

HEMATOPOIETIC STEM & IMMUNE CELLS

HEMATOPOIETIC STEM & IMMUNE CELL — COLLECTIONS

iSpecimen’s proprietary Marketplace and its network of strategic partners enable researchers to gain access to the largest industry Donor pools which means more choices for selectable attributes (inclusion/exclusion criteria) and cell phenotypes suitable for your specific RUO application. Marketplace products include:

- **Whole Bone Marrow Aspirate**
- **Mononuclear Cell (MNCs) Leukapheresis**
- **Mobilized Mononuclear Cell (MMNCs) Leukapheresis**
- **Peripheral Whole Blood.**

Such tissues contain key hematopoietic and immune primary cell types which are pervasively used in:

- Autoimmune and infectious disease research
- Drug discovery
- Preclinical development (e.g. target identification & validation, predictive toxicology)
- Research and development of stem cell and immunotherapies (autologous & allogeneic)
- Diagnostic assays involving cell-based calibrators and controls
- Numerous other life science research applications.



All tissue collections are approved by a licensed Medical Director and Independent Review Board (IRB).

iSpecimen Marketplace includes qualified partners who provide high quality products, as defined by cell counts, percent cell viability, cellularity, validated packaging, and on-time delivery service. Researchers may also select Donor testing options shown in Table 1 (below) when submitting a **Request for Quote**. Tissue collections may include an option to obtain a flow cytometry report (see EXHIBIT B). Collection lead times are typically two weeks for non-mobilized leukapheresis collections, six weeks for mobilized leukapheresis collections, and three weeks for bone marrow, but lead times may vary depending on Donor Center, specificity of requested Donor characteristics, and collection criteria. Products can be shipped under cold or ambient conditions as requested, with an option to include a temperature logger.

Table 1

Serological Testing	ABO/Rh, Syphilis, Antibody Screen, Anti-CMV
Infectious Disease	Minimum Testing: Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV)
	Expanded Testing: 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, WNV Nucleic Acid Testing, Trypanosoma cruzi Antibody (Selective Chagas disease testing, a single lifetime test per donor)
	Active healthy Donors may be tested for the absence of infectious disease every 90 days, or more frequently depending on customer requirements e.g. prior to every scheduled tissue collection



BONE MARROW ASPIRATE (UNPROCESSED)

Whole Bone Marrow is aspirated via sterile needle from a Donor’s posterior iliac crests. An anticoagulated syringe (typically sodium heparin or other anticoagulant, as requested) is connected to the aspiration needle which is inserted through the bone multiple times to optimize total cell count and cellularity, collecting up to 100 ml of aspirate per Donor.

Recallable Donors are subject to repeat donation limits specified in the applicable bone marrow collection protocol. As an option, autologous blood may be collected from the same Donor on the same day of bone marrow collection.

PRODUCT	DETAILS
Fresh Whole Bone Marrow Aspirate, Healthy Donor	Typically >15 million cells/ml, up to 100 ml per Donor
Fresh Autologous Whole Blood (option for collection of whole blood concurrently with bone marrow collection)	up to 100 ml, collection into sample tubes or into a collection bag containing anticoagulant



NORMAL MONONUCLEAR (MNC) COLLECTION — LEUKAPHERESIS

Mononuclear cell samples are collected using automated blood cell collection systems (e.g. Terumo-BCT Spectra Optia[®] Apheresis system) following approved standard operating procedures.

During this procedure blood is removed from a vein in one arm and passed through a cell separator within the automated cell collection system enabling collection of white blood cells. The remainder of the blood is returned to the Donor via a needle placed in the other arm.

White blood cells are enriched during this process and suspended in plasma in which a small amount of red cells and platelets may also be captured. This process is known as “Leukapheresis” and the collected product is sometimes referred to as a “Leukopack”. MNC collections typically require 2-4 hours for completion.

