Technical Information

Traceable to the Source

When scientists select their sera, an important factor taken into consideration is the source. Therefore, traceability of the serum is of paramount importance.
Biowest Fetal Bovine Serum is derived from clotted whole blood aseptically collected from fetus via cardiac puncture. 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. The product is analyzed, classified, and tested by Biowest before shipment to customers all over the world.
Our Quality system can trace raw materials back to the original supplier and slaughterhouse where they were collected. Biowest's system of vertical integration provides certainty of origin and traceability of all Fetal Bovine Serum (FBS).

Biowest Quality

FBS "quality" is defined in relation to growth promotion characteristics of a specific cell line when cultured in our sera. A batch of FBS which works well for one cell line may not work well for another cell line. Biowest customers can purchase FBS after performance-testing of a sample. There are thousands of different cell lines and no two batches of FBS are identical ; we therefore offer a very liberal sample and reserve policy. Each batch is delivered with a Certificate of Analysis.

Serum - Batch Reservations

Biowest is pleased to provide free samples of different batches combined with batch reservations during the test period up to 60 days. The general sample size for FBS is 50 ml / batch. Biowest can adapt these general policy to the needs of the customer if requested.
After batch testing, Biowest can hold a reservation up to 24 months for customers who do not have ample storage facilities. In this case, a regular shipment is planed to the customer.

Technical Support
Biowest's experienced Technical Service Staff is available to answer questions regarding our quality control and all Biowest products. We aim to provide timely, courteous and professional service.

Worldwide Sources
Biowest offers a wide range of sources from countries with excellent veterinary status. This includes South American sources as well as European Union (EU) and United States Department of Agriculture (USDA) approved sources. The choice of the FBS source is determined by import requirements and allowed supply available for the different markets.
Biowest is the ideal partner for academic researchers and biopharmaceutical companies who select FBS based on origin and performance.

Risk Classification GBR

Serum producing countries are designated with a Geographical BSE-Risk Level from GBR I to GBR IV. The Geographical BSE-Risk (GBR) is an indicator of the likelihood of the presence of one or more cattle being infected with BSE (Bovine Spongiform Encephalopathy), pre-clinically as well as clinically, at a given point in time. Where its presence is confirmed, the GBR gives an indication of the level of infection.

GBR level	Presence of one or more cattle clinically or pre-clinically infected with the BSE agent in a geographical region/country
I	Highly unlikely
II	Unlikely but not excluded
III	Likely but not confirmed or confirmed, at a lower level
IV	Confirmed, at a higher level

Regulatory Compliance

Countries vary in their guidelines for the import of FBS and its use in specific applications. Of primary concern is BSE and viruses. Countries in the GBR I and GBR II classification are those where BSE has not been detected and the risk is considered to be low; this is because animals are permitted to graze naturally. Countries in GBR Group III and IV are those where BSE has been detected or where the risk is considered to be high.

Country of Origin

This is defined as the country in which the donor/animal provides the serum. Biowest fetal bovine serum is sourced from the following countries :

Cat N° S1500 **Canada**

Cat N° S1520 **USA**

Cat N° S1560 **Chile**

Cat N° S1600 **Central America**

Cat N° S1650 **Mexico**

Cat N° S1700 **Australia**

Cat N° S1750 **Denmark**

Cat N° S1810 **South America**

Cat N° S1820 **France**

GBR I	GBR II	GBR III
Argentina	Brazil	Canada
Australia	Colombia	Chile
New Zealand	Costa Rica	Denmark
Panama	Nicaragua	France
Paraguay		Mexico
Uruguay		Spain
		USA

Filtration and Packaging
Raw pooled FBS is filtered through a triple series of 0.1 micron sterilizing filters. The sterile serum is true-pooled to ensure homogeneity. Biowest products are packaged via an aseptic filling process for which each step has been determined to ensure the production of a product meeting the industry standard sterility assurance level of 10^4 (i.e., product that demonstrates a bacterial and fungal contamination level of no more than 1 of 10,000 units during the manufacturing process). The highest level of sterility assurance (10^6) cannot be achieved without terminal sterilization. Filtration and dispensing are performed within positive pressure, HEPA-filtered, environmentally controlled rooms.

Final Filter Size : Triple 0.1 micron

Sterility
All sera are tested for the absence of aerobic and anaerobic bacteria, fungi, and yeast. Sterility test procedure is based on the European Pharmacopeia or US Pharmacopeia depending on the locale of final filtration. A representative number of samples from each production batch is selected for Sterility testing.

Mycoplasma
Each final product batch is tested for absence of mycoplasma. The sera are tested for the absence of Mycoplasma utilizing a cell culture assay in Axcell Biotechnologies media by culture method. Our test is accurate within limits of method detection.

