

Your Trusted Partner  
for Human Biological  
Solutions

**BioSupplies**

Biological material solutions

**Cell Therapy**

Leukopaks



## LEUKOPAKS

With its global collection capabilities  
and its expertise in apheresis,  
Grifols offers a supply  
of high quality leukopaks.

**GRIFOLS**

# 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.

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

## CELL SOURCING

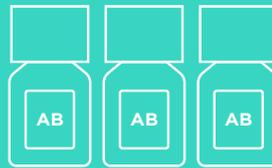
Providing a reliable and scalable cell supply, ensuring consistency, minimizing variability,<sup>1,2</sup> and reducing production delays.



LEUKOPAKS

## CELL CULTURE

Optimizing cell culture performance<sup>3</sup> and ensuring well-regulated, stable, and efficient conditions for cell expansion.



MALE AB SERUM



ALBUMIN

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.

# Grifols' Apheresis Expertise: A Solid Foundation for Reliable Leukapheresis

At Grifols, leukapheresis is the result of over 100 years of expertise in plasmapheresis and plasma science. Since 1909, we've pursued scientific progress to ensure safety, efficiency and donor care. A milestone came in 1965, when Dr. Víctor Grifols i Lucas patented a device that automated plasmapheresis, laying the groundwork for modern apheresis techniques, including leukapheresis.

Today, we use state-of-the-art devices and closed-loop systems that are rigorously inspected and meet international standards. The procedure takes about three hours, with continuous monitoring and a final check-up to ensure donor wellbeing.

With a global network of plasma donation centers, Grifols ensures a consistent, high-quality processes both in EU and Europe —backed by GMP standards, regulatory knowledge, and a strong commitment to safety and quality.

Grifols. Trusted worldwide. Advancing care through experience.

## LEUKOPAKS APHERESIS PROCESS

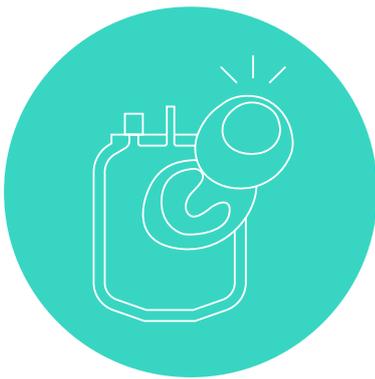


# Leukopaks: Robust Cell Sourcing for Cell Therapy

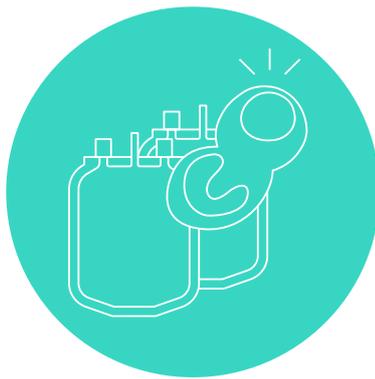
Leukopaks are a foundational starting material in the manufacturing of advanced cell therapies,<sup>4,5</sup> including CAR-T cells, stem cells, and immunotherapy research. Derived through leukapheresis, these blood-based products are rich in mononuclear leukocytes —primarily lymphocytes and monocytes— and are designed to meet the evolving needs of R&D and pharmaceutical manufacturing.

With high cell concentration, customizable formats, and a scalable global supply infrastructure, Leukopaks collected by Grifols are trusted by leading pharmaceutical and biotech companies to support from process development to clinical validation.

## THE LEUKOPAKS AVAILABLE ARE:



**FRESH  
LEUKOPAKS**



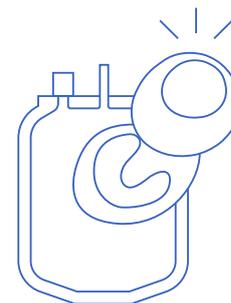
**SPLIT  
LEUKOPAKS**



**CRYOPRESERVED  
LEUKOPAKS**

## Fresh Leukopaks

Grifols fresh leukopaks, collected from rigorously screened healthy donors and shipped within 24 hours, ensure high viability and consistent performance. We offer reliable cell sourcing from U.S. and European donor networks, combining strict quality control with temperature-regulated delivery to preserve cellular integrity and securing optimal performance upon arrival.



