PRECISION for medicine | BIOSPECIMEN SOLUTIONS

Our Products and Services

Quality Biospecimens. Superior Science

PrecisionBiospecimens.com

BIOSPECIMENS

Thousands of IRB-approved, clinically annotated biospecimens ready to ship same-day to your lab

Precision for Medicine has built one of the world's most extensive biobanks and sample collection networks, capable of meeting the stringent needs of any disease research program. Whether using specimens for assay development, bench research, or generating big data for your research or development studies, we deliver.

Blood, Biofluids, and Derivatives

Diseased and healthy human blood, plasma, serum, CSF, stool, ascites fluid, saliva, urine, and more.

Tissues

Pathologist-verified, fresh, frozen, and fixed tissue specimens from healthy and diseased human subjects.

Viable Cells

HLA-typed cellular products including PBMCs, BMMCs, leukopaks, DTCs, and more.

Custom Biospecimen Collections

Global clinical network, regulatory approved, and ready to enroll.

Liquid Biopsy

Comprehensive services including kitting, collection, processing, and profiling from your patients or ours.

STUDY SPECIMEN COLLECTION KITS

Designed to simplify enrollment and maximize specimen and data quality

Study-specific specimen collection kits designed to simplify enrollment and maximize your specimen and data quality.

Study Kits Designed to Minimize Pre-Analytical Variables

- Biospecimen collection supplies (for blood, tissue, biofluids, and more)
- Study/time point-specific labels
- Shipping materials
- Study-specific forms and lab requisitions

Study Kit Distribution and Tracking

- End-to-end chain of custody and inventory management
- Domestic and international shipping
- Streamlined with pre-filled shipping labels and air bill documentation
- UN3373- and IATA-compliant
- On-demand reporting

SPECIALTY LAB SERVICES

A global footprint of ISO, CLIA, and CAP specialty labs available to generate robust biomarker data for your research projects

Precision for Medicine was purpose-built to support biomarker-driven development programs, with a strong focus on biomarker assay development. Our comprehensive approach starts with a foundation of expertise in key biomarker discovery and analysis methods such as immune monitoring, genomics, and bioanalysis.

DNA

- PCR—ddPCR, qPCR
- Sequencing—whole exome, targeted panels

RNA

- Gene expression profiling—NanoString
- RNAseq
- rtPCR

Cell

- Flow cytometry—up to 31 color panels, ICS, phospho flow
- Immunophenotyping via proprietary epigenetic platform
- Functional assays—eg, T-cell activation, ADCC, ELISpot, receptor occupancy
- Single-cell quantitative image analysis
- Proprietary cell separation technology for CTCs and cfDNA

Protein

- Comprehensive large molecule bioanalysis (PK, ADA, NAb)
- Multiplex cytokine profiling, receptor occupancy, tetramer staining
- Custom ligand binding assays—ELISA, MSD, Biacore
- Quantitative image analysis of protein expression (eg, phosphorylation, signaling)

Tissue

- Multiplex IHC with centralized pathology reading
- Quantitative IF—up to 9 concurrent markers
- FISH, ISH, sequencing

BIOSTORAGE SOLUTIONS

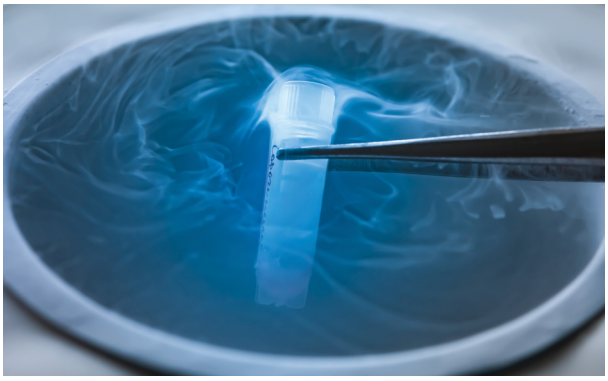
Spend more time researching, less time managing specimens

Precision offers global specimen logistics, long-term storage, and management of research and clinical study biospecimens. Outsourcing your biospecimen storage and bioprocessing provides advantages in both cost and quality. Our flexible and scalable services meet your evolving storage needs and provide secure, temperature-controlled, and monitored off-site storage of your biologics.

