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Clinical Grade Non-Transfusable, Fresh

Peripheral Blood Mobilized Leukopak®, G-CSF

Catalog#			
	cMLE3GCSF4	3-Day Injection	Apheresis Day 4
	cMLE3GCSF5	3-Day Injection	Apheresis Day 5
	cMLE4GCSF5	4-Day Injection	Apheresis Day 5
	cMLE4GCSF6	4-Day Injection	Apheresis Day 6
	cMLE5GCSF6	5-Day Injection	Apheresis Day 6
	cMLE5GCSF7	5-Day Injection	Apheresis Day 7

Clinical Products

StemExpress offers clinically transfusable and clinically non-transfusable products. The collection of these products are the same but the approval process to receive clinically transfusable products requires additional steps. StemExpress processes are in place to only allow shipment of Clinical Grade Transfusable products to companies that have protocols with documented FDA (or relatable international agency) approval. These products will not be used to treat or be transfused to any patients without the associated FDA (or relatable international agency) approved IND and IRB approval.

Product Description

Clinical Grade Non-Transfusable Peripheral Blood Mobilized Leukopaks® are collected using the Spectra Optia® Apheresis System, an FDA approved closed, continuous-flow apheresis system, from healthy donors. Mobilized Leukopaks are from donors that are injected with 10µg/kg/day Granulocyte-Colony Stimulating Factor (G-CSF). Collection occurs on day 4, 5, 6, or 7-post injection.

Human tissue collection protocols are approved by StemExpress' Medical Review Board and Independent Review Board (IRB) in accordance with FDA CFR 21 Part 50 and 56.

Sample Collection and Processing

Mobilized Leukopaks are collected using aseptic techniques with FDA approved clinical grade reagents and components that are manufactured and controlled under an ISO 13485 certified quality system.

Infectious disease testing for HIV, HBV, and HCV is performed on a sample of donor blood. Only samples with negative results within 90 days of collection are shipped. All testing is performed by a CLIA-certified lab.

Format

All Leukopaks are stored in sterile bags containg the anticoagulant ACD-A and shipped in a 2-8°C validated shipper.

Storage

Fresh products should be used or processed immediately upon receipt. The warranty only covers items whose specifications are tested at the time they are received.

Cell Counting Instructions

Important: This cell viability/counting step is required to ensure the quantity of cells provided. Be sure to count the cells before washing. Be aware that cell loss is expected and may be up to 30% during wash steps. Recovery rates vary depending on technique.

Materials

- Cleaned hemocytometer
- Trypan Blue

Protocol

1. Prepare an appropriate dilution of a well-mixed cell suspension from the Leukopak using PBS. We recommend starting with a 100-fold dilution.
2. Make a 1-in-2 dilution with 20µl each of well-mixed cell suspension and Trypan Blue.
3. Make a 1-in-2 dilution with 20 µL each of well-mixed cell suspension and Trypan Blue.
4. Load one side of the hemocytometer, being careful not to over- or under-fill the chamber.
5. Count viable (clear, round, bright) and non-viable (blue, irregular shape, dull) cells in the four corner squares. Adjust your dilution if there are more than 100 cells/square.
6. Determine the number of total viable cells in the original sample. One square is equal to 100 nL.

   Viability = live cells/all cells
   Cell Concentration = Mean cells/square × Dilution Factor × 104
   Total Cell Count = Cell Concentration × Starting Volume
   Total Viable Cell Count = Total Cell Count × Viability

Warning

This product contains human tissue or other biological material and MUST be handled at Biosafety Level 2 or higher. All biological products should be treated as potentially infectious or contaminated material, even if infectious disease screening reports are negative. Follow universal precautions and wear appropriate personal protective equipment.

Product Warranty

For our product warranty, please review our Terms and Conditions at stemexpress.com/terms-and-conditions/.

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THE PURITY, VIABILITY & QUALITY YOU NEED™