

Doc. No.	Rev	Effective Date
PI20	2	08JUL2024

Foetal Bovine Serum

Product Description

Of all the different types of animal serum available, Foetal Bovine Serum (FBS) is the most widely used basal media supplement for *in vitro* cell culture. FBS contains very low level of antibodies, which combined with a higher concentration of growth factors (compared with adult or newborn sera), means FBS is effective in promoting and sustaining the growth of both mammalian and insect cells.

FBS aids cell culture growth in three key areas:

- **Hormonal factors:** to stimulate cell growth and function. Different cell lines are stimulated by different growth factors and by different concentrations of hormones.
- **Attachment and spreading factors:** many cell lines must first adhere to a surface before they can spread and proliferate effectively.
- **Transport proteins:** these shuttle minerals, lipids, vitamins and other essential nutrients within the cell.

In addition, the supplementation of basal media with FBS serves to increase its buffering capacity. This can be important for slow growing cell types, or where the seeding density is low, such as during cell cloning experiments.

What exactly is serum? Serum is the liquid fraction of clotted whole blood. Unlike plasma, no anti-coagulant will have been added to the blood following collection from the animal. Serum is centrifuged to separate the clot from the liquid phase, resulting in a product that is depleted of cells, fibrin and clotting factors.

Country of Origin

The country of origin for FBS refers to country in which the raw blood was collected.

Major FBS producing countries are Australia, Canada, Central America, New Zealand, South America and the U.S.A. While some countries may be considered more desirable sources of FBS than others, it is not true that FBS is of better quality from any given country. Desirability is linked to the disease status for each country (as described by the World Organization for Animal Health (OIE)) relevant to the application to which the serum is to be used. In addition, supply and demand plays a role making some sources of FBS more expensive than others. This is especially the case for New Zealand and Australia whose island nations have left the countries largely untouched by bovine diseases.

The OIE monitors the global incidence of animal disease including BSE and publishes this information on a regular basis. Regulatory authorities and processors use it as one of the critical determinants in deciding which countries may be used as a source of serum for certain applications with those sera acceptable for industrial use such as vaccine manufacture usually demanding the highest price in the market.

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Life Science Production

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What does it mean when FBS is labelled USDA Grade or European (EU) Grade?

USDA Grade FBS is FBS of non U.S.A. origin that the United States Department of Agriculture (USDA) considers to be acceptable for importation in the U.S.A. These countries are defined as being free of bovine spongiform encephalopathy (BSE) and foot and mouth disease (FMD). Countries include New Zealand, Australia, Mexico and other Central American countries. With the exception of New Zealand (which can be imported without additional testing), serum must first be quarantined on importation prior to samples being tested at USDA facilities to ensure freedom from Bluetongue virus and, in the case of Australian serum, Akabane virus.

EU Grade FBS is FBS of South American origin that is permitted for importation into the EU under Commission Regulation (EU) No 142/2011. This material is also permitted to be imported into certain countries in Asia. EU Grade is currently not permitted to be imported into the U.S.A.

Special note: Should the ultimate goal of your research be to produce a product that will be shipped into the U.S.A. at some point now, or in the future, we strongly recommend that special attention is paid to the origin of serum used, as well as any documentary requirements. The USDA impose strict guidelines and these apply to both production as well as the final product.

Collection and Processing

The quality of FBS is inherently linked to the collection and processing methods used and not the country of origin. A closed-system collection method (cardiac or venepuncture) and rapid processing are essential to produce a quality product. Low levels of endotoxin and haemoglobin are excellent indicators of the care with which collection and processing have been carried out.

LSP has over 30 years' experience in the collection and processing of Foetal Bovine Serum (FBS). Every batch of FBS is rigorously controlled throughout the process, from collection to treatment and finally packaging. This ensures complete traceability right back to the source. All our serum is collected and treated in accordance with current European regulations.

LSP FBS is manufactured at our facility in the UK in batches of up to 1000 litres. Each batch is triple filtered to 0.1 micron prior to Quality Assurance testing.

LSP can provide FBS from a variety of geographies to suit both budgetary and research requirements. Major companies that collect and sell FBS globally are members of the International Serum Industry Association (ISIA). LSP is both a member and a major contributor to the Association. Further details can be found at www.serumindustry.org.

Specifications

Quality Assurance testing precedes the release of a batch for sale. Full batch documentation can be provided including Certificates of Origin, Certificates of Analysis showing country of origin, and batch filtration records.

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LSP FBS typically has endotoxin levels of below 10 EU/mL with some batches having endotoxin levels of below 1 EU/mL. Each batch is tested to ensure freedom from mycoplasma and specific viruses. Batches are also tested for the ability to support growth of specific cell lines. In addition, each batch is also tested for standard parameters. These include pH, osmolality, protein content, albumin, IgG and haemoglobin levels.

