LSG LIFE SCIENCE GROUP

Product Information Sheet

Version v03 PI70 | Date 17.07.2026

Human AB Serum

Product Overview

Selecting the appropriate human AB serum is critical for ensuring consistency in cell culture and clinical applications, particularly since it is being used as a xeno-free substitute for foetal bovine serum (FBS) in the culture of sensitive human cell lines in research and manufacturing environments.

The most important criteria focus on traceability of material, reducing batch variability, ensuring sterility and minimizing immune reactivity.

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.

Key Selection Criteria

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 Hematopoietic 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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Production Method

Off-the-clot (OTC): Produced by allowing whole blood to clot naturally. It contains a richer, more diverse range of growth factors and is considered the "closest to normal human material".

Plasma-derived (Converted): Produced by defibrinating pooled plasma (using calcium or thrombin). It is more cost-effective and suitable for large-scale manufacturing but may contain trace processing agents. Conversely, plasma-derived material may have a lower risk profile from off-clot donations. Donors for plasma collections are typically donors who have been known to the collection facility for many years, donate regularly and are closely monitored for health issues.

Sterility and Safety Testing

Viral Screening: All donor units must be tested for pathogens like HIV-1/2, HBV, HCV, Syphilis, West Nile Virus, and HTLV I/II.

Sterility: Serum must be 0.1 micron or 0.2 micron filtered to remove bacteria, fungi, yeast and mycoplasma. The finished lot then undergoes sterility-testing before release (USP/EP)

Endotoxin Levels: Low endotoxin levels are crucial for healthy cell growth, typically tested using the Limulus amebocyte lysate (LAL) test.

Haemoglobin: High levels of free haemoglobin (typically) can indicate poor processing and may be toxic to sensitive cells

Manufacturing Quality (cGMP)

Selecting products produced under current Good Manufacturing Practices (cGMP) ensures traceability and quality control, which is essential for clinical applications.

Heat Inactivation

While optional, heat-inactivated serum (typically 56°C for 30 minutes) is often required to destroy complement activity, which can interfere with cell growth or specific assays.

Lot-to-Lot Consistency

Because serum is a natural product, consistency is critical. Suppliers should offer lot testing and reservation services to ensure reproducibility over long-term projects.

Donor Qualification and Testing

Donor Profile Criteria

- **Male-Only Donors:** Preferred to eliminate the risk of antibodies against MHC antigens that can be present in female donors who have been pregnant.

- **Donor Age:** Younger donors (typically <35 years) often produce serum with higher growth potential and lower markers of senescence compared to older donors (>45 years).
- **Health and Diet:** Donors must be healthy, as diet (especially dietary fats) can cause visible lot-to-lot variations in serum appearance.
- **Origin:** Ensure the serum is collected from reputable, licensed facilities (e.g., FDA-licensed centers in the US) to guarantee traceability.
- **AB Blood Type:** It must be derived from type AB blood, which lacks anti-A and anti-B antibodies, ensuring it will not cause immune reactions with cultured cells.

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

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.

Plasma donations from healthy donors are collected in a 4% sodium citrate solution by automated plasmapheresis in FDA licensed facilities. These donors are typically known to the collection center and can provide lots with little batch-to-batch variation.

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EU origin

This material can be either Human AB Off-clot material or converted plasma product converting using bovine thrombin. This is only available as a Research Grade product.

Quality Assurance

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.

Ordering Information

Research Grade Human AB Serum

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 Serum for further manufacturing (cGMP)

The following products are produced from material sources 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	Pack Size
S-103B-HI-GI-US	Human Serum AB, male only - Off clot - USA - cGMP - Heat Inactivated, Gamma Irradiated, , 0.1 micron filtered	100 mL

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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 - , 0.1 micron filtered	100 mL
S-104A-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin, , 0.1 micron filtered	500 mL
S-104A-HI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin - Heat Inactivated, , 0.1 micron filtered	500 mL
S-104A-HI-GI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin - Heat Inactivated, Gamma Irradiated, 0.1 micron filtered	500 mL
S-104B-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin, 0.1 micron filtered	100 mL
S-104B-HI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin - Heat Inactivated, 0.1 micron filtered	100 mL
S-104B-HI-GI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - bovine thrombin - Heat Inactivated, Gamma Irradiated, 0.1 micron filtered	100 mL
S-115A-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free	500 mL
S-115A-HI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free - Heat Inactivated	500 mL
S-115A-HI-GI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free - Heat Inactivated, Gamma Irradiated	500 mL
S-115B-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free	100 mL
S-115B-HI-GI-US	Human Serum AB, male only - Converted - USA - cGMP Grade - xeno-free - Heat Inactivated, Gamma Irradiated	100 mL
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-100-512-100	GemCell™ U.S. Human Serum AB	100 mL
GEM-100-512G-100	GemCell™ U.S. Human Serum AB - Gamma Irradiated	100 mL
GEM-100-912-100	GemCell Plus™ U.S. Human Serum AB - Xeno-Free, cGMP	100 mL
GEM-100-912-750	GemCell Plus™ U.S. Human Serum AB - Xeno-Free Bag (minimum 200 bags), cGMP	Bag
GEM-100-912G-100	GemCell Plus™ U.S. Human Serum AB - Xeno-Free, Gamma irradiated, cGMP	100 mL
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

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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.

Custom Packaging and Manufacturing

Advanced therapy developers and manufacturers have gravitated to closed systems to reduce contamination risk during manufacturing and streamline their workflow. GeminiBio's clinical grade products are now available in the Aseptic Assurance System™ cryo-bags to improve customer's aseptic processes and reduce risk. These are represented in our product rage as a GEM-code

To further improve customer workflows, the Aseptic Assurance System™ products can be customized as required with specific product fill requirements or additional customization (e.g., addition of supplements such as growth factors and cytokines).

GeminiBio human serum comes standard in 125mL bottles (100mL fill) and now 750mL Aseptic Assurance System™ cryo-bags. Custom manufacture is available to meet customer's unique fill size, containment or other requirements. In addition, Life Science Group can manufacture media or cell culture supplements containing human serum based on customer's specific formulations and packaging requirements. Our custom manufacturing streamlines customer workflows and improves their overall aseptic processes

Aseptic Assurance System™ – Product Overview Bag Design

- Bags are made of an EVA film optimized for complete drainage of the bags*.
- The bags are intended for a single-cycle of freezing, storage (down to -196˚C) and subsequent thawing (at +37˚C), but have been shown to be durable over multiple freeze-thaw cycles.
- The bag has the flexibility to have tubing welded to the tubing tail provided or can be accessed through the two spike ports giving flexibility to the user.

Closed System Access

- The EVA tubing (~14.0 cm) is weldable and enables sterile connections to closed systems.
- Spike ports can be accessible through sealed twist-off protective caps that prevent cross-contamination.

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.

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Additional Treatment

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

Shelf life

Human AB serum typically 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.

Handling

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.



Storage

Recommended storage is -20˚C or below. Protect serum from exposure to light. Typically, stable for up to 5 years at -20˚C.



Packaging & Shipping

Product ships frozen on dry ice.

Need advice?

Speak to LSG to discuss your specific requirements and we would be happy to recommend material for evaluation.

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