



Cell and Gene Therapy  
GMP Product Catalog



# The Patient, their Hope, and our Commitment.

Hope enables the patient to endure the adversity and pain of disease. Hope motivates people to participate in clinical research studies and biospecimen donation. Time is the worst enemy of hope. As time passes, it prolongs and intensifies pain while diminishing the body and spirit.

Our mission is to restore hope by speeding the development of innovative diagnostics and effective treatments to improve care. We believe that the passing of time should increase the joy of the patient and their loved ones rather than extinguish it.

At Discovery Life Sciences, we commit to acquiring the leading technologies and employing the most dedicated and brightest minds from every culture, walk of life, and region of the world. We come together to accelerate and advance science. We accomplish this by partnering with researchers in industry, academia, and governments enhancing their abilities to complete their vital work faster by providing them with the highest quality products and services. We commit to acting ethically and with integrity while strictly adhering to all laws and regulations.

We will never waiver from these commitments...

*Because Patients Are Waiting<sup>®</sup>.*

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## Science at your Service™

Discovery combines the world's largest commercial biospecimen inventory and procurement network with preeminent multi-omic service laboratories.

Our consultative, innovative approach helps our customers and partners overcome obstacles to reach quality results faster.



# AllCells®

Serving the Complete Cell and Gene Therapy Continuum.

High quality RUO and GMP human primary cells

RUO/GMP Mobilized and Non-Mobilized Leukopaks, Isolated Cells, Thousands of Recallable/HLA-Typed Donors

## Genomics Services

WES, RNA-Seq, Single-Cell, Targeted-Seq, Pan-Cancer, WGS, HiFi LRS, Epigenomics, qPCR

## Proteomics Services

Targeted & Untargeted LC-MS/MS, Luminex, Olink (Explore HT, Explore, Target, Focus, Flex), Multi-omics

## Assay-Ready Biospecimens

The World's Largest Biospecimen Inventory Powered by Discovery Partners® Network

## Molecular Pathology Services

IHC, mIF, ISH, Histology, Digital Pathology, Quantitative Gene Expression

## In Vitro Preclinical Solutions

Hepatocytes, HLM, Supersomes™, TransportoCells™, ADMET Services, Hematopoietic CFC Assay Services

## Clinical Flow Cytometry Services

Clinical Flow Cytometry, FACS, Dissociations, Single Cell & Spatial Library Prep, In Vitro Culture

# High Quality Starting Cellular Material to Support GMP Manufacturing

Sourcing high-quality cellular material is one of the biggest industry challenges for the development of cell and gene therapies. AllCells, a Discovery Life Sciences company, is the industry leader in providing starting materials to support the full continuum of cell and gene therapy production – from basic discovery through commercialization and across various modality types. Operating the largest and most diverse repository of healthy, recallable donors, AllCells is well-suited to fulfill a variety of donor attributes.

