

EXCELLOS™

Better Cells for Better Therapies

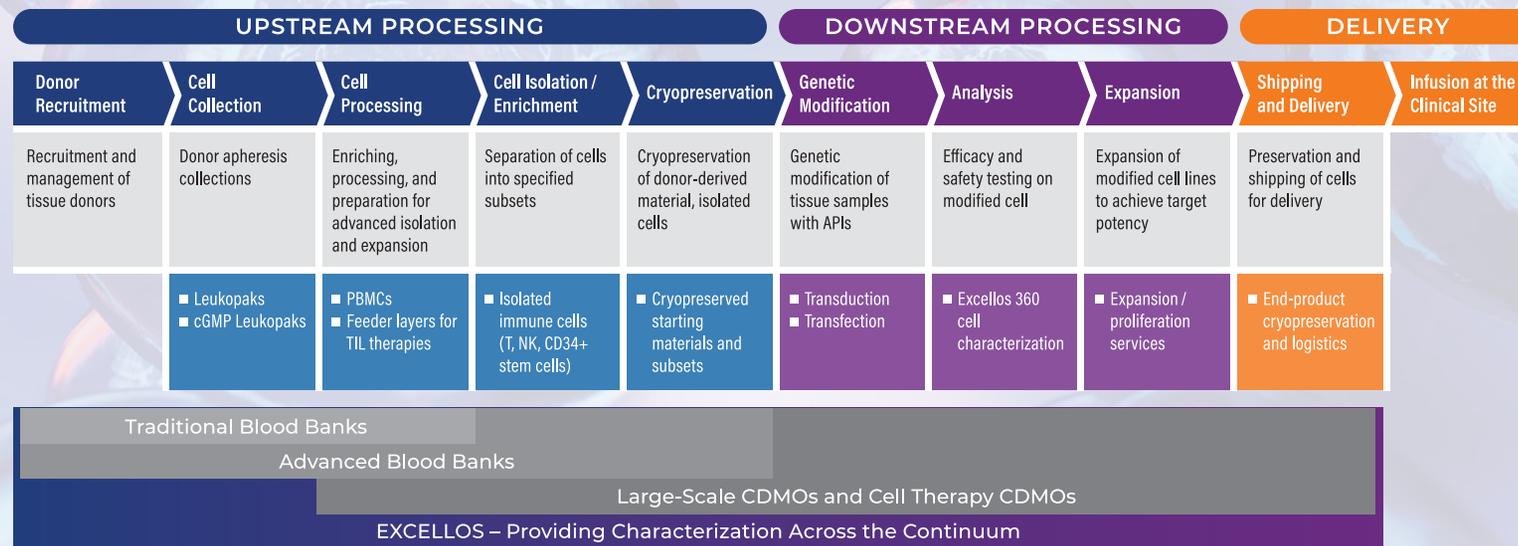
A 3D rendering of a cell with a blue, textured surface and several purple, cluster-like receptors. The cell is surrounded by other similar cells in a dark blue environment.

Product and Service Catalog

YOUR NEXT THERAPEUTIC BREAKTHROUGH STARTS HERE

Excellos is your ideal partner for achieving your research and clinical goals, from tailored collections to process development and manufacturing.

For the last seven years we have been using our full-service cGMP manufacturing facility to develop a comprehensive range of advanced cell therapy products and services. We offer everything from the recruitment of donors, blood and apheresis collections, cell isolation and purification, cell transduction, cell expansion, and final fill-to-finish under cGMP standards.



THE EXCELLOS DIFFERENCE

- 4 The Right Starting Materials
- 6 End-to-end Product Lifecycle Support
- 9 Comprehensive Quality Assurance and Regulatory Affairs Support
- 11 A Broad Range of Research Use Only Product



THE RIGHT STARTING MATERIALS

We facilitate reaching your research or cell therapy development goals with a high-reliability supply of premium fresh, and cryopreserved Research Use Only cellular products.



