

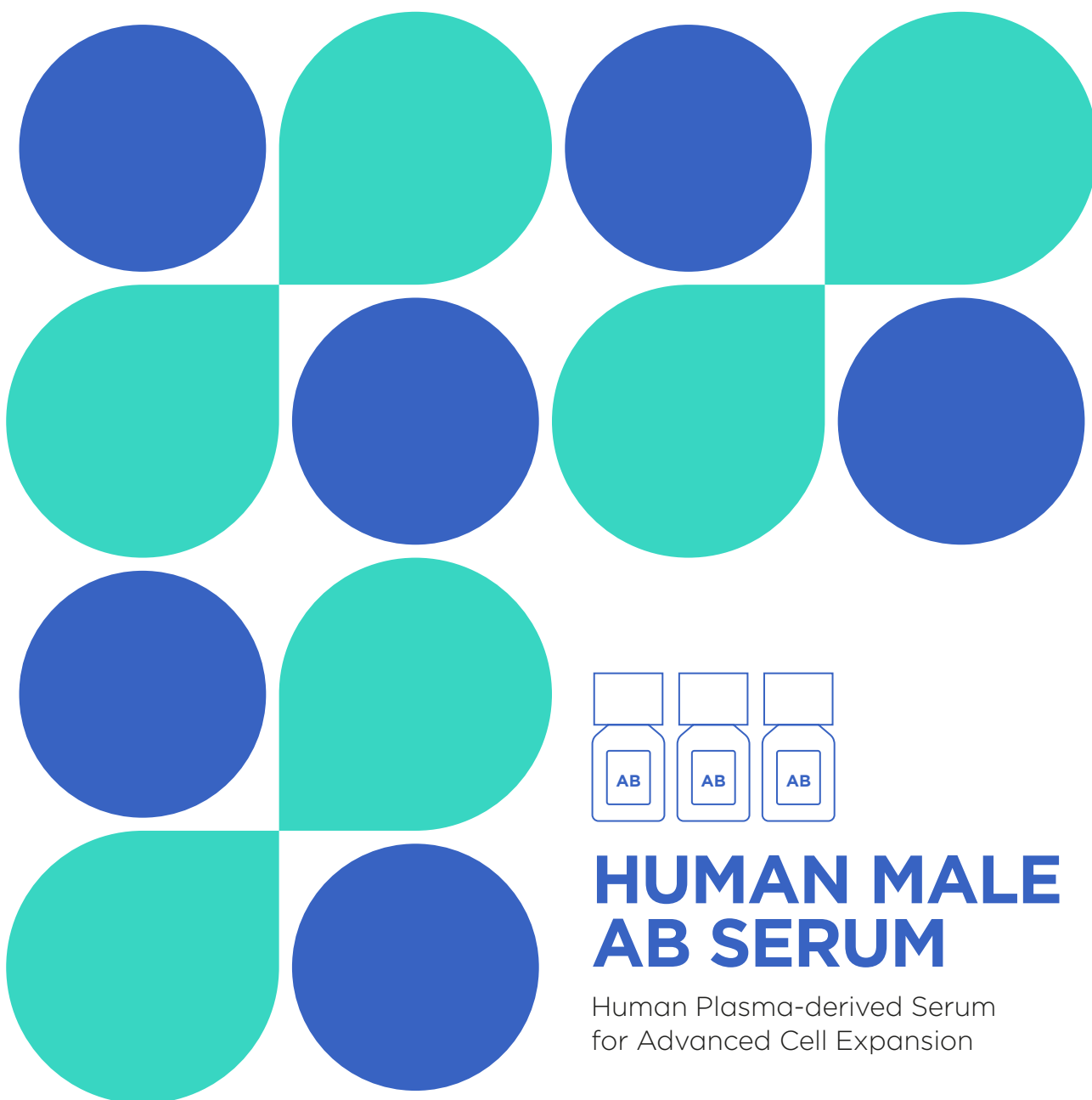
Your Trusted
partner for Human
Biological Solutions

BioSupplies

Biological material solutions

Cell Therapy

Male AB Serum



HUMAN MALE AB SERUM

Human Plasma-derived Serum
for Advanced Cell Expansion

GRIFOLS

The product presented here is not for therapeutic use.

