OrganaBio

CONSISTENCY.
PURITY.
RELIABILITY.

High-yield, high-purity leukopaks & cell products from a recallable donor pool - designed to take you seamlessly from discovery to GMP manufacturing.

QUALITY BY DESIGN

OUR STANDARDS

- FDA Registered Blood & Tissue Establishement
- Fully Consented, Pre-screened Donors
- Comprehensive Disease Testing Panel
- Terumo BCT Spectra Optia™
- <24 hr Processing From Time of Collection

PRODUCT CHARACTERIZATION

- 34-point CoA for every product
- HLA Typing for Class I and Class II Genes
- Post-thaw Purity & Viability
- Complete Blood Count

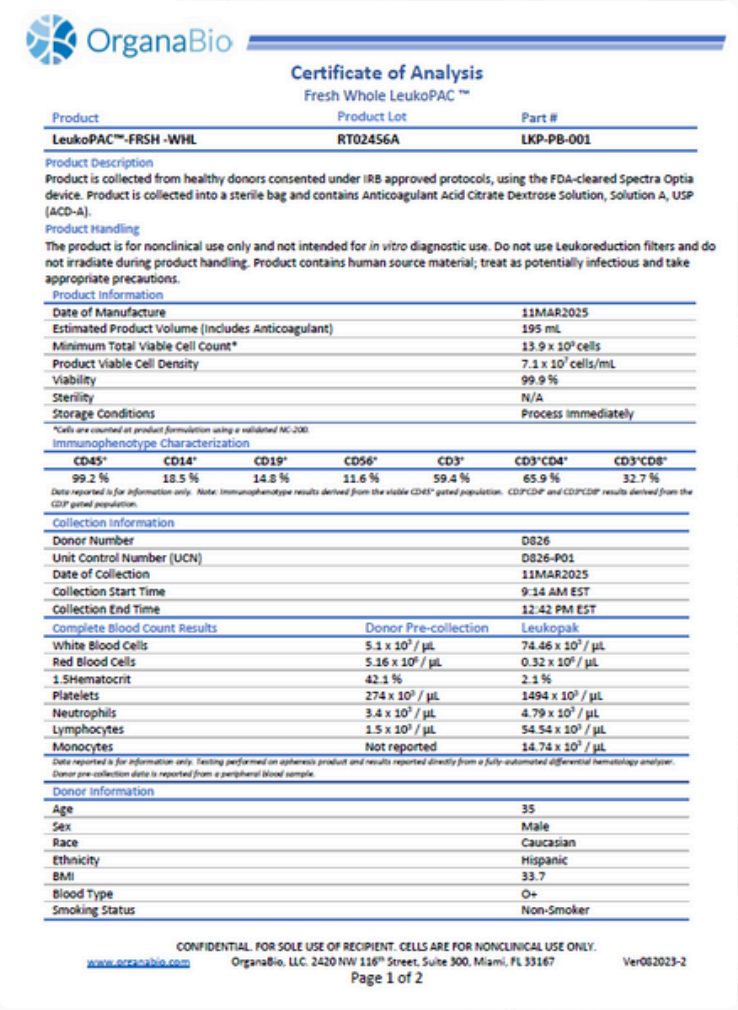
START WITH CONSISTENCY.
END WITH CONFIDENCE.

305.676.2586 hello@organabio.com www.organabio.com

CONSISTENT, RECALLABLE, READY

Apheresis-derived Materials That Move Your Program Forward.

Product	Product Format	Cell Count	Format
Leukopak	Fresh / Frozen	≥10Bn TNC / collection on average	Whole, half, quarter RUO & GMP
PBMC	Fresh / Frozen	10M–100M	Vials, bags, custom
CD56+ NK Cells (Pos./Neg. Sel.)	Frozen	5M, 10M	Vials, bags, custom
CD3+T Cells (Pos./Neg. Sel.)	Frozen	10M, 25M	Vials, bags, custom



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Certificate of Analysis

Fresh Whole LeukoPAC ™

Product	Product Lot	Part #
LeukoPAC™-FRSH -WHL	RT02456A	LKP-PB-001

Product Description

Product is collected from healthy donors consented under IRB approved protocols, using the FDA-cleared Spectra Optia device. Product is collected into a sterile bag and contains Anticoagulant Acid Citrate Dextrose Solution, Solution A, USP (ACD-A).

