American Red Cross | Cell and Gene Therapy Solutions

FAQs About Our Allogeneic Starting Material

What types of Leukopaks does the American Red Cross provide?

The American Red Cross provides Leukopaks collected from unstimulated, non-mobilized healthy donors. Leukopaks can be shipped fresh or cryopreserved—with or without processing, based upon client preference.

How many cells are in a Leukopak?

The American Red Cross does not currently perform cell counts on fresh Leukopak products. Using our standard collection parameters, it is reasonable to assume that each full Leukopak will contain a minimum of 15 billion cells.

How is the quality of your product maintained?

The quality of our Leukopak products begins with our healthy donors. All potential Leukopak donors undergo a thorough pre-screen process, including infectious disease (IDT) and complete blood count (CBC) testing, as well as completion of a thorough Healthy History Questionnaire. Those donors cleared to participate in our Leukopaks program undergo repeat IDT and CBC testing, as well as completing the Health History Questionnaire and health assessment at each pre-screen appointment and on the day of collection.

The American Red Cross also maintains a strict adherence to a standard national procedure for our Leukopak collections—a single Quality Management System, and any specific client requests, ensuring that the standards for Leukopak collection and all aspects of support for that procedure have been followed.

What is the turnaround time?

We request two-week's advance notice for scheduling an ad hoc Leukopak collection. However, stat requests—those with less than two weeks' notice, are also welcome. The American Red Cross will provide feedback on the ability to meet a specific stat request within 24 hours of receipt of such request. Regular standing orders can also be established, based upon client preference.

Can donors be recalled?

Yes, the American Red Cross can recall specific donors at the request of the client.

What geographic area does the American Red Cross serve?

We provide Leukopaks for use across the United States as well as internationally. Leukopak collections are currently performed at American Red Cross sites in Long Beach, CA, Atlanta, GA, Gahanna, OH, Portland, OR, and Philadelphia, PA. These five sites provide same-day delivery to clients within a select radius, depending upon couriers, and can provide next-day delivery to all clients within the United States.

FAQs About Our Allogeneic Starting Material (continued)

Does American Red Cross offer custom or specialty services?

Yes, we provide custom services, including adhering to select collection parameters, such as Total Blood Volume (TBV) to be processed and autologous plasma add-back or separate collection. In addition, we provide a wide range of additional testing services and can meet specific additional donor requirements, such as donor BMI, smoker status and CMV status, among many others.

We also offer specialty processing and cryopreservation services to meet client needs. Leukopaks can be processed utilizing the American Red Cross' standard processing protocol or in accordance with clients' individual processing procedures.

Does American Red Cross have testing capabilities?

Yes, we offer extensive internal testing capabilities and have established relationships with key external specialty testing providers. Our current range of testing includes IDT, CBC, HLA, immunophenotyping, sterility, endotoxin and mycoplasma testing, among others. We are also experienced in bringing on new testing partners to meet unique testing needs of our Leukopak clients.

What resources are available to me when working with the American Red Cross?

Each of our Leukopak customers are supported by a dedicated Client Relationship team at Biomedical Headquarters (BHQ) consisting of operational and quality leads. Our operational leads work with American Red Cross collection and processing sites across the country to ensure standardization in the provision of our Leukopak products, while our quality leads work with their counterparts at our clients to coordinate audits and lead any quality-to-quality communications.

Clients also have easy access to our apheresis collection and cellular therapy lab technical leads. These experts can provide guidance and feedback on how best to modify collection parameters and how to develop and implement specific processing protocols to ensure that our clients' unique needs are met.

What processing, storage and cryopreservation capabilities does American Red Cross have?

We currently perform Leukopak processing, storage and cryopreservation at three full-service Cellular Therapy Labs across the country – Portland, OR, Philadelphia, PA, and Salt Lake City, UT. Our lab in Philadelphia also contains three cleanrooms for Leukopak processing. Processing can be performed according to American Red Cross' standard processing procedures or in accordance with client-specific processing procedures. Resulting products are cryopreserved and stored in liquid nitrogen. Long-term storage is available upon request.

How does the American Red Cross support rapid expansion and ensure material consistency?

American Red Cross has a significant distribution of collection sites, donors and staff across the country. While we currently perform Leukopak collections in five sites, we have an opportunity to expand to 70+ sites within the American Red Cross system at which we currently perform autologous MNC collection procedures and can readily upscale production as needed. Our nationwide network of collection sites, donors and staff provide us with significant expansion capability for Leukopak collections across the country.

We ensure material consistency by strictly adhering to a set of standard national collection and processing procedures, a single Quality Management System, and any unique specification provided by the client, ensuring that the collection and processing procedures, and all aspects of support for those procedures, are as standard as possible.

For more information visit RedCrossBlood.org/cellulartherapy or contact us at CellandGeneTherapy@redcross.org

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