800 Hudson Way, Suite 1700
Huntsville, AL 35806
Phone: (866)838-2798
Email: premiersupport@dls.com
Web: www.dls.com

Donation ID Number	Donor ID Number	Date of Donor Prescreening	Date of Product Collection
Data Recorded by:			
Date:			

GMP Discovery Leukopak™ Certificate of Analysis

Product Information

Leukopak derived from peripheral blood collected from a healthy, IRB-approved volunteer donor suitable for use in GMP manufacturing.

Donor screening and eligibility testing was performed in accordance with 21 CFR Part 1271 and FDA Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps), 2021.

All aspects of product collection and handling were performed under DLS ISO 13485-compliant quality system and under CRF part 1271 regulations. DLS is an FDA-registered Tissue Establishment (registration # 3015189545).

Instruction

Upon arrival, use as soon as possible or transfer for long-term cryostorage at temperature below -140C. Liquid nitrogen vapor phase is recommended.

Safety

All human-derived materials should be considered potentially infectious. Universal Precautions (PPE) for preventing transmission of bloodborne infections should be used at all times when handling biological samples. Handle with care.

Donor Information from date of collection

Age (Years)	Sex at Birth	Race	Weight (lbs.)	Height (in.)	Tobacco History	Alcohol History	Blood Type
Data Recorded by:							
Date:							

Collection Information

Nurse performing collection procedure:	
Collection Start Date:	Time:
Collection End Date:	Time:
Data Recorded by:	
Date:	

DISCOVERY LIFE SCIENCES GMP

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Donor Testing at Pre-screen

Donor pre-screen testing was completed within one week of apheresis collection at Huntsville Hospital a CLIA accredited contract laboratory (CLIA ID#: 01D0303123) in Huntsville, AL.

Donor Pre-screening DIN:	Donor Pre-screening Date:
Hepatitis B Core Antibody (Anti-HBc EIA)	Negative/Non-Reactive
Hepatitis B Surface Antigen (HBsAg EIA)	Negative/Non-Reactive
Hepatitis C Virus Antibody (Anti-HCV EIA)	Negative/Non-Reactive
Human Immunodeficiency Virus Antibody (HIV 1/2)	Negative/Non-Reactive
Human T-Lymphotropic Virus Antibody (HTLV-I/II)	Negative/Non-Reactive
HIV-1/HCV/HBV Nucleic Acid Testing	Negative/Non-Reactive
WNV Nucleic Acid Testing	Negative/Non-Reactive
Zika Virus, PCR	Negative/Non-Reactive
Trypanosoma cruzi Antibody	Negative/Non-Reactive
Syphilis Antibody	Negative/Non-Reactive
Indirect Agglutination Test	Negative/Non-Reactive
CMV Antibody, IgG	
CMV Antibody, IgM	
Data Recorded by:	
Date:	

Initial Product Testing

Initial product testing was performed using a Nexcelom Cellometer.

Measurement	Acceptance Criteria	Result	
Total Nucleated Cells	For Information Only		x 10^9 Cells
Viability	For Information Only		%
Volume	For Information Only		mL
Data Recorded by:			
Date:			

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Hematological Analysis of Apheresis Material
Hematology analyzer data was obtained using a Sysmex XN350 hematology analyzer.

Measurement	Acceptable Range	Count	Percent
Total Nucleated Cells	For information only	xxx x 10^3 / µL	N/A
Total Neutrophil	For information only	xxx x 10^3 / µL	xxx %
Total Lymphocyte	For information only	xxx x 10^3 / µL	xxx %
Total Monocyte Count	For information only	xxx x 10^3 / µL	xxx %
RBC	For information only	xxx x 10^6 / µL	N/A
HgB	For information only	xxx g/dL	N/A
HCT	For information only	N/A	xxx %
MCHC	For information only	g/dL	N/A
Total Platelet Count	For information only	xxx x10^3 / µL	N/A
Data Recorded by:			
Date:			

Flow Cytometric Analysis of Apheresis Material
Flow cytometry was performed on apheresis material on a Miltenyi MACSQuant Analyzer 16.

Antibody	Acceptance Criteria	Result
CD45+	For information only	
CD14+	For information only	
CD19+	For information only	
CD56+CD3-	For information only	
CD3+	For information only	
CD3+CD4+	For information only	
CD3+CD8+	For information only	
Data Recorded by:		
Date:		

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Data Recorded by:			
Date:			

Review Released by

Name (Printed) and title:	
Signature:	
Date:	