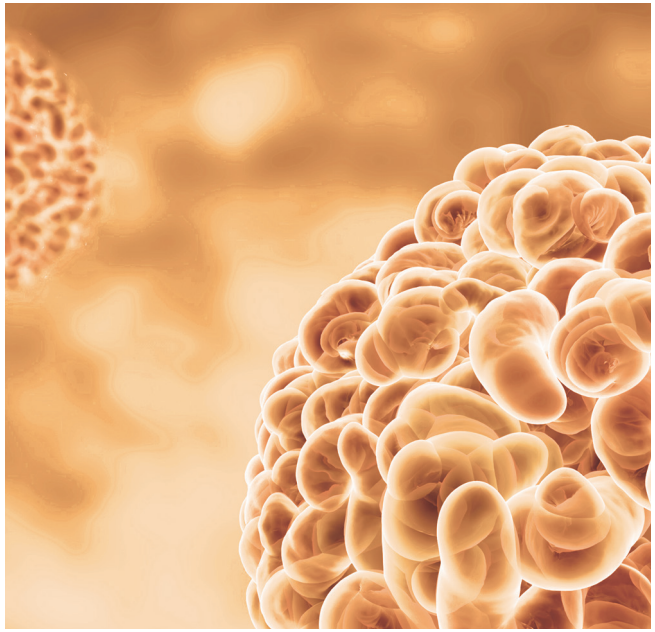
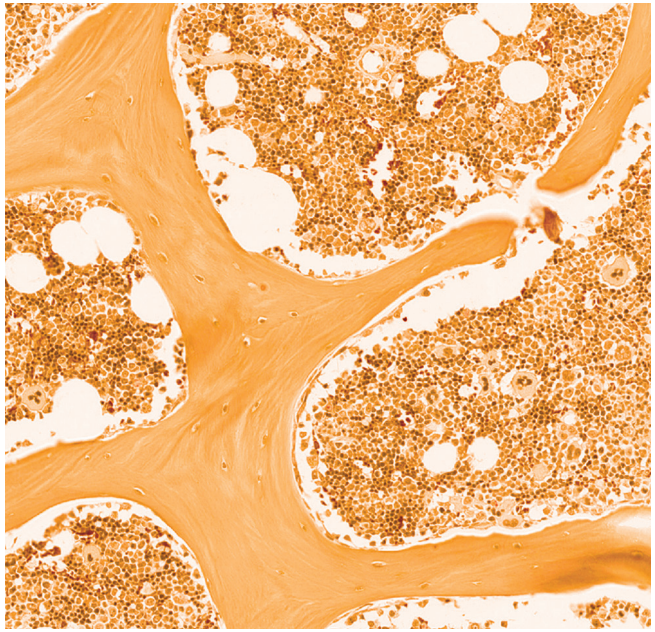
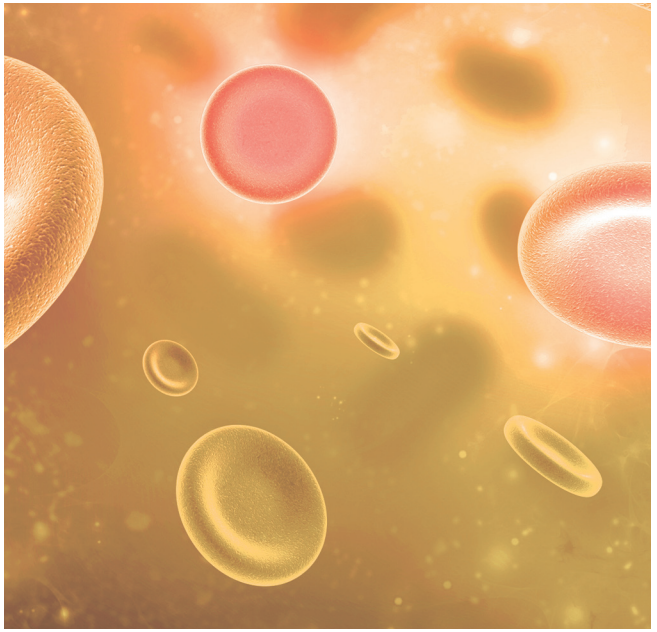
ALLCELLS®

A DISCOVERY LIFE SCIENCES DIVISION







GMP PRODUCT CATALOG 2023

ALLCELLS®
A DISCOVERY LIFE SCIENCES DIVISION

High Quality GMP Raw Material to Support the Cell and Gene Therapy Industry

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 GMP and RUO starting materials to support the full continuum of cell and gene therapy production – from basic discovery through commercialization. Operating the largest and most diverse repository of healthy, recallable donors, AllCells is well-suited to fulfill a variety of donor attributes.