## **UNPARALLELED ABILITY TO DELIVER**

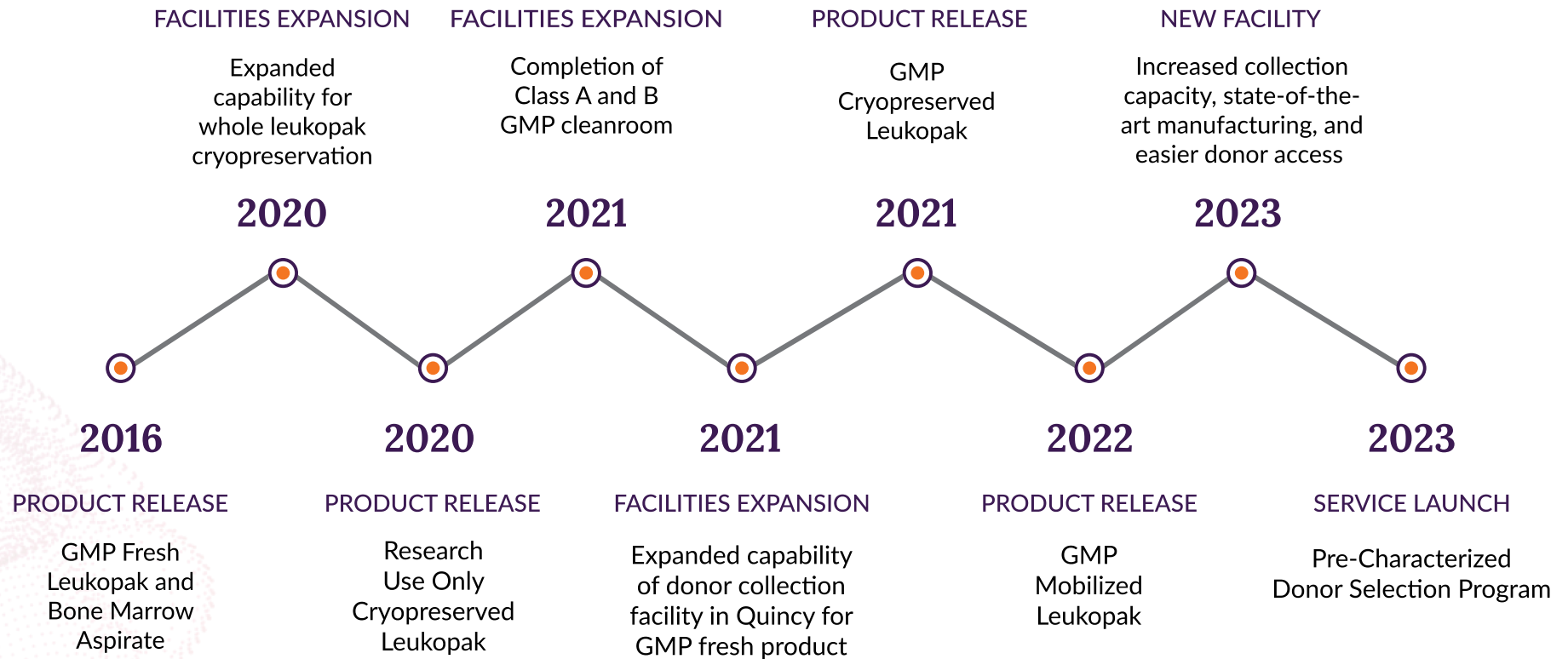
### **Extensive and Loyal Client Base**

- 400+ unique clients in the past year
- Global reach with fresh and cryopreserved shipments to domestic and international countries

### **Deliverability Rate of 99%**

- 500+ products provided in support of process qualification and GMP manufacturing for cell therapy developers
- Highly communicative and collaborative team with < 24 hour response time
- Dedicated donor facing brand and operations for effective donor recruitment and management
- Characterized donor and inventory ecosystem to support streamlined donor screening and selection
- Built-in risk mitigation measures, including parallel donor screening

AllCells is continuously at the forefront of market requirements, providing the highest quality products and services.





# GMP Fresh Leukopak

*A leukopak is an enriched leukapheresis product collected from normal peripheral blood, which contains a concentrated fraction of mononuclear cells like lymphocytes and monocytes.*

Ideal for cell and gene therapy applications requiring isolated hematopoietic stem cells (HSCs) and immune cells (i.e., T cells, NK cells) (Fig 1).

AllCells' GMP leukopak products are collected from qualified, healthy, and consenting donors per IRB-approved protocols by our team of experienced clinicians and processed in our FDA-registered facilities. Stringent quality systems ensure regulatory compliance requirements are met. All our GMP products are subjected to an extensive quality review and are provided with supporting extended documentation during batch release.



GMP Fresh Leukopaks are collected from healthy human donors using the Spectra Optia® Apheresis System directly into ACD-A anticoagulant.

GMP Leukopak products are quality controlled for: volume, viability, total nucleated cell (TNC) concentration, and sterility USP <71>. The product is shipped using a validated shipping container.

Catalog Number: CG, LP, FR, Full Pak

### SPECIFICATIONS

- Anti-coagulant: ACD-A
- Volume: ≥280mL
- Viability: ≥90%
- TNC concentration (x10<sup>6</sup> cells/mL): ≥26
- Sterility test USP <71>: No growth
- Shipping: 2 to 8°C in validated shipping container with temperature logger
- Documentation: Certificate of Analysis (CoA) and Summary of Records (SoR)

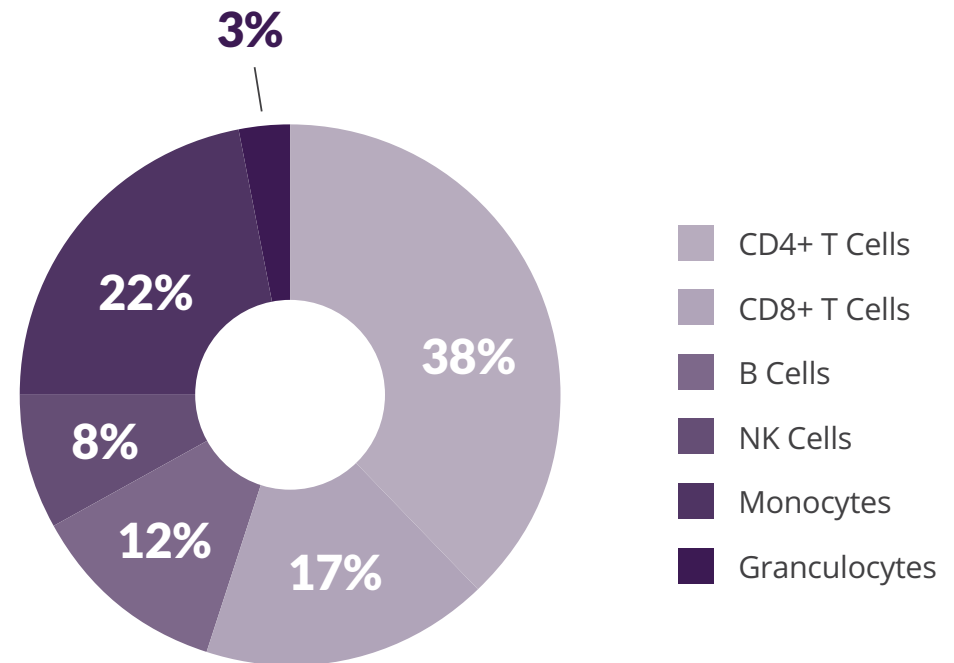


Fig 1: Cell Subpopulations in Fresh Leukopak (Donor Variability is Expected)

