

Precision Biospecimen Solutions: Paving the Way to Personalized Medicine

ACCELERATING RESEARCH. IMPROVING OUTCOMES.

The companies under the Precision for Medicine banner deliver 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. Our Biospecimen Solutions team supports this activity by providing ethically collected biospecimens and biospecimen processing, storage, and analysis under strict standard operating procedures to ensure consistency in your biospecimen collections. These offerings are further enhanced through management of your clinical trial and biostatistical analysis. Whether you are looking for full clinical trial or à la carte services, Precision's modular approach ensures your needs are met. Listed below is a summary of our offerings.



Specialized Sample Processing and Analysis

- Blood fractionation for isolation of serum, plasma, buffy coat layers
- PBMC isolation, cryopreservation and characterization
- DNA/RNA extraction and quantity, purity, and integrity assessment
- Cell line generation from clinical samples
- Cell line expansion
- Immunological assays including phenotypic analysis, intracellular cytokine staining, ELISpot and ELISA assays
- Custom assay development



Biological Sample Management System

- Complete sample management solution, whether specimens are physically located at our repository, at your facility, or other study collaborators
- Web-based, real-time access for tracking, reporting, and retrieval through proprietary reporting system
- Data collection, quality control process, and inventory tracking
- Clinical, demographic, consent, and sample attributes tracked in a single system
- Ability to manage samples stored in multiple repositories around the globe



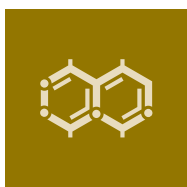
Biobanking and Advanced Specimen Management

- 40 years of biorepository management for over 25 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 LN₂ storage with 24/7 restricted access



Clinical Trial Management and Biostatistical Services

- A modular approach to clinical trial management adhering to GCP quality standards
- Strategy, design, and planning documents
- Development of clinical protocols and site documents
- Clinical site identification, preparation, and monitoring
- Integrated clinical trial management; from upstream planning through execution
- Efficient data management to accelerate downstream analysis and regulatory submission
- Biostatistics to support trial planning and provide empirical evidence
- Identification of target populations
- Post-hoc and retrospective data analysis
- Regulatory strategy and submissions



Maximizing Your Sample Assets

- Collection, utilization, and needs assessments
- Research use suitability determinations
 - Consent attributes
 - Clinical attributes
 - Sample attributes
- Precision Laboratory Network (PLN™) offers consistent sample collections, processing, and preservation of samples across the globe
- Acquisition of healthy and disease-state samples using a wide range of clinical sites
- Development of custom sample isolation and preservation methods



Quality System Development

- Design and implementation of standardized processes and quality systems for collection, processing, storage, distribution, and inventory of valuable client assets
- Industry leader in establishment of best practices and accreditation standards specific to biorepositories, with a leadership team that has served on the Council for the Society for Biorepositories, ISBER, Advisory Working Group for CAP, CAP BAP, and have been trained as CAP BAP Inspectors
- Quality management systems based on principles of cGMP, GCP, GLP, GTP, and CLIA standards
- Experienced Lead Inspectors for CAP BAP program



Our Scientific Expertise at Precision Medicine

- High-level scientific and industry expertise in research and clinical development of targeted therapies and diagnostics with expertise in
 - Immunology
 - Cell Biology
 - Molecular Biology
 - Genetics
 - Virology
 - Biospecimen Science
- Practical experience in the design and execution of clinical trial protocols covering diverse disease areas:
 - Oncology
 - Infectious Disease
 - Automimmune Disorders
 - Blood Disorders
 - Transfusion Medicine



OVER 40 YEARS' EXPERIENCE PROVIDING THE HIGHEST QUALITY SERVICE IN BIOLOGICAL SAMPLE PRESERVATION

Our Facilities

- Over 65,000 sq ft dedicated to repository operations
- BSL-1 and BSL-2 sample refinement, molecular, and cellular laboratories
- Expansive repository storage area with immediate reserve capacity

Biorepository

- State-of-the-art accredited to the College of American Pathologists Biorepository Accreditation Program and certified to ISO9001 and ISO13485 standards
- Primary and backup storage at controlled room temperature, +4°C, -20°C, -80°C, and LN₂
- Diverse materials including human biological, environmental, and finished drug product
- 24/7 restricted-access security, redundant power systems, validated backup freezers and in-house HVAC and freezer technicians
- Flexible storage models at the sample, box or freezer level, either in Precision or client-owned freezers

PEGASIS™ Sample Management Solution

Locate samples quickly and easily through our web-based reporting and retrieval systems

- Fully validated, 21 CFR Part 11 compliant, fully auditable chain of custody
- Flexible security model
- Government approved Information System Security Plan (ISSP)

Easy-to-use interface for secure access to your inventory

- Project portal
 - Study documents
 - Schedule and communication plans
 - Instant dashboard reports
 - Collection and protocol level
 - Data across multiple locations/institutions
 - Key performance indicators
 - Key quality indicators
 - Easy view and request of specimens
 - Sample attributes
 - Result data
 - Ethical permissions/restrictions
 - Clinical and demographic parameters
 - Configurable, customizable, and scalable
 - Web-based, 24/7 access for tracking, reporting, and retrieval via your computer or mobile device