### KEY FEATURES

#### Delivery Optimization

To ensure optimal cell viability and functionality, shipments are made within 24 hours of collection under temperature-controlled conditions for maximum cell viability.

#### Dual Sourcing from USA and Europe

Access to well-characterized donor base from FDA-compliant U.S. centers and GMP-certified EU facilities.

#### High Cell Concentration

Each leukopak contains a high yield of mononuclear cells with a leukocyte concentration of  $\geq 40 \times 10^9$  cells/L.

#### Proven Safety

Donors are pre-screened through medical exams and virology testing. All donations are tested for a full panel of viral markers, including: HIV, HBV, HCV (NAT and serology), HTLV I/II, HAV, HEV, PVB19, WNV, syphilis, and Chagas (varies by region and regulatory requirements). Leukopak donors belong to Grifols qualified plasma donor pool, providing an added layer of safety.

#### Detailed Blood Profile

Includes hemoglobin, hematocrit, complete blood count, lymphocyte and monocyte counts.

#### Research Use and GMP-Compliant Formats Available

Available in RUO (Research use only) and GMP formats to meet various development and manufacturing needs.

#### Reliable Scheduling

Optimized pickup and backup donor scheduling to ensure on-time availability and delivery.

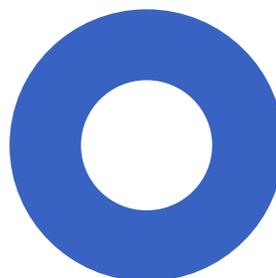
Ready to incorporate Grifols Bio Supplies fresh leukopaks into your workflow?  
Contact us here: [biosupplies\\_contactus@grifols.com](mailto:biosupplies_contactus@grifols.com)



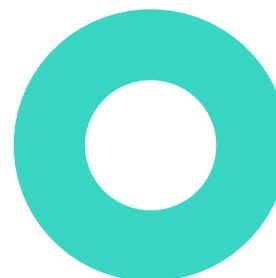
With a wide network of plasma centers and proven apheresis expertise, Grifols is ready to scale up leukopaks to meet growing demand.



Our fresh leukopaks are available in multiple formats — from full to half leukopaks — to meet your specific needs.



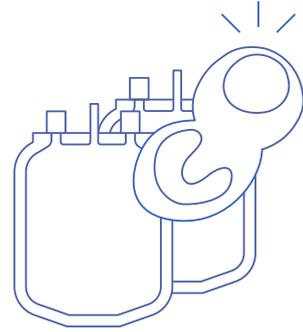
Rigorous screening. fresh leukopaks backed by Grifols' safety standards.



High-quality starting material for cell therapy

## Split Leukopaks

Grifols split leukopaks are aseptically divided from a healthy donor fresh leukopak into two units using sterile welding and validated bags. Each unit retains the full cellular profile of the original leukopak, ensuring consistency, repeatability, and control. Ideal for assay development, validation, and multi-site studies, all teams start with the same cellular material.



### KEY FEATURES

#### Identical Cellular Composition

Each split unit contains the same leukocyte populations and concentrations as the original full leukopak—perfect for comparative work.

#### Customizable Format

Typically split into two equal units, with custom fill sizes and a number of splits available upon request to fit your study needs.

#### Sterile, Closed-System Processing

Aseptic division using closed-loop sterile welding ensures contamination-free handling and consistent quality.

#### Research Grade

Available in RUO (Research use only).

