Frequently Asked Questions (FAQs): Human AB Serum

What is Human AB Serum?

Human AB Serum is a vital cell culture reagent for some human cell types providing growth factors, vitamins, nutrients as well as trace elements and transport factors, ensuring faster growth rates than mixed blood group serum. Human AB is proven to grow many human cell lines at a faster rate and with a smaller percentage of serum than mixed blood group serum[1-9]. Human AB serum is now widely used in a variety of Cell Therapy applications.

How is it collected?

US origin

Human AB serum is collected from healthy volunteer male donors of the AB serotype at FDA-registered facilities in the United States and collected in compliance with health requirements established by 21CFR 640, subpart G.

Converted serum is routinely screened for the presence of animal contaminants. This is performed by DNA analysis.

French origin

Human AB serum is collected from healthy volunteer male donors of the AB serotype at EU registered facilities. Please note that in France some donations are made for purely non-therapeutic purposes. In these cases the age of the donors can be significantly higher than standard donations and also transplanted/transfused donors may be selected to donate.

No Animal derived ingredients (ADI) are used in the production of French origin Human AB serum. The manufacturing process does not use any ingredient of animal origin.

How many donors contribute to a lot of human serum?

Each lot of human serum type serum, both off-clot and converted typically derives from 200-250 pre-screened donors. Smaller batches may be made available to a specific number of individual donors for research use only.

What are the advantages of using all male donors?

Women who have been pregnant may develop antibodies against major histocompatibility class (MHC) antigens carried on the father's cells and/or the foetus' cells. Male donors present no such risks.

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What are the benefits to using Human AB Serum instead of FBS?

Human serum from type AB donors lacks antibodies against the A and B blood-type antigens and is therefore commonly used when there is the need to minimize immunoreactivity.

What is the difference between Converted and Off-clot?

Off-the-clot serum is collected from blood that is allowed to coagulate naturally after collection. It has not been exposed to any anticoagulant. Plasma derived serum is produced by defibrinating pooled human blood collected in the presence of bovine thrombin. Plasma derived serum is generally more economical and popular than the off-the-clot product. Both Off-the-clot serum and plasma derived serum are available in both pooled lots and individual transfer packs from specific donors.

Can I use Human AB Serum in diagnostic or therapeutic applications?

Human AB serum supplied by LSG is suitable for research, diagnostic and further manufacturing purposes. Full details as to the collection and processing of human AB serum is available on request. Specific batches of serum may be subjected to additional viral testing, as required. LSG is very happy to discuss specific batch and collection requirements to meet individual regulatory requirements. All human AB serum supplied for further manufacturing is collected only at FDA Licenced facilities.

Are donors compensated for blood donations?

Yes, in the US, blood donors are compensated by cash payments for donations. Only donors known to the donor centre are permitted to donate. These donors are medically monitored for their suitability to donate over a long period of time prior to donations being acceptable for use.

In the EU blood donors are not compensated.

What is the difference between Standard Grade and Manufacturing Grade material?

Manufacturing grade Human AB serum offers the guarantee of sourcing from FDA Licenced facilities, enhanced donor traceability and additional viral testing compared with standard grade. This material has a proved track record and is used routinely for manufacturing by over 40 companies developing cell and gene therapies.

What tests are carried out on Human AB Serum?

Each batch of Human AB serum is tested to ensure freedom from bacteria, fungi, yeast, mycoplasma *(M. pneumonia, M. hominis and M. salivarium)*. In addition, each batch is also tested for standard parameters. These include endotoxin, pH, osmolality, protein content, albumin, IgG and haemoglobin levels. Details for each batch are supplied on the Certificate of Analysis (COA).

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Is Human AB serum tested for the presence of viruses?

All donor units that form each batch are tested for HBsAG, anti-HCV, anti-HIV1 and 2, HIV-1, and Syphilis. Additional viral testing on both individual donors and pooled material is available to meet current regulatory standards for further manufacturing.

Viral testing on human AB donor material is carried out by FDA Licenced testing laboratories in the US and at equivalent facilities in the EU. Testing is carried out on a variety of viruses and units are only released for use once all viral testing has been completed. Full details of the viral testing is available on request and is carried out to the limit of the FDA/CE marked validated licenced processes.

Is Human AB serum sterile?

Each batch of Human AB serum is tested for the absence of bacteria, fungi, yeast, mycoplasma. Our Human AB serum is also sterile filtered to either 0.1 µm pore size-rated filters (US Origin) or 0.2 µm pore size-rated filters (French Origin). Results of microbe testing of each batch of serum is supplied in the COA. However, please note that sterility is not guaranteed after opening. The use of aseptic techniques during handling is recommended.

Can my Human AB Serum be treated before shipping?

Yes. Human AB serum is available as heat inactivated, gamma irradiated, dialysed and charcoal stripped material.

