

HemaPrime™ Cryopreserved Leukopak

Key Advantages

Viability. Processed shortly after collection preserving viability during extended shipping and storage.

Consistency. Adherence to strict procedures and protocols for consistent starting materials.

Flexibility. Store materials until you are ready to proceed simplifying scheduling and processing logistics.

Purity. Low granulocyte options for optimal recovery of your cell of interest.

Overview

A leukopak is an enriched cellular product collected from peripheral blood via leukapheresis, the process of extracting white blood cells from the blood and returning the remaining components to the donor. Due to high levels of mononuclear cells present in leukopaks, they are used in a variety of scientific applications from research and development to commercialization.

High-Quality and Consistent Starting Material

The path to commercialization begins with the HemaPrime family of cryopreserved leukopaks which are structured to address all your research use needs from benchtop R&D, where controlled cell numbers and guaranteed low granulocyte counts are beneficial, to process development, where inherent differences between donors is of importance to design your product for a patient population. With consistent processes between our HemaPrime and GMPrime™ product lines, you can easily transition to GMP-compliant materials as you transition into clinical trials and commercialization.

Cryopreservation Simplifies Complex Logistics, Maintains Stability, Ensures Consistency, and Allows Flexibility

Maintaining optimal function of key raw materials that are used in the development of next generation cell-based products is of vital importance. Factors such as site-to-site shipping of fresh leukopaks can impact cell viability and function. Immediate processing and cryopreservation will significantly improve difficult logistical obstacles by protecting product quality, mitigating risks during shipping, and allowing scheduling flexibility when planning and coordinating downstream processing activities. The HemaPrime cryopreserved leukopaks are processed shortly after collection using strict and consistent protocols, thus preserving quality and stability.

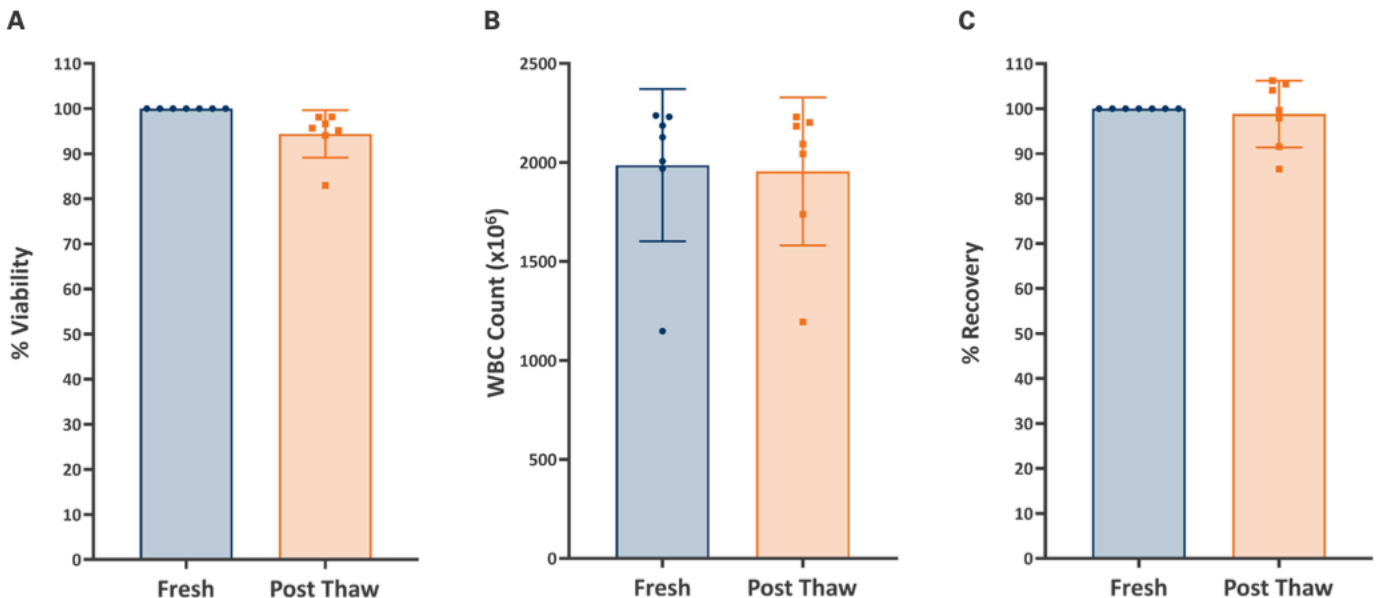


Figure 1. HemaPrime cryopreserved leukopaks maintain a high level of white blood cell (WBC) viability, yield, and recovery following cryopreservation. Cells are counted using the NucleoCounter® NC-200™ automated cell counter with acridine orange to stain the nuclear material and DAPI to stain for live/dead cells. Average viability in the cryopreserved leukopaks is 94.4% post thaw (n=7 donors) (A). Average total WBC yield in the fresh leukopaks is 1,986 x10⁶ cells/unit as compared to 1,954 x10⁶ cells/unit in the thawed leukopaks (B). Average recovery in the cryopreserved leukopaks is 98.8% post thaw (C)