# GMP Cryopreserved Leukopak

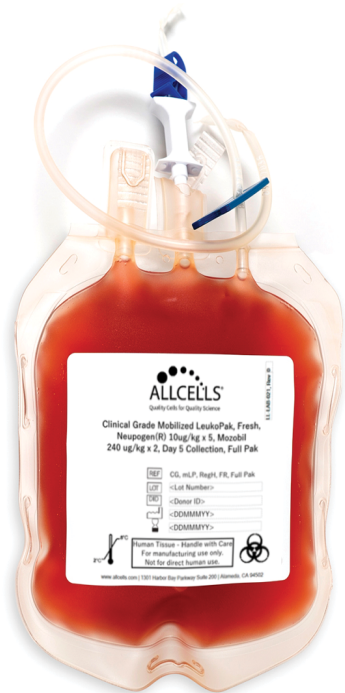
*Cryopreserved leukopaks demonstrate comparability to fresh leukopaks*

AllCells' optimized cryopreservation protocols deliver high cell viability of important lymphocyte populations with low-granulocyte contamination.

**Catalog Number:** CG, LP, CR, Solo 2.5-3.0B

## SPECIFICATIONS

- Anti-coagulant: ACD-A
- Format: Full donor collection processed and split into a minimum of 3x CS250 bags per lot with up to 8 retention vials
- Pre-cryopreservation TNC count per bag:  $\geq 2.5$  billion cells
- Cryopreservation media: CS10
- Pre-cryopreservation viability %:  $\geq 90$
- Sterility test USP <71>: No growth
- Shipping:  $< -150^{\circ}\text{C}$  in a validated shipping container with temperature logger
- Documentation: CoA, SoR, Immunophenotyping Report, and CBC 5-Part Differential Report



## CASSETTE AND FRAME

Item	Details
Cassette	97.0%
Cassette Dimension (HxWxD)	6.0" x 7.55" x 0.44"
Cassette Frame	ZF4-ZC021
Cassette Frame Dimension (HxWxD)	25.69" x 6.38" x 0.56"

GMP Cryopreserved Leukopaks tested at two different sampling timepoints (<1 week and 12-months) maintained high cell viability (Fig 2a), yield (Fig 2b), and demonstrated comparable cell subpopulation distribution (Fig 2c).