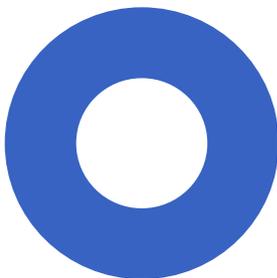
### APPLICATIONS

#### Consistency You Can Count On

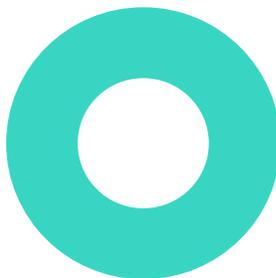
Split leukopaks are a valuable tool for a wide range of applications, including:

- Validation studies, assay development, and proficiency testing
- Comparison studies across groups, timepoints, or locations
- Technology transfer and multi-site protocol alignment
- Longitudinal and stability studies using repeat donors over time

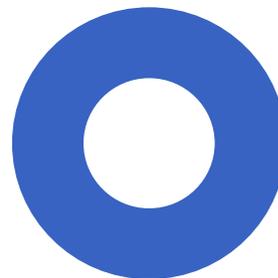
Ready to incorporate Grifols Bio Supplies split leukopaks into your workflow? Contact us here: [biosupplies\\_contactus@grifols.com](mailto:biosupplies_contactus@grifols.com)



Our leukopaks are split at the point of collection and dispatched to the customer-specified locations, maintaining uniform conditions for site validation.



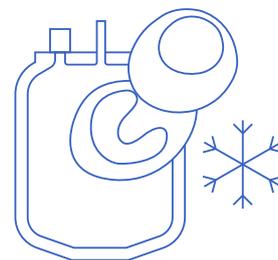
Uniformity and reliability in studies are supported with split leukopaks.



Experience the versatility of a split leukopak —identical components, expanded applications.

## Cryopreserved Leukopaks

Grifols cryopreserved leukopaks offer a reliable, long-term solution without compromising quality. Collected from healthy, pre-screened donors and frozen with a controlled-rate protocol and cryoprotectant, they preserve cell integrity and performance, ensuring high post-thaw viability and consistency.



### KEY FEATURES

#### Ready When You Are

Long shelf life enables flexible use and study planning, reducing the pressure of immediate processing.

#### Origin: Fresh, High-Quality Leukopaks

Each cryopreserved unit is derived from a single fresh leukopak, aseptically split into up to six cryobags.

#### High Post-Thaw Performance

Viability  $\geq 90\%$   
Recovery  $\geq 80\%$ .

#### Donor information

Units delivered with full donor documentation, including age, gender, race, blood type, and viral screening records.

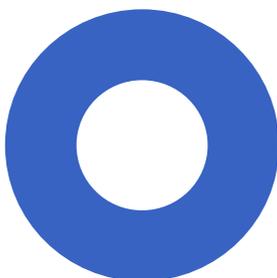
#### Proven Safety

Donors are pre-screened through medical exams and virology testing. All donations are tested for a full panel of viral markers, including: HIV, HBV, HCV (NAT and serology), HTLV I/II, HAV, HEV, PVB19, WNV, syphilis, and Chagas (varies by region and regulatory requirements). Leukopak donors belong to Grifols' qualified plasma donor pool, providing an added layer of safety.

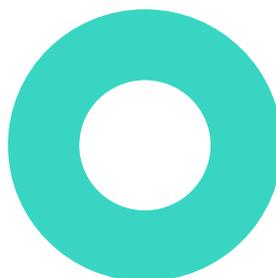
#### Research Grade

Available in RUO (Research use only).

Ready to incorporate Grifols Bio Supplies cryopreserved leukopaks into your workflow?  
Contact us here: [biosupplies\\_contactus@grifols.com](mailto:biosupplies_contactus@grifols.com)



Long-term stability  
with Consistent  
Performance.



Long-term storage,  
reducing the pressure  
of immediate processing.



Post-thaw  
viability  $\geq 90\%$ .