UNPARALLELLED ABILITY TO DELIVER

Providing GMP Materials to leading CGT Companies

- Autologous, allogeneic
- CAR-T/NK, iPSC-derived immune cells, MSC- and HSC-based therapies

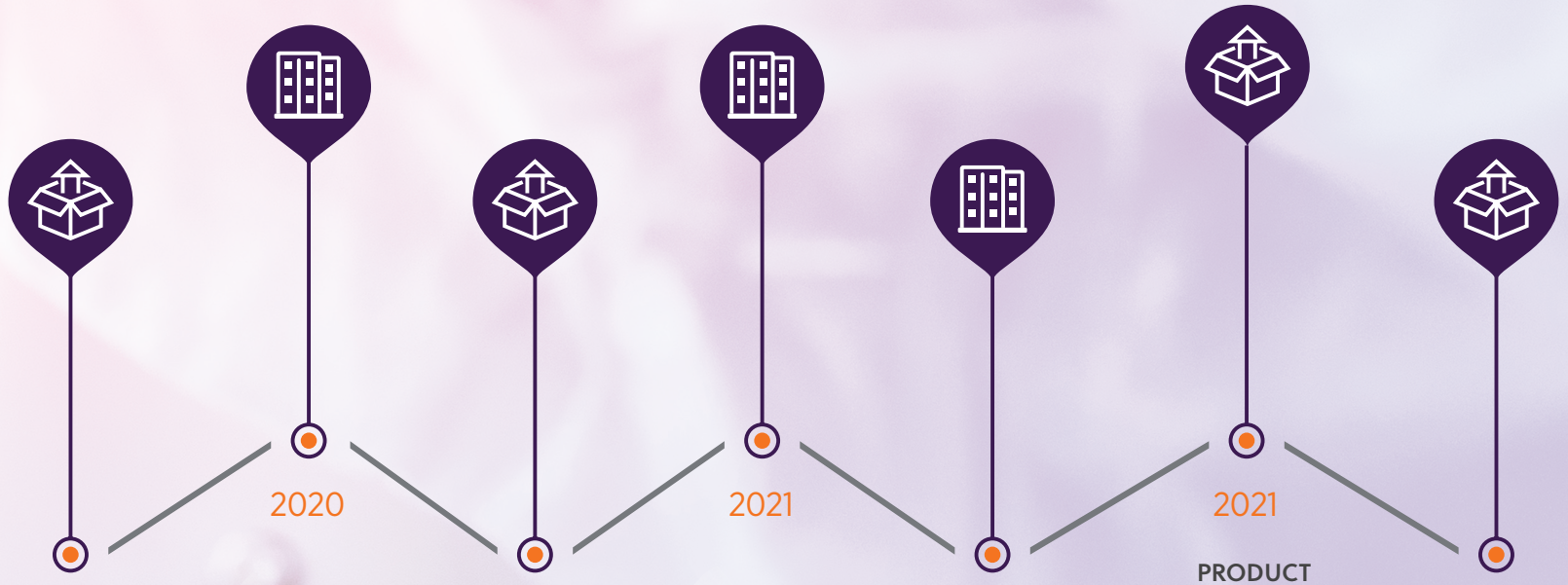
Extensive and Loyal Client Base

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

Deliverability Rate of 99%

- 300+ GMP products provided in support of cell therapy development
- Highly communicative and collaborative team with < 24hr response time
- Dedicated donor facing brand and operations for effective donor recruitment and management