From pharma to pharma. From science to solutions

At Grifols Bio Supplies, we believe cell therapy is the future of medicine. Backed by 115+ years in plasma science, we provide high-quality, ethically sourced biological materials to help pharma and biotech companies develop life-changing therapies.

Our mission is to ensure every patient, anywhere, can access the best therapies to improve their health and quality of life. This is why we supply trusted human-derived materials that accelerate cell therapy research and development.

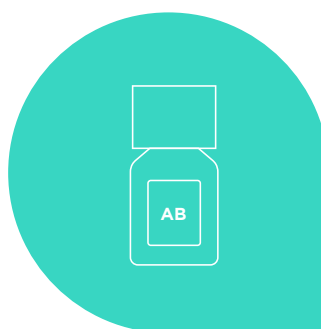
As a leading pharmaceutical company specialized in human biological materials, we stand for excellence, safety, innovation, collaboration, and community—values that guide our work and ensure reliability and safety for our clients.

To accelerate cell therapy, we rely on 2 main product lines:



CELL SOURCING

Providing a reliable and scalable cell supply, ensuring consistency, minimizing variability^{1,2} and reducing production delays.



CELL CULTURE SUPPLEMENTS

Optimizing cell culture performance³ and ensuring well-regulated, stable, and efficient conditions for cell expansion.



Grifols' Plasma Expertise: A Solid Foundation Addressing the Importance of Serum for Cell Expansion

At Grifols, our journey in cell therapy begins with plasma. With nearly **400 plasma donation centers worldwide** and over a century of experience, we have become a global leader in plasma collection and processing. This expertise is not just about scale—it's about setting the standard for quality, **safety, and reliability** in every unit we deliver.

OUR COMMITMENT TO QUALITY

- Rigorously screened, well-characterized donors
- Collections under strict FDA and EMA regulations
- Full control and traceability from donation to delivery (vertical integration)
- GMP standards at every stage

WHY IS SERUM CRITICAL FOR CELL EXPANSION?

Human serum is much more than a simple supplement—it is a complex source of:

- Essential nutrients
- Growth factors
- Attachment agents

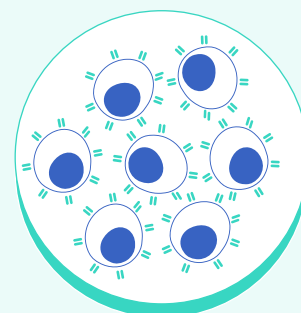
These components are fundamental for supporting robust cell proliferation and viability.

RELIABLE SUPPLY FOR CELL THERAPY

Our robust infrastructure allows us to provide:

- Reliable and scalable supply of serum
- Consistent quality to meet the evolving needs of cell therapy manufacturers worldwide

By supplementing cell culture media with high-quality human serum, researchers and manufacturers can achieve the consistency, safety, and performance demanded by modern cell therapy applications.



At Grifols, our commitment to plasma excellence is the foundation that enables the next generation of cell therapies to become a reality.

Grifols Male AB Serum

DESIGNED FOR CELL AND GENE THERAPY

What makes Grifols Human Male AB Serum suitable for cell therapy?

REDUCED IMMUNOREACTIVITY

- **Male only sourcing** significantly reduces the likelihood of introducing anti-Rh antibodies. These antibodies may form in Rh-negative women following exposure to Rh-positive fetal blood, posing a potential immunogenic risk. By eliminating this variable, the serum offers enhanced safety and reduced immunoreactivity, making it highly suitable for cell and gene therapy applications.³
- **Why AB blood group?** AB serum lacks anti-A and anti-B antibodies, minimizing the risk of immune reactions with cultured cells.⁴

QUALITY INDICATORS

- Collected at FDA- and/or EMA-approved centers
- Manufactured in ISO-certified, cGMP facilities

