Quality Counts:

Expertise-driven, high-yield cell collections for leukopaks

Key highlights:

- Overview of cell counts from leukapheresis collections
- Versiti leukopak: flow cytometry example

Executive Summary:

Versiti leukopak products are collected following formal quality systems that result in reduced variability and risk.

Versiti's expertise in donor management, product characterization, flow cytometry, and dedicated quality and regulatory expertise helps to ensure your projects progress smoothly throughout the duration of your research.

Leukopak Overview

Leukopaks are a rich source of white blood cells that provide a higher mononuclear cell count (MNC) and higher purity than white cells collected from whole blood donations. Leukopaks are the starting material of choice for cell therapy applications and manufacturing.

Leukopak products are collected via a leukapheresis procedure, the process of extracting white blood cells from the peripheral blood using an apheresis machine. The remaining blood components are returned to the donor.

Leukopaks can be fresh or cryopreserved, sourced from healthy donors or those with specific disease states. Products may be either non-mobilized or mobilized (stimulated mobilization of CD34+ cells). Leukopaks can be used in research, cell-based assays, cell therapy process development, and drug development and manufacturing. Versiti provides two tiers of leukopak products: research-use only (RUO), useful in discovery and pre-clinical phases; and clinical grade (FDA 21 CFR 1271 compliant), to support manufacturing in clinical phase trials and commercialization.

Cell Counts from Leukapheresis Collections

Leukopak products vary in cell counts due to several reasons, including execution of the leukapheresis collection process and system utilized, donor characteristics, and whether the donor was able to provide the required blood volume to process the total number of cells required by the research protocol.

The leukopak collection process uses one single donor per leukopak product collected. The volume of white blood cells in a single leukopak allows the researcher to perform necessary assays, validation and quality assurance.

As with any human-derived starting material, innate variability exists in leukapheresis collections donor-to-donor, and even collection-to-collection from the same donor. Each donor's cell characteristics and quantification may impact the types of cells collected during leukapheresis. To maximize cell quality or quantity, a commitment to staff education and robust training on leukapheresis procedures and donor management is essential.

Dedicated resources and training provided to staff on leukapheresis protocols and cell therapy collections increases collection efficiency to meet cell yield requirements for the researcher, as well as provides for a positive donor experience. Protocols should be developed to assist with streamlining the collection process for both the researcher and donor.

A comprehensive donor management strategy is needed to support a research project or study. Identifying, recruiting, screening and managing donors is integral to collecting leukopak products. Managing the health of a donor is important to prevent fatigue and reduced cell counts. To mitigate donor challenges and help ensure consistency in production, having committed, recallable donors assigned to a specific project ensures a consistent yield of cells to keep the progress running smoothly throughout the duration of research. Adhering to stringent donor criteria, operating under an IRB-approved protocol ensures a safe leukapheresis procedure for the donor.

Versiti Leukopak Cell Counts - Quality Matters

Versiti leukopak products are collected following formal quality systems that result in reduced variability and risk to help ensure your projects progress smoothly throughout the duration of your research.

The expected total nucleated cell count (TNC) of a whole Versiti leukopak product is 10-12 billion cells. The leukopaks contain high concentrations of monocytes and lymphocytes, as well as low concentrations of neutrophils. Leukopaks are collected at Versiti's FDA-registered collection center from IRB-consented, healthy human donors by leukapheresis using the Spectra Optia Apheresis System under approved SOPs in accordance with all applicable federal and state regulations.

Every clinical-grade product release is subject to review by an independent quality assurance representative and approval of the batch record. A certificate of analysis (COA) is provided with each product.

