Specialty Lab and Immunological Testing Services
OVER 30 YEARS OF SPECIALTY LAB EXPERIENCE

Precision for Medicine recognizes the critical role that sample testing and handling play in achieving high-quality, accurate study results. Precision's strong capabilities and experience in immunologic testing make us the perfect partner—use our services individually or as a complete package of project or clinical trial support in conjunction with our repository, cell biology, and sample processing and molecular capabilities.

- Global PBMC isolations, same or next-day processing worldwide
- Blood fractionation for isolation of serum, plasma, buffy coat layers
- DNA/RNA extraction and quantity, quality, and purity assessment of cell subsets
- Cell line generation with >97% EBV immortalization success rate
- Cell line immortalization and expansion
- Custom processing and characterization studies offered to meet your exact needs
- Standardized SOPs for laboratory services
- Custom kit development and collection

**Immunological Testing Services Include:**

- Phenotyping and functional assays
- Flow cytometry (and immunophenotyping) for high-throughput, multi-parameter analysis of cell subsets
- Molecular assays
- Cell proliferation assays to provide in-depth information on the effects of the experimental intervention
- Intracellular 14-color cytokine staining (ICS) to measure antigen-specific responses for immune monitoring studies
- ELISpot testing across multiple phases of clinical trials
- Lymphocyte proliferation assays
- Monocyte-derived dendritic cell differentiation to support T-cell stimulation in vitro
- Antibody-dependent cellular cytotoxicity (ADCC) assays and suppression
SCIENTIFIC EXPERTISE PAVING THE WAY TO PERSONALIZED MEDICINE

Precision delivers specialized strategic and scientific services, infrastructure, and technologies to help life science organizations develop and commercialize individualized medicines and targeted therapies that can change patient outcomes. We are committed to partnering with our customers to accelerate development and support commercialization through personalized medicine. We support this activity by providing high-quality, consistent specialty lab services focused on streamlined testing through preparation and pre-qualification of your biological samples and characterization of specimens to obtain reliable and meaningful results in research and development programs. Following is a high-level summary of our offerings.

**Our Specialized Sample and Cellular Processing**

- Blood fractionation for isolation of serum, plasma, buffy coat layers, and purified cell subsets
- PBMC isolation, cryopreservation, and characterization
- Cell line generation with >97% EBV immortalization success rate and cell line expansion
- Phenotyping and functional assays including 14-color flow cytometry, ELISA, ELISpot, ICS, dendritic cell differentiation, cytotoxicity, suppression and proliferation neutralizing antibody, and other custom assays
Our Biological Sample Management System

- Web-based, real-time access for tracking, reporting, and retrieval through proprietary inventory system
- Data collection, quality control, process and inventory, and clinical, demographic, consent, and sample attributes tracked in a single system
- Assay results and sample attributes
- Ability to manage samples stored in multiple repositories around the globe

Our Biobanking and Advanced Specimen Management

- 40 years of biorepository management for over 20 million samples from over 750 protocols
- Experienced, industry-leading management team
- Over 65,000 square foot state-of-the-art, CAP-accredited and ISO-certified facility with immediate scalability and reserve storage capacity
- Secure controlled ambient to LN$_2$ storage with 24/7 restricted access

Our Scientific Expertise for Precision Medicine

- Our industry leadership is on the board of the leading society for biorepositories, the International Society for Biological and Environmental Repositories (ISBER)
- Working Group for the College of American Pathologists (CAP) Biorepository Accreditation Program (BAP), and Biorepository Accreditation Committee
- Experienced lead inspectors for CAP BAP program
- High-level scientific and industry expertise in research and clinical development of targeted therapies and diagnostics
- Discovery and validation of biomarkers; pharmacokinetics/pharmacodynamics
- Practical experience in accelerating research via active clinical trial support including custom collection kit production, biological sample processing and isolation, immunology and molecular biology testing, and customized therapy storage, distribution, and tracking

Our Human Cellular Products

- AccuCell® cryopreserved human peripheral blood mononuclear cells (PBMC) and cord blood mononuclear cells (CBMNC)
  - Functionality comparable to fresh isolations
  - High survival and post-thaw recovery rates
  - HLA type reported
  - Cell batches tested for functionality in proliferation and ELISpot assays
- A valuable alternative to prospective sample collections:
  - Optimize assay efficiency
  - Standardize test results using large lots of cells
  - Wide demographic selection
  - Custom processing and characterization
OUR PRECISION LABORATORY NETWORK (PLN™) ACCELERATES SELECTION AND INTEGRATION OF LAB PARTNERS, ELIMINATES DEVELOPMENT RISK, AND ENSURES QUALITY GLOBAL ACCESS THROUGH:

- Accelerating lab partnership timetables with fully compliant, ready-to-go network specializing in esoteric methods and testing
- De-risking the development process
- Quality-assured samples for drug and assay validation
- Guidance through high-risk transition phases
- Ongoing quality guarantee for partner labs
- Providing hassle-free global access through development-phase support for greater clinical trial consistency, launch, and ongoing trial performance

Immunological testing services include:

- Quality that is integrated into all Precision procedures; we operate in a continuous improvement environment with a focus on first-time quality and efficiency
- Global standardization processes including the use of the same validated platforms, assays, and SOPs across all PLN™ partners
- Precision’s Quality Management System, which is designed to follow the International Society for Biological and Environmental Repositories (ISBER), National Cancer Institute (NCI) best practices, and industry gold standards including:
  - GMP, GLP, GCP, GTP elements
  - ISO9001:2008 Quality Management System
  - CAP Biorepository Accreditation Program
  - ISO13485:2003 Medical devices - Quality management systems
Our proactive management style and problem-solving philosophy stimulates our staff to constantly look for innovative solutions and provides consistent and dependable results with high productivity.

**Quality Assurance**

Precision knows that quality sample handling and processing are essential for preserving data integrity in biological research and clinical testing, and implements procedures that are consistent with relevant regulations to ensure the highest-quality sample processing and storage.

For more information about our specialty lab services, please contact us at info@precisionformedicine.com, call 855-222-5010, or visit precisionformedicine.com.