PROVEN SAFETY

- Gamma-irradiated and heat-inactivated options for enhanced safety
- Tested for viral markers, mycoplasma, endotoxin, and more

REGULATORY SUPPORT

- Viral clearance studies available to support regulatory submissions
- Documentation provided that help to accelerate regulatory processes: certificate of origin (CoO), certificate of analysis (CoA), viral inactivation Study, security data sheet (SDS), processing overview document

ENHANCED CONSISTENCY

- Large lot sizes for better reproducibility



Human Serum Albumin

SAFETY BY DESIGN: HUMAN THROMBIN, GAMMA IRRADIATION & HEAT INACTIVATION



HUMAN THROMBIN

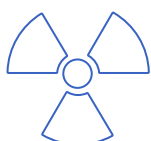
Pharmaceutical-Grade
for Maximum Safety

WHY IS THROMBIN USED?

Thrombin is essential for converting plasma into serum by clotting fibrinogen. In Grifols Male AB Serum, only human, pharmaceutical-grade thrombin—manufactured in-house—is used.

WHY NOT BOVINE THROMBIN?

Using human thrombin eliminates the risk of animal-derived contaminants and ensures compatibility with human cell therapy applications. This approach meets safety and regulatory standards.



GAMMA IRRADIATION

Viral Clearance
and Regulatory Support

WHAT IS GAMMA IRRADIATION?

Gamma irradiation is a validated method for viral inactivation, commonly employed to further minimize the risk of viral contamination in biological products. Its use is supported by regulatory guidance, including ICH Q5A.

REGULATORY ADVANTAGE

Grifols offers gamma-irradiated serum with supporting viral clearance studies, facilitating regulatory submissions and ensuring compliance with global standards.



HEAT INACTIVATION

Additional Safety Layer

WHAT IS HEAT INACTIVATION?

Heat inactivation is a process in which plasma is heated to 56 °C for 30 minutes. It is useful for inactivating heat-labile components of the immune complement system, which may otherwise inhibit or destroy cells under certain conditions.

WHY IS IT IMPORTANT?

This process is important for immunological applications and for culturing immune-type cells.

Together, these processes—pharmaceutical-grade human thrombin, gamma irradiation, and heat inactivation—ensure that Grifols Human Male AB Serum meets the rigorous standards of safety, quality, and regulatory compliance for cell and gene therapy manufacturing.

Male AB Serum Product Options

Our Male AB Serum portfolio is designed to support the evolving needs of cell therapy development, offering high-quality, defibrinated plasma using **human, pharmaceutical-grade thrombin** manufactured by Grifols. This approach enhances safety and regulatory alignment across all stages of development. Our Male AB serum is manufactured to ensure consistency, scalability, and compliance with global standards. The following table outlines the key features of our product.



Thrombin	Human (Pharma Grade)
GMP Documents Support	Yes
Stage of Use	Clinical & Scaled Commercial
FDA Viral Testing	Yes
EU Viral Testing	Yes
Heat Inactivated	Available
Gamma Irradiated	Available
Viral Inactivation Validation Study	Yes
Xeno Free	Yes
Packaging	100 ml - 500 ml

Empowering Innovation from the Source

At Grifols Bio Supplies, we know that every great therapy begins with a reliable foundation. That's why we've built an infrastructure that delivers confidence at every stage of your process. From donor to delivery, every element of our supply chain is designed to give you what you need most: consistency, flexibility, and reliability, backed by a global donor network, robust supply capabilities, and end-to-end superior quality.