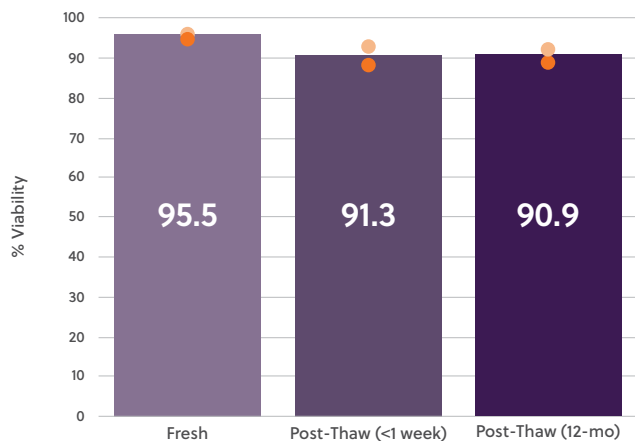


Fig 2a: Average % Viability Pre-Freeze vs. Post-Thaw

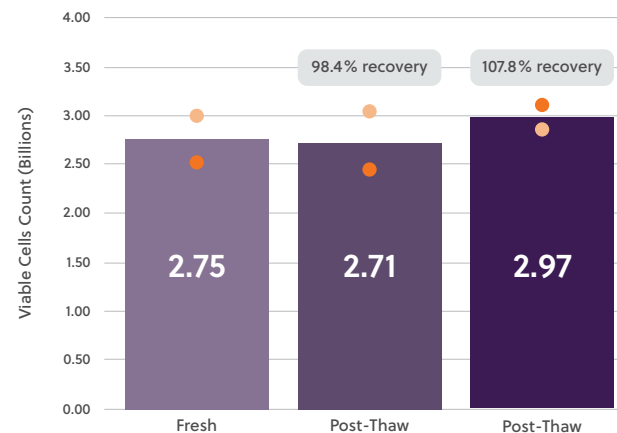


Fig 2b: Average Viable Cell Count Pre-Freeze vs. Post-Thaw

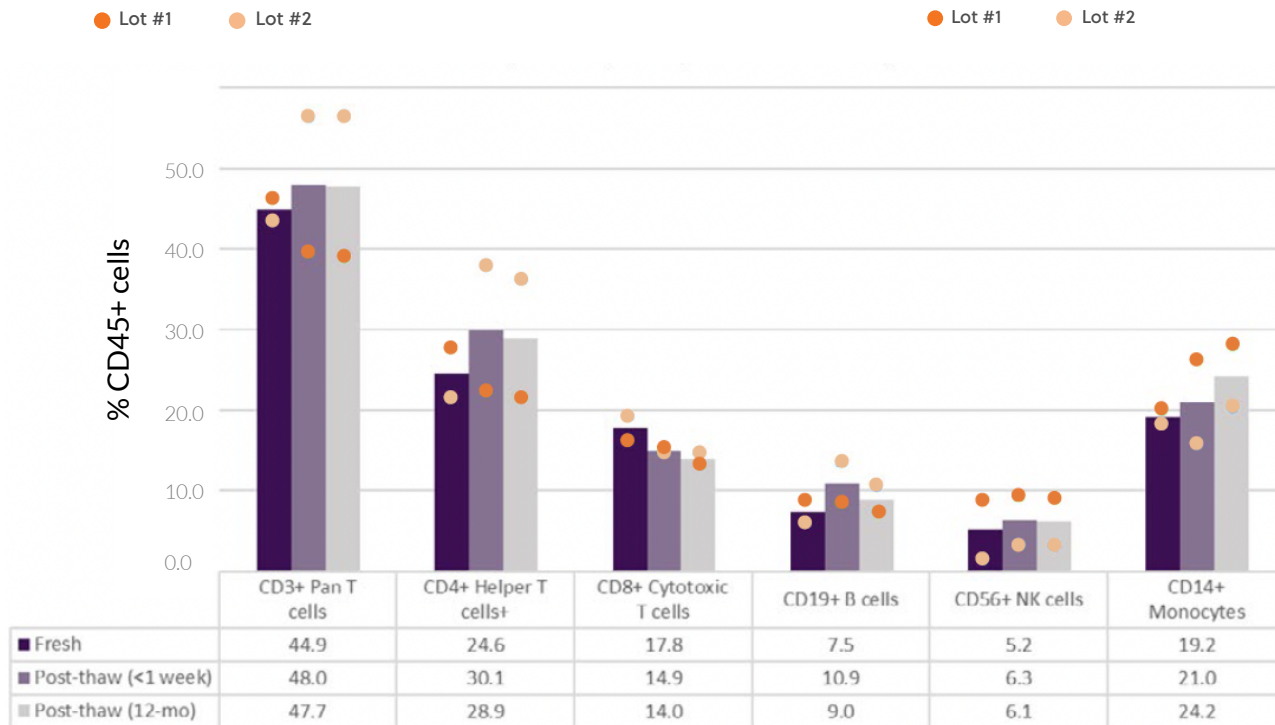
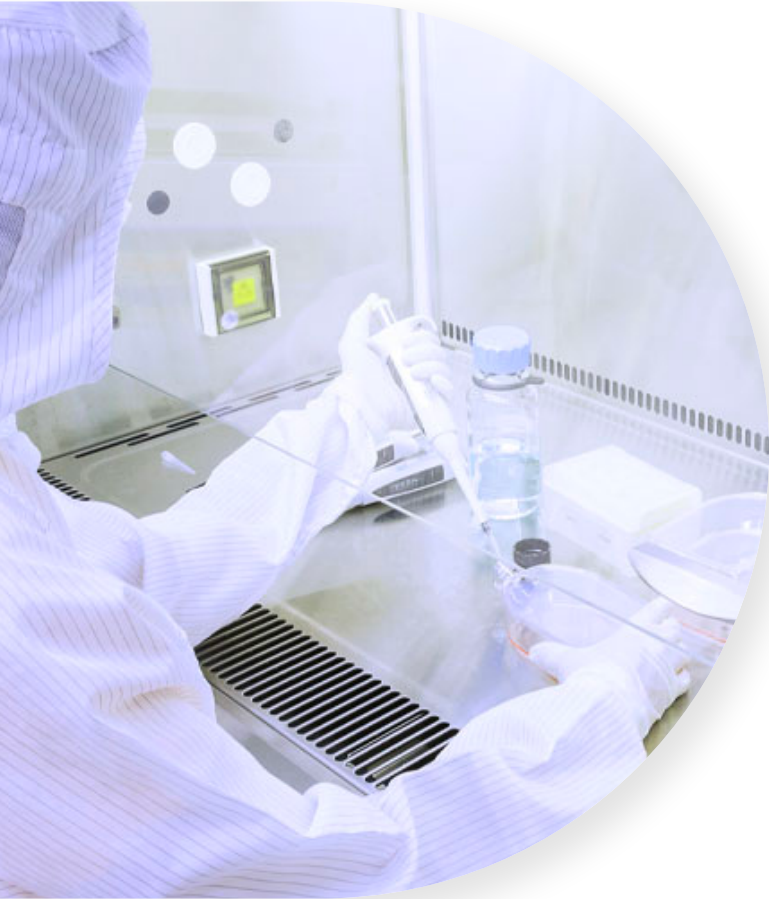


Fig 2c: Average Distribution of Immune Cell Subpopulations



# AllCells' GMP Cleanroom

All cryopreservation steps occur within the class ISO 7 cleanroom with grade A and B zones according to Master Batch Record.