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



2016

PRODUCT RELEASE

GMP Fresh Leukopak and Bone Marrow Aspirate

2020

FACILITIES EXPANSION

Expanded capability for whole leukopak cryopreservation

2020

PRODUCT RELEASE

Research Use Only Cryopreserved Leukopak

2021

FACILITIES EXPANSION

Completion of Class A and B GMP cleanroom

2021

FACILITIES EXPANSION

Expanded capability of donor collection facility in Quincy for GMP fresh product

2021

PRODUCT RELEASE

GMP Cryopreserved Leukopak

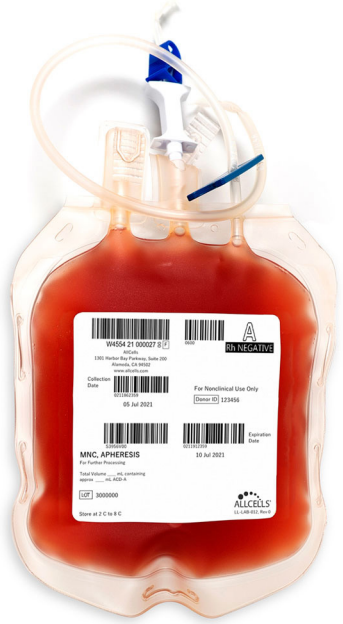
2022

PRODUCT RELEASE

GMP Mobilized Leukopak

Product Portfolio

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).

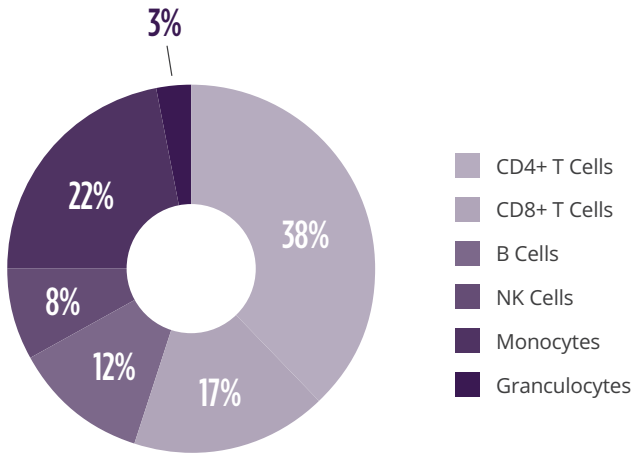
AllCells' GMP leukopak products are collected from qualified, healthy, and consenting donors per IRB-approved protocols by our team of experienced clinicians and processed in our FDA-registered facilities. Stringent quality systems ensure regulatory compliance requirements are met. All our GMP products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

GMP 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.

SPECIFICATIONS

- Anti-coagulant: ACD-A
- Volume: ≥280mL
- Viability: ≥90%
- TNC Concentration (x10^6 cells/mL): ≥26
- Sterility Test USP <71>: No growth
- Shipping: Validated shipping container

Fig 1: Cell Supopulations in Fresh Leukopak



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. 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 sub-population distribution (Fig 2c).

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: ≥2.5 Billion cells
- Cryopreservation media: CS10
- Pre-cryopreservation viability %: ≥90
- Sterility Test USP <71>: No growth
- Shipping: GMP shipping container

ALLCELLS' GMP CLEANROOM

All cryopreservation steps occur within 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

