

Sanguine

Apheresis Portfolio

Single-donors, billions of white blood cells to advance research and therapeutic development from discovery to manufacturing

LeukoCore™

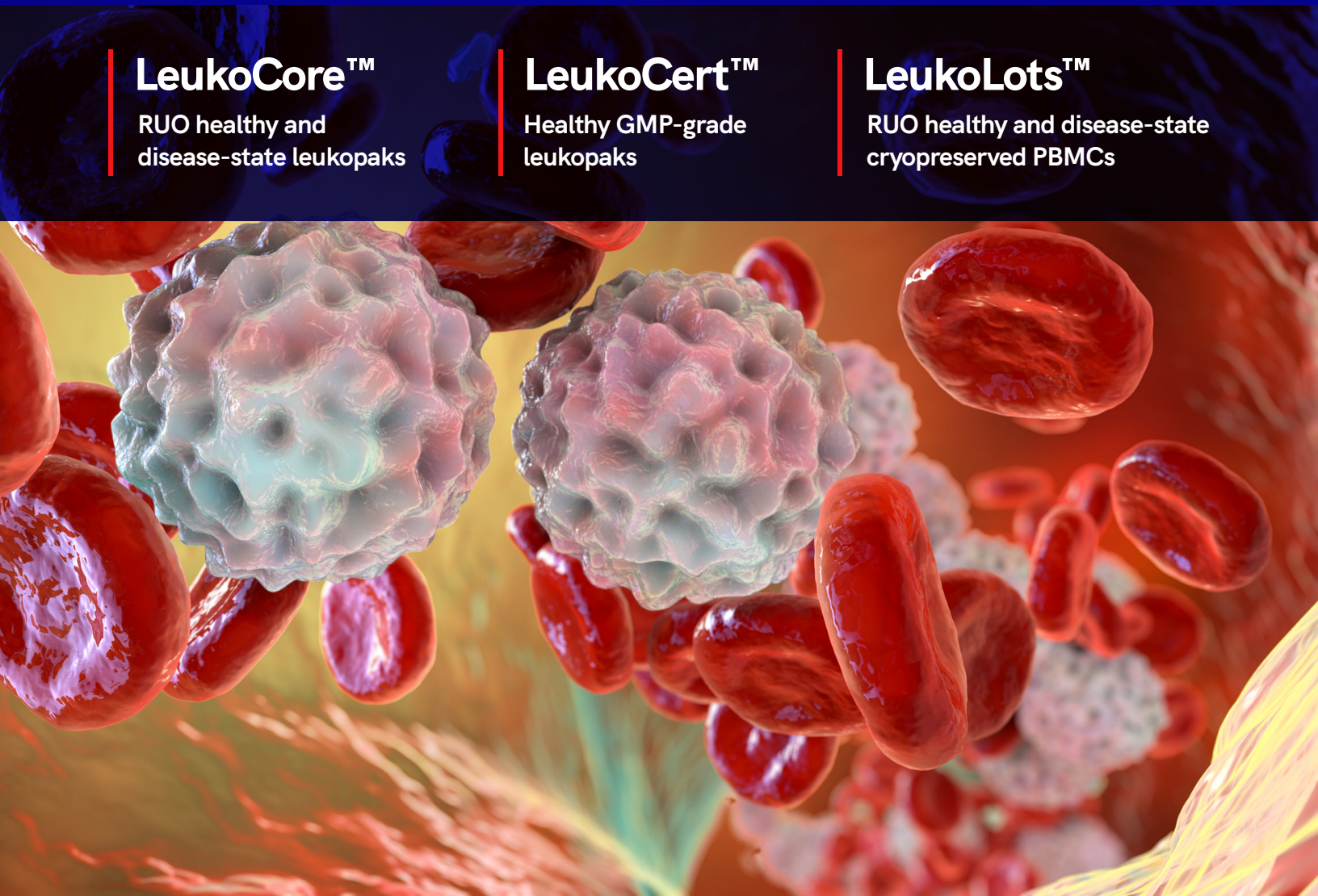
RUO healthy and disease-state leukopaks

LeukoCert™

Healthy GMP-grade leukopaks

LeukoLots™

RUO healthy and disease-state cryopreserved PBMCs



Billions of white blood cells from a single donor

A major challenge in developing therapeutics for many diseases is having the type, quality, and quantity of cells for your experiments. Apheresis products come from the extraction of the white blood cells (WBCs) from the peripheral blood, resulting in a high concentration of lymphocytes (T cells, B cells, NK cells), monocytes, and dendritic cells compared to whole blood. The advantage of large quantities of immune cells allows many more experiments from a single donor which removes variability and increases reproducibility. Further, with Sanguine, we can leverage our direct donor model for recallability.



Immunotherapy research



Biomarker discovery



Vaccine development



Functional assay development



Assay validation



Isolation of rare cell types



Process development



Cell therapy research

Sanguine recruits and screens donors from our network



Leukapheresis is performed at a Sanguine qualified clinic



Fresh or cryopreserved leukopaks are shipped directly to you



Samples may be further processed at our lab before shipping to you

Follow-up samples can be collected from recallable donors



HIPPA compliant

IRB approved

21 CFR Part 11 compliant

ISO certified

Learn more about Sanguine's commitment to quality and compliance



LeukoCore™

RUO Healthy and Disease-state Leukopaks

Sanguine provides fresh healthy and disease-state leukopaks delivered as fast as the same day and always within one day¹ post collection from our in-house apheresis center. Additionally, leukopaks are available cryopreserved, or further processed to provide aliquots of PBMCs, T, B, or NK cells.



Our Donor Network provides unique advantages for researchers to find the right donor for your needs:



Demographics (race/ethnicity, age, gender, height, weight)



Lifestyle (smoking, alcohol, drug usage)



HLA typing



Study Specific Questions



Recallability

