

Doc. No.	Rev	Effective Date
PI70	2	31 Dec 2025

## 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.

Human serum from type AB donors lacks antibodies against the A and B blood-type antigens and is therefore commonly used when there is a need to minimise 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, which 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 standardised limbal epithelial stem cell graft generation and transplantation
- Tissue culture of human cell lines
- Serological typing and as a blocking agent

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## 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. Further viral testing includes West Nile Virus and Chagas.

### EU origin

Human AB serum is collected from healthy volunteer male donors of the AB serotype at EU-registered facilities. 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.*

## Specifications

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 may be achieved using a method that requires the addition of thrombin or other methods reliant on the use of calcium. This material can also be referred to as 'Plasma-derived'.

Human AB serum 'converted' is available manufactured using recombinant human thrombin or bovine thrombin, as required.

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

### US origin

Available as either off clot material or converted plasma product.

Off-clot material typically requires 200-250 pre-screened donors per batch with a maximum of 300 donors used per pool. Each individual donation can produce approximately 200 mL serum.

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Plasma donations from healthy donors are collected in a 4% sodium citrate solution by automated plasmapheresis in FDA licensed facilities.

#### EU origin

This material can be either Human AB Off-clot material or converted plasma product converting using bovine thrombin. Please see full product listing for further information.

#### 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 in accordance with the regulations in the country of collection. Additional viral testing is available to meet current regulatory standards for further manufacturing.

All products produced are free from Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) with respect to source, manufacture and treatment. Donors with a potential risk of transmission of spongiform encephalopathies (TSEs) are excluded by a qualified medical practitioner in accordance with the national guidelines in the country of collection.

#### Comparison Table

Country of Origin	US origin, male-only donors.	US and EU, male-only donors.
<b>Sterility</b>	Each batch of sera is tested for the absence of bacteria, fungi, yeast and Mycoplasma. Please note, this product is not supplied as STERILE A	Each batch of sera is tested for the absence of bacteria, fungi, yeast and Mycoplasma. Please note, this product is not supplied as STERILE A
<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, and Syphilis.	All donor units that go into making each batch, are tested for HBsAG, anti-HCV, anti-HIV1 and 2, HIV-1, and Syphilis.
<b>Endotoxin</b>	All sera are tested to determine the levels of endotoxins using the Limulus amebocyte 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.

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<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.
<b>Available as cGMP</b>	Yes	No
<b>Suitable for further manufacturing</b>	Yes	No

## Human AB Serum Research Grade

Product Code	Product Description	Pack Size
S-101B-	Human Serum AB, male only - Off clot	100 mL
S-101B-HI	Human Serum AB, male only - Off clot Heat Inactivated	100 mL
GEM-100-512-100	GemCell™ U.S. Human Serum AB	100 mL
GEM-100-512G-100	GemCell™ U.S. Human Serum AB -- Gamma Irradiated	100 mL

## Human AB for further manufacturing (cGMP)

The following products are produced from material sourced in the US from fully compliant collection facilities and is manufactured in batch sizes of 1 litre to 250 litres. The manufacturing facility is certified to cGMP. This material is available as off clot serum or converted serum using either bovine thrombin or a xeno-free product using recombinant human thrombin.

Product Code	Product Description	Size
GEM-100-318-100	Human Serum AB (Off the Clot), cGMP	100 mL
GEM-100-318-100HI	Human Serum AB (Off the Clot) Heat inactivated, cGMP	100 mL
GEM-100-318-750	Human Serum AB (Off the Clot) (minimum 200 bags), cGMP	Bag
GEM-100-318G-100	Human Serum AB (Off the Clot) Gamma irradiated, cGMP	100 mL
GEM-100-912-100	GemCell Plus™ U.S. Human Serum AB - Xeno-Free, cGMP	100 mL
GEM-100-912G-100	GemCell Plus™ U.S. Human Serum AB - Xeno-Free, Gamma irradiated, cGMP	100 mL

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GEM-100-912-750	GemCell Plus™ U.S. Human Serum AB - Xeno-Free Bag (minimum 200 bags), cGMP	Bag
GEM-100-916-100	GemCell Plus™ Xeno-Free, World Grade , cGMP	100 mL
GEM-100-916-750	GemCell Plus™ Xeno-Free, World Grade - Bag (minimum 200 bags), cGMP	Bag
GEM-100-916G-100	GemCell Plus™ Xeno-Free, World Grade - Gamma Irradiated, cGMP	100 mL
S-103B-HI-GI-US	Human Serum AB, male only - Off clot - USA - cGMP - Heat Inactivated, Gamma Irradiated, 0.1 micron filtered	100 mL
S-103B-HI-US	Human Serum AB, male only - Off clot - USA - cGMP - Heat Inactivated, , 0.1 micron filtered	100 mL
S-103B-US	Human Serum AB, male only - Off clot - USA - cGMP	100 mL
S-104A-HI-GI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin - Heat Inactivated, Gamma Irradiated	500 mL
S-104A-HI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin - Heat Inactivated	500 mL
S-104A-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin	500 mL
S-104B-HI-GI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin - Heat Inactivated, Gamma Irradiated	100 mL
S-104B-HI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin - Heat Inactivated	100 mL
S-104B-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin, , 0.1 micron filtered	100 mL
S-115A-HI-GI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free - Heat Inactivated, Gamma Irradiated	500 mL
S-115A-HI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free - Heat Inactivated	500 mL
S-115A-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free	500 mL
S-115B-HI-GI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free - Heat Inactivated, Gamma Irradiated	100 mL
S-115B-HI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free - Heat Inactivated	100 mL
S-115B-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free	100 mL

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## Presentations

Standard presentation is 100 mL bottles, although other presentations are available on request such as smaller volumes (e.g. 50 mL, 25 mL). This material is also available as special presentations such as single dose bags or bottles with septum.

## Batch Sampling

Samples of Human AB serum are available for testing prior to selection of a suitable batch. Typical sample size is approx. 25 mL and reservations are held for a period of four weeks, pending evaluation.

## Additional Treatment

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

## 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.

## 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.
2. Chimenti, I., et al. (2014) Serum and supplement optimization for EU GMP-compliance in cardiospheres cell culture. *J. Cell. Mol. Med.*, 18(4): 624–634.

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10. Shahdadfar, A., *et al.* (2005) *In vitro* expansion of human mesenchymal stem cells: choice of serum is a determinant of cell proliferation, differentiation, gene expression, and transcriptome stability. *Stem Cells*, 23(9): 1357–1366.
11. Stute, N., *et al.* (2004) Autologous serum for isolation and expansion of human mesenchymal stem cells for clinical use. *Exp. Hematol.*, 32(12): 1212–1225.

## 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

To learn more, contact us by telephone at +44 1234 889180 or email at [sales@lifesciencegroup.co.uk](mailto:sales@lifesciencegroup.co.uk)

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