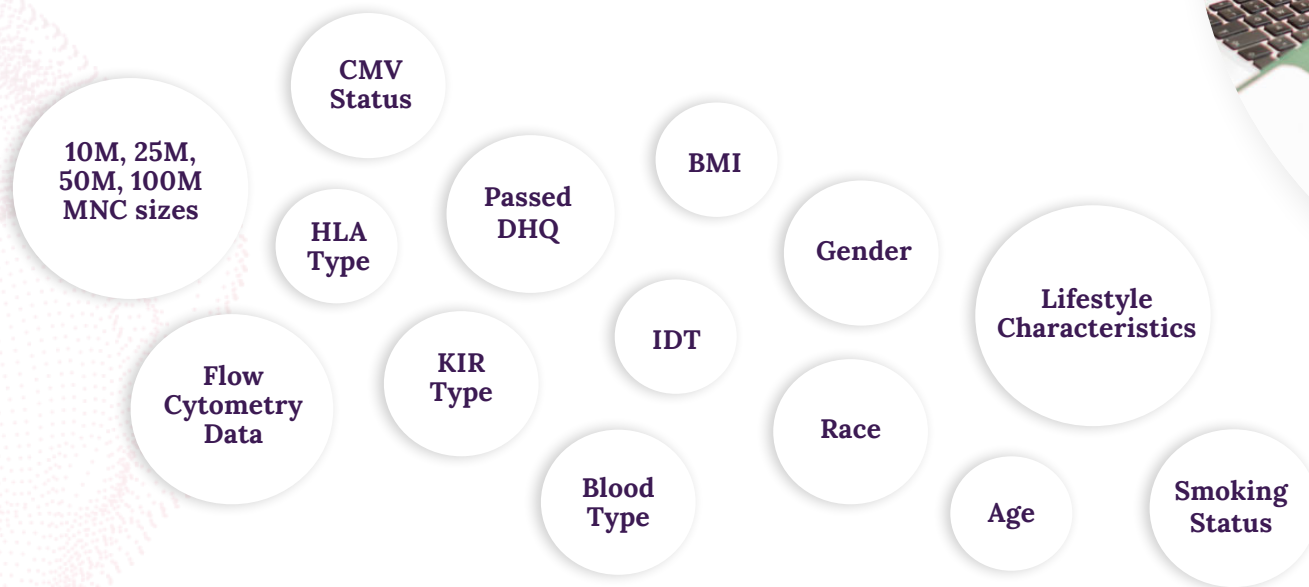
- Robust environmental monitoring
- Adjacently located to an AllCells collection facility
- One-way product flow
- Cryogenic storage with continuous temperature monitoring and alarming
- Dedicated controlled environment room operations, equipment management, and staff training

# Pre-Characterized Donor Selection Program

## Characterized Starting Materials

Donor attributes including age, BMI, race, gender, health history, and viral testing per 21 CFR 1271 regulations along with HLA typing and KIR profiling are compiled for donors eligible for GMP product collections. We also perform a 9-color flow panel immunophenotyping analysis to provide additional characterization data on different immune cell subsets.

- Visualize the real-time status of donors and characterization data
- Streamline and accelerate donor selection process

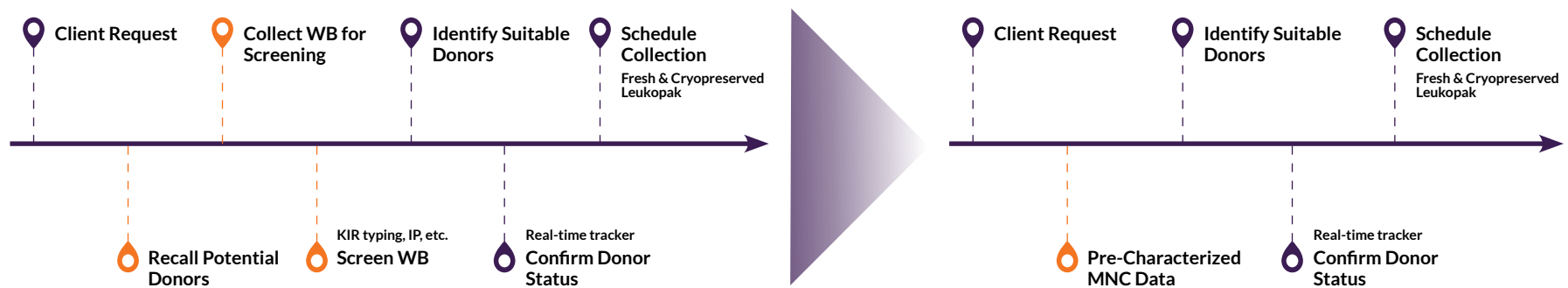


## Optimized Donor Selection

Our dedicated team helps clients utilize the donor characterization datasets to select the most suitable donors with the attributes that align with their program-specific requirements, and coordinate scheduling of these donors for collections of fresh or cryopreserved leukopak products. This high-resolution data also provides valuable insights about how starting material attributes influence the final CGT product, which helps researchers and process engineers develop more robust and controlled manufacturing processes to ensure consistency and quality throughout the entire production workflow.

## Streamlined Workflow

AllCells' streamlined approach significantly reduces the timeline compared to conventional workflows, where it is necessary to recall donors for whole blood screening\* and characterization, prolonging the donor selection process.



