



# Work With a Leading Provider in Allogeneic Collections

Your Cell Sourcing Partner From Discovery Through Late Stage Development



**American  
Red Cross**

Cell and Gene  
Therapy Solutions







## A Nationwide Provider With Over a Decade of Experience

Nearly 75 years after we pioneered the first nationwide civilian blood program, the American Red Cross has become a nationwide leader in the provision of allogeneic products for cell and gene therapy, playing key roles in the development and delivery of drug therapies based on blood components. With over 30 years of apheresis collections experience, a single centrally managed nationwide apheresis network, and the ability to leverage a large diverse donor base, we are uniquely positioned to serve the market as a single-source provider for allogeneic collections.

### Cell and Gene Therapy Solutions History and Experience



**75+ Years of Donor Management Experience**

**30+ Years of Apheresis Collection Experience**

**5+ Years Supplying Allogeneic Leukopaks in Support of Cellular Therapies**

**300+ Allogeneic Leukopak Products Provided in Support of Clinical-Stage Cellular Therapy Manufacturing**

**20+ Clients Supported in Various Stages of Research and Development**

### Work With a Team of Experts

Our centralized client relationship management approach offers clients direct access to the Cell and Gene Therapy Solutions product team, technical leads, and apheresis experts and provides you with a single point of contact to access donors and apheresis collections across the country. We offer consultation on how to efficiently deliver products and develop and implement specific custom collection protocols to ensure your unique needs are met.

A Standard Certificate of Conformance (COC) and Standard Certificate of Analysis (COA) can be provided with each Leukopak product. Should you have specific product documentation requirements outside of the Standard Certificates, we can create customized documentation in accordance with your standard operating procedures (SOPs), streamlining your review and acceptance of key raw materials.

## Customization Capability

We have experience in supporting clients in determining donor demographics that may impact their Leukopak products' use in a client's specific process. Our team can guide the provision of customized solutions to include:

- Donor selection capabilities based on factors such as BMI, ethnicity, age, lifestyle, as well as extensive testing and typing services
- Processing to reflect specific cell targets, supplies, and/or equipment utilized in cell separation and customized product aliquoting and cryopreservation
- Type of equipment, total blood volume to be processed, the target volume of the final product, target cells to be collected, and addition of autologous plasma

## Resources To Support You From Discovery to Late Stage Development

We offer a range of allogeneic starting material, supporting uses from bench research, process development, validation, and training, through clinical use material. Our starting material products offer consistency and limited variability achieved through standardized GMP-compliant collection procedures, supporting a smooth translation of cell therapies from RUO through late-stage clinical trials.

## The Red Cross Has the Resources You Need

Pre-Clinical Phase



Clinical Phase 1



Clinical Phase 2



Clinical Phase 3

### Red Cross Cell and Gene Therapy Solutions Leukopak Products

- Pre-clinical Leukopaks
- Lower, cost-effective leukocyte products available for early use:

#### Generic Buffy Coats

- » Unable to specify donor selection

#### Specialty Buffy Coats

- » Non-identifiable donor demographics available
- » Donors matching specific donor demographics criteria can be requested
- » Can recall a specific donor for future Leukopak collection

- Clinical-use Leukopaks from healthy donors
- Dedicated staff to support processing and cryopreservation services
- Depending upon client requirements, processing can be performed in a Red Cross cellular therapy lab or in a dedicated cleanroom

Multiple locations performing Leukopak collections support scale-up in the provision of Leukopaks to meet increasing product volume needs as you move from Phase 1 through Phase 3 clinical trials

## Reduce Starting Material Variability With Our Standardized Approach

We minimize the variability in cellular raw materials that can impact the cell therapy manufacturing processes by standardizing apheresis collection processes across sites. Our single centrally managed nationwide apheresis network of five active collection sites supports the coordination and standardization of all collection needs across our system, regardless of where collections take place. This, along with the capability to expand to an additional 70+ sites, allows us to scale up quickly and provides flexibility to implement custom collection protocols or adjustments to standard collection parameters.

All collections adhere to Good Tissue Practices (GTP) and can be performed according to our standard parameters or your specific requirements. While the majority of Leukopak collections are performed on the Terumo Spectra Optia, we also can perform collections on the Fresenius Kabi Amicus.



