IVD and CDx Solutions

Comprehensive Services From Research to Regulatory

PRECISION for medicine

A Partner to Bring Your Diagnostic From Research to Realization

Successful diagnostic development is a complex process, requiring not only scientific expertise but also an ability to navigate the intricacies of global regulatory frameworks—and for novel or high-risk diagnostics, a strategic and effective clinical trial process.

Precision for Medicine brings together a robust biobank of biospecimens along with comprehensive development, regulatory, and clinical trial support services to help make your product a reality.

Biospecimens

Clinical Trial Support

Kitting & Logistics

Biomarker & Assay Development Solutions

Regulatory Services

Biospecimens

Blood, Biofluids, and Derivatives

- Diseased/healthy
- Blood/plasma
- Serum
- CSF
- Stool
- Ascites fluid
- Saliva
- Urine

Tissues

- Fresh/frozen/fixed
- Healthy/diseased
- FFPE tissues
- Tissue microarrays
- Pathologist verified

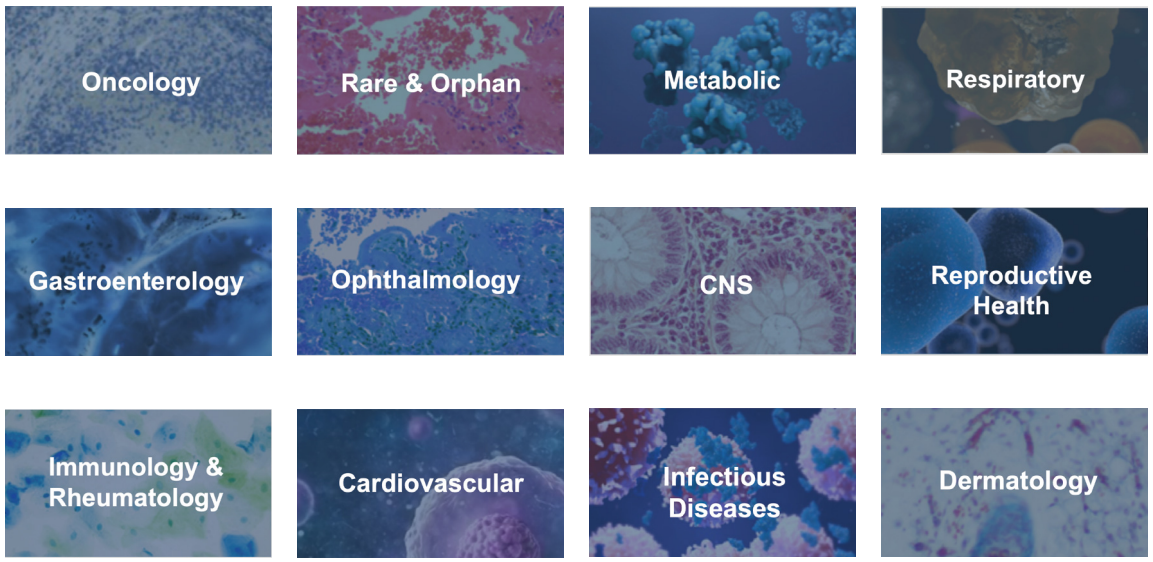
Liquid Biopsy

- Custom specimens
- Fresh/same-day/ next-day
- Matched surgical biopsies
- Pre- and post-treatment
- Longitudinal collections

Viable Cells

- PBMCs
- BMMCs
- Leukopaks
- Mobilized leukopaks
- Dissociated tumor cells
- Purified cell subsets (eg, CD34+)
- HLA typed

Therapeutic Areas



NGS Characterized Biospecimens

Precision for Medicine offers clinical samples characterized via next-generation sequencing (NGS) to help researchers optimize biomarker and diagnostic development. These samples include many oncology indications, including melanoma, lung, breast, thyroid, brain, and pancreatic cancer, and have been characterized via popular NGS panels to profile specific mutations.

Researchers can select from among Precision's NGS-characterized library of both FFPE tissue blocks and liquid biopsy biospecimens to find characterized samples of interest.