\* Whole blood screening options are available for custom donor attributes not included in inventory

# GMP Mobilized Leukopak

*GMP Mobilized Leukopaks are collected from healthy, human donors using the Spectra Optia Apheresis System after the donors have been treated with FDA-approved drugs, filgrastim and plerixafor, to stimulate mobilization of CD34+ hematopoietic stem and progenitor cells from the bone marrow to the peripheral blood.*

GMP Mobilized Leukopak products are quality controlled for: volume, viability, and sterility USP <71>. The product is shipped using a validated shipping container. Available in fresh format only.

In normal, non-mobilized peripheral blood, the frequency of CD34+ cells is extremely low, at only 0.01– 0.05%. Mobilization of HSPCs from the bone marrow to the peripheral blood using FDA-approved drugs is an effective mechanism to boost CD34+ frequency prior to leukapheresis collection. On average, the CD34+ cell count from a dual mobilization is more than 180 times that of a single bone marrow collection.



## VIABILITY AND CELL COUNT

Average TNC count ( $10^6$ ) per donor	Average % Viability	Average % CD34+ Cells (ISHAGE)
127,792	97.0%	1.25%

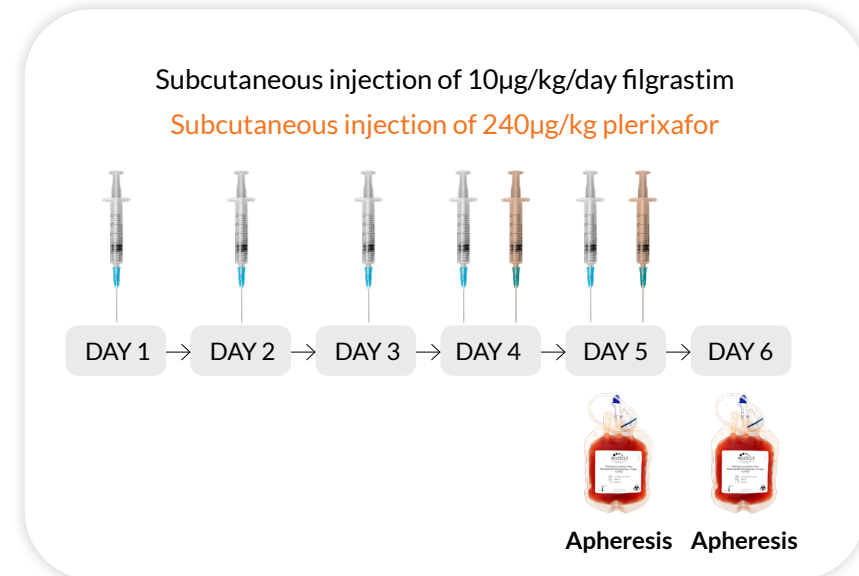
Catalog Number: CG, mLP, RegH, FR, Full Pak / CG, mLP, RegH, FR, Full Pak 2

## SPECIFICATIONS

- Mobilized Regimen: Filgrastim x 5 days, + Plerixafor x 2 days (RegH)
- Format: Fresh, 2 Paks
- Anticoagulant: ACD-A
- Fill Volume:  $\geq 280$ mL per bag
- Viability:  $\geq 90\%$
- Sterility Test USP <71>: No growth
- Shipping Condition: 2 to 8°C in validated shipping container with temperature logger
- Documentation: CoA and SoR
- International Society of Hematotherapy and Graft Engineering (ISHAGE) report and CBC 5-Part Differential report are available upon request

## REGIMEN DETAILS

- Filgrastim 10 $\mu$ g/kg/day x 5 days + Plerixafor 240 $\mu$ g/kg/day x 2 days on day 4 and 5 (evenings)
- Apheresis on day 5 and 6





# GMP Bone Marrow

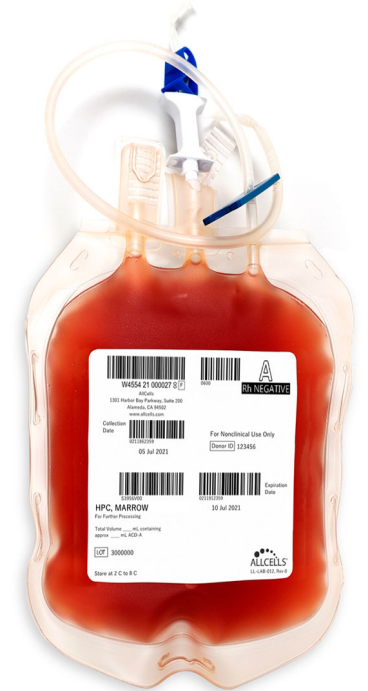
*Bone Marrow aspirate products are a rich source of CD34+ cells, mesenchymal stem cells (MSCs), and other leukocytes.*

GMP Bone Marrow is collected from healthy, human donors by needle aspiration from the posterior iliac crest. GMP bone marrow products are quality controlled for: volume, viability, TNC concentration, and sterility USP <71>. Available in fresh format only.

