

## Human AB Serum

### Product Description

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<sup>1-9</sup>. Human AB serum is now widely used in a variety of Cell Therapy applications.

There are two types of Human AB serum commercially available:

**Converted serum** is produced by defibrinating pooled human plasma that was collected via plasmapheresis, in the presence of an anticoagulant such as sodium citrate. Defibrination is achieved through the use of bovine thrombin. This material is also referred to as 'Plasma-derived'.

**Off-clot serum** is collected from blood that is allowed to coagulate naturally after collection, in the absence of any anticoagulant.

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. Furthermore, male only serum is especially advantageous compared with female or mixed gender serum, because there is no risk of the presence of antibodies against major histocompatibility class (MHC) antigens, that can be produced by female donors against antigens carried on the father's cells and/or the foetus' cells during pregnancy.

### Applications

Human serum provides a more comparable cell culture environment compared with other animal sera such as Foetal Bovine Serum (FBS). It is the serum of choice when working with immune cells like lymphocytes and macrophages. In addition, the use of human serum may be necessary in order to meet regulatory requirements on the use of animal derived material.

- Transplantation and cell therapy applications for the expansion of mesenchymal stem cells (MSC) from adipose tissue or mesenchymal stromal cells from human bone marrow
- For *ex vivo* expansion of NK cells from peripheral blood in Haematopoietic Stem Cell Expansion Medium
- For upgrading pre-transplant human islet culture technology
- Tissue engineering
- Antibody-based HLA (Human Leucocyte Antigen ) tissue-typing technologies
- For standardized limbal epithelial stem cell graft generation and transplantation
- Tissue culture of human cell lines
- Serological typing and as a blocking agent

## Donor Qualification and Testing

### US origin

Human AB serum is collected from healthy volunteer male donors of the AB serotype at FDA-licensed facilities in the United States and collected in compliance with health requirements established by 21CFR 640, subpart G. All approved donor units are also tested according to testing requirements for communicable disease agents as stated in 21 CFR 610.40. All units are negative (non-reactive) for HBsAG (Hepatitis B Surface Antigen), HIV-1/2 (Human Immunodeficiency Virus Type 1 and 2), and HCV (Hepatitis C Virus) and syphilis using FDA approved methods. The final pool is also tested for HCV RNA, HBV (Hepatitis B Virus) DNA, HTLV-1/2 (Human T-Lymphotropic Virus) and HIV-1 RNA.

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. The material is CE marked and ANSM approved IVDMD. All units are negative (non-reactive) for HBsAG (Hepatitis B Surface Antigen), HIV-1/2 (Human Immunodeficiency Virus Type 1 and 2), and HCV (Hepatitis C Virus) RNA, HTLV-1/2 (Human T-Lymphotropic Virus), HIV-1 RNA and syphilis. 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 Human AB serum. The manufacturing process does not use any ingredient of animal origin.

## Specifications

### US origin

Off-Clot material typically requires 200-250 pre-screened donors per batch. Each individual donation can produce approximately 200 mL serum.

Human AB serum produced from converted plasma may be manufactured from a pool of material from a maximum of 10 donors. It offers a more reproducible product with a reduced potential risk of cross infection.

### French origin

Serum only available as off-clot material.

<b>Country of Origin</b>	US origin, Male only donors.	French origin, Male only donors.
<b>Sterility</b>	Each batch of sera is tested for the absence of bacteria, fungi, yeast and Mycoplasma.	Each batch of sera is tested for the absence of bacteria, fungi, yeast and Mycoplasma.
<b>Viral Testing</b>	All donor units that go into making each batch, are tested for HBsAG, anti-HCV, anti-HIV1 and 2, HIV-1,	All donor units that go into making each batch, are tested for HBsAG, anti-HCV, anti-HIV1 and 2, HIV-1, and Syphilis.

	and Syphilis.	
<b>Endotoxin</b>	All sera are tested to determine the levels of endotoxins using the Limulus amoebocyte lysate test (LAL).	All sera are tested to determine the presence of endotoxins.
<b>Mycoplasma</b>	Tested for <i>M. pneumonia</i> , <i>M. hominis</i> and <i>M. salivarium</i> .	Tested.
<b>Growth promotion</b>	Biological performance of final batches of sera is assessed by cell culture in Jurkatt cells.	Not tested.
<b>Filtration</b>	Final batches of sera are filtered to 0.1 µm to ensure sterility before being dispensed, aseptically into sterile bottles.	Final batches of sera are filtered to 0.2 µm to ensure sterility before being dispensed, aseptically into sterile bottles.

## Presentation

Life Science Production recognises the need for flexibility in the production of Human AB for cell therapy applications. 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. For further information concerning bespoke packaging requirements, please contact [info@lifesciencegroup.co.uk](mailto:info@lifesciencegroup.co.uk) for further information.