PRODUCT	DETAILS
Fresh Normal Mononuclear Cell (MNC) Collection - Leukapheresis, Healthy Donor	Full Leukopack collection is typically >10 billion WBCs and volume of 300-500 ml depending upon Donor weight and other factors



G-CSF MOBILIZED MONONUCLEAR CELL (MNC) COLLECTION — LEUKOPHERESIS

A hematopoietic mobilizing agent, granulocyte colony stimulating factor (G-CSF, filgrastim/Neupogen), is administered to Donors on a daily basis according to the approved collection protocol (e.g. 5-10ug/kg by subcutaneous injection).

Once the desired daily dose has been administered, MNC collection will be performed. Mobilized MNC collections typically require 4-6 hours for completion.

As an option, researchers may request one additional collection; in such situations, specific consent for the additional collection is required and the collection is performed the day following the initial collection (i.e. second Day collection).

PRODUCT	COMMENTS
Fresh Mobilized Mononuclear Cell (MNC) Collection - Leukapheresis: Day 1, Day 2, Day 3, Day 4, Day 5, second Day collection available, Healthy Donor	For example, Day 1 full Leukopack collection is typically >50 billion WBCs, >98% cell viability, and volume of 300-500 ml depending upon Donor weight and other factors. Day 2 full Leukopack collections is typically >30 billion WBCs, >97% cell viability



WHOLE BLOOD COLLECTION

Whole blood is collected following approved standard operating procedures by performance of venipuncture of the Donor's antecubital vein or other peripheral vein and venous blood collected up to 500 ml into a blood collection bag or various tube types containing anticoagulant and/or preservative and some which may contain no anticoagulant and/or preservative.

PRODUCT	COMMENTS
Fresh Whole Blood, Healthy Donor	Blood bag or various tube types up to 500 ml per single Donor



DISEASED HEMATOLOGIC TISSUE COLLECTION

iSpecimen Marketplace provides hematologic tissue, Whole Blood or Bone Marrow Aspirate, from a wide variety of patient disease states such as:

- Solid tumors
- Liquid tumors
- Autoimmune
- And other diseases

Researchers can identify selectable attributes and Request for Quote. Diseased specimens are richly annotated and may include data such as patient demographics, diagnoses, medications, procedures, outcomes data, lab test results, pathology reports, family history, and social history.