Specimens characterized via low-, medium-, and high-throughput sequencers

- 8 million throughput sequencer
- 60 million throughput sequencer
- 260 million throughput sequencer
- 15 billion throughput sequencer

Precision's NGS-Characterized Specimen Library Contains

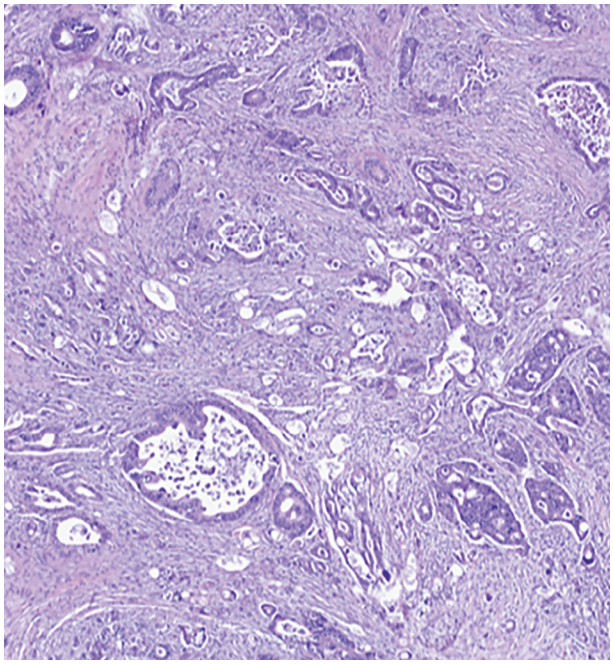
>12,000
FFPE TISSUE BLOCKS

>350
LIQUID BIOPSY SAMPLES

Digital Pathology

In addition to millions of available tissue, cell, and liquid biopsy biospecimens, Precision has created an archive of digital images from our specimen library. These H&E-stained images can be delivered securely through the cloud and are a powerful tool for quantitative pathology, development of predictive AI models, or other digital pathology uses.

- Digital images scanned via Leica Aperio GT 450 or 3DHISTECH
- Physical tissue samples available as FFPE blocks, curls, or slides
- Additional data enrichment via NGS is available
- Histology services via CLIA lab, including standard and special stains
- Custom pathology annotation



Clinical Trial Support

To support diagnostic clinical trials, Precision has partnered with over 150 clinical collection sites to collect samples as needed, based on medical condition and patient phenotype. Our team can provide support to overall project planning, management, and quality as well as regulatory review and submissions.

- Planning feasibility and study design
- Design of collection procedures
- Population selection
- Data capture, management, and reporting
- Patient enrollment and collection

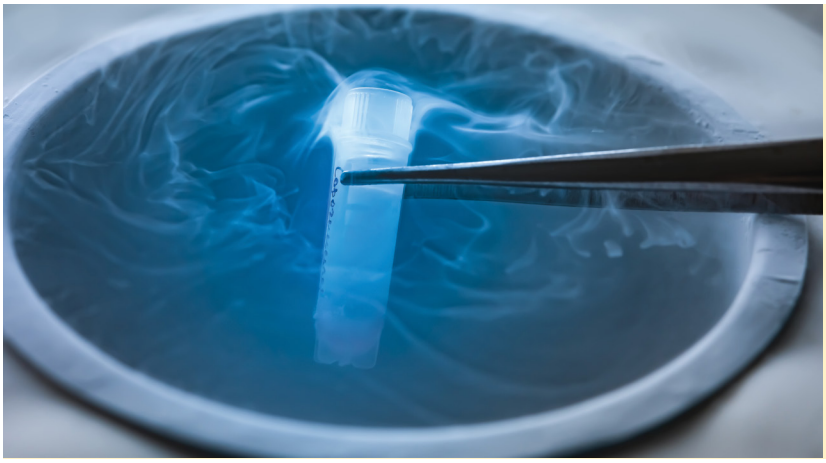
150+
CLINICAL COLLECTION SITES

PROSPECTIVE COLLECTIONS IN
90+
MEDICAL CONDITIONS

Kitting and Logistics

Precision for Medicine's specimen collection kits, manufactured within our world-class facility, are customized to meet your collection protocols, processing, and shipping needs. We manage global shipping and logistics and can store samples in our 100,000 square feet of biostorage at a range of temperatures.

- Biospecimen collection supplies (for blood, tissue, biofluids, and more)
- Study-specific labels, forms, and lab requisitions
- ePortal* access for inventories, kit reorder, and shipment status
- End-to-end chain of custody and inventory management
- Temperature-controlled biostorage:
  — Ambient, +4°C, –20°C, –80°C, liquid nitrogen
- Backup generators and around-the-clock monitoring and alarm response



35M
SAMPLES MANAGED

*Availability based on project.

Biomarker, Assay Development, and Validation Solutions

With 7 specialty labs across the US and Europe and expertise across all types of biomarker assays, Precision can support diagnostic and CDx development from biomarker discovery through clinical trial assay development and to full IVD development.