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

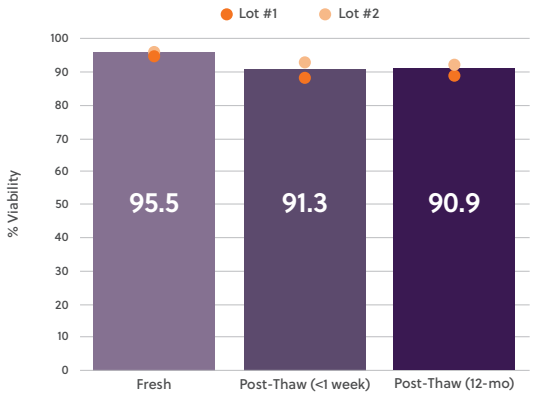


Fig 2b: Average Viable Cell Count Pre-Freeze vs. Post-Thaw

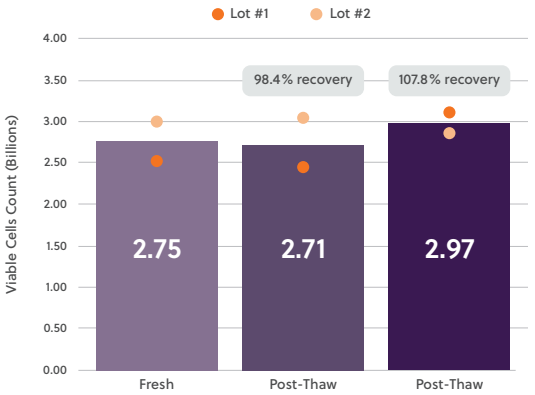
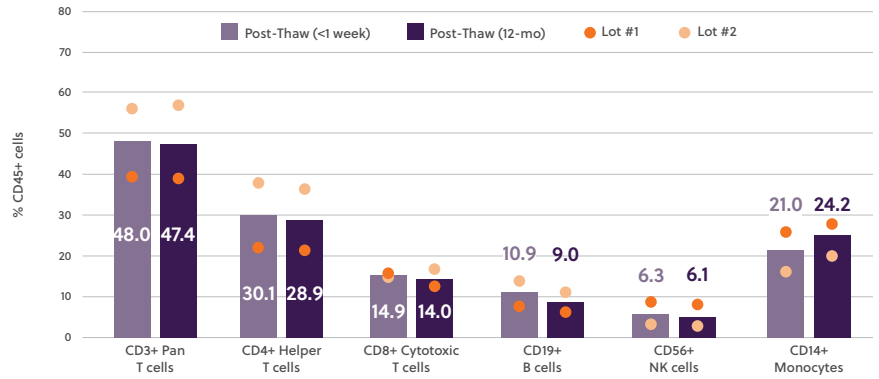
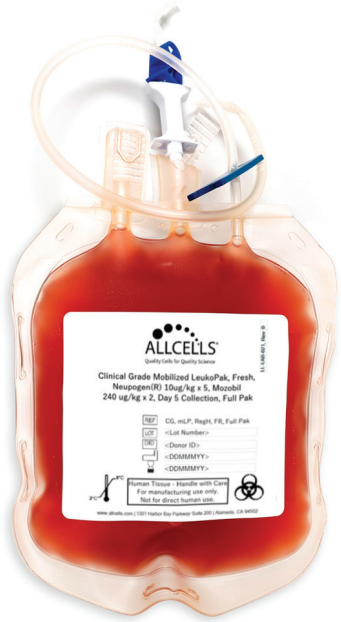


Fig 2c: Average Distribution of Immune Cell Subpopulations



Product Portfolio

GMP Mobilized Leukopak



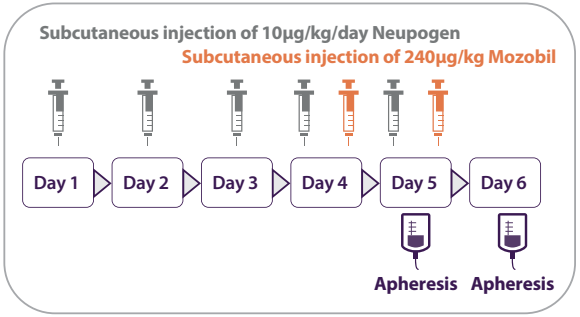
GMP Mobilized Leukopaks are collected from healthy, human donors using the Spectra Optia Apheresis System after the donors have been treated with FDA-approved drugs, Neupogen® and Mozobil®, to stimulate mobilization of CD34+ hematopoietic stem and progenitor cells from the bone marrow to the peripheral 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 RegH 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%

Regimen details:
Filgrastim (Neupogen) 10ug/kg/day x 5 days + Mozobil 240ug/kg/day x 2 days on day 4 and 5 (evenings), apheresis on day 5 and 6.

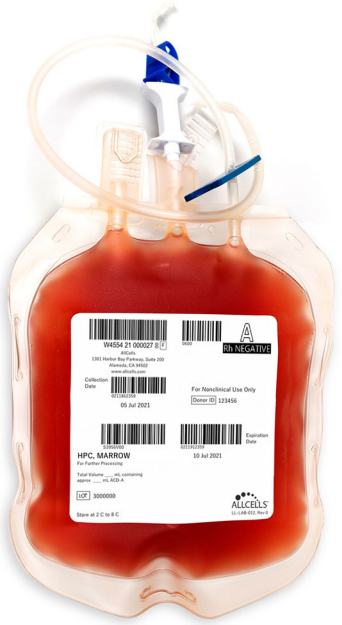


SPECIFICATIONS

- Mobilized Regimen: Neupogen x 5 days, + Mozobil x 2 days (RegH)
- Format: Fresh, 2 Paks
- Anticoagulant: ACD-A
- Fill Volume: ≥ 280mL per bag
- Viability: ≥ 90%
- Sterility: No growth after 14 days USP <71>
- Shipping Condition: 2 to 8°C in validated shipping container with temperature logger
- Documentation: Certificate of Analysis, Summary of Records

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, and total nucleated cell (TNC) concentration. Available in fresh format only.



