GMPrime™ Cryopreserved Leukopak

Key Advantages

Viability. Processed shortly after collection, viability is preserved 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.

Quality. Rigorous quality assurance and review to ensure GMP compliance.

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, Consistent, and GMP-Qualified Starting Material

New cell therapies are progressing from discovery to clinical application at an extraordinary pace, and with that comes the crucial need for GMP-compliant starting materials. To ensure product consistency throughout the research and development continuum, GMPrime leukopaks are collected and processed the same way as our HemaPrime™ (RUO) product. Therefore, researchers can now seamlessly transition from development to clinical trial and beyond with confidence.

Cryopreservation Simplifies Complex Logistics, Maintains Stability, and Ensures Consistency

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 significantly improve difficult logistical obstacles by protecting product quality, mitigating risks during shipping, and allowing scheduling flexibility when planning and coordinating downstream processing activities.

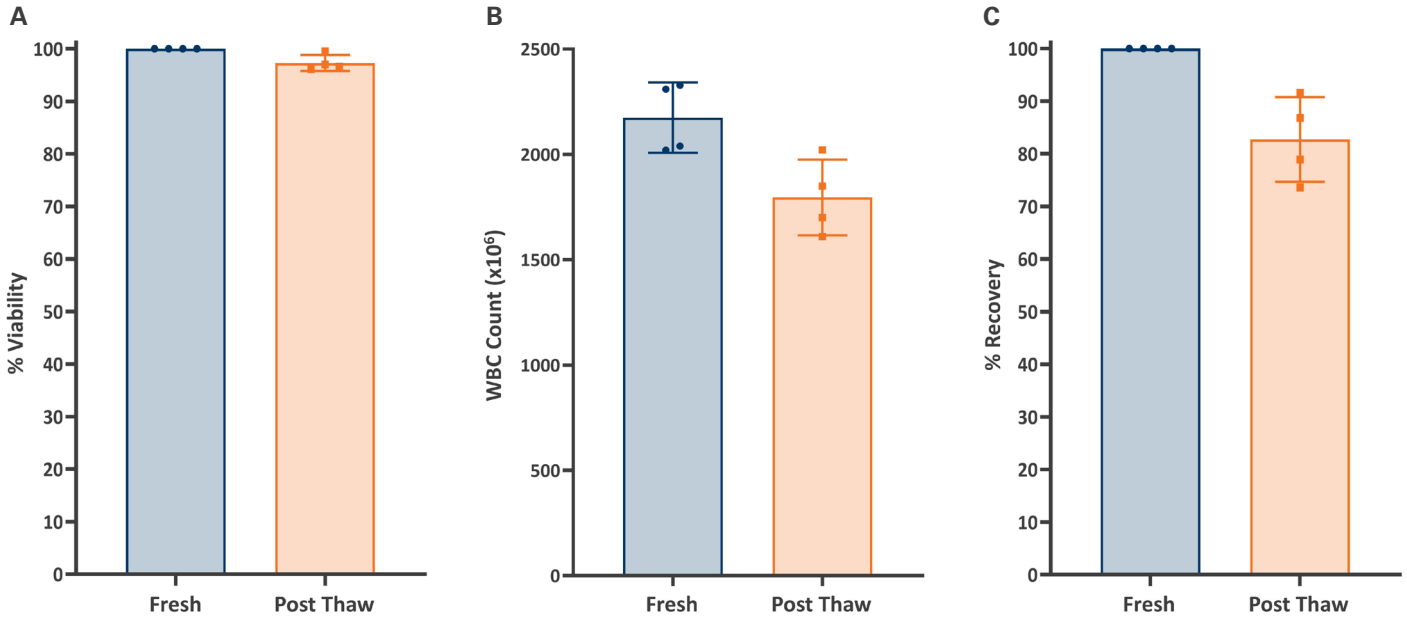

Figure 1. GMPrime cryopreserved leukopaks maintain high white blood cell (WBC) viability, yield, and recovery post thaw. Average percent viability in the cryopreserved leukopaks collected from 4 donors is 97.3% post thaw **(A)**. Average total WBC count in the fresh leukopaks is 2,175 x10^6 cells/unit as compared to 1,795 x10^6 cells/unit in the same leukopaks post thaw **(B)**. Average recovery in the cryopreserved leukopaks is 83% 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 (GMP-grade freeze media) using an internally developed procedure within a cleanroom environment. GMPrime leukopak is accompanied with robust quality-assured documentation and meet the strict quality standards as defined by the FDA (21 CFR 1271) and AABB.

Catalog Number	Description	Size	Format	Price
PB001CLP-GMP-1-KIT	Leukopak	Full Collection (including up to 10 retention vials)	Cryopreserved	Inquire

Donor Specifications

Specification	Description	Included
Donor	Qualified, reliable normal random healthy donor who has completed multiple successful donations	✓
History Assessment	Donor history assessed using the current AABB Donor History Questionnaire for HPC, Apheresis which ensures compliance with FDA current Good Tissue Practices (cGTP) regulations under 21 CFR 1271 for assessing donor eligibility; includes physical exam	✓
Testing Timelines	Pre-screen performed 5-7 days before collection; also test on day of collection	✓
Standard Testing Panel	• CBC • ABO/Rh • Treponema pallidum antibody (Syphilis) • Red Blood Cell Antibody Screen • CMV Antibody (Anti-CMV IgG and IgM) – if donor must be CMV negative • 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) • Zika Virus Nucleic Acid Testing	✓
Additional Testing	Dependent on testing	Additional Fee

Product Specifications

Specification	Description
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
Sterility	No Growth
Mycoplasma	Negative
Endotoxin	< 5 EU/mL

Shipping Specifications

Specification	Description	Included
Packed and Shipped by Courier	GMP-compliant shipping container and trained packaging personnel must be provided by the customer or customer-contracted provider (i.e. Biocair, World Courier, or QuickStat)	Additional Fee
Packed by HemaCare	Customer provided instructions *Must be included in MBR*	Additional Fee

Quality Specifications

Specification	Description	Included
Release Department	HemaCare Operations, HemaCare Quality Assurance	✓
Regulation Compliance	Fully compliant with 21 CFR 1271	✓
Master Batch Record (MBR)	Includes name, address, shipping arrangement *4-6 week lead time*	✓
MBR with Minor Modifications	Example: customer provided shipping instructions *6-8 week lead time*	Additional Fee
MBR with Major Modifications	Example: additional donor recruitment/testing *8-12 week lead time*	Additional Fee

HemaCare Corporation
8500 Balboa Boulevard, Suite 130, Northridge, CA 91325 USA
(877) 397-3087 | sales@hemacare.com | www.hemacare.com