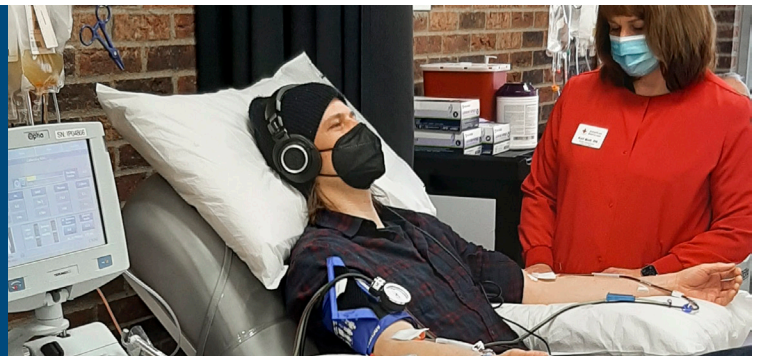




**American
Red Cross**

Cell and Gene
Therapy Solutions

FAQs About Our Autologous Starting Material



How is material collected? Who performs the collections?

The American Red Cross performs autologous mononuclear cell (MNC) collection procedures utilizing either the Spectra Optia or the Fresenius Kabi Amicus device. These collection procedures are performed by trained American Red Cross RN staff, operating under a single national collection procedure and a single Quality Management System. American Red Cross staff are accustomed to performing autologous MNC collection procedures in accordance with our clients' leukapheresis manuals.

Where can leukapheresis be performed?

The American Red Cross can perform leukapheresis at any of our 70 fixed site locations across the country, as well as in hospital locations, and Principal Investigator offices.

How is testing completed?

The American Red Cross has agreements in place with key testing vendors to provide testing services to our autologous MNC clients. The most common testing performed is Infectious Disease Testing and Complete Blood Count testing, for which we utilize Creative Testing Solutions and Quest Diagnostics, respectively.

How is the quality of your product maintained?

As autologous MNC products are collected from patients or subjects enrolled in a clinical study, the resulting cell counts of the products can vary based upon the patient or subject's condition. The American Red Cross maintains a strict adherence to a standard national procedure, a single Quality Management System, and our clients' leukapheresis manual.

What training does your staff have?

American Red Cross staff who perform autologous Mononuclear Cell (MNC) collection procedures undergo standard training on our national autologous MNC collection procedure, as well as standard training related to any supporting procedures. Clients typically provide training to American Red Cross staff on the specifics of their leukapheresis manual, including training on packaging and shipping of the collected cells. All training, including training provided by the client, is documented within the American Red Cross' Learning Management System.

Does the American Red Cross offer custom or specialty services?

Yes, multiple aspects of autologous MNC collection procedures can be customized, including parameters such as the number of Total Blood Volumes (TBVs) to be processed, equipment type, and autologous plasma add-back or separate collection. In addition, we offer specialty services including special testing (patient/subject or product), Central Venous Catheter (CVC) dressing changes, and educational materials for both physicians and patients/subjects on leukapheresis.

FAQs About Our Autologous Starting Material (continued)

Where can products be shipped?

Products can be shipped domestically and internationally. The majority of our autologous MNC customers arrange for couriers to pick up and handle shipment of the collected products.

What is the average lead time to get material?

The American Red Cross can typically begin performing autologous MNC collection services within 4–6 weeks following execution of a contract for the services. The exact timeframe is dependent upon the training to be provided to American Red Cross staff by the client, as well as any new services and/or customizations that are being requested, such as implementation of a new test on the product.

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

Our autologous MNC customers are supported by a dedicated Client Relationship team at Biomedical Headquarters (BHQ). This team consists of operational leads and quality leads. The operational leads work with American Red Cross sites across the country to ensure standardization in the provision of our autologous MNC collection services. Our quality leads work with their counterparts at our clients to coordinate audits and lead any quality-to-quality communications.

Prior to clearing a patient/subject to move forward with leukapheresis, an American Red Cross Regional Medical Director reviews the patient's/subject's CBC test results and History and Physical (H&P). These regional Medical Directors are available to support prescribing physicians and local Principal Investigators throughout the country with education on leukapheresis and feedback on specific patients/subjects. Also, our Executive Medical Director for Direct Patient Care Services is available for consultation at any time.

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



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