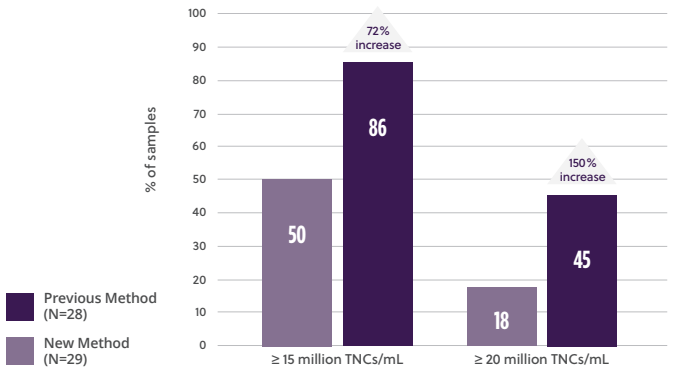
SPECIFICATIONS

- Anti-coagulant: Na Heparin or ACD-A
- Volume: 100mL
- Viability: ≥90%
- TNC Concentration (x10^6 cells/mL): ≥8
- Shipping: Validated shipping container

PROCESS IMPROVEMENT

AllCells has implemented a proprietary process change to improve our bone marrow aspiration protocol that delivers a higher viable TNCs and CD34+ yield from a single donor ensuring sufficient cells for your downstream workflow, minimizing experimental variability, compared to our previous protocol (Fig 4). Our new protocol shows a 72% increase in donor samples with more than 15 million TNCs/mL and a 150% increase in donor samples with more than 20 million TNCs/mL. Additionally, this method reduces cell contamination from red blood cells and granulocytes. Overall, these are attributed to a higher quality bone marrow aspirate product.

Fig 4: New Method vs. Previous Method Bone Marrow Aspiration



Serving the Full Continuum of CGT

FOR YOUR PRECLINICAL TO COMMERCIAL APPLICATIONS

AllCells maintains the same high quality material and stringent protocols for both RUO and GMP products for the full continuum of cell and gene therapy production. AllCells provides a seamless transition from research use only to GMP products with minimal variability.

	PRE-CLINICAL PHASE RESEARCH USE ONLY	CLINICAL PHASES I / II / III GMP MATERIAL	COMMERCIALIZATION GMP MATERIAL
Donor Assessment and Testing	Eligible donors are screened against HIV, Hepatitis B, and Hepatitis C.	Donors are subject to viral testing per FDA-mandated 21 CFR 1271 as well as CDC, NIH, and AABB recommendations. Donors also undergo a MD-administered physical exam.	
Donor Consent (IRB Approved)	For research use only.	For commercial and research use.	
Operational SOPs	Validated SOPs/e-batch records.	GMP operational SOPs and extensive batch records.	
Regulatory Compliance	Research Use Only	GMP/GTP, 21 CFR 1271 Parts A–C.	
Quality	E-documentation, product specifications based on process experience, certificate of analysis.	QMS-governed GMP documentation e.g. batch records, equipment validation, stability studies, to support product for further manipulation.	
Processing Facility	GMP-like collection and processing facilities.	Class A and B clean room.	
Packaging Protocol and Packaging	Commercial Grade	Packaging validated to ISTA standards including temperature logger.	
Sterility Testing	Bioburden Test (Cryo products only)	Sterility Test USP <71>	

Key Advantages

RELIABLE AND TRUSTED GMP SUPPLIER

With over 5 years of GMP expertise and over two decades in the industry, AllCells is your reliable and trusted supplier of high-quality GMP starting material.

ROBUST AND ASSURED SUPPLY CHAIN

AllCells' highly reliable, recallable, and dedicated GMP-qualified donor pool and geographically diverse facilities are designed for scalability.

INTEGRATED PROJECT MANAGEMENT

Our collaborative and dedicated GMP team of scientists, quality, donor and project management experts will customize your project, pulling from extensive experience and donor data.

99% GMP COLLECTIONS DELIVERABILITY

Mitigate the cost of failure with built-in risk reduction steps including infectious disease screening across various time points and parallel donors.