Product Handling

The product is for nonclinical use only and not intended for *in vitro* diagnostic use. Do not use Leukoreduction filters and do not irradiate during product handling. Product contains human source material; treat as potentially infectious and take appropriate precautions.

Product Information

Date of Manufacture	11MAR2025
Estimated Product Volume (Includes Anticoagulant)	195 mL
Minimum Total Viable Cell Count*	13.9 x 10^9 cells
Product Viable Cell Density	7.1 x 10^7 cells/mL
Viability	99.9 %
Sterility	N/A
Storage Conditions	Process immediately

*Cells are counted at product formulation using a validated NC-200.

Immunophenotype Characterization

CD45+	CD14+	CD19+	CD56+	CD3+	CD3+CD4+	CD3+CD8+
99.2 %	18.5 %	14.8 %	11.6 %	59.4 %	65.9 %	32.7 %

Data reported is for information only. Note: Immunophenotype results derived from the viable CD45+ gated population. CD3+CD4+ and CD3+CD8+ results derived from the CD3+ gated population.

Collection Information

Donor Number	D826
Unit Control Number (UCN)	D826-P01
Date of Collection	11MAR2025
Collection Start Time	9:14 AM EST
Collection End Time	12:42 PM EST

Complete Blood Count Results	Donor Pre-collection	Leukopak
White Blood Cells	5.1 x 10^3 / µL	74.46 x 10^3 / µL
Red Blood Cells	5.16 x 10^6 / µL	0.32 x 10^6 / µL
1.5Hematocrit	42.1 %	2.1 %
Platelets	274 x 10^3 / µL	1494 x 10^3 / µL
Neutrophils	3.4 x 10^3 / µL	4.79 x 10^3 / µL
Lymphocytes	1.5 x 10^3 / µL	54.54 x 10^3 / µL
Monocytes	Not reported	14.74 x 10^3 / µL

Data reported is for information only. Testing performed on apheresis product and results reported directly from a fully-automated differential hematology analyzer. Donor pre-collection data is reported from a peripheral blood sample.

Donor Information

Age	35
Sex	Male
Race	Caucasian
Ethnicity	Hispanic
BMI	33.7
Blood Type	O+
Smoking Status	Non-Smoker

