

Foetal Bovine Serum: Product authenticity

Product Description

Foetal Bovine serum (FBS) is collected in many geographies and each of these geographies determines the specific price of this product. New Zealand origin FBS currently demands the highest price since this serum is considered to be suitable for use in pharmaceutical manufacturing and South American FBS is a more cost-effective product for use for general research applications.

Adult bovine serum and newborn bovine serum also grown cells. There have been instances in the past of contamination of FBS with both of these products. Until now it has been difficult to indicate both origin and age of the serum in any given bottle of serum however tests have been developed to enable both origin of serum and age of serum to be determined.

All serum, human and animal, is a complex mix of water, protein, salts, sugar, amino acids, vitamins, enzymes, growth factors and other components. These components will vary based on the age of the animal at collection, breed, sex, different geographic origin, feed, water, seasonal climatic variation, and many other factors.

The International Serum Industry Association (ISIA) was formed in 2006 to promote and provide guidelines on compliance for standards and ethics in the business practices of global animal derived products including FBS. The ISIA has developed a traceability standard for members and traceability certified facilities are facilities that have been audited for and comply with this standard. Life Science Group Ltd are an ISIA Traceability certified company.

Biomarkers

In an effort to inform and educate end users, the ISIA has identified two biochemical markers that will identify FBS by age. The ISIA has data that definitively confirms that two biomarkers, Immunoglobulin G (IgG) and Gamma-Glutamyltransferase (GGT) can be used to determine the age of the host animal from which the serum was collected and also if foetal collected serum has been contaminated with serum from an older animal.

Immunoglobulin G (lgG)

IgG is the most common antibody found in the blood and is present both in low levels in FBS and higher levels in newborn or adult serum. Low levels of IgG in media are important in the manufacture of antibodies. All healthy foetuses are agammaglobulinemic because, in cows, the placental barrier prevents the transmission of IgG from the dam (mother) to the foetus. In newborn calves the antibody is largely acquired via colostrum from the maternal mammary gland causing the IgG levels of the calf to increase dramatically in the first 24-36 hours post-partum. It can be seen that IgG levels in serum can be a clear determinant of the age of the animal from which the material was collected. An individual foetus will have IgG levels no higher than $3000 \mu g/ml$, due to batch processing methods and pooling of material from a large number of animals, the final levels of IgG in FBS have an expected overall value of less than $300 \mu g/mL$. It is important to note that the end user should be cautious when comparing unit values of IgG in certificate of analyses. It can often appear that the values are outside the normal range but the units are expressed differently; for example, $\mu g/mL$ can be also expressed as mg/dl. There are certain geographies in which foetal serum can genuinely have levels of IgG higher than the normal levels and it is for this



reason that IgG levels should always be read in association with gamma-glutamyltranspeptidase or GGT levels.

Gamma-Glutamyltransferase (GGT)

GGT, sometimes called gamma-glutamyltranspeptidase, is a transferase enzyme found in the cell membranes of tissues throughout the body. This enzyme is important for the transmembrane movement of amino acids as well as the metabolism of molecules such as glutathione. Inconsistent levels of GGT can have a profound effect on the reproducibility of cell-based assays, particularly with *in vitro* cancer models due its key role in redox regulation. The serum levels of this enzyme are vastly different pre- and post-partum because, like IgG, GGT is found in colostrum. In mammals, the GGT levels in foetal serum change as the gestation period progresses, but remains lower when compared to newborn calf or adult origin serum. This enzyme serves as a distinct biomarker for determining the age of the animal from which the serum is collected due to the disparate differences in the levels seen within foetal serum (-0-5 IU/L) and those seen in, for instance, calves (160-1000 IU/L). Variations are expected to be seen based on country of origin and equipment used. Typical GGT levels for FBS in US origin product usually fall below 5 IU/L while that for Australia/NZ usually fall below 12 IU/L.2

With experimental reproducibility or paramount importance it is important to know what variables are being introduced into *in vitro* systems. By testing for both GGT and IgG, scientists can be confident in the serum they are using for their cell culture.

Geographical testing

The ISIA, working with a New Zealand company, Oritain, has developed a bovine serum data base for determining the origin of bovine serum.

The science used by Oritain originated in the criminal forensic field where it has been used in multiple investigations. The methodology has been thoroughly peer-reviewed and subject to numerous scientific journal publications over the last 20 years.

The origin of a product may be determined using 'fingerprints' derived from the chemical composition of plant and animal material. These compounds vary naturally throughout the global environment.

Ratios of stable isotopes are indicative of different regions and these vary based on soil conditions, feed consumed and farm practice. Along with isotopes, Oritain also analyses the trace elements that occur in products via uptake of the chemical composition of soils, water and feeds. These 'fingerprints' obviously vary considerably from one geography to another.

By using this method, the ISIA and Oritain have developed a database of information enabling samples of bovine serum to be analysed through the unique statistical model to determine the origin of the serum.

Resources:

https://www.serumindustry.org

https://www.serumindustry.org/standardization/serum-definitions/

https://oritain.com/how-it-works/the-science/



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Support

Life Science Production is a division of Life Science Group Ltd. Life Science Production is <u>ISIA Traceability Certified</u> Life Science Group Ltd is an ISO 9001:2015 Certified company

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