# 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.



# A Leading Worldwide Donor Network

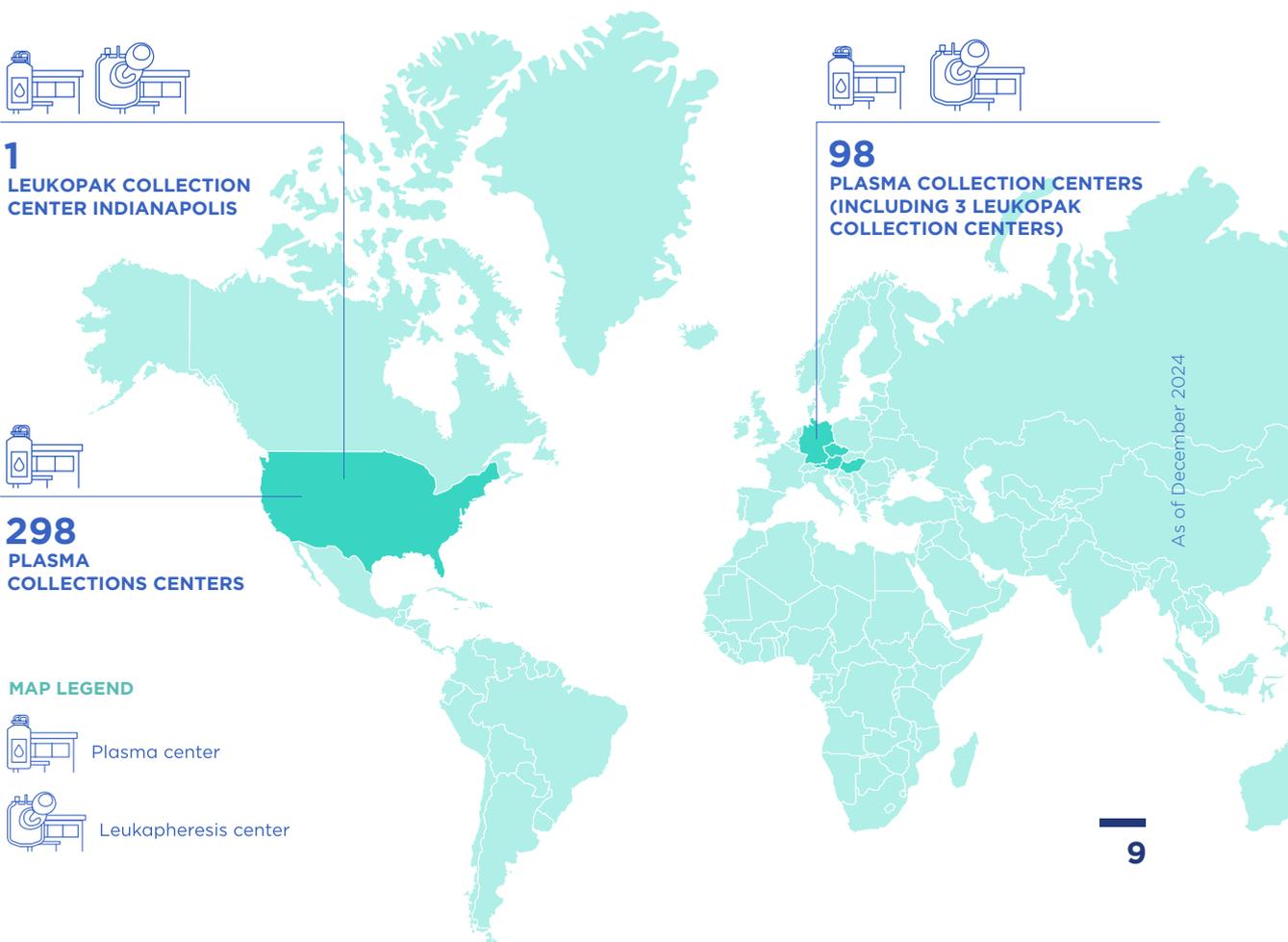
## TWO CONTINENTS. ONE MISSION.

With over 400 apheresis centers across the U.S. and Europe, Grifols runs one of the world’s largest and most advanced donor networks.

We provide reliable, scalable delivery—with the right material, from the right donor, at the right time.

Our rigorously screened, well-characterized donors meet specific research and manufacturing needs. From rare blood types to precise cell counts, we offer a diverse, traceable, and wide donor pool. Robust recall and backup systems ensure seamless continuity with minimal disruption.