Disclaimer: Data is a representative sampling of cryopreserved leukopaks that were processed onsite in HemaCare's donor center. As these are human-derived raw materials and highly variable, received samples may have varying levels of WBC yield, viability, and recovery. HemaCare accepts no responsibility for cellular variations in the received materials.

Leukopaks are collected at HemaCare's FDA-registered collection center from healthy human donors who have consented under an IRB-approved protocol. This mononuclear cell-rich leukapheresis product is extracted using continuous flow centrifugal technology (Spectra Optia® Apheresis System) directly into a collection bag containing ACD-A anticoagulant. The leukopak is quickly cryopreserved on site in CryoStor® CS10 freeze media using an internally developed procedure.

Catalog Number	Description	Total Cell Count	Stage of Research	Granulocyte %	Format	Price
PB001LCLP	SoloPak (1 Bag)	2-2.5 Billion Cells	R&D	Guaranteed <15% (Avg <5%)	Cryopreserved	\$3,500
PB001LCLP-2-KIT	TwoPak (2 Bags)	4-5 Billion Cells	R&D	Guaranteed <15% (Avg <5%)	Cryopreserved	\$5,500
PB001LCLP-4-KIT	FourPak (4 Bags)	8-10 Billion Cells	R&D	Guaranteed <15% (Avg <5%)	Cryopreserved	\$7,500
PB001LCLP-6-KIT	SixPak (6 Bags)	12-15 Billion Cells	R&D	Guaranteed <15% (Avg <5%)	Cryopreserved	\$9,500
PB001CLP-1-KIT	Full Collection	Collection Dependent	Process Development	Collection Dependent	Cryopreserved	\$7,500

Donor Specifications

Specification	Description	Included
Donor	Qualified, reliable normal random healthy donor who has completed multiple successful donations	✓
History Assessment	Healthy donors are assessed in accordance with current FDA requirements for allogeneic blood donation. Donors are screened with current FDA-approved Donor History Questionnaire (DHQ).	✓
Standard Testing Panel	<ul style="list-style-type: none"> CBC ABO/Rh Treponema pallidum antibody (Syphilis) Red Blood Cell Antibody Screen Hepatitis B Core Antibody (Anti- HBc EIA) Hepatitis B Surface Antigen (HBsAg EIA) Hepatitis C Virus Antibody (Anti-HCV EIA) Human Immunodeficiency Virus Antibody (HIV 1/2 plus O) Human T-Lymphotropic Virus Antibody (HTLV-I/II) HIV-1/HCV/HBV Nucleic Acid Testing West Nile Virus Nucleic Acid Testing Trypanosoma cruzi Antibody (Chagas Disease) 	✓
Additional Testing	Dependent on testing	Additional Fee

Product Specifications

Specification	Description	Included
Collection System	Spectra Optia® Apheresis System	✓
Anticoagulant	ACD-A	✓
Vessel	OriGen CS250 Bag	✓
Cryopreservation Media	CryoStor® CS10	✓
Final Fill Volume	65-70 mL	✓
Pre-cryopreservation Cell Count Per Bag	2.0-2.5 x 10 ⁹	✓

Packaging and Shipping Specifications

Specification	Description	Included
Packing and Shipping	<p>Customer provided instructions. HemaCare's standard shipping contractor for cryopreserved products is Cryoport</p> <p>Cryopreserved leukopaks are transferred to protective cassettes (client keeps) and placed in stationary racks (returns with tank) in LN2 tanks</p>	Additional Fee
COA Details	<ul style="list-style-type: none"> Basic de-identified donor information (gender, age, height, weight, BMI, ethnicity, and blood type) HLA results (if donor is typed) Flow cytometry analysis (standard 8 color immunophenotyping assessment) CBC with 5-part differential 	<ul style="list-style-type: none"> ✓ ✓ ✓ Additional Fee

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