

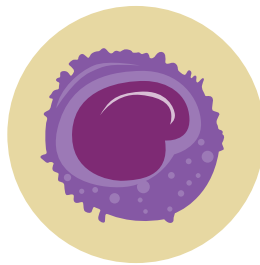
LeukoPak®

Peripheral Blood Mononuclear Cells (PBMC)

Versiti's peripheral blood mononuclear cell (PBMC) product is an enriched leukapheresis product composed of high concentrations of monocytes and lymphocytes, but may also contain lower concentrations of platelets, plasma and red cells.

LeukoPaks® are sourced from individual donors and are separated from other blood components by an apheresis procedure.

LeukoPaks are an effective, large-scale replacement for buffy coat material isolated from whole blood, and can be used directly as source material in standard methods for enrichment of specific lymphocyte cell populations. LeukoPak® products are available with or without G-CSF mobilization to meet your specific cellular therapy or research needs.



Quality Assurance

PBMC products are collected in Versiti's FDA-registered collection centers following SOPs and formal quality systems that result in reduced variability and risk. PBMCs are collected from a single IRB-consented contributor by leukapheresis using the Spectra Optia Apheresis System continuous mononuclear cell (CMNC) collection procedure. Contributor eligibility is established prior to PBMC collection. A general health assessment, testing for infectious disease and additional characterization tests are performed to determine eligibility. Contributors may be mobilized with filgrastim prior to collection to increase the total nucleated cell (TNC) count yield in final product. Every PBMC product release is subject to an independent quality assurance representative's review and approval of the batch record.

Product Criteria

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| Standard Blood Volume Processed | ~8-12 Liters Standard operating procedure is two blood volumes from a healthy contributor. |
| Expected Total Nuclear Cell (TNC) Count | ~10-15B TNC Product TNC yield may vary, depending on individual contributors. |
| Standard Infectious Disease Screening | CMV Antibody, Hepatitis B Surface Antigen, Hepatitis C Core Antibody, Hepatitis C Virus Antibody, HIV Antibody, Human T-Lymphotropic Virus, Trypanasoma cruzi Antibody (Chagas), West Nile Virus (WNV), Zika Virus |
| Collection Quality Assurance | LeukoPaks® are collected at Versiti's FDA-registered collection center from IRB-consented healthy human donors by leukapheresis CMNC collection protocol in ACD-A anticoagulant. |

Additional screening or characterization is available upon request to meet your unique project needs. Visit [Versiti.org/biomaterials](https://www.versiti.org/biomaterials) to learn more.

For more information contact:

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