800 Hudson Way, Suite 1303
Huntsville, AL 35806
Phone: (866) 838-2798
Web: www.dls.com

GMP Discovery Fresh Leukopak™ Certificate of Analysis

Product Code	xxxxxxx	**Donation ID Number**	xxxxxxx
Product Name	Discovery Fresh Leukopak™	**Donor ID Number**	xxxxxxx
Manufacture Date	mm/dd/yyyy	**Shipping Date**	mm/dd/yyyy
Manufacturing End Time	hh:mm CST/CDT	**Shipping Time**	hh:mm CST/CDT

Product Description
Unmobilized human apheresis product for manufacture or administration. This product was collected in compliance with FDA good tissue practices requirements and is suitable for use in GMP manufacturing of cell or gene therapy product(s).

Product Source
This product was obtained from a healthy donor under IRB approved donor consent from Discovery Life Sciences' Discovery Donor Clinic. Apheresis material was collected on a Spectra Optia Apheresis System under approved DLS SOPs and in compliance with all applicable FDA and state guidelines and regulations. Donors met all eligibility requirements as defined by the FDA.

Instruction
Upon arrival, either prepare cells for long term frozen storage in liquid nitrogen vapor phase or use immediately.

Safety
All human-derived materials should be considered potentially infectious. Universal Precautions for preventing transmission of bloodborne infections should be observed when handling. Handle with care. In case of emergency, please contact premiersupport@dls.com.

Donor Information from date of collection

Age (Years)	Gender	Ethnicity	Weight (lbs.)	Height (in.)	Smoking Status	Alcohol Use	Blood Type
Data Recorded by:			Date:				

Product Information
Cell count and viability measurements were performed on a Nexcelom Cellometer with AOPI staining

Measurement	Acceptable Range	Result
Total Cell Count	≥ 9.5 billion cells	Pass
Viability Percentage	≥ 90%	Pass
Volume	For information only	xxx mL
Data Recorded by:	Date:	

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Collection Information

Serial Number of Spectra Optia used for collection: _____
Collection Start Time and Date: _____
Collection End Time and Date: _____
Data Recorded by: Date:

Supplies Used for Collection

Supply	Manufacturer	Lot Number	Expiration Date
Saline (0.9% NaCl)	Baxter		
Saline (0.9% NaCl)	Baxter		
ACD-A Anticoagulant (750mL)	Terumo BCT		
ACD-A Anticoagulant (500mL)	Baxter		
Apheresis Kit	Terumo BCT		
Data Recorded by:		Date:	

Donor Testing at Pre-screen

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

Donor Pre-screening DIN: _____	Donor Pre-screening Date: _____
Hepatitis B Core Antibody (Anti-HBc EIA)	Negative or Non-reactive
Hepatitis B Surface Antigen (HBsAg EIA)	Negative or Non-reactive
Hepatitis C Virus Antibody (Anti-HCV EIA)	Negative or Non-reactive
Human Immunodeficiency Virus Antibody (HIV 1/2)	Negative or Non-reactive
Human T-Lymphotropic Virus Antibody (HTLV-I/II)	Negative or Non-reactive
HIV-1/HCV/HBV Nucleic Acid Testing	Negative or Non-reactive
WNV Nucleic Acid Testing	Negative or Non-reactive
Trypanosoma cruzi Antibody	Negative or Non-reactive
Syphilis Antibody	Negative or Non-reactive
Data Recorded by:	Date:

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Hematology Analysis of Apheresis Material

Hematology analyzer data was obtained using a Sysmex XN350 hematology analyzer.

Measurement	Acceptable Range	Count	Percent
Total mononuclear cells	≥ 9.5 x 10^9 cells	xxx x 10^3 / µL	xxx %
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:	

Report Compiled by

Name (Printed) and title:	
Signature:	
Date:	

Report Released by

Name (Printed) and title:	
Signature:	
Date:	