EXCELLOS™

Human Cord Blood Unit
100 mL
Product ID: CBU
Lot# W21452300000
Manufactured: DDMMYYYY
Store: -150°C
Non Clinical Research Use Only

Rx only



47-40-12-754 REV: A

REF 4R0837MC



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THE RIGHT STARTING MATERIALS



RESEARCH USE ONLY (RUO)

Our RUO human primary cell products provide a robust starting point for your basic research or early-stage research and development needs. Our wide array of highly consistent, high-quality, and well-characterized cellular materials meet the quality standards established by the FDA, EMA, and other government regulatory agencies.



DONOR MANAGEMENT SERVICES

Our team of experts will help you navigate the complexities of donor requirements and provide integrated project management to design a donor pool suitable for your needs now, as well as enable an easy transition and bidirectional movement between research and clinical program phases in the future.



GMP-COMPLIANT HUMAN CELLS

Our cell sourcing for superior leukopak and cord blood starting material adheres to strict cGMP requirements for the advancement of allogeneic cell therapies.



MADE-TO-ORDER PRODUCTS AND SERVICES

Our made-to-order products and services help you meet requirements for all of your requirements. Our team of experts will help you define, design and deliver your primary cell material to match your study-specific criteria.



Up to now, the benefits and growth potential of cell and gene therapies for cancer treatment have been restricted by variabilities in development and clinical results. This variability stems from three main factors: tumor/host biology, inherent tumor resistance mechanisms, and variability in the cell therapy product itself. Excellos™ 360 employs Excellos's deep cell characterization approach to address these variabilities by going deeper than typical cell and donor screening to create a comprehensive immune cell profile for each donor, as well as an assessment of the metabolic and effector potential of their cells that sees beyond surface markers.

Using this approach, Excellos 360 is working to improve the potency of cell-based treatments for reduced clinical response variability, in order to:

- Improve clinical outcomes,
- Lower safety liability by making therapies effective in lower dosages
- Lower the cost of goods associated with cell and gene therapy manufacture.

Excellos 360 will allow you to accelerate the development and production of more effective and accessible cell and immunotherapy treatments.

A blue-tinted background image showing a top-down view of several petri dishes containing cell cultures. The cells are visible as intricate, circular patterns within the dishes, which are arranged in a grid-like fashion. The lighting is soft, highlighting the texture of the cell colonies.

END-TO-END PRODUCT LIFECYCLE SUPPORT

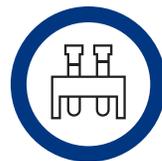
Our fully integrated CDMO services support you throughout the entire product lifecycle. You can leverage our manufacturing expertise and Excellos™ 360 characterization across the continuum to take investigational cellular products and advanced therapies from development to commercialization.