## Product Information

Product Code	Product Description	Pack Size
S-101A-US	Human AB Serum, Male only, off clot, US Origin, sterile filtered, 0.1 micron Standard Grade	500 mL
S-101B-US	Human AB Serum, Male only, off clot, US Origin, sterile filtered, 0.1 micron Standard Grade	100 mL
S-101C-US	Human AB Serum, Male only, off clot, US Origin, sterile filtered, 0.1 micron Standard Grade	50 mL
S-101C-US-SEP	Human AB Serum, Male only, off clot, US Origin, sterile filtered, 0.1 micron Standard Grade, supplied in bottle with Septum	50 mL
S-102A-US	Human AB Serum, Male only, Converted, US Origin, sterile filtered 0.1 micron Standard Grade*	500 mL
S-102B-US	Human AB Serum, Male only, Converted, US Origin, sterile filtered 0.1 micron Standard Grade*	100 mL
S-102C-US	Human AB Serum, Male only, Converted, US Origin, sterile filtered 0.1 micron Standard Grade*	50 mL
S-103A-US	Human AB Serum, Male only, off clot, US Origin, sterile filtered, 0.1 micron Manufacturing Grade†	500 mL
S-103B-US	Human AB Serum, Male only, off clot, US Origin, sterile filtered, 0.1	100 mL

	micron Manufacturing Gradet	
S-103C-US	Human AB Serum, Male only, off clot, US Origin, sterile filtered, 0.1 micron Manufacturing Gradet	50 mL
S-104A-US	Human AB Serum, Male only, Converted, sterile filtered 0.1 micron Manufacturing Grade*†	500 mL
S-104B-US	Human AB Serum, Male only, Converted, sterile filtered 0.1 micron Manufacturing Grade*†	100 mL
S-104C-US	Human AB Serum, Male only, Converted, sterile filtered 0.1 micron Manufacturing Grade*†	50 mL
S-101A-EU	Human AB Serum, Male only, off clot, EU Origin, sterile filtered 0.2 micron Standard Grade	500 mL
S-101B-EU	Human AB Serum, Male only, off clot, EU Origin, sterile filtered 0.2 micron Standard Grade	100 mL
S-101C-EU	Human AB Serum, Male only, off clot, EU Origin, sterile filtered 0.2 micron Standard Grade	50 mL
S-101-C-EU-SEP	Human AB Serum, Male only, off clot, EU Origin, sterile filtered, 0.1 micron Standard Grade, supplied in bottle with Septum	50 mL

\* Product has been converted from plasma, using bovine thrombin. † Manufacturing grade also offers enhanced donor traceability and additional viral testing.

## Quality

Each batch of Human AB is subjected to rigorous control from the point of collection, through testing of individual donor units and subsequent processing Human AB is produced in batches of typically 1-100 litres, sterile filtered to 0.1 micron. Sera is tested for the absence of bacteria, fungi, yeast and Mycoplasma. 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.

## Presentation

Human AB serum can also be supplied in different presentations including individual supplier packs. Human AB serum is normally supplied in 100 mL bottles, although other presentations are available on request such as smaller volumes (e.g. 50 mL, 25 mL). APS are also able to offer special presentations such as material supplied in single dose bags.

## Batch Sampling

LSP offer samples of Human AB 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.

## Additional Treatment

Human AB serum is also available heat inactivated, gamma irradiated, charcoal stripped and dialysed.

## Shelf life

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.

## Storage & Handling

Recommended storage is -20°C or below.

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 all Human AB serum.

**Please note:** whilst it is possible to perceive differences in the appearance of different batches of human serum, APS goes to great lengths to ensure that the collection and handling process result in a highly consistent product. Differences in appearance can be largely attributed to the variation in human diet, and in particular to dietary fats. In addition, slight differences in appearance can result from the inconsistent storage and/or handling of the material once in the laboratory. Since human serum is especially sensitive compared with other sources of serum, it is essential that particular attention be paid to the care and handling of the material.

## Shipping

Product ships frozen on dry ice.

## Literature

1. Cánovas, D., and Bird, N., (2012) Letter: Human AB serum as an alternative to fetal bovine serum for endothelial and cancer cell culture. *Altex*, 29(4): 426-428.
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5. Kocaoemer, A., *et al.* (2007) Human AB serum and thrombin-activated platelet-rich plasma are suitable alternatives to fetal calf serum for the expansion of Mesenchymal Stem Cells from adipose tissue. *Stem Cells*, 25(5): 1270-1278.
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8. Paloni, A., *et al.* (2009) Selection of CD271+ cells and human AB serum allows a large expansion of mesenchymal stromal cells from human bone marrow. *Cytotherapy*, 11(2): 153-162.
9. Qasim, W., *et al.* (2017) Molecular remission of infant B-ALL after infusion of universal TALEN gene-edited CAR T cells. *Science Translational Medicine*. 9(374), DOI: 10.1126/scitranslmed.aaj2013
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## Precaution

All Human serum products have been thoroughly tested to strict guidelines. However, while all of the human donors that go into producing each batch of human serum have been tested and have been found negative for several virus antibodies and antigens, there is no known test method can offer complete assurance that human derived blood products are not capable of transmitting an infectious disease. It is therefore important that human serum be considered potentially infectious and handled accordingly.

## Support

Life Science Production is a division of Life Science Group Ltd.  
Life Science Production is [ISIA Traceability Certified](#)  
Life Science Group Ltd is an ISO 9001:2015 Certified company

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