

biowest

The serum professionals



bio**s**era

Company Profile

Biowest, founded in 1987, is a leading supplier of sera, media and related products. Raw serum is sourced and processed by Biowest, then sold throughout the world by Biowest LLC in the USA, Biowest SAS in France and Germany and Biowest Ltd in the UK, as well as our network of international distributors elsewhere.

Source of Material

Initially Biowest was the supplier of quality sera for Boehringer Mannheim (now Roche Diagnostics). When Roche decided to end their distribution of sera in 1999 Biowest began selling to end users and today supplies customers around the world.

Processing of Material

With outbreaks of viral diseases in animals becoming prevalent in so many countries, it has become more important than ever to know the source of sera. Biowest has in place a system of vertical integration that allows us to be certain of the origins and traceability of our Fetal Bovine Serum (FBS). We work with a small number of reputable suppliers to acquire each batch and then monitor its movement in our own system, through treatment and production on our premises, to final packaging.

Tracking

Biowest Fetal Bovine Serum is derived from clotted whole blood aseptically collected from the fetus via cardiac puncture using a closed sterile bag system. The blood is centrifuged and the serum frozen for transfer to our processing facilities. On receipt at the processing plant the serum is thawed, tested for acceptability, pooled and passed through three 100nm (0.1µm) filters. The serum is bottled in our Class 10,000 cleanroom in a Class 10 hood. Some special treatments are carried out before and some after bottling.

Regulatory Controls

Biowest maintains full traceability of all sera. The bottle labelling system is linked to our information systems and is designed for batch to batch clarity. Serum is delivered frozen in dry ice.

Testing

Serum is manufactured in a manner consistent with the relevant Good Manufacturing Practice (GMP) guidelines. Raw materials are from EC approved sources in all cases, and where relevant they are also USDA approved. Quality checks are made at each step of the production process and each batch is sample tested by independent laboratories. The National Veterinary Service controls the import and export of all products from or to third countries.

Sterility

Biowest rigorously tests serum for sterility, mycoplasma, specific viruses and the ability to support cell growth. Certified and Special Certified sera are also subjected to a large battery of further tests.

Mycoplasma

All sera are tested for the absence of bacteria under aerobic and anaerobic conditions, fungi and Mycoplasma. The tests (based on the method described by the European Pharmacopeia) are carried out over 15 days for bacteria and fungi and 21 days for Mycoplasma.

Viruses

Serum is tested for Mycoplasma by inoculation of Mycoplasma test broth, followed by subculturing onto 3T3 cell mono layers and Mycoplasma test agar plates. The cells are incubated and stained, and the plates visually examined for Mycoplasma.

Endotoxin

All of our serum is tested for Bovine Viral Diarrhoea (BVD), Infectious Bovine Rhinotracheitis (IBR) and Parainfluenza Type 3 (PI3). Tests are conducted on cultures that are grown for a minimum of 21 days in medium supplemented with 15% test serum, with subculturing at least twice during this period. Virus inoculated cultures are tested in parallel. Test cultures are examined for cytopathic indications and by fluorescent antibody staining, inclusion body staining and haemadsorption. The sera must also pass ELISA testing.

BSE

Endotoxin testing is carried out qualitatively with a chromokinetic test and quantitatively with a turbidimetric test. The endotoxin standard against which the endotoxin levels are measured is standardised by USP Reference Endotoxin Standard LAL method.

Cell Culture

Prion tests are carried out when sera is from a region which has had BSE. When blood is harvested from the fetus, a sample of the mother's brain is assayed for the presence of prions by a registered veterinary lab. [The brain is chosen because it has the highest concentration of prions.] Only batches shown to be free of BSE are then used. This system delivers probably the only guaranteed BSE free sera in the world.

Other Tests

Biological performance is assessed using cell culture medium supplemented with the serum being tested at a final concentration of 10%. During the test period, cultures are examined microscopically for any morphological abnormalities that may indicate toxic components in the serum. Cell growth, plating efficiency and cloning efficiency are all tested, using HeLa, L929, SP2/O-AG8 and MRC-5 cell lines.

Biowest routinely assays Certified and Special Certified sera for levels of the following:

- haemoglobin
- chemical components: ions, enzymes, precursors
- characteristic electrophoretic protein patterns
- total protein.
- osmolality
- pH

Certified Fetal Bovine Serum

Certified FBS is our traditional, high quality FBS and meets the requirements of the most discriminating FBS users.

Over 50 tests are carried out on our Certified FBS and the serum must pass all of them to be accepted.

Countries are graded due to their potential risk of BSE and the lowest risk is GBR 1 (Geographical Bovine Spongiform Encephalopathy Risk Category). Serum is generally sourced from these countries although the European serum from Countries with a history of BSE is screened by testing the mothers' brain for the prions and serum sourced from the USA is from USDA approved suppliers.