END-TO-END PRODUCT LIFECYCLE SUPPORT



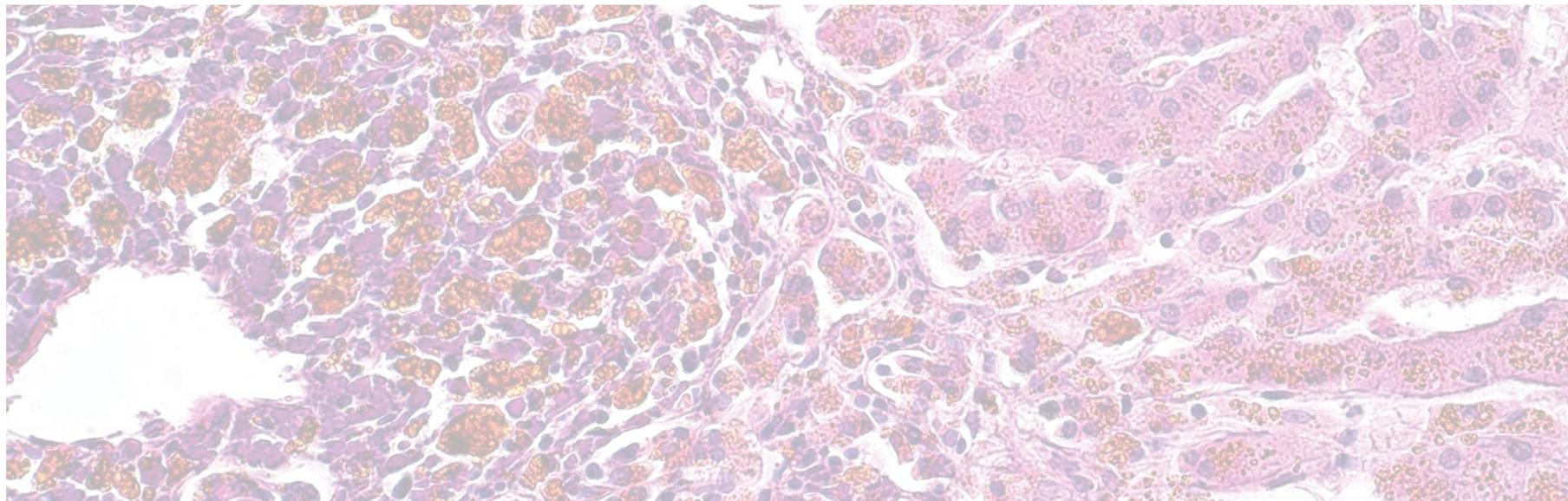
SCIENTIFIC ADVISORY SERVICES

With decades of industry experience and proven abilities to navigate the complex and changing Cell and Gene Therapy landscape, our R&D team can design and manage lean and robust preclinical programs providing flexible, responsive, and personalized support. Our team is uniquely qualified to map your journey through drug development from early discovery to market support.



SCREENING & PROFILING ASSAYS

Assay development is the most critical aspect of a hit-finding campaign. Create the foundation for success with custom assay design or expert evaluation of your own assay before screening begins. Our scientists can help you select the right type of assay and relevant compounds, establish rigorous quality control parameters, define appropriate hit acceptance criteria, and determine the most efficient automated execution.



END-TO-END PRODUCT LIFECYCLE SUPPORT



ACCREDITATION AND LICENSURE

- California License for the Production of Biologics
- Tissue Bank License
- GMP-qualified cleanrooms
- IRB-approved donor consents and collection protocols through San Diego Blood Bank and others