*Catalog Number: CG, BM, FR, 1ea (100mL)*

## SPECIFICATIONS

- Anti-coagulant: Na Heparin or ACD-A
- Volume: 100mL
- Viability:  $\geq 90\%$
- TNC Concentration ( $\times 10^6$  cells/mL):  $\geq 8$
- Sterility test USP <71>: No growth
- Shipping: 15 to 30°C in validated shipping container with temperature logger
- Documentation: CoA and SoR



# Serving the Full Continuum of CGT

AllCells maintains the same high quality material and stringent protocols for both research and GMP use products for a seamless transition.

	PRE-CLINICAL PHASE RESEARCH USE ONLY	CLINICAL PHASES I / II / III GMP USE	COMMERCIALIZATION
<b>Donor Assessment and Testing</b>	Eligible donors are screened against HIV, Hepatitis B, and Hepatitis C.	Donors are subject to infectious disease marker testing in compliance with 21 CFR 1271, as well as those recommended by CDC and AABB. Donors also undergo an MD-administered physical exam and must pass the donor health questionnaire.	
<b>Donor Consent (IRB Approved)</b>	For research use only.	For reasearch and commercial use.	
<b>Operational SOPs</b>	Validated SOPs/e-batch records.	Validated SOPs and extensive batch records.	
<b>Regulatory Compliance</b>	Research Use Only	Products are manufactured in accordance with FDA Title 21 Part 1271 Subparts A-C and provisions of Subpart D deemed applicable by AllCells under Section 1271.150(c) and good industry practice.	
<b>Quality</b>	E-documentation, product specifications based on process experience, certificate of analysis.	QMS-governed documentation e.g. batch records, equipment and product validation, stability studies, to support product for further manipulation.	
<b>Processing Facility</b>	GMP-like collection and processing facilities.	ISO 7 cleanroom with Grade A and B zones.	
<b>Packaging Protocol and Packaging</b>	Commercial Grade	Packaging validated to ISTA standards including temperature logger.	

# Donor Qualification for GMP Products

AllCells follows donor eligibility infectious disease marker testing in compliance with 21 CFR 1271, as well as the recommendations by CDC and AABB.

- Human immunodeficiency virus Type 1 antibodies and RNA
- Human immunodeficiency virus Type 2 antibodies and RNA
- Hepatitis B antibodies and DNA
- Hepatitis C antibodies and RNA
- Human T-lymphotropic Virus I/II antibodies
- Cytomegalovirus (CMV) antibodies
- West Nile virus RNA
- Trypanosoma cruzi parasite (Chagas Disease) antibodies

Donor health questionnaire to rule out risk of Human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease and Zika virus.

AllCells performs the FDA specified HCT/P donor screening  $\leq 30$  days prior to collection to assure that the donor meets inclusion criteria at the  $\leq 7$  day time point. We employ a Parallel Donor Program to mitigate the risk of donor deferrals.

Additional infectious disease marker testing and screening time points may be customized.

## **DONORS TO BE IDENTIFIED BASED ON THE STANDARD CRITERIA**

- Donors selected from the community at large in compliance with the donor eligibility criteria outlined in 21 CFR Part 1271 Subpart C - Donor Eligibility
- Gender: Male or Female
- Age: 18 to 45 years old
- Weight: 140 to 275 pounds
- No self-reported abuse of drugs or alcohol
- Not pregnant

# Donor Management Services



## Recruitment

Ongoing and client-specific donor recruitment efforts



## Screening

Standard viral screening and/or client-specific protocols



## Monitoring

Premier access to AllCells donor database to identify donors with study-specific attributes



## Retention

Active donor engagement to foster repeat/recallable donors; maintain minimum client-specific donor pool size

## MEETING YOUR SPECIFIC DONOR REQUIREMENTS

At AllCells, we understand that donors meeting the stringent regulatory criteria is just as critical as meeting the specific project needs for the success of the product and subsequent application.

We maintain an exclusive donor pool that is highly reliable, characterized, and qualified for collection of GMP products, in order to ensure that we are able to deliver high quality products on your timeline. AllCells' proprietary Donor Management System (DMS) enables us to optimize our processes from recruitment, screening, monitoring, and retention, ultimately empowering us to provide the right donor for every project with the shortest lead times in the market.

Our diverse, dynamic, and continuously expanding donor pool enables AllCells to provide the match customers need to successfully complete their study.

- Healthy donors
- Recallable or unique donors
- HLA type (low and high resolution)
- KIR type
- CMV status (negative or positive)
- Blood type
- Demographics (gender, age, ethnicity)
- Specific lifestyle characteristics (BMI, smoking status, and more)
- Additional custom criteria (screening or testing)
- Dedicated donor pools

All collections are from donors who are qualified for participation in accordance with the IRB approved informed consents and meet AllCells' quality standards.