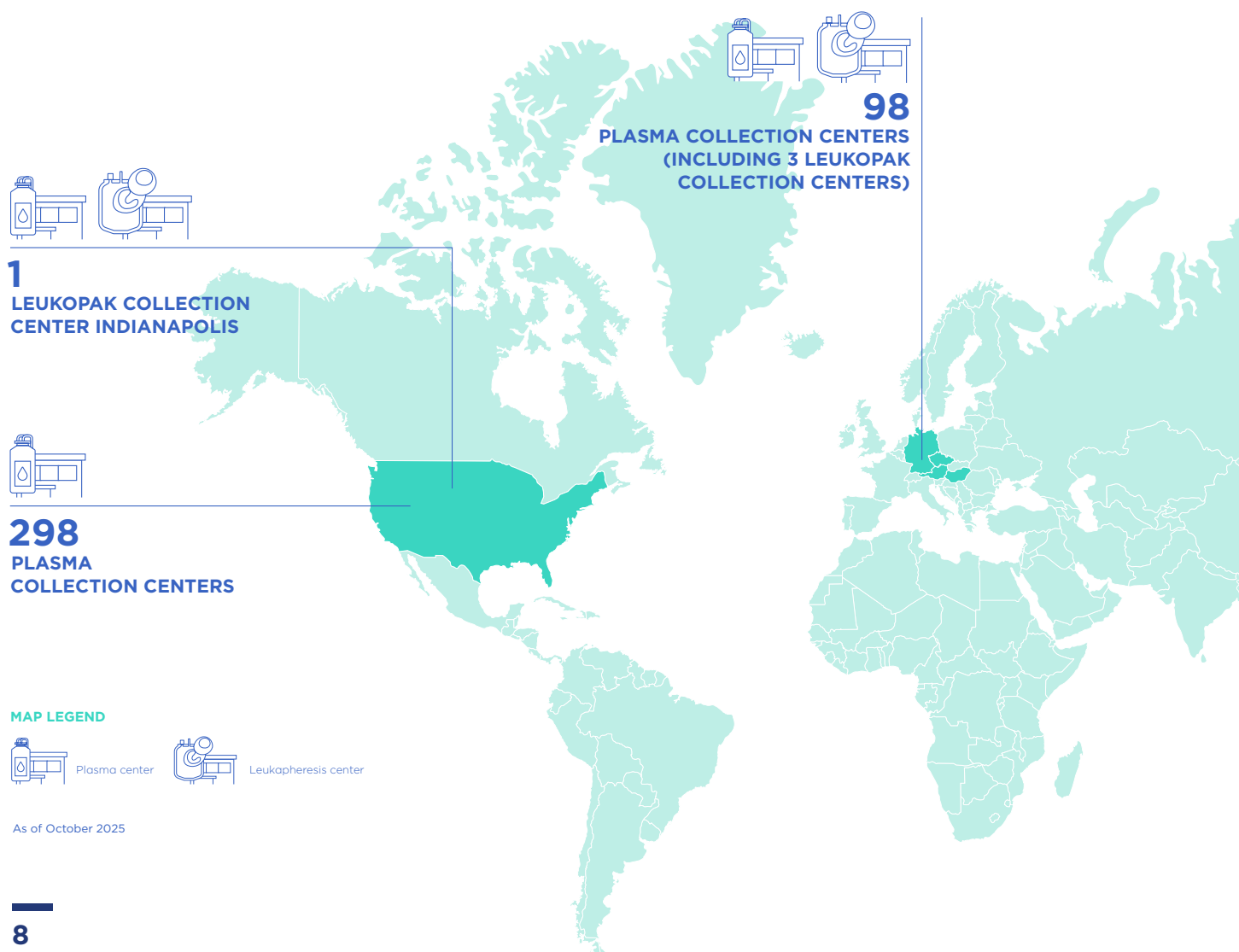


Empowering Innovation from the Source

STRONG SUPPLY CAPABILITY

In a field where timing is critical, Grifols Bio Supplies delivers consistency and quality through a strong global supply infrastructure.

- Robust, global supply infrastructure that meets demands of even the most time-sensitive workflows
- Manufacturing facilities in EU and USA
- Vertically integrated model: from plasma collection to final product
- Reliable delivery for standard and specialized applications



Empowering Innovation from the Source

REGULATORY EXPERTISE

With decades of experience navigating global regulatory frameworks, Grifols provides comprehensive support for product registration, compliance, and documentation.