State-of-the-Art Biorepositories

Trusted by life science industry, academic, and government agencies worldwide, including the NIH, NIAID, NHLBI, NIDDK, NIA, NCI, and CDC.

- Onsite storage capacity of more than 100,000,000 specimens
- Backup generators and redundant HVAC systems
- 24/7/365 monitoring system and alarm response
- On-demand web-based reporting
- ISO 9001:2008, ISO:13485:2003, CAP accredited, 21 CFR 11-compliant, cGMP-compliant



Temperature-Controlled

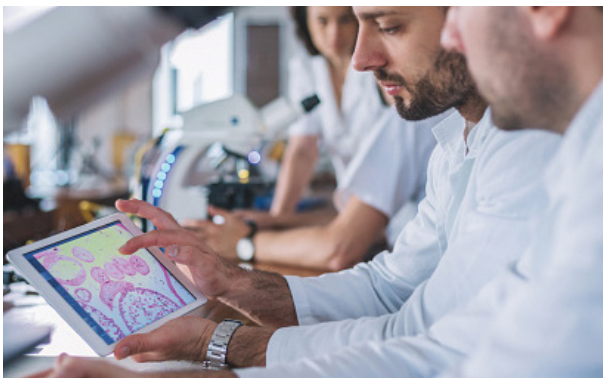
Validated and temperature-mapped storage chambers, monitored 24/7/365, optimizing storage conditions of your research and clinical trial specimens.

- Vapor phase liquid nitrogen storage (<-135°C)
- Ultra-low storage (-70°C to -90°C)
- Frozen storage (-15°C to -25°C)
- Refrigerated storage (2°C to 8°C)
- Ambient storage (20°C to 25°C)

CLINICAL TRIALS & DATA SCIENCE

A full-service CRO

We succeed by pairing personalized clinical services with translational medicine excellence, making us the first fully integrated clinical research organization created expressly to help advance the promises of precision medicine.



Clinical Trials

End-to-end CRO services for your biomarker-driven clinical trials.

- Clinical trial feasibility, design, and management
- Clinical trial assay optimization and regulatory filings
- Virtual sample inventory management
- Specialty lab services

Data Science

Data aggregation, harmonization, and analysis for your biomarker program leveraging our proprietary QuartzBio platform and team.

- Translational informatics, biomarker selection, and computational biology
- Biostatistics
- Clinical data management
- Biometrics

REGULATORY AND MARKET ACCESS SUPPORT

Building value into advanced diagnostics for optimized capture in the marketplace

At Precision, we understand the intricacies of IVD and companion diagnostic development and can help you prepare and integrate regulatory and market access strategies that facilitate market entry and successful uptake of both the test and associated drug.

100+
IVD PRESUBMISSIONS, PRECLINICAL TRIAL DESIGNS, AND EXECUTIONS

250+
MARKETING CLEARANCES AND APPROVALS FOR IVD SUBMISSIONS

100+
DX REGULATORY FILINGS IN COUNTRIES AROUNDTHE GLOBE

100+
DX AND CDX MARKET ACCESS PROJECTS

15+
MARKETS ON 3 CONTINENTS FOR MARKET ACCESS PROJECTS

Regulatory Strategy and Submission

Our experts can support you through regulatory strategy and submissions for CDx, IVD, and LDTs. Our team has helped hundreds of clients gain authorizations, clearances, and approvals for their diagnostics.

- Regulatory pathway and strategy
- Global submissions including United States (EUA, 510(k), De Novo, PMA, and Breakthrough), European Union (CE Mark to IVDR), Japan (PMDA), Health Canada, and more, applied to traditional in vitro diagnostics, or CDx
- Presubmission package development, submission, and interactions with FDA
- Quality systems gap assessments, implementation, and oversight

Commercial Consulting

Our team of experienced market access and reimbursement strategists can help you develop and execute on your go-to-market strategy.