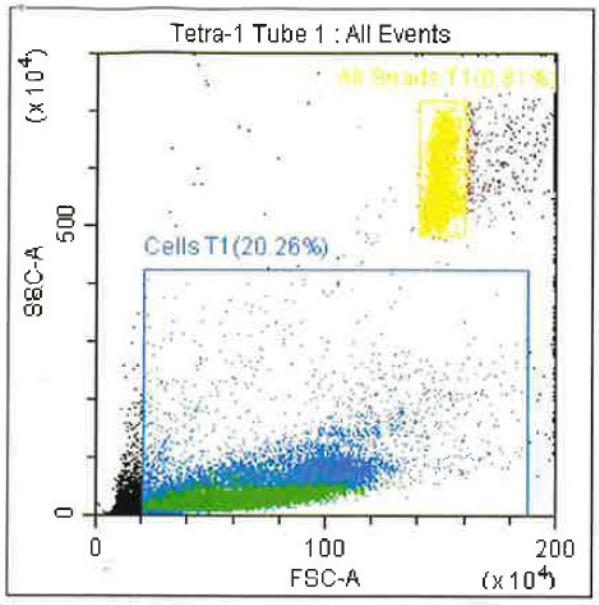
Versiti Leukopak Cell Count Example Using Flow Cytometry

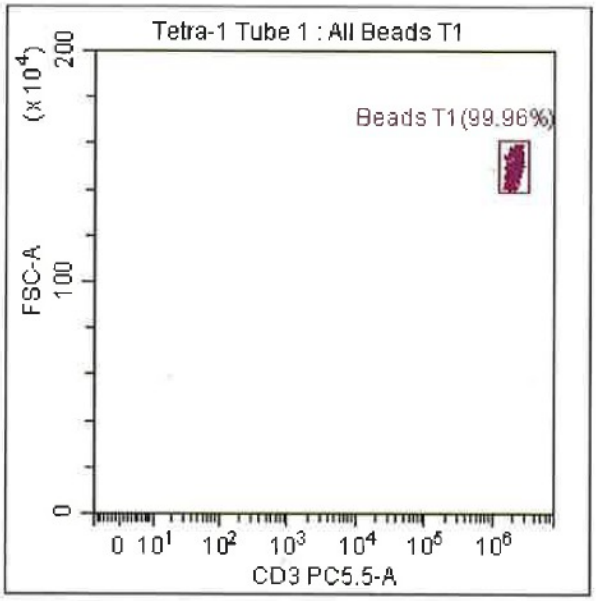
The data and charts below represent a sample breakdown of expected cell type and mix counts of a Versiti leukopak product using flow cytometry. Product flow cytometry results are investigational-use only and are not to be used for diagnostic or clinical purposes.

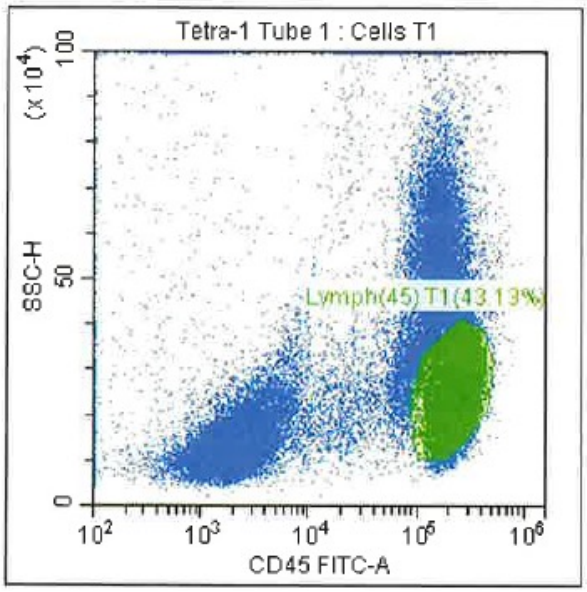
This product was collected under an IRB-approved protocol, as per 45 CFR 46 and 21 CFR 50 and 56, for use in research and further manufacturing. Testing of the product was in accordance with 42 CFR 493.

