

Certificate of Analysis



Product Information

Catalog ID	Product Name	Size	Unit Volume	Vessel
PB001F-1	Fresh HemaPrime™ Leukopak	Full Collection	309 mL	Bag

Donation Identification Number (DIN)	Collection Date	Start Time	End Time	Instrument
W000000000000	2020-02-07	08:30 PT	11:54 PT	Spectra Optia

Description Leukopak from peripheral blood was collected from a healthy, IRB-approved volunteer donor. This mononuclear cell-rich leukapheresis product is extracted using continuous flow centrifugal technology directly into the collection bag containing ACD-A anticoagulant.

Handling Instructions Upon receipt, use or process immediately.

Donor Information

Source ID	Age	Gender	Height	Weight	BMI	Ethnicity	ABO/Rh
D000000	45	Male	6'4"	224 lbs	27.26	Caucasian	O-NEG

HLA -A	HLA-B	HLA-C	HLA-DRB1	HLA-DRB3	HLA-DRB4	HLA-DRB5	HLA-DQB1	HLA-DPA1	HLA-DPB1
01:01	08:01	07:01	03:01	01:01	01:03	-	02:01	01:03	01:01
25:01	18:01	12:03	04:01	-	-	-	03:02	02:01	03:01

Displayed HLA results are from donor's previous screening. HemaCare can further test donor for an additional fee.

Testing Information

Donors are tested at collection. Donor of this product was previously tested according to current FDA requirements for allogeneic blood donation, with the exception of Zika, and all results were acceptable at that time. The following screening tests have been performed:

- Syphilis
- Red Blood Cell Antibody Screen
- CMV Antibody (Anti-CMV IgG and IgM) – *result upon request*
- Hepatitis B Core Antibody (Anti-HBc EIA)
- Hepatitis B Surface Antigen (HBsAg EIA)
- Hepatitis C Virus Antibody (Anti-HCV EIA)
- Human Immunodeficiency Virus Antibody (HIV 1/2 plus O)
- Human T-Lymphotropic Virus Antibody (HTLV-I/II)
- HIV-1/HCV/HBV Nucleic Acid Testing
- West Nile Virus Nucleic Acid Testing
- Trypanosoma cruzi Antibody (Chagas Disease)

Product Complete Blood Count (CBC)

Product Volume	HCT	RBC
309 mL	1.9 %	0.19 x 10 ⁶ /μL

Total WBC Yield	Neutrophil Yield	Lymphocyte Yield	Monocyte Yield	Platelet Yield
0.973 x 10 ¹⁰	0.076 x 10 ¹⁰	0.738 x 10 ¹⁰	0.129 x 10 ¹⁰	3.652 x 10 ¹¹

Product CBC results were obtained from hematology analyzers which have been validated for whole blood samples collected in EDTA, but **NOT for apheresis product samples** anticoagulated with ACD-A.

Biosafety This material should be handled following biosafety level 2 biohazard procedures. Universal precautions should be utilized when working with this material.

Released By John Smith

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