Precision's instrumentation and capabilities include all major immunohistochemistry (IHC) platforms, multiplex immunofluorescence (mIF), multiple NGS and genomics platforms, immunoassays, and gene therapy immunogenicity. Precision also has redundant instrumentation at multiple labs, allowing for the assessment of site-to-site variability.

- Assay development, transfer, validation to CLIA/CAP standards
- Clinical trial sample testing
- Controls and validation set creation
- 510(k)-specific testing
- Special expertise in gene therapy immunogenicity assessments and CDx development
- Centralized pathology reads

7

SPECIALTY LABS IN US AND EUROPE

2000+

THERAPEUTIC, DIAGNOSTIC, AND CDx PROGRAMS SUPPORTED

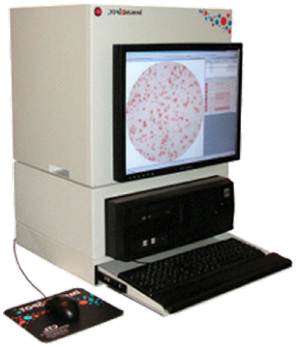
Precision's Diagnostic Development Instruments and Assays Include

IHC and mIF

- Leica BOND
- Dako Omnis, Dako Link 48, Artisan
- Ventana BenchMark
- Akoya PhenoImager™ HT
- Pathology services

NGS and Genomics

- NGS: Illumina, Thermo Fisher
- NanoString
- ddPCR, qPCR
- 10× genomics



Immunoassays

- NAb/TAb
- ELISpot
- ELISA
- Cytokine profiling
- Flow cytometry up to 31 colors

*CLIA/CAP, Clinical Laboratory Improvement Amendments/College of American Pathologists.

Regulatory Services

Precision for Medicine provides expertise and support across IVD development, offering comprehensive regulatory strategy, early agency interactions, design of analytical validation studies, clinical trial designs, and global regulatory submissions.

- Regulatory strategy development and regulatory pathway identification (eg, FDA/LDT, product class/IVDR)
- Diagnostic protocol designs and IRB submissions
- IDE, 510(k), Special 510(k), EUA, De Novo, and PMA submissions
- ANNEX XIV submissions and IVDR technical documentation file development for EU
- Global registration filings

200+
IVD & CDx PRESUBMISSIONS, IDEs, ITAs, AND ANNEX XIV SUBMISSIONS

250+
510(k), SPECIAL 510(k)s, EUAs, DE NOVOs, PMAs, PMA SUPPLEMENTS FOR IVD & CDx SUBMISSIONS IN THE US

100+
IVD & CDx GLOBAL REGISTRATIONS

Companion Diagnostics (CDx) Regulatory Expertise

The development of companion diagnostics can carry challenges beyond the development of a stand-alone diagnostic (IVD), including the need to coordinate the CDx development with its therapeutic to align parallel approvals.

Precision's CDx Regulatory Team excels at supporting co-development, from early phase biomarker development through therapeutic and CDx market authorizations.

- Global CDx regulatory strategies and submissions to ensure successful CDx and therapeutic approvals
- Diagnostic clinical trial testing strategy for patient selection; central lab vs multiple LDTs
- Clinical trial assay analytical validation study plans and execution; CLIA vs CLSI Guidelines
- Dx clinical protocol development and IRB approvals
- Clinical trial enabling IVD regulatory submissions globally (SRD, Q-Sub, IDE, Annex XIV, ITA)
- Therapeutic/diagnostic partnering strategy, identification, and support

Preclinical to Phase 1	Phase 2	Phase 2/3	Phase 3
Identify Biomarker Signature	Partner ID & IVD Clinical Trial Submissions	Analytical Study Designs & Presubmissions	Ensure Timely Regulatory Approval

Solving the most complex challenges in biomarker-driven and precision therapeutic and diagnostic development

7.5
MILLION
LIQUID
BIOSPECIMENS

3.5
MILLION
TISSUE
BIOSPECIMENS

7
LABS ACROSS
NORTH AMERICA
AND EUROPE

90+
MEDICAL
CONDITIONS FOR
PROSPECTIVE
COLLECTIONS

350+
IVD AND CDx
SUBMISSIONS
AND GLOBAL
REGISTRATIONS

Providing End-to-End Solutions for IVD and CDx Development

Biospecimens | **Clinical Trial Support** | **Kitting & Logistics** | **Lab Services** | **Regulatory Consulting**

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Rev. 01

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