- Global collection network in the U.S. and Europe
- 400+ centers dedicated to plasma, some specialised in leukapheresis
- Well-characterized, pre-screened donor pool
- Donors of all genders, blood groups, ages, and backgrounds
- Recall donors available on request
- Backup donor scheduled for every donation
- Leukopak donors are qualified individuals with prior plasma donation experience, adding an extra layer of safety to the process



## Strong Supply Capability

### RELIABILITY ISN'T JUST A PROMISE—IT'S BUILT INTO OUR SYSTEM.

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

With leukapheresis centers and processing facilities in Europe and the U.S., we offer global reach through one integrated provider—reducing complexity and maximizing reliability.

- Fresh and cryopreserved formats to meet different workflow needs
  - Fresh leukopak delivered within 24 hours of collection
  - cryopreserved formats maintained under strict cold chain protocols to preserve cell integrity
- Flexible volumes: full, half, or split leukopak for tailored study design
- Strategic locations in the U.S. and Europe for on-time, global delivery
- Single-source partner for global leukopak supply

## Superior Quality, End-to-End

### BUILT FOR EXCELLENCE. TRUSTED FOR PERFORMANCE.

At Grifols, quality is not a checkpoint; it's a continuous, integrated process. From donor eligibility and collection to testing, packaging, and delivery, every stage is governed by strict GMP protocols and compliance with FDA and EMA standards.

Our certified facilities, trained staff, and validated SOPs ensure full control, traceability, and consistency.

Each leukopak is extensively tested for safety and performance—giving you confidence to move forward.

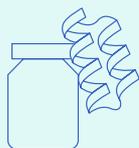
- EMA- and FDA-audited collection centers
- SOP-driven operations and highly trained personnel for total process control
- Viral marker testing performed on every donation
- Complete blood count and cell concentration analysis included
- Optional immunophenotyping: CD3, CD4, CD8, CD14, CD19, CD56 (on demand)
- Low hemoglobin and hematocrit levels ensure high cell purity

# Meet our Cell Culture Solutions to Support Therapeutic Success

Beyond sourcing cells, supporting their growth and stability is essential to the success of any cell therapy. At Grifols Bio Supplies, we offer a carefully selected portfolio of human-derived materials designed to optimize cell culture performance—ensuring consistency, safety, and scalability from early research to full-scale production.

Explore our full range of bio supply solutions at [biosuppliesproducts.com](https://biosuppliesproducts.com)

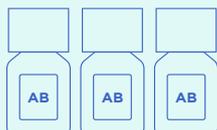
## THE CURRENT CELL CULTURE SOLUTIONS ARE:



### HUMAN SERUM ALBUMIN (HSA)

Recognized for its versatility, human serum albumin plays a critical role in stabilizing, protecting, and transporting biological molecules.<sup>6</sup> 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.



### MALE AB SERUM

A widely used supplement in cell culture media, male AB serum offers a balanced mix of growth factors, hormones, and attachment agents.<sup>7</sup> Derived exclusively from male donors with AB blood type, it minimizes immunological risks and ensures high consistency across applications.

# 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 donor 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.

Partner with Grifols Bio Supplies for reliable and high-quality leukopaks  
[biosupplies\\_contactus@grifols.com](mailto:biosupplies_contactus@grifols.com)

#### References:

1. Fesnak A, Lin C, Siegel DL, Maus MV. CAR-T Cell therapies from the transfusion medicine perspective. *Transfus Med Rev.* 2016;30(3):139-145.
2. Gómez I, Schäffer JM, Winterstein K, Wahler A, Baumann-Baretti B, Gonnermann D, Belda FJ. 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. Tyagarajan 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.
5. Sa S, Yu L. Simplified cell therapy manufacturing with direct-from-source T cell selection workflow. *Blood.* 2024;144 (Suppl 1):2089.
6. Ashraf 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.
7. Tyagi S, Mani S. Media and Buffer Preparation for Cell Culture. In: *Animal Cell Culture: Principles and Practice.* Springer. 2023; 77-88.

Download and save  
this brochure on your phone



**GRIFOLS**

For ordering information,  
contact us here  
[biosupplies\\_contactus@grifols.com](mailto:biosupplies_contactus@grifols.com)  
[biosuppliesproducts.com](http://biosuppliesproducts.com)