Virus Testing
Each batch of bovine serum is tested for adventitious viruses using cell culture techniques. The serum is tested for :

- Bovine Viral Diarrhoea (BVD)
- Infectious Bovine Rhinotracheitis (lBR)
- Parainfluenza Type 3 (Pl3)

Sera are tested for the absence of the indicated viruses by inoculation with GBK cells. The revelation is made by indirect immunofluorescence. Antibody Testing : presence of specific antibodies is detected utilizing an Elisa Assay. The serum from equidea is tested for the presence of Equine Infectuous Anemia antibodies.

Osmolarity
Osmolarity is determined by the lowered freezing temperature. The osmometer is calibrated using traceable standards.

Cell Culture Testing
Each batch of serum is tested for its ability to support in vitro growth of specific cell lines. Therefore, in addition to verify that each batch of sera passes our exacting quality control specifications, three important performance criteria are evaluated in our Quality Control Program:
- Growth Promotion

- Cloning Efficiency
- Plating Efficiency

Biological performance is assessed using cell culture medium supplemented with a final concentration of 10% serum. During the test period, cultures are examined microscopically for any morphological abnormalities that may indicate toxic components in the serum.

The following cell lines are utilized to determine growth promotion and functionality:

Cell Line	Type	Species
HeLa	Cancer	Human
L929	Fibroblast, Macrophage	Mouse
Sp2/O-Ag14	Lymphoma	Mouse
MRC-5	Lung	Human

pH
All pH meters are daily calibrated with standard solutions.

Bovine Spongiform Encephalopathy (BSE) Testing
According to the European Regulation EC n° 999/2001, female donor animals are tested for BSE before the corresponding fetal blood is allowed to be processed.
EU is pioneer in BSE testing and individual identification of animals through ear tagging, which ensures the best possible traceability and the lowest BSE risk and makes the EU origin the first choice of researchers in Japan and other selective markets.

TEST	Prionics	Bio-Rad
METHOD	Western blot	ELISA

Chemical and Enzyme Profile

Items	Methods
Sodium	Indirect potentiometry
Potassium	Indirect potentiometry
Chloride	Indirect potentiometry
Calcium	Arsenazo colorimetry
Phosphorus	Phosphomolybdate colorimetry
Alkaline Phosphatase	Colorimetry kinetic at 37°C
LDH	UV kinetic at 37°C
SGOT	UV kinetic at 37°C
SGPT	UV kinetic at 37°C
Gamma >GT	Colorimetry kinetic at 37°C
Cholesterol	Cholesterase Trinder

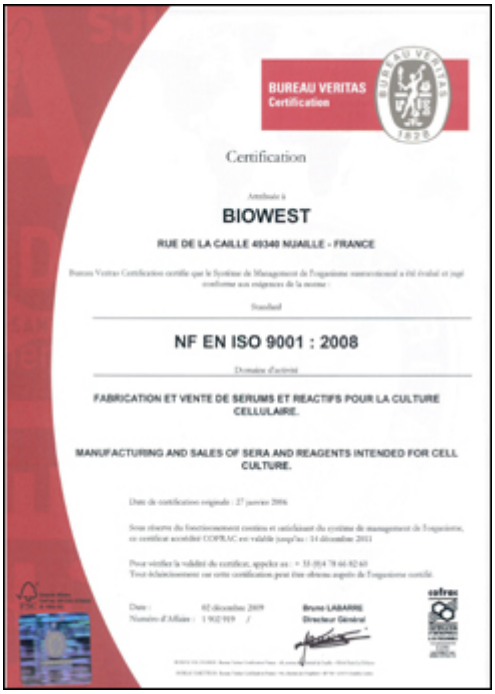
	colorimetry
Bilirubin	DPD / cafeine colorimetry
Glucose	Hexokinase UV
Urea	Urease UV
Creatinine	Colorimetry kinetic (jaffe)
Triglyceride	Glycerokinase Trinder colorimetry
Iron	TPTZ colorimetry

Storage and Shelf Live

Animal Sera and Plasma is stored at -20°C. The shelf life for animal Serum is 60 months, and for animal plasma 48 months.

Certificate of Analysis

ISO 9001 Certificate


BUREAU VERITAS
Certification

Certification

BIOWEST

RUE DE LA CAILLE 49340 NUAILLE - FRANCE

NF EN ISO 9001 : 2008

FABRICATION ET VENTE DE SERUMS ET REACTIFS POUR LA CULTURE CELLULAIRE.

MANUFACTURING AND SALES OF SERA AND REAGENTS INTENDED FOR CELL CULTURE.

Bruno LABARRE
Directeur Général

ISO9001 Certificate

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