



INTEGRICELL® CRYOPRESERVATION SERVICES

Supported by peer-reviewed research and decades of industry experience, IntegriCell® seamlessly integrates cryopreservation with global logistics, storage, and regulatory expertise in a single-vendor solution from Cryoport Systems.



The Automated Closed Process (ACP)

Our ACP delivers high-quality, manufacture-ready cryopreserved leukopaks with minimized contamination risks. Transfer your existing cryopreservation to our IntegriCell® teams or collaborate with us for customized process development tailored to your specific requirements. Our ACP offers:



High Viability & Recovery:

Post-thaw recovery and viability rates provide reliable cell quality for further processing and downstream manufacturing.



Risk Mitigation:

The ACP reduces operator-related variability and ensures consistent performance across multiple batches.



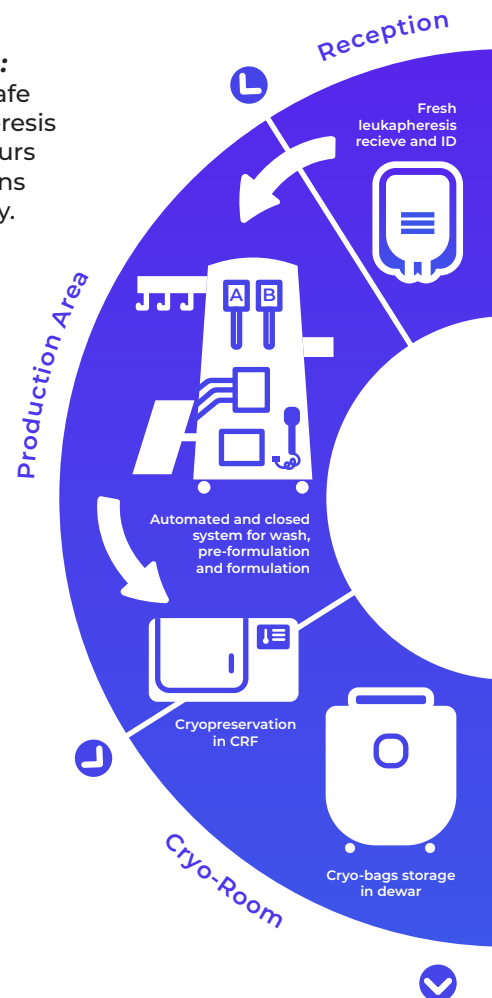
Scalable Efficiency:

Rapid, reliable, and safe processing of leukapheresis material within 24 hours of collection maintains optimal cell integrity.

Overview of the ACP Process

Performed under a full batch record, the ACP process is designed with a focus on automation and standardization to meet GMP compliance:

- 1 Leukapheresis Preparation -**
Fresh material is controlled, visually inspected, and documented.
- 2 Washing -**
Cells are washed using spinning membrane filtration, then cell count and automated cell concentration adjustments are made.
- 3 Formulation -**
Addition of CryoStor CS10 cryoprotectant (DMSO-based) and transferred into cryo-bags.
- 4 Freezing -**
Controlled rate freezer (CRF) ensures reproducible freezing cycles for optimal cell viability.



ACP consistently demonstrates high cell recovery and viability, while significantly reducing variability typically associated with manual processing.

Using optimized process parameter conditions, ACP demonstrated high cell recovery and viability comparable to manual cryo-process while reducing variability:

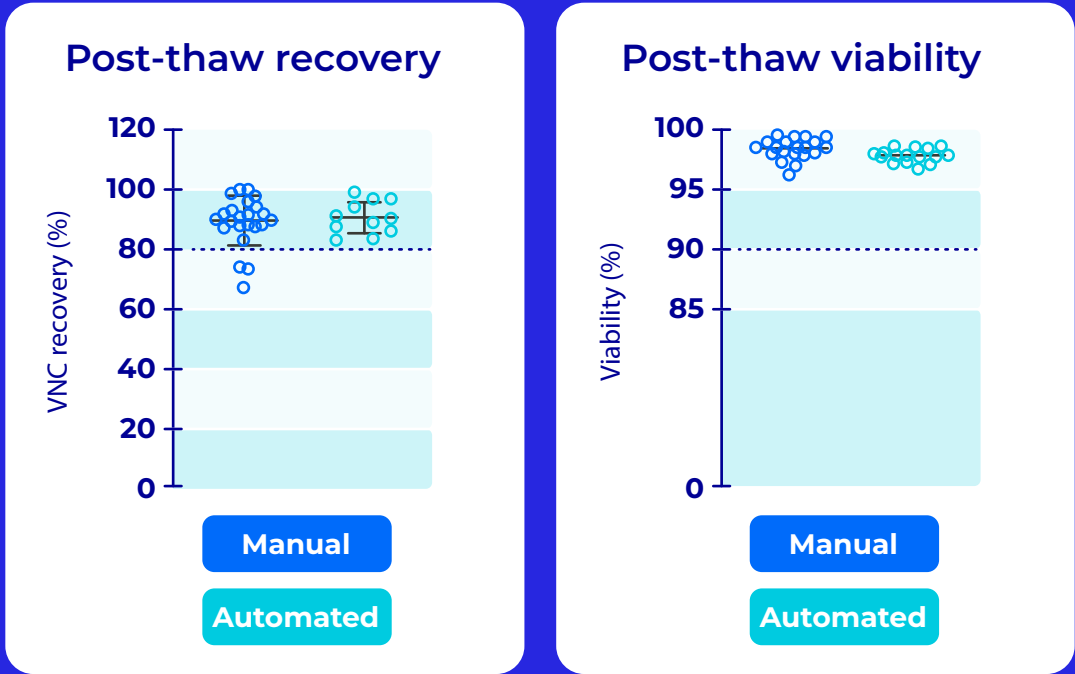


Figure 1. Viable Nucleated Cell (VNC) Recovery (left) and Viability (right) from healthy donor leukapheresis cryopreserved with manual or automated cryo-processes.

Product Specifications and Performance Metrics

IntegriCell® cryopreservation services result in cryopreserved leukapheresis products with high quality and consistency.

Product	Cryopreserved Leukopak, 3.5B*
Description	Leukapheresis material cryopreserved in a solution of Cryostor CS10, Plasmalyte and HSA
Format	CryoMACS 250 bag
Final DMSO Concentration	5%
Post-Formulation Viability	≥ 70%
Target Cell Concentration	50M per mL ±10%
Target fill Volume	70mL per CryoMACS 250 bag

*Note: Leukapheresis material can be cryopreserved per custom specification. Additional cell characterization including flow cytometry, sterility, and endotoxin can be performed upon request.

Cryoport Systems’ End-to-End Support with the IntegriCell® Model

Cryoport Systems’ IntegriCell® cryopreservation services expand into an end-to-end model that supports clients’ entire temperature-controlled supply chain. The IntegriCell® model combines Cryoport Systems’ standardized cryopreservation services with our world-renowned logistics and supply chain expertise to facilitate the timely delivery of manufacture-ready cryopreserved leukopaks to manufacturing sites.