Case Study: Recallability for fresh leukopaks



Background and Challenge:

A pharmaceutical company has a very specific responder assay where the cellular composition from some donors behaves much more robustly than others. They would ideally like multiple leukopaks from the same donor throughout the year.



Solution:

Our direct connection with our donor network provides a higher chance of recallability of the same donor. In addition, we do have the option of screening PBMCs from donors before selecting which donors to recall for apheresis for fresh leukopaks. The ability to screen and recall reduces the work and cost for our client.

¹ Within the continental United States

LeukoCore™

RUO Disease-state Leukopak

Biospecimens from Sanguine come directly from our own donor network. We have over 30 conditions approved for apheresis collection from our donor network of over 70K. Further as we work directly with our donors, we can provide comprehensive donor data - providing much more than just the leukopak:

- Electronic Medical Records (EMR) to gain insight into treatment history, lab results, and comorbidities
- Patient-reported outcomes to understand the individual's experience
- Surveys and questionnaires using an existing validated metric or built for your needs

Disease-state leukopak are available fresh or cryopreserved in full-or half-pack. We can leverage our donor network to find the exact donors that fit your research needs.



Case Study: Isolating rare cell type for therapeutic development



Background and Challenge:

Antiretroviral therapies (ART) for HIV have been a game changer for people with HIV; preventing transmission as they drastically reduce a person's viral load. ART however is not a cure and thus the goal to eradicate HIV is still vital. As many people living with HIV have such low levels of virus, HIV particles within the blood are quite rare.



Solution:

Leukopak from donors diagnosed with HIV provide significantly more PBMCs than a blood draw as a single leukopak is equivalent to about 100 standard blood draws. Sanguine was able to recruit 20 donors, providing the equivalent of 2000 blood draws with 20 leukopak for a pharma company focused on eradicating HIV. This high volume of cells allowed researchers to isolate latent HIV-infected cells necessary for their studies.