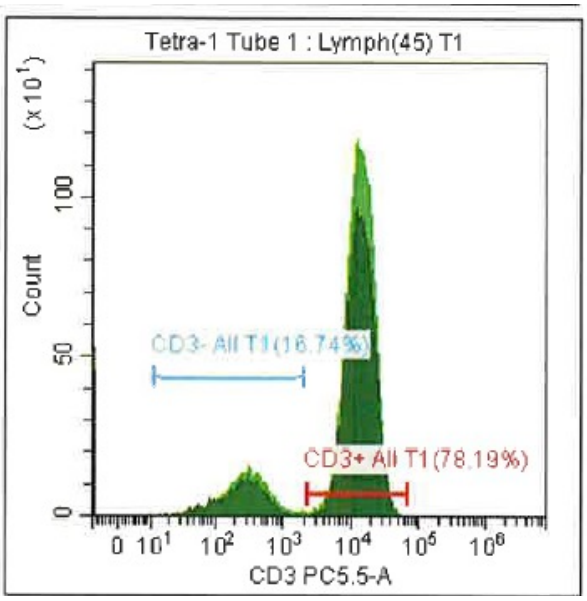
CELL TYPE	CELL MIX PERCENTAGE
CD3%	78.19%
CD4%	41.18%
CD8%	37.27%
NK Cells	14.59%
CD19%	4.88%

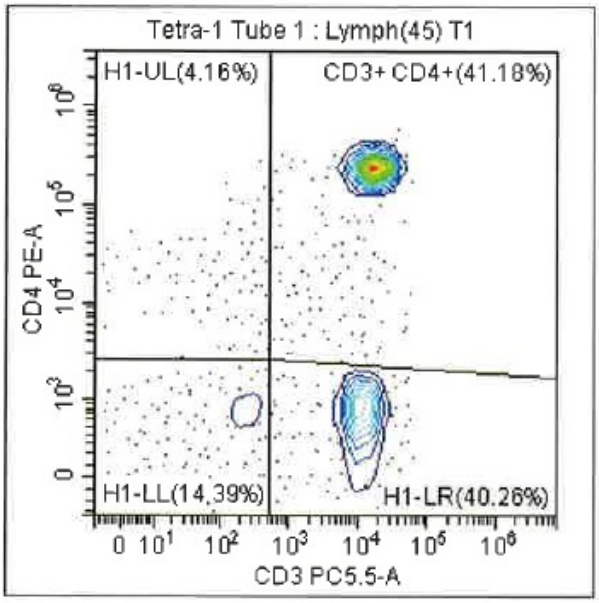
Histograms:

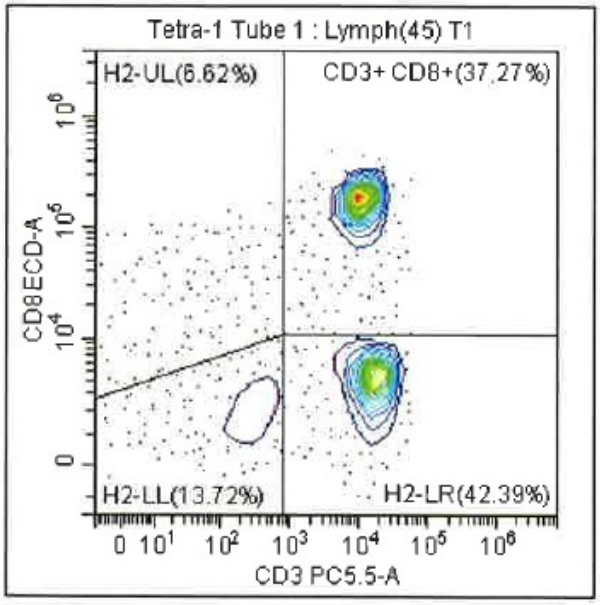


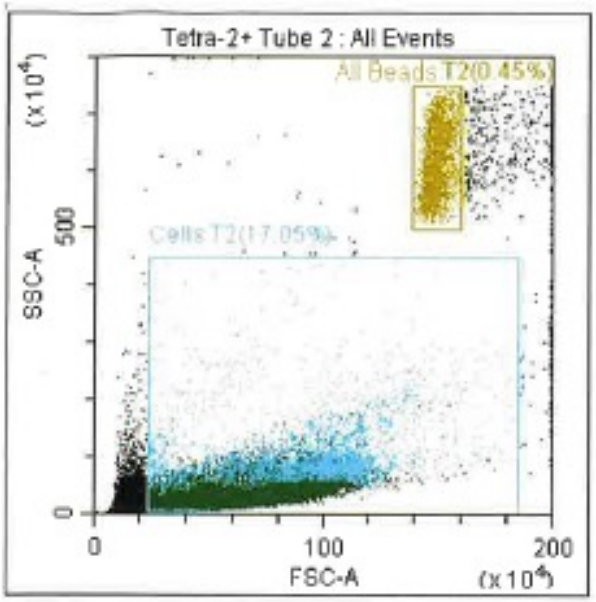


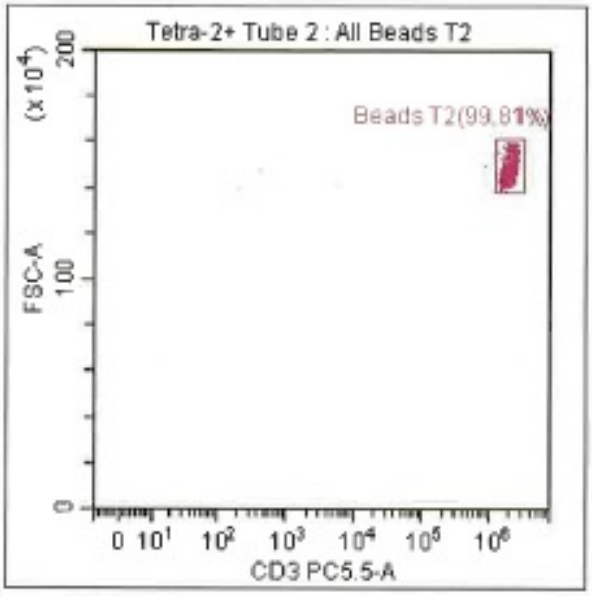


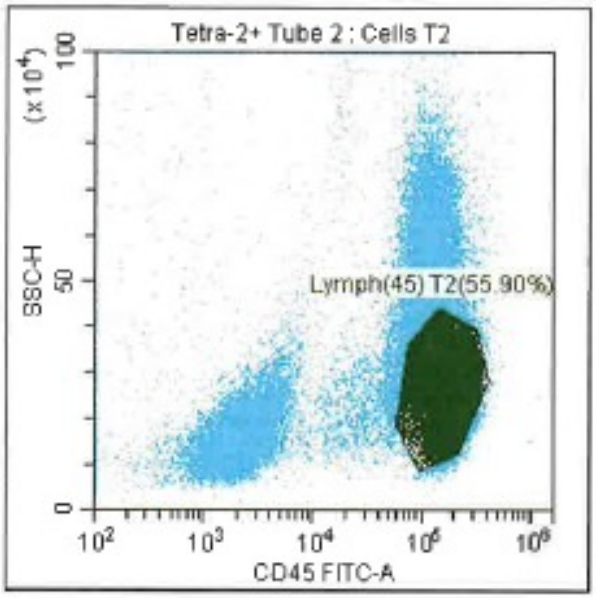


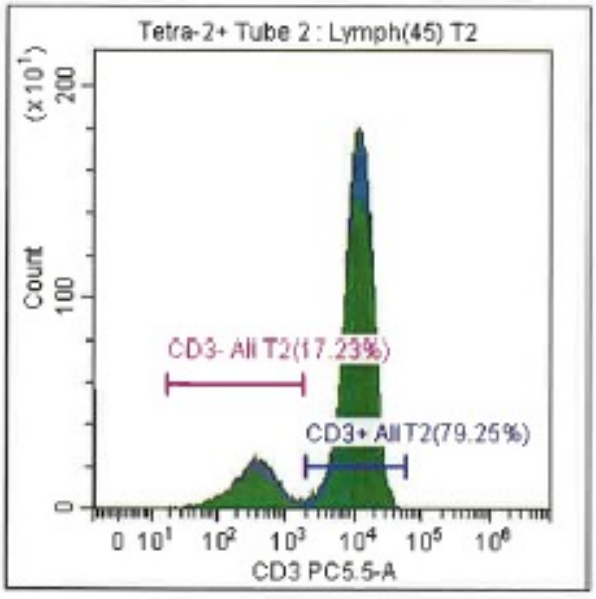

Tetra-1 Tube 1 : Lymph(45) T1
H1-UL(4.16%)
CD3+ CD4+(41.18%)
H1-LL(14.39%)
H1-LR(40.26%)
CD4 PE-A
CD3 PC5.5-A