Country of Origin	All LSP FBS is from a single origin. The country of origin for each batch will be stated on the COA.
Sterility	Each batch of sera is tested for the absence of bacteria, fungi, yeast and Mycoplasma.
Viral Testing	FBS is tested for Bovine Viral Diarrhoea Virus (BVD-V), Bovine Parainfluenza-3 virus (PI3), Infectious Bovine Rhinotracheitis (IBR) and Bovine Viral Diarrhoea Virus antibodies (BVD-AB).
Endotoxin	All sera are tested to determine the levels of endotoxins using the Limulus amebocyte lysate test (LAL).
Growth promotion	Biological performance of final batches of sera is assessed for cell growth, plating efficiency and cloning efficiency.
Mycoplasma	Tested for <i>M. bovis</i> , <i>M. arginini</i> and <i>A. laidlawii</i> .
Filtration	FBS is filtered through three sequential 100 nm (0.1 µm) pore size-rated filters.
Documentation	Full traceability for serum production is demonstrated through the stringent records maintained by LSG at their facility. These records are maintained in both hard copy and electronic copy. These records are audited through the ISIA Traceability Audit program

Complete results are reported on the Certificate of Analysis supplied with each batch.

Presentation

FBS can be supplied in a variety of different presentations including individual supplier packs. FBS is normally supplied in 500 mL bottles, although other presentations are available on request such as larger or smaller volumes (e.g. 1 L or 100 mL).

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Batch Sampling

LSP offer samples of FBS for testing prior to selection of a suitable batch. Typical sample size is 50 mL and reservations are held for a period of four weeks, pending evaluation.

Additional Treatments and Testing

FBS is also available heat inactivated, gamma irradiated, dialysed and charcoal stripped.

Heat Inactivation: Sterile filtered serum is heated to 56°C for 30 minutes with continuous agitation. This process will inactivate various components of the serum including complement factors which can interfere with certain immunoassays. However, the routine treatment of serum is not desirable for all applications, so it is recommended to test the benefit of heat inactivation prior to having a batch treated in this way. Heat inactivation can increase the presence of precipitates and may also impede the growth enhancing properties of the FBS.

Gamma Irradiation: Can be used as part of the sterilisation process. After the serum has been sterile filtered, it is bottled and then exposed to 2.5-3.5 mRads (25-35 kGy) to guarantee freedom from micro-organisms. Some bovine viral species are resistant to gamma-irradiation, such as parvovirus. As the gamma irradiation is carried out in the final packaging vessels, it will cause both glass and PETG bottles to darken in colour. It can also impair the efficiency of the serum and reduce shelf life.

Dialysis: In order to remove small molecules such as glucose, salts, hormones, cytokines, amino acids and also antibiotics, chilled serum is dialysed from 10kDa up to 30,000kDa. This processing method is useful for receptor studies (and radiolabelling assays). However, dialysis does not remove serum bound hormones and it can reduce the growth promotion capabilities of the serum.

Stem Cell Qualified: Sterile filtered serum is tested for the ability to support Embryonic stem cells. Typically mouse embryonic stem cells are grown for 2 passages in a complete medium supplemented with foetal bovine serum.

Tetracycline negative: Sterile filtered serum is tested by an external laboratory for the presence of tetracyclines. This serum is suitable for use in all assays where the presence of tetracyclines is of concern.

Charcoal: Dextran Stripping: Serum is processed through an activated charcoal filter to remove lipophilic material including oestradiol, progesterone, cortisol, testosterone, T3, T4 and insulin. The level of stripping can be either medium or heavy. The processing method is ideal for applications requiring low levels of hormones such as steroid and steroid receptor research, immunoassay systems and insulin assay methods. However, impaired growth promotion can be found in cells requiring the presence of certain hormones.

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Shelf life

FBS has a shelf life of 5 years from the date of manufacture, provided it is stored appropriately. We would recommend enquiring about the shelf life of each available batch if it is important to have a long shelf life following purchase.

While there may be a drop off in growth promotion properties over time, the level of any change will depend on the cell type and assay conditions. Therefore, should a batch of serum be coming up to its original expiry date and it is still performing adequately, rather than destroy the material, LSP is happy to extend the expiry date by 12 months. This re-test may be performed on a rolling 12 month basis. This means that the considerable time and investment in batch testing of a large batch of material need not be wasted should the supply last longer than forecasted.

Storage & Handling

Recommended storage is -20°C or below.

Protect serum from exposure to light.

It is recommended to avoid freeze-thaw cycles as this can lead to a deterioration in serum qualities. Ideally, material should be thawed under controlled conditions and re-aliquoted into smaller volumes before re-freezing. It is not recommended to store or refreeze partially used serum as degradation is rapid if microbial contamination occurs. All biological material should be handled as potentially infectious. It is essential that universal precautions should be employed when handling FBS.

Shipping

Product ships frozen on dry ice.

Support

To learn more, contact us by phone at +44 1234 889180 or email sales@lifesciencegroup.co.uk

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