Case Study: Replicating the final product for process development



Background and Challenge:

CAR-T has proven to be an effective treatment for some blood cancers and is now being investigated with promising results in patients with certain autoimmune diseases. The manufacturing of these therapeutics involves significant process development as ultimately the leukopak from a patient will be manipulated and returned to the patient. Process development scientists need to establish parameters including cell expansion, genetic modification, and cryopreservation. Cells from healthy donors however behave differently and thus are not ideal for process development.



Solution:

Leukopak from donors with Crohn's Disease and multiple sclerosis (MS) were obtained for a cell and gene therapy company providing material for optimizing their process before clinical trials with the diseases they aim to treat. Disease-state leukopak for process development allowed the team to be more prepared for the final autologous therapy products.

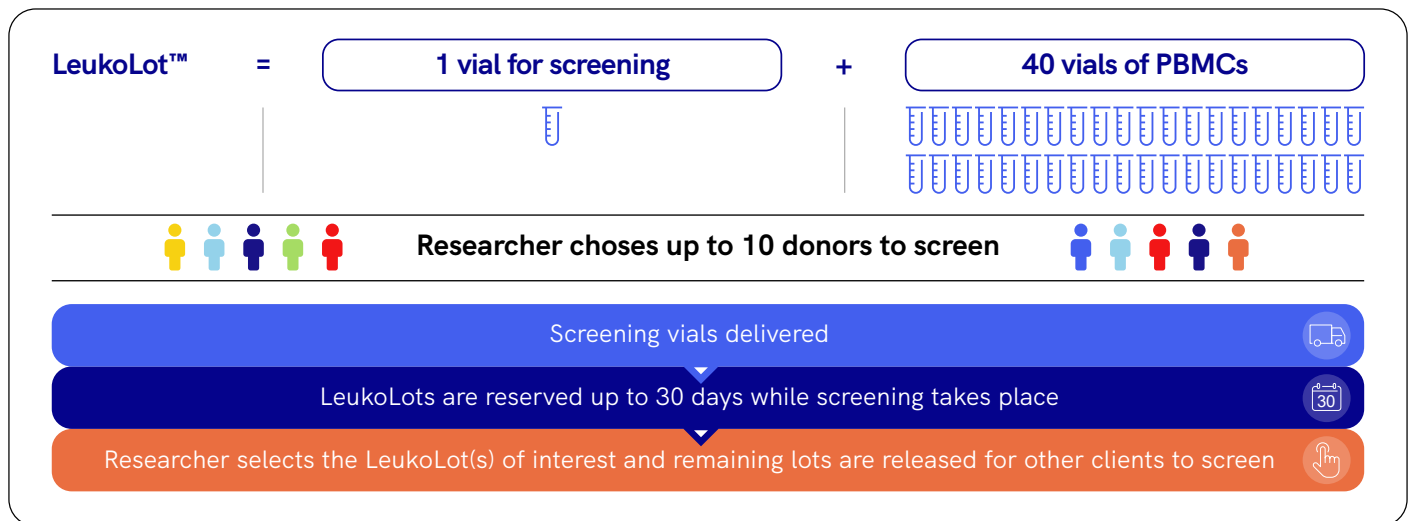
LeukoLot™

RUO Leukopak-derived PBMC Collections

A LeukoLot is a batch of PBMCs isolated from a leukopak, aliquoted, and then cryopreserved. Sanguine's LeukoLot offers distinct advantages for researchers:

- Isolated PBMCs may be more desirable for your research
- Aliquots of 100 million cells limits freeze-thaw cycles, thus maintaining viability and function
- Screening vials are available to screen multiple LeukoLots to identify the ideal donor(s) PBMC composition

General workflow for LeukoLot screening



Some common use cases for screening are identifying the donor with:

- A specific biomarker signature or level
- High quantities of a desired immune cell subtype
- Uncommon HLA alleles
- Response to a specific assay



Case Study: Functional cells in mouse model



Background and Challenge:

A group at a biomedical research organization is injecting human immune cells into immunodeficient mouse models. They adhere to strict quality control parameters and thus need to ensure the cells meet their specific requirements. In addition, each batch of cells may behave differently in their models so being able to test before committing to the lot offers a distinct advantage.