At the time of writing Biowest serum is sourced from the following:
 Europe – France*, Denmark*
 South America – Paraguay, Uruguay, Chile, Brazil, Argentina**, Colombia***
 Central America - Costa Rica***
 North America - USA***
 Other – Australia**

* BSE tested ** GBR 1 countries *** GBR II countries

Fetal Bovine Serum (South American Origin)	S1810
Fetal Bovine Serum (European Origin)*	S1820
Fetal Bovine Serum (Central American Origin)	S1600
Fetal Bovine Serum (Australian Origin)	S1700
Fetal Bovine Serum (US Origin)	S1520

* BSE tested

Other regions of origin available on request

Biowest offers specially treated Certified FBS to meet customers' specific requirements. If you require a treatment not listed here please contact us.

FBS treated with charcoal activated dextran has reduced levels of various hormones and other factors, making it useful for assaying cells used in receptor and other signal related studies:

Fetal Bovine Serum (South American Origin)	S181F
Fetal Bovine Serum (European Origin)	S182F
Fetal Bovine Serum (Central American Origin)	S160F
Fetal Bovine Serum (Australian Origin)	S170F
Fetal Bovine Serum (US Origin)	S152F

FBS is dialysed against an osmo-equivalent saline solution using membranes with a cutoff rated at 10,000 Daltons. The concentration of small components such as ions, salts, nucleotides, amino acids, vitamins, some hormones and other metabolites is substantially reduced.

Fetal Bovine Serum (South American Origin)	S181D
Fetal Bovine Serum (European Origin)	S182D
Fetal Bovine Serum (Central American Origin)	S160D
Fetal Bovine Serum (Australian Origin)	S170D
Fetal Bovine Serum (US Origin)	S152D

Our highest quality FBS lots are screened for use with stem cells. Using cells specifically grown by a leading stem cell company, we assay these lots for growth rate, plating efficiency, colony morphology and toxicity.

Fetal Bovine Serum (South American Origin)	S181S
Fetal Bovine Serum (French Origin)	S182S

Please enquire about stem cell tested serum from other regions.



Certified Products

Special Certified Serum

Charcoal Treated Fetal Bovine Serum

Dialysed Fetal Bovine Serum

Stem Cell Tested Fetal Bovine Serum

Low IgG Fetal Bovine Serum

The level of IgG in FBS is normally low but can increase significantly if there has been an immune challenge to the mother.

By screening each sample of FBS with an IgG ELISA we identify and pool those samples which have very low levels of IgG. Low IgG FBS is especially useful for the production of monoclonal antibodies. The purification of some target proteins can also be improved by the use of low IgG FBS. By sourcing naturally low IgG FBS Biowest avoids the need to chemically treat the serum, maintaining a higher quality and simplifying a customer's regulatory processes.

Fetal Bovine Serum (South American Origin) S1811
Fetal Bovine Serum (French Origin) S1821

Please enquire about low IgG serum from other regions.

Gamma-Irradiated Fetal Bovine Serum

Serum is γ -irradiated by a ^{60}Co source with 25 kGy to eliminate mycoplasma and γ -radiation sensitive viruses.

Fetal Bovine Serum (South American Origin) S181G
Fetal Bovine Serum (European Origin) S182G
Fetal Bovine Serum (Central American Origin) S160G
Fetal Bovine Serum (Australian Origin) S170G
Fetal Bovine Serum (US Origin) S152G

Qualified Fetal Bovine Serum

Biowest offers a cell growth tested serum for customers working with robust cells or under budget constraints. Qualified FBS is processed similarly to Certified FBS but does not undergo the same level of testing. All serum is tested for sterility, mycoplasma and viruses. Most importantly the Qualified FBS must pass stringent requirements for cell growth, using 3 different cell types, to ensure the serum is satisfactory for most customers' needs. The lowered costs associated with producing this serum allows Biowest to offer it at a discount.

Definitions

Animal Free: Does not contain materials of animal origin.

BSE: Bovine Spongiform Encephalopathy is a disease affecting the central nervous system.

Calcium Depleted: The product has reduced levels of calcium.

Charcoal Treated: The product has been treated with charcoal/dextran, reducing the level of some hormones.

Country of Origin: The country or region in which the donor/animal serum was harvested.

Dialysed: The product has been dialysed with a cutoff of 10,000 Daltons against an osmo-equivalent saline solution.

EC Approved: Meets with European Community requirements.

Gamma Irradiated: Treatment with γ -radiation to inactivate certain viruses.

Heat Inactivated: Incubated at 56°C for 30 minutes to inactivate complement.

Low Lipid: The level of lipids and lipoproteins is reduced by treatment.

Low IgG: The serum has levels of IgG below 5 mg/l.

NCCC Guidelines: Many of our test methods are based on the approved guidelines set by the National Cell Culture Center.

Source: The country or region in which the donor/animal serum was harvested.

USDA Approved: Used to describe a source that meets USDA (United States Department of Agriculture) importation requirements.

Virus Tested: The product has been tested for the viral groups noted on the product analysis.



SOCOCHIM^{SA}
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