certificate of Suitability; CoS; R1-CEP 2001-032), virus tested acc. to EMEA guidelines Storage temperature: -20 °C	S 0413	100 ml
	S 0415	500 ml
	S 0410	1000 ml

Biochrom AG FBS is:

- **Virologically tested** on Hoof and Mouth Disease, Bovine Rhinotracheitis (IBR), Bovine Parainfluenza (PI3), Bovine Diarrhoeovirus (BVD), and additionally if necessary on Blue Tongue Virus (BTV). FBS from Australia, and Argentina is even wider tested according to the EMEA Directive for Pharmaceutical Raw Material of Bovine Origin.
- **BSE-free** due to its origin: Biochrom AG principally buys and processes only raw sera from countries that have no original BSE cases according to the permanently updated list of the World Organization for Animal Health (OIE) in Paris.
- **Endotoxin-reduced** due to precise accumulating and clearing processes. Endotoxins are residues of the bacterial cell wall. It is very difficult even with the help of filtration processes to subsequently remove endotoxins from the sera.

Import of FBS

In the last years the worldwide FBS need increased permanently. However, the import and export of the serum is strictly regulated for the USA and the European Union. Though the European Union (EU) allows the import of South American serum ("EU approved"), while the USA makes it generally impossible, bio pharmaceutical producers in Europe are requested to use FBS from Australia or the US, in order to make the finished product worldwide marketable.

The EU currently allows the import of FBS under two alternative conditions:

- The raw serum can be imported without prior treatment, if it has its origin in the regions where the serum is veterinary-regulatory tested on the above-named viruses, and where no vaccination against these forms of viruses has been effected.
- Sera that are not certified according to the described instructions, need prior treatment whether gamma-irradiation of minimum 25 kGray, or alternatively heat treatment of 3 hours at +65 °C, or exposure to 3 hours pH-value-lowering onto 5.

It is incumbent upon the respective EU country that imports the serum first to control these import conditions.

The imported raw FBS from South America or Australia is delivered to Biochrom AG without interruption of the cold chain, and after assay and approval by the quality control, defrozen under standardized conditions, and sterile filtered with a multilevel filter-cascade. The usual processing lots have a standard volume of 1000 litres or 2000 litres for industrial customers. Before the filtrated serum is released for sales, it undergoes a sterility control according to the European Pharmacopoeia directives and a test on bovine viruses in an independent laboratory. Fillings of 100 ml for testing are available of each of these lots. The quality control results are reported in batch-related certificates that are provided together with the serum samples (request for samples see appendix).

Documentation

Especially if FBS is used in mayor quantities for productions ("bio-processing"), a complete chain of evidence in the documentation, from the origin to the sterile filtration, is condition to its acceptance. This is certified for FBS with particular origin with the Certificate of Suitability (CoS) issued by the EDQM in Strasbourg for Pharmaceutical Raw Materials of Bovine Origin. Together with the Sterility Quality Control Certificate, a mycoplasma-free testing and a successful pre-testing on standard-cell lines, the identification badge for the integrity and functionality of each lot is given. An independent laboratory additionally raises a series of clinically-chemical data provided to the customers together with the samples.

Storage and handling

FBS offers at moderate costs a complex mixture of valuable growth factors and trace elements for cell culture. The delicate texture of most of the components requires a cooling of the FBS of < -20 °C from the extracting of the raw serum to the use of the finished product. A correct handling of the cold chain preserves the FBS during a long storage and use. An unrestricted use of 5 years of the Biochrom AG serum is guaranteed under previously described conditions.

For some purposes, the sterile filtered serum may need further processing. For the biopharmaceutical use for example, a γ -irradiation on a minimum of 30 kGray is necessary for virus safety. In order to preserve an optimal efficiency regarding the benefit of the cell growth, freezing and de-freezing should result as quickly as possible to reduce the phenomenon of salt loss and to avoid the production of high salt concentrations (in not yet frozen parts of the serum) (see above "Sera").