INTEGRATED ANALYTICAL SERVICES

- HudsonAlpha Discovery Sequencing + Bioinformatics
- Flow cytometry and cell sorting
- *In vitro* cell culture
- NGS, 10x library prep and single cell sequencing services

GMP Clean Room

FDA-registered,
AABB Compliance

Extended Virals

Competitive
Pricing

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 and GMP-qualified donor pool that is highly reliable, recallable, and characterized 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

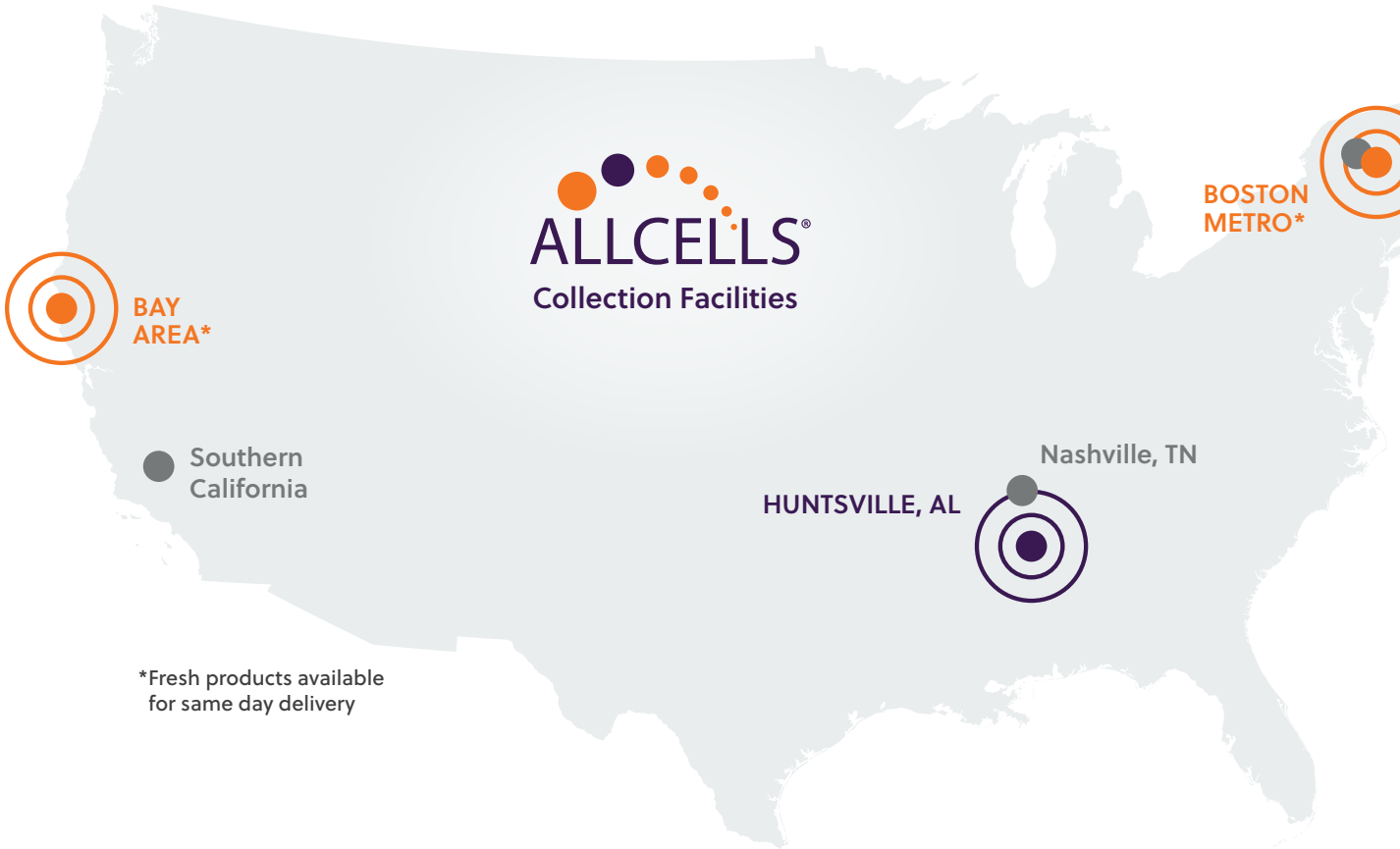
All collections are from donors who are qualified for participation in accordance with the IRB approved informed consents and meet AllCells' quality standards.

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.

- GMP and RUO products available
- RUO products available
- Coming soon



FDA registered, AABB-compliant facilities

Experienced technical and clinical team

Strict IRB compliance, regulatory oversight

Donors meeting FDA 21 CFR 1271 requirements

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