What does heat inactivation do to the serum?

Human AB Serum may be heat inactivated by heating to 56°C for 30 minutes to inactivate various components in the serum such as complement factors.

Should I heat-inactivate my serum?

At one time, heat inactivation was considered necessary because of concerns over the presence of contaminants in serum. However, the process of heat inactivation is known to degrade valuable biomolecules, such as growth factors, vitamins, and amino acids. Many protocols still call for serum to be subjected to heat treatment prior to use without consideration as to whether it remains desirable. Should it be required, LSP can provide heat inactivation as a custom processing option.

What does gamma irradiation do to the serum?

The gamma irradiation of GMP Grade Human AB serum is a requirement for serum used in further manufacturing. Gamma Irradiation is a validated process to mitigate the risk of active viruses being present in the serum and is a requirement of regulatory authorities for the use of Human AB serum in further manufacturing.

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What pack sizes are available for Human AB Serum?

Human AB may be supplied in any bottle size e.g. 1 litre, 500 mL, 100 mL, 50 mL, 25 mL, as required, including bottles fitted with septums for the aseptic removal of serum. Human AB serum may also be processed into single use bags with tubing sets to meet individual production requirements.

Can I sample batches of Human AB Serum?

Yes. We offer samples of Human AB Serum for testing prior to selection of a suitable batch. Typical sample size is 25 mL and reservations are held for a period of four weeks, pending evaluation.

What is the shelf life for Human AB Serum?

Human AB Serum 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.

What is the recommended storage and handling for Human AB Serum?

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 Human AB serum.

Are there any specific precautions required when using Human AB Serum?

Despite all testing, proper safety precautions for potentially infectious agents must be taken. All human blood products should be handled in accordance with currently acceptable bio-safety practices and guidelines for the prevention of blood borne viral infections.

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Can donors who have received blood transfusions, donate blood for Human AB Serum collection purposes?

US Origin

The deferral time for any transfusion patient to stop donating blood products is 12 months. After this time, these donors can return to donating blood, serum or plasma. Transfusion grade collections don't allow for transfused patients to donate. However, only some sites collect "transfusion grade" serum while others don't. This means that blood from transfused patients can be present in material pooled from a number of different sites.

EU Origin

In France it is permitted for people who have received blood transfusions to donate blood for non-therapeutic applications

Why might it be a problem to use serum that is made from donors who have received a blood transfusion?

HLA antibodies are not naturally occurring and can only be acquired by pregnancy, transfusion of blood products or transplantation. Therefore, for a donor pool of un-transfused male donors with blood group AB, provided the donors are healthy, you can expect a very low incidence of HLA antibodies.

Depending on your specific application, you would need to use serum from non-transfused patients if it is important that the serum you receive is HLA free.

Also see question: Can donors who have received blood transfusions, donate blood for Human AB Serum collection purposes?

How is Human AB Serum shipped?

Human AB serum will be shipped frozen, by overnight courier in polystyrene moulded boxes with dry ice unless we are specifically requested not to do so. This will ensure that the material arrives frozen in good condition.

Why do different bottles of human serum sometimes look different from one another?

LSP goes to great lengths to ensure that our human sera are the most consistent products commercially available. Although our human serum is manufactured using raw material from congruous donor pools and according to time-tested protocols, it is possible to perceive differences in the physical appearance of this product from lot-to-lot. This phenomenon can be largely attributed to variation in diet amongst human beings (particularly with respect to dietary fats). Another source for slight differences comes from non-

uniform storage conditions and/or handling variations in the laboratory setting. Due to the special sensitivity of this product (as compared to other sera), it is critical that human serum be cared for as recommended by the manufacturer.

What should I do if I get precipitation in my Human AB Serum?

When serum is thawed, some precipitation may be seen. This is a normal phenomenon and it does not compromise the quality of serum in any way. To remove the precipitate, transfer the serum to sterile tubes and centrifuge for 5 mins at 400g.

To limit the amount of precipitation, we recommend that the serum is thawed in a refrigerator at 2-8°C. The serum should be regularly mixed during this process.

In the unusual event of serum arriving partially thawed, please note that it is inadvisable to refreeze from this state as partially thawed serum must be allowed to thaw completely at 4°C.

When the serum has thawed completely, gently invert the container several times to achieve thorough mixing and refreeze as soon as possible to -20°C. To avoid repeated freeze/thaw cycles dispense the serum into single use aliquots before freezing.

How long can frozen human serum be stored?

Although it is impossible to claim stability data for every possible application and use, for human serum AB we conservatively estimate that if this product is stored properly at -20ºC, it can be used up to 5 years from the date of manufacture without any decrease in product performance. Storage at any other temperature may affect results. However, once thawed and opened for use, it is not recommended to store or refreeze partially used serum as degradation is rapid if microbial contamination occurs.

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