

TISSUES AND CELLULAR
STARTING MATERIALS FOR
CELL AND GENE THERAPY
DEVELOPMENT

OrganaBio provides ethically sourced adult leukapheresis products and birth tissues, from a diverse and engaged donor pool, including leukopaks, PBMCs, T cells, NK cells, placenta, umbilical cord, umbilical cord blood, HSCs, and a variety of immune cells. All products are manufactured to enable the development and delivery of innovative cell and gene therapies and vaccines.

OrganaBio's portfolio of human tissue and tissue-derived cells is designed for the development of allogeneic cell therapies. Products are provided in various formats, with "off-the-shelf" and custom specifications, and delivery available on the same or next day after collection, depending on the product and location.

OrganaBio provides products for preclinical development and cGMP-compliant analogous products for clinical translation and commercial manufacturing of cell and gene therapies.













# **LeukoPAC™** Portfolio

Product	Description	Formats	Product Format
LeukoPAC-FRSH/FRZN	≥ 10 Billion TNC per collection	Whole, Halves, Quarters	Fresh, Frozen
LeukoPAC-PBMC	Single donor PBMCs	Vials, Bags	Frozen
LeukoPAC-NK-PB	Single donor NK cells; Positive or negative selection	Vials, Bags	Frozen
LeukoPAC-T-PB	Single donor T cells; Positive or negative selection	Vials, Bags	Frozen

#### HematoPAC™ Portfolio

Product	Description	Formats	Product Format
HematoPAC-CB-FRSH	TNC by validated automated cell counter	Bags	Fresh, Frozen
HematoPAC-HSC-CB	Single donor CD34+ from cord blood	Vials	Frozen

# ImmunoPAC™ Portfolio

Product	Description	Formats	Product Format
ImmunoPAC-T-CB	Single donor T cells from cord blood	Vials	Frozen
ImmunoPAC-NK-CB	Single donor NK cells from cord blood	Vials	Frozen



# **Birth Tissue and Apheresis Donors**

OrganaBio provides access to over 1,000 qualified donors for birth tissue and apheresis derived materials. Our custom donor screening protocols and curated donor pools grow weekly as we actively qualify more donors.

# **Donor Pool**

## **Highly Recallable Donor Pool**

OrganaBio places an emphasis on maintaining an ethnically diverse and highly recallable leukapheresis donor pool to ensure clients' program success. Clients have the option to view product inventory and select cell lots or recall donors based on sex, age, race, ethnicity, blood type, HLA genotype, immunophenotype, CMV/EBV status, BMI, and smoking status.



## **HLA Typed Donors**

Designed for allogeneic cell therapy development, OrganaBio's cell-based products are HLA typed, giving researchers the ability to review high resolution genotyping by NGS for HLA-A, B, C, DR, DQ, DP on all donors. Developers can select products from donors with common or rare HLA alleles to test the effects of HLA matching or mismatching on cell persistence, immune response, and immune rejection.

## Highly Characterized Products (CoA Differentiation)

OrganaBio's products are backed by defined attributes and quality oversight, yielding cell products with high purity and viability. Each product lot is accompanied by a comprehensive Certificate of Analysis (CoA) with extensive data on product critical quality attributes (CQAs). Access to the immunophenotyping profile enables selection of material based on specific cell subsets, such as T cell, B cell, monocyte, or NK cell composition, enabling development and manufacturing with characterized, standardized starting materials.

# **Clinically Relevant**

OrganaBio's products are manufactured with clinical translation in mind. OrganaBio screens donors and determines donor eligibility in accordance with US FDA 21 CFR 630 and 1271 through administration of an AABB and FDA approved Donor History Questionnaire (DHQ). GTP- and GMP-compliant SOPs and manufacturing batch records (MBRs) are specially designed for flexibility and scalability to meet each customer's unique needs. Clinical grade products are manufactured in an ISO 7 cleanroom within OrganaBio's cGMP manufacturing facility.

#### NeoPAC™ Portfolio

Product	Description
NeoPAC-PL	Human placenta from healthy, full-term births
NeoPAC-UC	Human umbilical cord from healthy, full-term births
NeoPAC-PL-UC	Human placenta and umbilical cord from healthy, full-term births

#### MesenPAC™ Portfolio

Product	Description
MensenPAC-MSCs	Placenta- or umbilical cord-derived Mesenchymal Stromal Cells

# **Ethics & Regulatory Compliance**

### Ethically Sourced Perinatal and Adult Tissues: PAC™-ed with Potential

All tissues are sourced through OrganaBio's wholly owned, FDA registered blood and tissue establishments, GaiaGift and HemaCenter. All DHQs are FDA and AABB approved. Donors are recruited and consented under IRB-approved protocols and procedures using informed consent as soon as the second trimester for GaiaGift and again before the due date. GaiaGift OB/GYNs are trained to follow best practices in adherence with American College of Obstetrics and Gynecology (ACOG) delayed cord clamping guidelines in collection of placenta, umbilical cord, and umbilical cord blood.

Adult leukapheresis products are collected with donor safety and well-being at the forefront, starting with a comprehensive physical exam and CBC analysis to determine suitability for donation on day of collection. Donors are screened for infections, diseases, and adventitious agents per US FDA 21 CFR 1271 guidelines, and donor apheresis occurs only every 8 weeks per FDA best practices for blood donations.

All products are supported by quality and regulatory documentation to facilitate the rapid development of cell-based therapies. Collections are US FDA and EU compliant.

OrganaBio owns and operates the entire supply chain to ensure controlled, traceable, and ethical collection of perinatal and adult tissues.







# **Proprietary Supply Chain**

OrganaBio owns and operates the entire supply chain to ensure controlled, traceable, and ethical collection of perinatal and adult tissues.

As an agile and flexible supply chain organization in the cell therapy industry, OrganaBio can accommodate custom orders to provide birth tissue- and apheresis-derived materials that meet customer timelines and product requirements.

Contact us at sales@organabio.com or call 305.676.2586 to schedule a consultation.

# **Channel Partners**

- Scientist.com approved vendor
- Science Exchange approved vendor
- VWR / Avantor Marketplace approved vendor