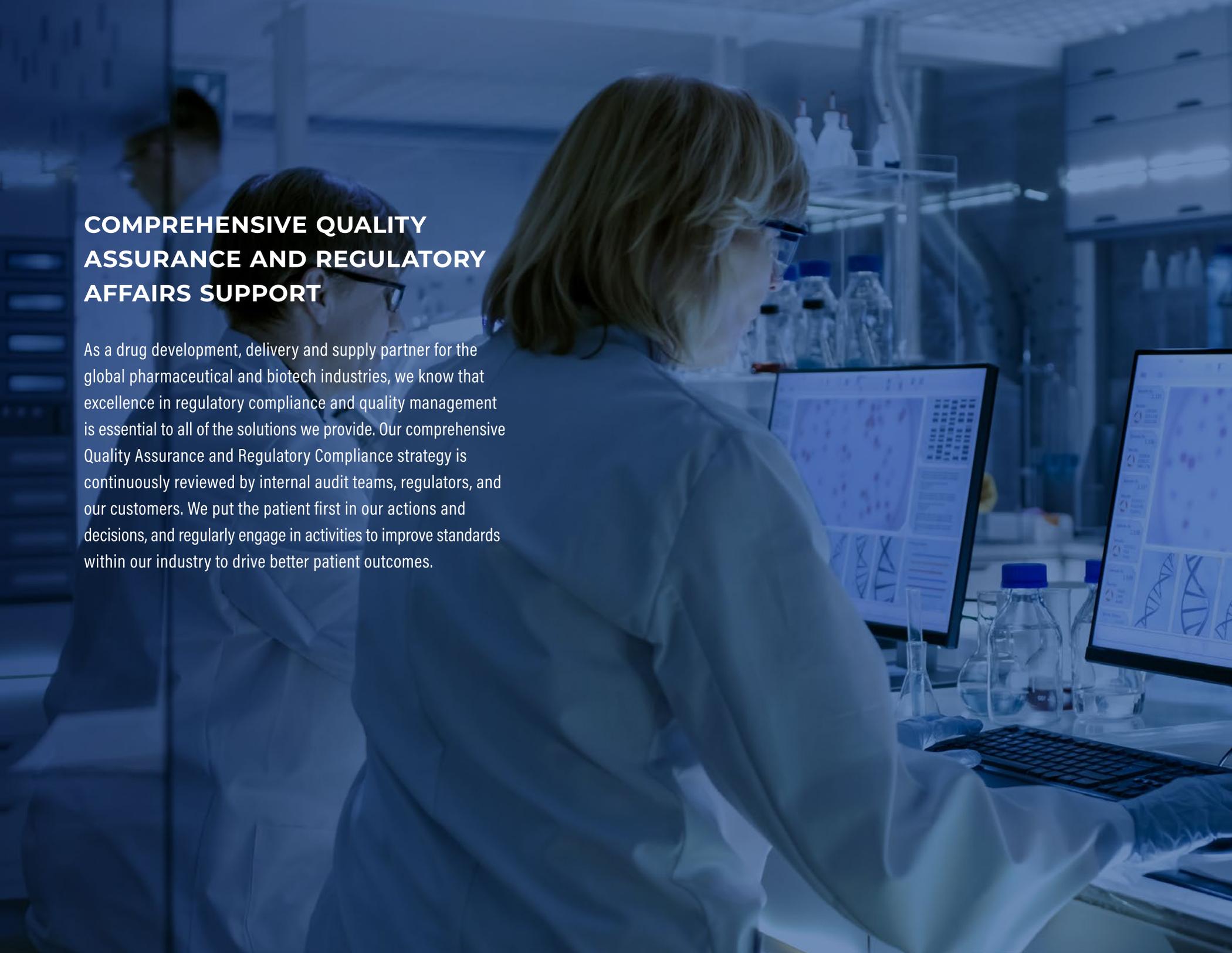
MANUFACTURING

Our two locations provide everything from research and development to cGMP clinical and commercial applications:

- Cell isolation
- Cell expansion
- Cell transduction
- Cell analysis
- Fill and finish of final product
- Cryopreservation
- Storage
- Stability testing
- Characterization / final release

- Total Area: 36,383 ft²
- Multipurpose location: administration, R&D and PD lab space, five new ISO 7, cGMP cleanrooms with independent ISO 8 access and return corridors
- Additional cGMP cleanrooms offsite at the San Diego Blood Bank
- Five new cGMP cleanrooms to be completed and validated by late summer 2023





COMPREHENSIVE QUALITY ASSURANCE AND REGULATORY AFFAIRS SUPPORT

As a drug development, delivery and supply partner for the global pharmaceutical and biotech industries, we know that excellence in regulatory compliance and quality management is essential to all of the solutions we provide. Our comprehensive Quality Assurance and Regulatory Compliance strategy is continuously reviewed by internal audit teams, regulators, and our customers. We put the patient first in our actions and decisions, and regularly engage in activities to improve standards within our industry to drive better patient outcomes.

COMPREHENSIVE QUALITY ASSURANCE AND REGULATORY AFFAIRS



QUALITY BY DESIGN (QbD)

Our QbD methodology starts with a product profile that will meet business and patient needs and the quality profile for the product, including potency. From there, the design phase of the development and manufacturing plan begins by considering risk assessments and conducting experiments to develop the process. Once the design is set, a control strategy is implemented to support regulatory filings. The product is managed throughout its lifecycle to uncover opportunities for continuous improvement.