# The Right Donors for Every Project

## Premier Access to our Donor Repository

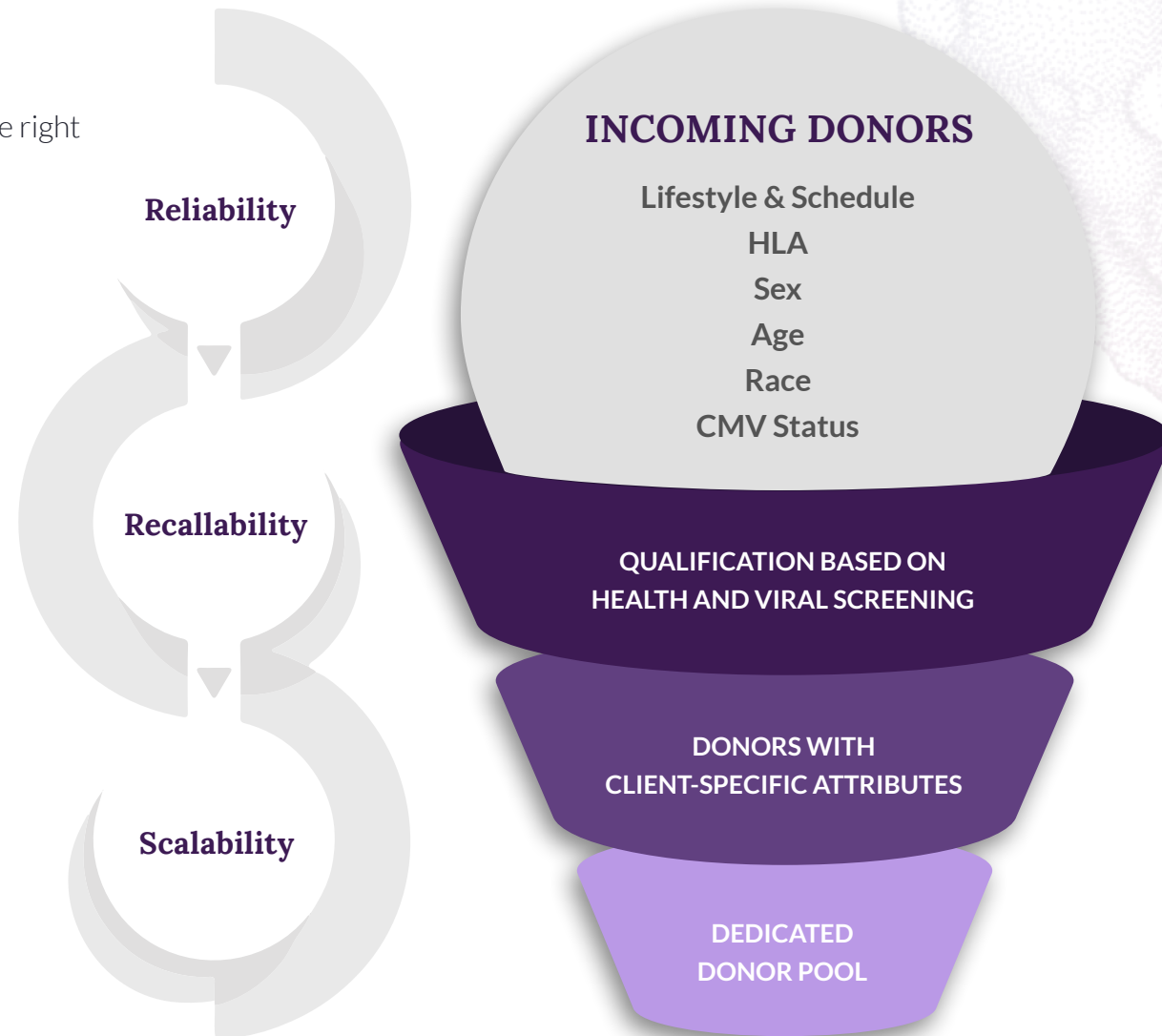
AllCells has the largest, most diverse donor pool in the industry, with facilities strategically located across the United States. GMP products are available at our Alameda, CA and Quincy, MA locations, enabling geographic diversity for supply chain risk mitigation. Fresh products for same day delivery are available across sites.



# A Unique Donor Ecosystem

Reliability and recallability is built into the program.

- Innovative software targets specific donors to get the right donors for every project
- Collection cadence / timeline specifications
- Recruitment based on demand and forecast
- Dedicated, reserved donor pool options available



# 99% GMP Collections Deliverability

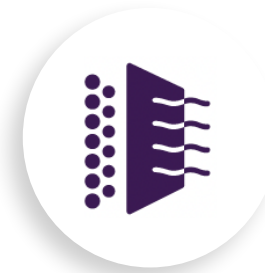
*The interplay of a robust donor ecosystem, donor characterization and deliverability of high quality starting materials helps establish robust manufacturing processes.*

With years of providing materials for GMP use and over 20 years in the CGT industry, AllCells is your reliable and trusted supplier of high-quality starting material to support your cell therapy commercialization journey.

AllCells' dynamic and continuously expanding donor pool and facilities provides you continuous and assured access to high-quality starting material to support scalability throughout your product lifecycle.

Our dedicated team of scientists, clinicians, quality and logistics experts will partner with you to define, design and manage your project to deliver a product that meets your specific needs.

For more information on AllCells' GMP products and services, please visit [allcells.com/gmp](https://allcells.com/gmp).



**GMP  
CLEAN ROOM**



**REGULATORY  
COMPLIANCE**



**EXTENDED  
VIRALS**



**COMPETITIVE  
PRICING**



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or visit our website at  
[www.allcells.com](http://www.allcells.com)