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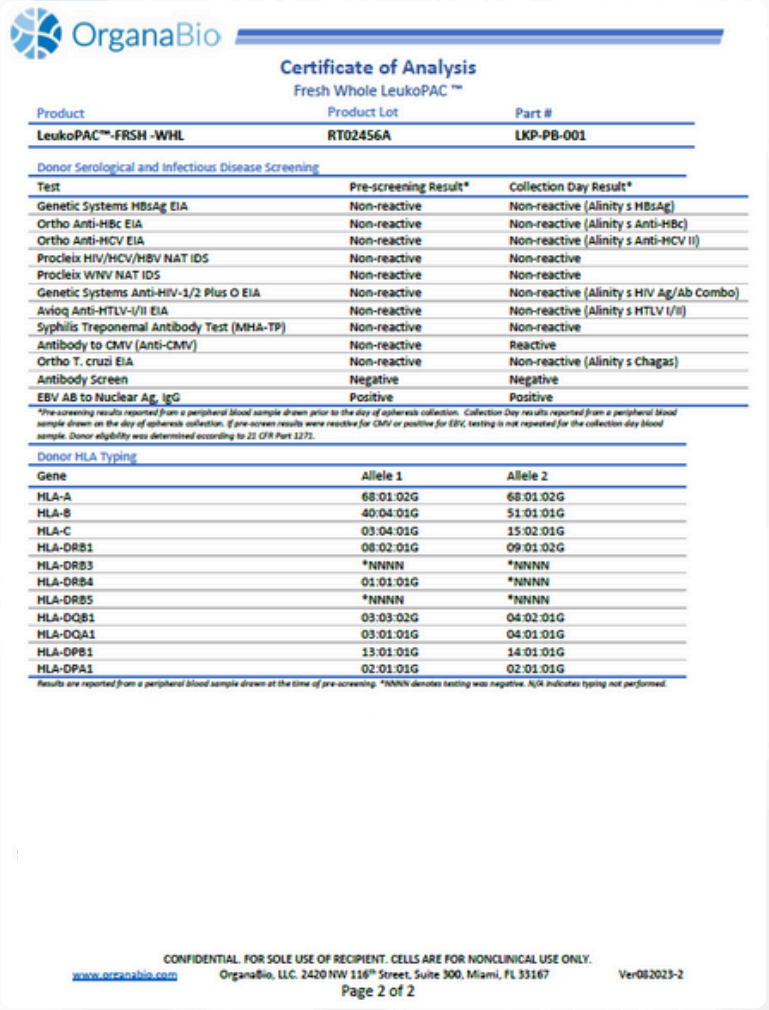

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Certificate of Analysis

Fresh Whole LeukoPAC ™

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LeukoPAC™-FRSH -WHL	RT02456A	LKP-PB-001

Donor Serological and Infectious Disease Screening

Test	Pre-screening Result*	Collection Day Result*
Genetic Systems HBsAg EIA	Non-reactive	Non-reactive (Alinity s HBsAg)
Ortho Anti-HBc EIA	Non-reactive	Non-reactive (Alinity s Anti-HBc)
Ortho Anti-HCV EIA	Non-reactive	Non-reactive (Alinity s Anti-HCV II)
Procleix HIV/HCV/HBV NAT IDS	Non-reactive	Non-reactive
Procleix WNV NAT IDS	Non-reactive	Non-reactive
Genetic Systems Anti-HIV-1/2 Plus O EIA	Non-reactive	Non-reactive (Alinity s HIV Ag/Ab Combo)
Avioq Anti-HTLV-I/II EIA	Non-reactive	Non-reactive (Alinity s HTLV I/II)
Syphilis Treponemal Antibody Test (MHA-TP)	Non-reactive	Non-reactive
Antibody to CMV (Anti-CMV)	Non-reactive	Reactive
Ortho T. cruzi EIA	Non-reactive	Non-reactive (Alinity s Chagas)
Antibody Screen	Negative	Negative
EBV AB to Nuclear Ag, IgG	Positive	Positive

Pre-screening results reported from a peripheral blood sample drawn prior to the day of apheresis collection. Collection Day results reported from a peripheral blood sample drawn on the day of apheresis collection. If pre-screen results were reactive for CMV or positive for EBV, testing is not repeated for the collection day blood sample. Donor eligibility was determined according to 21 CFR Part 1271.

Donor HLA Typing

Gene	Allele 1	Allele 2
HLA-A	68:01:02G	68:01:02G
HLA-B	40:04:01G	51:01:01G
HLA-C	03:04:01G	15:02:01G
HLA-DRB1	08:02:01G	09:01:02G
HLA-DRB3	*NNNN	*NNNN
HLA-DRB4	01:01:01G	*NNNN
HLA-DRB5	*NNNN	*NNNN
HLA-DQB1	03:03:02G	04:02:01G
HLA-DQA1	03:01:01G	04:01:01G
HLA-DPB1	13:01:01G	14:01:01G
HLA-DPA1	02:01:01G	02:01:01G

*Results are reported from a peripheral blood sample drawn at the time of pre-screening. *NNNN denotes testing was negative. N/A indicates typing not performed.*

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