MANUFACTURING BY DESIGN (MBD)

The Excellos QbD methodology addresses process characterization and is vital to the quality of the end product, but it is not the only requirement for success. Alleviating autologous and allogeneic manufacturing challenges is critical to scaling cell therapies, increasing efficiency and lowering costs to drive widespread acceptance and use of the treatment.

Excellos developed its MbD methodology to assess and improve the manufacturing process to support product quality and provide a robust and rapid tech-transfer strategy. Starting with target product profiles and critical quality attributes, MbD establishes the target manufacturing profiles and critical manufacturing attributes necessary to meet quality goals. Target manufacturing profiles are determined by reviewing economics (cost of goods, business continuity), process efficiency (scalability, operability, robustness), end-to-end vision (drug substance, drug product, analytical strategy, raw material and supplies), and other considerations such as regulatory and intellectual property.

REGULATORY AFFAIRS

Our regulatory consulting team keeps you up to date with ever-changing regulations throughout the world, providing advice on legal requirements, developing a regulatory strategy for your product's lifecycle, interfacing with relevant regulatory agencies, and assisting in the preparation of documents required for market approval. Our experts have experience throughout all stages of the product lifecycle.



A BROAD RANGE OF RESEARCH USE ONLY PRODUCT

Our Research Use Only (RUO) human primary cell products provide a starting framework for your basic research or early-stage research and development needs. We offer a wide array of consistent, high-quality biomaterial that includes leukopaks, PBMCs, T cells, NK cells, whole blood, platelets, plasma, serum, and more. Furthermore, our RUO products are available with Excellos 360, Excellos's deep cell characterization.

A BROAD RANGE OF RESEARCH USE ONLY PRODUCT

HUMAN LEUKOPAK

A leukopak is an enriched leukapheresis product collected from normal peripheral blood. It is composed of a variety of blood cells including monocytes, lymphocytes, platelets, plasma, and red cells. It contains a higher concentration of cells as compared to standard venipuncture collection methods or buffy coat products.

A leukopak typically contains 5 to 20 billion white blood cells (~50% T cells, 20% monocytes, 10% B cells, 10% NK cells).

Product Number	Description
PB-FULL	Full Collection

 VIABILITY	≥ 95%
 FORMAT	Fresh



HUMAN PERIPHERAL BLOOD MONONUCLEAR CELLS

Peripheral blood mononuclear cells (PBMCs) are isolated from peripheral blood and purified by a density gradient centrifugation.

Product Number	Description
PB-MC-VL100M	100M
PB-MC-VL50M	50M
PB-MC-VL10M	10M
PB-MC-IRR-VL100M	100M, Irradiated

 PURITY	≥ 90%
 VIABILITY	≥ 85%
 FORMAT	Cryopreserved

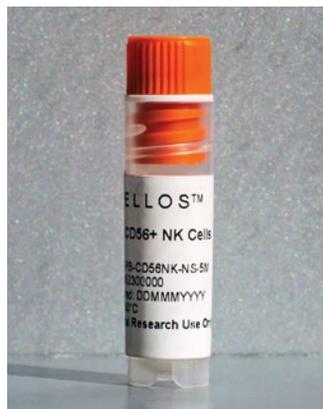


A BROAD RANGE OF RESEARCH USE ONLY PRODUCT

HUMAN CD56+ NATURAL KILLER (NK) CELLS

NK cells are cytotoxic members of the innate immune system and a major component of the immune system. CD56+ NK cells play a key role in the rejection of tumors and cells infected by viruses.