- Fully compliant with FDA and EMA standards
- Smooth market access
- Sustained product confidence

Documents provided:

- Certificate of origin (CoO)
- Certificate of analysis (CoA)
- Viral inactivation Study
- Safety data sheet (SDS)
- Processing overview document



Empowering Innovation from the Source



QUALITY, SAFETY AND CONSISTENCY

Built for excellence. Trusted for performance. Every step of the process—from plasma collection to final packaging—is governed by strict safety standards and regulatory compliance, ensuring reliable performance across diverse applications.

- State-of-the-art facilities and advanced technologies
- Collected at FDA- and EMA-licensed centers within the United States and manufactured following a current good manufacturing process under a strict quality assurance system
- Gamma-irradiated and heat-inactivated options for major safety
- Use of pharmaceutical-grade human thrombin for defibrinating processes

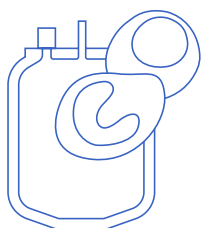
Meet our Cell Sourcing and Cell Culture Solutions to Support Therapeutic Success

To support therapeutic success for cell-therapy manufacturing, we accompany the process from beginning to end. At Grifols Bio Supplies, not only high quality EP/USP-grade albumin and male AB serum is offered to support the growth and stability of the cells, but also leukopaks, the starting material in the manufacturing of advanced cell therapies,^{5,6} essential for any cell therapy.

Explore our full range of
bio supply solutions at
biosuppliesproducts.com



CELL SOURCING



LEUKOPAKS

Derived through leukapheresis, these blood-based products are rich in mononuclear leukocyte- primarily lymphocytes and monocytes- and are designed to meet the evolving needs of R&D and pharmaceutical manufacturing

CELL CULTURE



HUMAN SERUM ALBUMIN (HAS)

Recognized for its versatility, human serum albumin plays a critical role in stabilizing, protecting, and transporting biological molecules.⁷ It is ideal for use as an excipient in cell therapy and vaccine production, and is manufactured to therapeutic-grade quality under USP and EP standards.

This product is not for therapeutic use.

Your Ally in Cell Therapy

At Grifols Bio Supplies, we're committed to advancing cell therapy by providing high-quality, ethically sourced human biological materials.

We understand the challenges of developing life-changing treatments and aim to make that journey faster, safer, and more reliable.

Our global donation network and supply strength allow partners to focus on innovation, research, and improving patient outcomes.

We stand for trust.

The certainty that when you choose the best, you are in the best hands.

Choose Grifols and enhance your cell culture processes with a trusted partner

REFERENCES:

1. Fesank A, Lin C, Siegel DL, Mus MV. CAR-T Cell therapies from the transfusion medicine perspective. *Transfuse Med Rev.* 2016;30(3):139-145.
2. Gómez I, Schaffer JM, Winterstein K, et al. Optimizing cell sourcing for cell therapy by reducing donor variability with recallable leukopak donors for enhanced standardization. *Cytotherapy.* 2025;27(5 Suppl):S141.
3. Diez JM. AB male human serum: cell proliferation assays. Barcelona: R&D Bioscience Industrial Group. Grifols; 2017.
4. Arbeláez-García CA. Sistema de grupo sanguíneo ABO. *Medicina & Laboratorio.* 2009;15(7-8):329-347.
5. Tygrjn S, Schmitt D, Acker C, Rutjens E. Autologous cryopreserved leukapheresis cellular material for chimeric antigen receptor-T cell manufacture. *Cytotherapy.* 2019;21(12):1198-1205.
6. Sa S, Yu L. Simplified cell therapy manufacturing with direct-from-source T cell selection workflow. *Blood.* 2024;144 (Suppl 1):2089.
7. Asharf S, Qaiser H, Tariq S, et al. Unraveling the versatility of human serum albumin - A comprehensive review of its biological significance and therapeutic potential. *Curr Res Struct Biol.* 2023;6:100114.

For ordering information,
contact us here:



biosupplies_contactus@grifols.com

GRIFOLS

Grifols Bio Supplies Inc.
2410 Grifols Way
Los Angeles, CA 90032
Tel. +1-323-405-0600
biosupplies_contactus@grifols.com
www.biosuppliesproducts.com