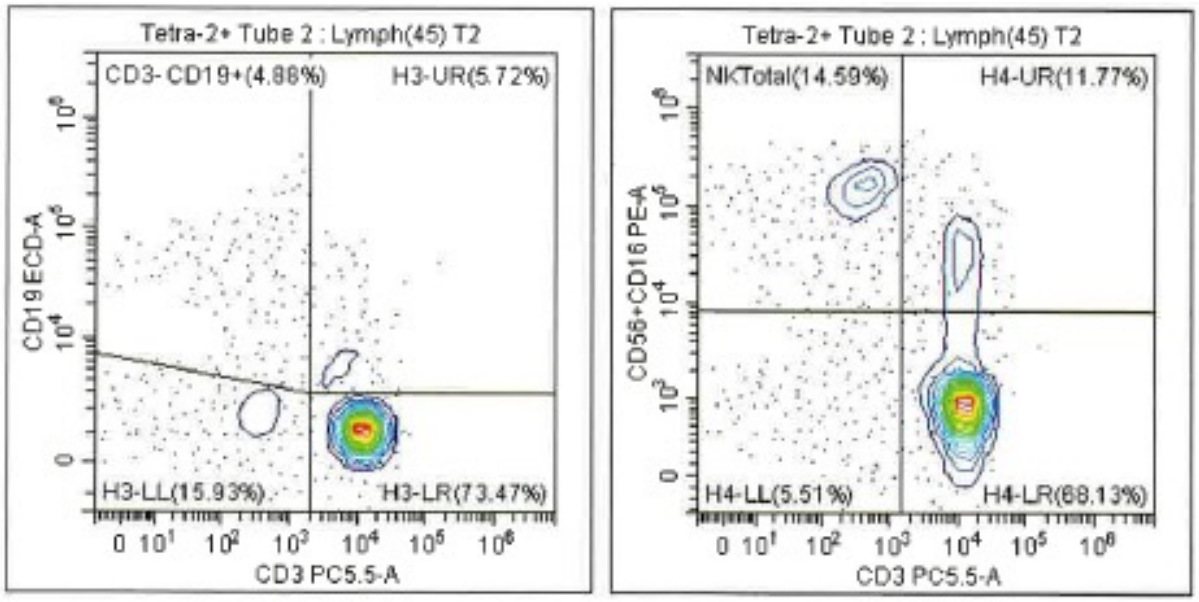

Tetra-1 Tube 1 : Lymph(45) T1
H2-UL(6.62%)
CD3+ CD8+(37.27%)
H2-LL(13.72%)
H2-LR(42.39%)
CD8ECD-A
CD3 PC5.5-A


Tetra-2+ Tube 2 : All Events
All Beads T2(0.45%)
Cells T2(17.05%)
SSC-A
FSC-A


Tetra-2+ Tube 2 : All Beads T2
Beads T2(99.81%)
FSC-A
CD3 PC5.5-A


Tetra-2+ Tube 2 : Cells T2
Lymph(45) T2(55.90%)
SSC-H
CD45 FITC-A


Tetra-2+ Tube 2 : Lymph(45) T2
CD3- All T2(17.23%)
CD3+ All T2(79.25%)
Count
CD3 PC5.5-A



Summary

Having a partner like Versiti, with expertise not only in leukapheresis procedures, donor management and flow cytometry testing, but also robust and dedicated quality and regulatory expertise, helps to ensure your projects progress smoothly throughout the duration of your research.

Leukopaks are collected at Versiti's FDA-registered collection center from IRB-consented, healthy human donors by leukapheresis using the Spectra Optia Apheresis System. The expected total nucleated cell count (TNC) is 10-12 billion cells.

Leukopak products are collected following formal quality systems that result in reduced variability and risk. Every clinical-grade product release is subject to review by an independent quality assurance representative and approval of the batch record. A certificate of analysis (COA) is provided with each product.

versiti™