## High Quality Leukopaks

Our Leukopaks are an enriched leukapheresis product collected from normal peripheral blood and are collected in our FDA-registered collection centers from IRB-consented pre-screened healthy human donors by leukapheresis. All potential donors undergo a pre-screening process to determine their eligibility. Those accepted are entered into our donor database and can be recruited to support your future Leukopak needs.

The Red Cross offers extensive testing capabilities which include HLA, KIR, Immunophenotyping, Standard and Expanded IDT testing. We can also perform product characterization for Lymphocytes (T, B, NK), CBC, TNC, and Stem Cells (CD34). Quality control testing is available, including Mycoplasma, Endotoxin, and sterility testing. Custom quality control testing protocols can also be implemented as needed.

Processing and cryopreservation services on our Leukopak products are also available at our full-service Cellular Therapy Labs. We can utilize our standard protocols for these services or implement client-specific protocols where required. Our cell handling, post-collection processing, and cryopreservation activities are GMP-compliant, supporting the production of high-quality raw materials and driving speed and efficiency for your cell sourcing processes.

## The Value of Extensive Experience

Our Unique Capabilities	The Positive Impact on Your Therapy
<b>High-Quality Sourcing Material</b>	To limit the variability in starting material, all collection sites operate under a single National Quality Management System (QMS) and standardized apheresis collection procedures, along with strict adherence to protocols approved by our in-house IRB, ensuring consistency in your starting material
<b>Reliability and Availability</b>	The capacity to collect and deliver on your timeline as well as same-day delivery post-collection availability in multiple geographies ensures your therapy development efforts and commercial delivery activities remain on target. Automatic scheduling of backup donors and flexible staffing around donor constraints helps ensure the provision of Leukopak products when you need them
<b>Extensive Geographical Coverage for Collections</b>	As a leading provider of apheresis collections for cellular therapy, with over 70 active apheresis collection sites and hundreds of facilities across the country, we can rapidly scale and expand collections, eliminating the need to contract with multiple vendors for nationwide coverage
<b>Robust and Diverse IRB-Consented Donor Pools</b>	Our extensive donor management experience, with strong donor recallability, helps ensure coverage and backup reliability, providing you peace of mind that your orders will be filled. If needed, dedicated donor pools can be created and maintained from your specific projects
<b>Streamlined Audit Process</b>	Only one QMS and one set of national procedures must be audited, resulting in a streamlined audit process with local audits focused on the review of individual-site items such as local staff training and equipment records, driving speed and efficiency in on-boarding and maintaining supplier reviews of your cell sourcing vendor
<b>Full-service Testing Capabilities</b>	With five decades of experience and established relationships with qualified specialty labs, we serve as your single source for all desired donor and product testing
<b>Reduced Lead Time</b>	Our wide availability of collection sites can result in a shorter time between donor collection and receipt of delivery when fresh product is desired, or between collection and initiation of processing and cryopreservation in our cellular therapy labs, reducing lead time



## We Offer Cell Processing, Cryopreservation, and Storage Services

Our full-service on-site cellular therapy labs across the country can perform same-day processing, freezing, and storage of Leukopak products so that there are no travel or shipment delays between collection and initiation of processing. Acquisition and manufacturing occur in both our Philadelphia, PA, and Portland, OR facilities. Our Leukopak products can be shipped immediately following collection or can be cryopreserved post-collection at our labs, with or without processing, and stored for delivery when needed.

- Your manufacturing stage can be accommodated — from early-stage development to late-stage clinical manufacture
- We offer GMP-compliant processing for raw material products — either a cell therapy lab or cleanroom environment, for both minimal cell handling as well as processing and cryopreservation needs
- On-site cryopreserved starting material storage options at multiple locations

## Our Nationwide Footprint

With our nationwide network of collection locations and opportunity to expand to 70+ sites, we are uniquely positioned to supply you with the quality product you need and the reliability you require to deliver on your timeline with same-day delivery post-collection available in multiple geographies.



## **We Are Committed to Your Success**

As a nationwide leader with over 10 years of experience in the provision of apheresis collections in support of cell and gene therapy, the Red Cross Cell and Gene Therapy Solutions team of experts can provide you with customized solutions.

Contact us at 833-760-0625 to discuss your project and learn how we can partner with you to ensure consistency with your processes as you scale from discovery through late stage development.

Visit [RedCrossBlood.org/Leukopak](https://RedCrossBlood.org/Leukopak) to learn more.



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