Product Number	Description	Selection Method
PB-CD56NK-PS-10M	10M	Positive
PB-CD56NK-PS-5M	5M	Positive
PB-CD56NK-PS-1M	1M	Positive
PB-CD56NK-NS-10M	10M	Negative
PB-CD56NK-NS-5M	5M	Negative
PB-CD56NK-NS-1M	1M	Negative



	PURITY	≥ 90%
	VIABILITY	≥ 90%
	FORMAT	Cryopreserved



A BROAD RANGE OF RESEARCH USE ONLY PRODUCT

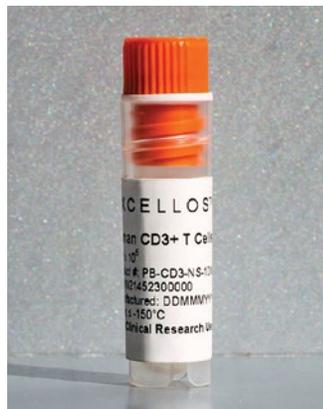
HUMAN T CELLS

Purified adaptive immune T cells respond to peptides derived from viruses, bacteria, tumor cells, and normal tissues.

HUMAN CD3+ T CELLS

CD3+ T cells are isolated from peripheral blood by either positive or negative selection using immunomagnetic cell separation procedures.

Product Number	Description	Selection Method
PB-CD3-PS-25M	25M	Positive
PB-CD3-PS-10M	10M	Positive
PB-CD3-PS-5M	5M	Positive
PB-CD3-NS-25M	25M	Negative
PB-CD3-NS-10M	10M	Negative
PB-CD3-NS-5M	5M	Negative



	PURITY	≥ 90%
	VIABILITY	≥ 90%
	FORMAT	Cryopreserved

HUMAN CD3+ GAMMA DELTA T CELLS

Gamma Delta T cells are not abundant in the body, and are found in the gut mucosa, skin, lungs, and uterus. These cells are involved in the initiation and propagation of immune responses. They are considered to represent a link between innate and adaptive immunity. They can secrete particular effector cytokines in a subtype- and context-specific manner and are capable of phagocytosis.

Product Number	Description	Selection Method
PB-CD3GD-PS-2M	2M	Positive
PB-CD3GD-PS-1M	1M	Positive
PB-CD3GD-PS-500K	500K	Positive
PB-CD3GD-NS-2M	2M	Negative
PB-CD3GD-NS-1M	1M	Negative
PB-CD3GD-NS-500K	500K	Negative



	PURITY	≥ 90%
	VIABILITY	≥ 90%
	FORMAT	Cryopreserved

A BROAD RANGE OF RESEARCH USE ONLY PRODUCT

HUMAN CD4+ T CELLS

CD4+ T cells are isolated from peripheral blood by either positive or negative selection.

Product Number	Description	Selection Method
PB-CD4-PS-25M	25M	Positive
PB-CD4-PS-10M	10M	Positive
PB-CD4-PS-5M	5M	Positive
PB-CD4-NS-25M	25M	Negative
PB-CD4-NS-10M	10M	Negative
PB-CD4-NS-5M	5M	Negative



	PURITY	≥ 90%
	VIABILITY	≥ 90%
	FORMAT	Cryopreserved

HUMAN CD8+ T CELLS

CD8+ T cells are isolated from peripheral blood by either positive or negative selection.

Product Number	Description	Selection Method
PB-CD8-PS-25M	25M	Positive
PB-CD8-PS-10M	10M	Positive
PB-CD8-PS-5M	5M	Positive
PB-CD8-NS-25M	25M	Negative
PB-CD8-NS-10M	10M	Negative
PB-CD8-NS-5M	5M	Negative



	PURITY	≥ 90%
	VIABILITY	≥ 90%
	FORMAT	Cryopreserved

CORD BLOOD PRODUCTS

CORD BLOOD UNIT

Human cord blood consists of immune cells and is considered a rich source of hematopoietic stem and progenitor cells. Excellos's cord blood is needle aspirated from the umbilical cord vein into a sterile collection bag containing the anticoagulant citrate phosphate double dextrose (CPD). Multiple sizes based on TNC count available.