PRECISION AT A GLANCE

Controlled room temperature

+4°C
-20°C
-80°C

vapor and liquid phase | **LN₂** short- and long-term storage

65,000sf | dedicated to repository operations

Immediate reserve capacity available

OVER **25** MILLION

The number of samples managed

ISO9001 and **ISO13485** certified facility

Storage at the sample, box, or freezer level
in Precision or client-owned freezers



restricted-access security, redundant power systems, validated backup freezers, and in-house HVAC and freezer technicians

INCREASE THE VALUE OF YOUR EXISTING SAMPLE COLLECTIONS

Sample Preservation and Management

- Isolation of sample derivatives using our protocols or yours
- Validated procedures to process, aliquot, characterize, analyze, blind, anonymize, transform, and expand sample assets
- Rapid retrieval of specimens upon approved request

Clinical Trial Support Services— Preclinical, Clinical, and Surveillance

- Expert consultation on study design, global ethical consents, and execution
- Management of Ethical Board filings and use permissions/restrictions per consent and regional requirements
- Qualification of external study sites
- Budget development for sites
- Development of protocol and clinical study forms
- Site management
 - Site initiation, interim monitoring visits, and close-out visits
 - Coordination of shipment of clinical study documents and clinical trial material to sites
 - Site-affiliated laboratory audits
 - Monitoring of GCP compliance
 - Data entry and analysis
- Development of clinical study report, suitable for inclusion in regulatory submission

Global Logistics Management

- Sample acquisition, collection and processing manuals
- In-house custom kit design, production, supply, and resupply
- Distribution of Pharmaceuticals
- Validated and certified shipping systems
- Import and export permit coordination
- IATA, ICAO and DOT compliant shipping procedures

Virtual Sample Management

- Utilize our state-of-the-art repository or yours
- Satellite locations on 6 continents to receive and preserve specimens
- Primary repository with 65,000 sf
- Secure facilities with fully redundant infrastructure systems
- Virtual management of samples in our systems and other study collaborators
- Annotation of informed consent and related data for rapid queries of permitted and restricted uses
- Tracking and reporting of sample, clinical, demographic, and ethical attributes



CELLULAR PRODUCTS

Human Cellular Products

- AccuCell® cryopreserved Human Peripheral Blood Mononuclear Cells (PBMCs) and Cord Blood Mononuclear Cells (CBMNC)
 - Functionality comparable to fresh isolations
 - High survival and post-thaw recovery rates
 - HLA type provided tested for proliferative capability and cytokine production
- 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



- Normal healthy human PBMCs
 - Cryopreserved human PBMCs
 - Purified CD4 T-cells, CD8 T-cells, CD14 monocytes, and CD19 B-cells (each $\geq 80\%$ pure)
 - Cryopreserved using a controlled-rate freezing program
 - Real-time stability testing program demonstrates long shelf life
 - Large lot sizes available (up to 12 billion cells from a single donor)
 - Available in a variety of sizes to fit the needs of discovery research and high throughput screening
 - Custom isolations and aliquot sizes upon request
- Our AccuCell® PBMC product inventory encompasses more than 50 unique healthy donors, each characterized with testing and demographic data to fit your precise needs
 - Basic demographics include: age, gender, ethnicity
 - HLA Class-I and Class-II information available
 - IFN- γ responses against PHA, CEF, and CMV stimulants
 - ADCC testing results available on select lots
 - FACS purity analysis for purified subsets
 - Tested negative for HIV, HBV, and HCV
- AccuCell® products are for research use only
 - To find lot-specific information and order online, go to www.buypbmcs.com



PRECISION'S LABORATORY NETWORK (PLN™) IS A WORLD-WIDE NETWORK OF AUDITED AND QUALIFIED PARTNERS THAT SUPPORT LARGE MULTINATIONAL TRIALS ACROSS SIX CONTINENTS.

Advancements in precision medicine require well annotated, controlled biospecimens and standardized testing across the globe. Precision recognizes risk points in the drug and diagnostic development cycles and aims to reduce these risks. Our PLN™ -backed services help developers control for quality and reduce risks by offering the following capabilities:

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- Integrated services to facilitate transfer of your protocols into research or commercial partner labs
 - Ongoing quality assurance of lab partners from trials through commercialization
 - Quality-assured sample collection, processing, and storage
 - Competency assessment and monitoring of all participating PLN™ partners performed to ensure standard SOPs are followed
 - Real-time inventory tracking through our PEGASIS reporting system provides virtual sample management system for samples stored across the globe and at different institutions
 - Short- or long-term storage at optimal temperatures
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PLN™ GLOBAL SERVICES

- PBMC and Cell Subsets Isolations Services
 - Blood processed within 24-48 hours of draw anywhere in the world
 - High post-thaw viability, functionality, and recovery rates
- DNA and RNA Extractions
 - Automated and manual extraction from a variety of tissues and fluids
 - Quality, purity, and yield assessments
 - Centralized processing to eliminate batch variations
- Global Sample Transportation
 - Customs clearance and management of licenses and permits
 - Door-to-door shipment tracking
 - Use of quality-controlled dry shippers
- Custom Collection Kits
 - Specimen kit design, production, supply and resupply tracked and managed by Precision
- Long-Term or Short-Term Storage
 - Cryopreservation operations on a global scale
- Ensuring a Quality Worldwide Lab Network
 - Ongoing quality assurance of lab partners from trials through commercialization
 - Use of standardized, validated methods
- Our Biological Sample Management System
 - Real-time inventory tracking through our proprietary dashboard system to monitor sample locations at all times
 - Ability to manage samples stored in multiple repositories around the globe



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