- Market access and channel optimization
- Coding and payment strategy and tactical support
- Assay platform and format selection
- Utility evidence, value message development, and access to coverage

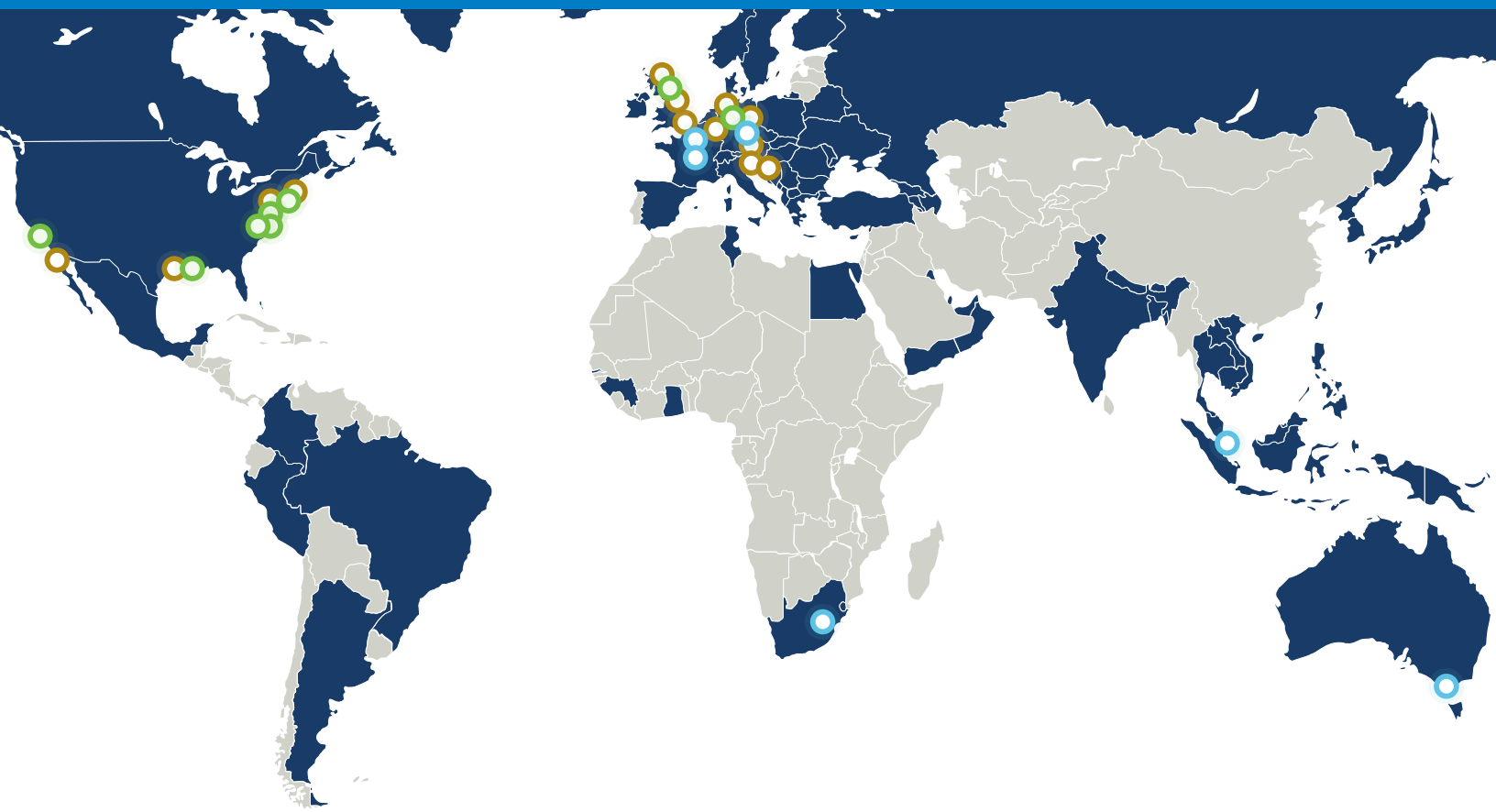
30
MILLION BIOSPECIMENS MANAGED

7
LABS: CAP, CLIA, ISO, & FDA-REGISTERED

500+
TRIALS CONDUCTED FOR IVD, CDX, & THERAPEUTICS

3
MILLION PBMC, DNA, & RNA ISOLATIONS

55+
COUNTRIES WITH REAL-TIME SAMPLE PROCESSING



- Clinical Reach
- Precision Labs
- Sample Processing Labs
- Offices/Entities

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