Product Code	Format
CB-FRSH-1B	Fresh
CB-CRYO-1B	Cryopreserved





TNCs

≥ 0.7B

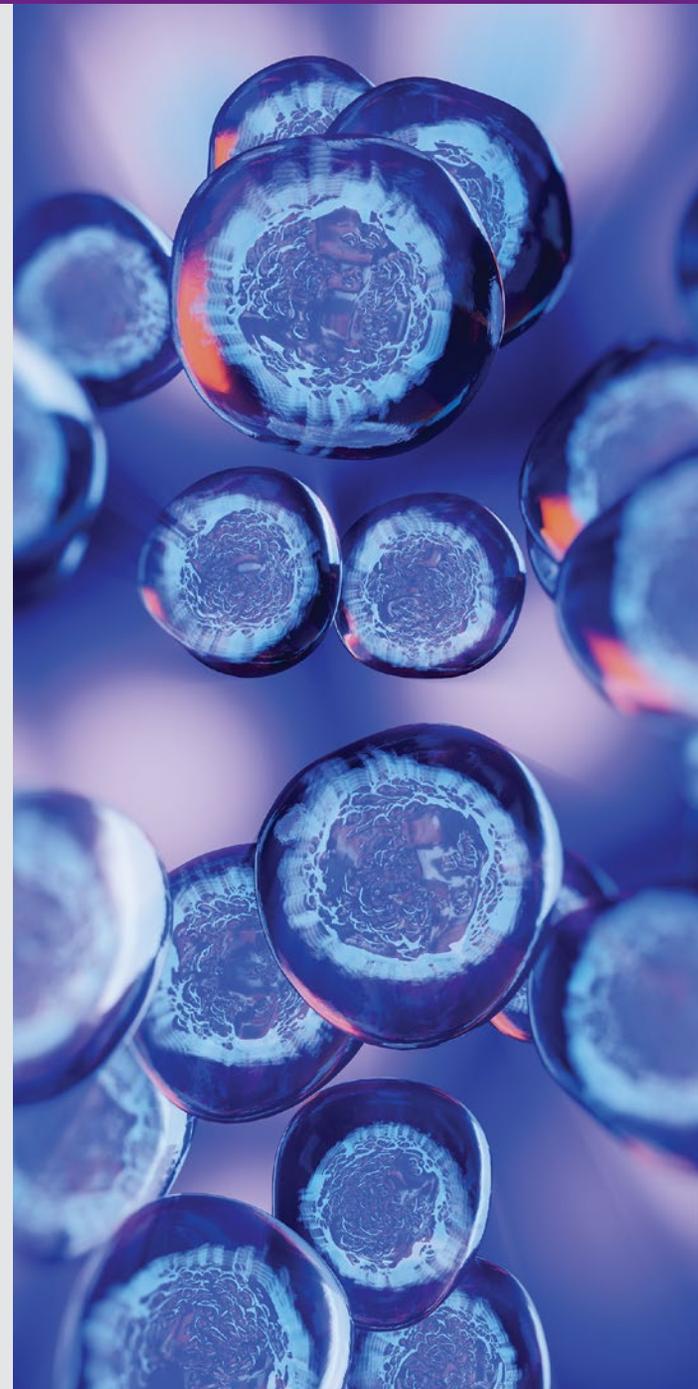
CORD BLOOD CD34+

CD34+ cells are regarded as more naïve and more primitive, having a higher proliferative engraftment and multipotent potential than other sources.

Product Code	Description
CB-CD34-1M	1M; Single Donor
CB-CD34-500K	500K; Single Donor
CB-CD34-200K	200K; Single Donor
CB-CD34-P-5M	5M; Pooled
CB-CD34-P-1M	1M; Pooled
CB-CD34-P-500K	500K; Pooled



	PURITY	≥ 90%
	VIABILITY	≥ 95%
	FORMAT	Cryopreserved
	SELECTION	Positive (negative available upon request)



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