EXHIBIT A: EXAMPLE OF GENERAL INCLUSION/EXCLUSION CRITERIA

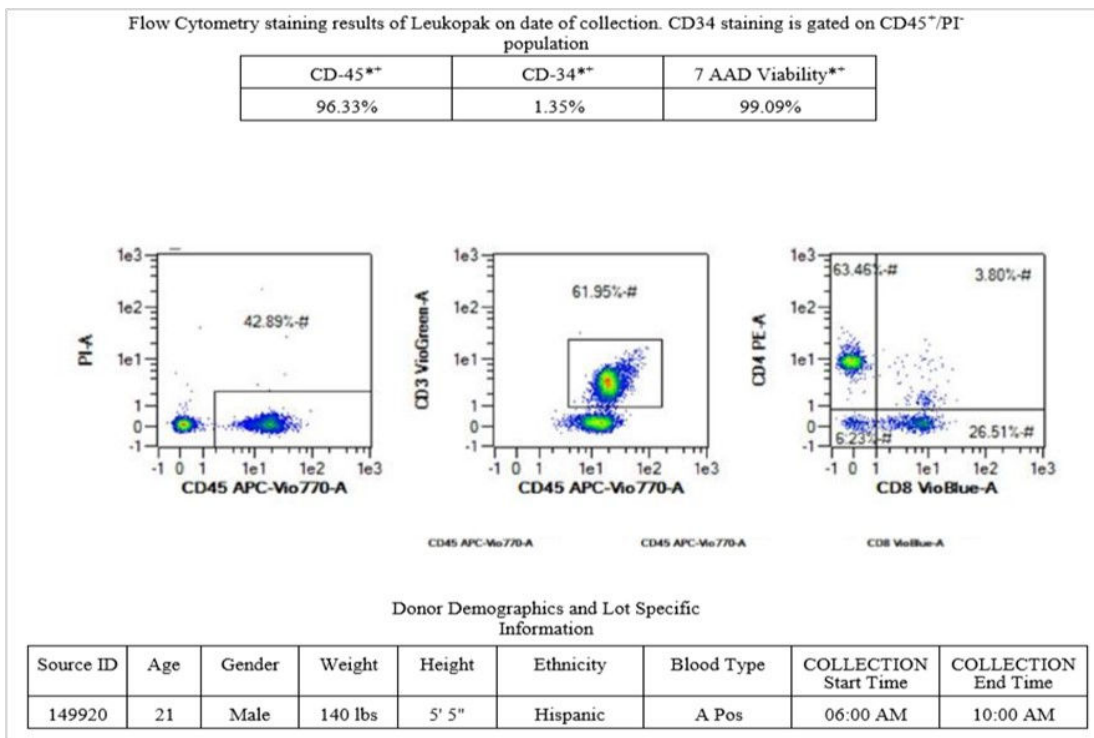
May vary between Donor Centers

Prescreening Questionnaire	For example..Have you traveled outside the US in the last 3 years, are you currently donating blood, plasma or platelets, have you ever had hepatitis or cancer, etc. Participants may be excluded based on responses that indicate risk factors for infectious disease or other health concerns
Age	18-75 years old for non-mobilized collections 18-65 years old for mobilized collections
Weight	> 110 pounds
Physical Screening	Pulse, temperature, and blood pressure
Hemoglobin	>12.5 g/dL (females), >13.0 g/dL (males)
Infectious Disease Screening	Negative for Human immunodeficiency virus (HIV), Hepatitis C virus (HCV), Hepatitis B virus (HCB), Human T-lymphotropic virus (HTLV) types I and II, syphilis, and other infectious disease testing as needed
Donation Frequency	Non-mobilized Leukopaks, Healthy Donor – every 5 weeks Mobilized Leukopaks, Healthy Donor – maximum of 2 donations >6 months apart Bone Marrow, Healthy Donor – maximum of 3 donations >3 months apart Whole Blood, Healthy Donor > 100 mL – every 8 weeks Whole Blood, Disease-state Donor < 50 mL – every 8 weeks
Healthy Donor Exclusions	Cancer, pregnancy, and any history of blood and bleeding disorders
Vulnerable Populations Excluded	Pregnant or breastfeeding women, prisoners, children, or people with diminished capacity

Note: In addition to the general inclusion/exclusion criteria listed above, each collection procedure (e.g., bone marrow, whole blood, MMNC, etc.) has a specific set of inclusion and exclusion criteria.

EXHIBIT B: MOBILIZED MONONUCLEAR CELLS (MNC) LEUKAPHERESIS FLOW REPORT

Tissue collections may include an option to obtain a flow cytometry report. Fresh Donor collections always involve primary and back-up donors at no additional fee to ensure tissue collections are completed and delivered on time.



The iSpecimen Marketplace Difference

iSpecimen's growing network of strategic partnerships enable access to numerous Donor Centers and clinical collection sites covering both healthy and diseased hematologic tissue.

Search by product types and **refine** your search by selecting an assortment of Donor attributes:

- Age
- Gender
- BMI
- HLA
- Blood types
- Race
- Ethnicity
- Etc.

Marketplace users can specify exclusion criteria and submit a Quote Request.

Compared with any single hematologic product supplier, Marketplace provides increased access to:

- A larger total eligible Donor pool
- Increased diversity of Donor phenotypes
- A broader selection of customizable Donor attributes

Effectively expand your ability to obtain the best possible cell phenotype(s) for a specific research application.

[Request a Quote](#) | [Search the Marketplace](#) | [Contact Us](#)