Solution:

LeukoLots allowed the team to do their own screening and functional testing before determining which LeukoLots best fit their needs. They now have a large supply of PBMCs that fit their exact criteria - saving time from additional screening and money by limiting the purchase of cells not ideal for their research efforts.

LeukoCert™

GMP Healthy Leukopaks

Sanguine's LeukoCert™ GMP-grade leukopaks are collected at our apheresis center from our Donor Network to fit your requirements for high-quality raw material for manufacturing cell-derived therapies. Fresh, healthy GMP leukopaks are available in full- and half-packs.

LeukoCert is more than the apheresis product:

- Donor demographics including height, weight, age, ethnicity, and medications
- 21 CFR Part 1271 Compliant Panel of infectious disease testing
- HLA-typing - targeted NGS HLA Class I/II
- Certificate of Analysis including ICCBBA ISBT 128 compliant and statement of conformity to FDA Title 21 CFR Part 1271 standards
- Dedicated project management to keep you informed at every stage of your project

Screen, Choose, and Reserve your Donor



Sanguine identifies donors

Sanguine has established criteria for indentifying reserved donors including success and interest in repeat apheresis collection as frequently as every 6 weeks



You choose your donor(s)

You screen as many RUO leukopaks from GMP-qualified donors as necessary to identify the right donor for your needs



Donor is reserved

Your donor(s) may only participate in your project until completion



GMP leukopaks collected

Collection from reserved donors takes place in the cadence established in the project plan

Sanguine's apheresis portfolio

	LeukoCore™	LeukoLot™	LeukoCert™
Donor Data	Height, weight, age, ethnicity, gender, smoking status, medications, EMR*	Height, weight, age, ethnicity, gender, smoking status, medications, EMR*	Height, weight, age, ethnicity, gender, smoking status, medications, HLA-typing (Class I/II)
Donor Type	Healthy and verified-conditions	Healthy and verified-conditions	Healthy
Sizes	Full pack (8 to 10 billion cells) Half pack (4 to 5 billion cells)	Full lot (40 vials) Half lot (20 vials)	Full pack (8 to 10 billion cells) Half pack (4 to 5 billion cells)
Fresh /Cryopreserved	Fresh and Cryopreserved	Cryopreserved	Fresh
Infectious Disease Testing	RUO Standard Panel: ABO/Rh blood type, HBsAg, HBcAb, Hep C Ab, HIV ½ plus O Ab, CMV	RUO Standard Panel: ABO/Rh blood type, HBsAg, HBcAb, Hep C Ab, HIV ½ plus O Ab, CMV	21 CFR Part 1271 Compliant Panel: RUO Standard + T. pallidum Ab, RBC Ab, HTLV-I/II, HIV/HCV/HBC NAT, WNV NAT, T. cruzi Ab

Deliverables with our apheresis products:



Donor demographics



Comprehensive medical records (disease-state only)



Infectious Disease Testing



HLA typing



Complete Blood Count



Certificate of Analysis*

Leverage our lab services for additional processing and analysis including



PBMC or further cell isolation



HLA typing and testing



Aliquoting



200+ additional CLIA-certified diagnostic tests

*available for select products

[Explore our apheresis portfolio and contact us to learn more](#)



Sanguine Biosciences strives to accelerate research and discovery by bridging the gap to obtaining biospecimens with a robust donor network. By directly engaging with donors, we can identify and collect the biospecimens necessary for advancing discovery. Our portfolio includes in-home prospective collections, apheresis product offerings, retrospective biospecimen collections, and a suite of biorepository services.

[Explore Sanguine Biosciences](#)



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