

# Pathology Services

PRECISION  
for medicine®



# Pathology Capabilities Overview

Our group of highly qualified board-certified pathologists support all areas of clinical research – biomarker discovery and evaluation, companion diagnostics development, and in vitro diagnostics (IVD) development, including clinical trial work, regulatory support, and optimizations. Precision for Medicine was built specifically to support biomarker-driven development programs, with a strong focus on biomarker assay development. Our global lab network combined with our kitting and logistics ensure rapid turnaround of results and stable transit of tissue samples to accelerate your development timelines.



## Pathology Services

With an integrated high-throughput histology laboratory, offering services such as pathologist review and annotation, Precision can support global clinical studies from early-phase discovery and IVD through late-phase studies.



## Digital Pathology Services

Precision for Medicine offers digital pathology solutions to enable simpler storage, sharing, and retrieval of whole slide images (WSIs)—for real-time collaboration across laboratories. Combined with our pathology capabilities, we can provide you with the right samples at the right time.



## Tissue Biospecimens

Our repository has over 3 million FFPE tissue samples and several million histology slides covering a full spectrum of oncologic and medical diseases, with quality control from our onsite pathologists. Additionally, Precision’s network of over 100 hospitals allows for prospective collections for custom-tailored projects.

## Our Pathologists



**Cullen Taylor, MD**  
Medical Director,  
Precision for Medicine



**Dawn Butler, MD**  
Pathologist,  
Precision for Medicine

# Pathology Services

With expertise across all areas of clinical research for biomarker discovery, CDx development, and IVD development, Precision's pathology services support sample characterization and assay validation, orthogonal data, and reproducibility studies.



## General Applications

- Perform laboratory-developed test (LDT) stains and FDA-approved companion diagnostic stains on our archived tissue specimens or client-provided tissue in CAP- and CLIA-accredited labs
- Utilize a large biorepository of next-generation sequencing (NGS)-characterized oncology tissues and high-density tissue microarrays (TMAs)
- Leverage large, comprehensive clinical pathology datasets for multiple disease indications to reveal biological complexity in each tissue section
- In vitro diagnostics (IVD) assay development and enablement



## Pathologist Expertise: Annotation Services

- Board-certified pathologist scoring, review, and annotation of tissues and cells
- Decades of experience in early- and late-phase studies and patient enrollment
- Expertise in study design, assay transfers, and validations
- Scoring consultation and custom scoring development

## Qualifications

- CAP, CLIA, ISO 9001, ISO 13485

## Immunohistochemistry (IHC): Validated Autostainers

With the ability to perform and interpret commercially available immunohistochemistry—such as ER, PR, HER2, and PDL1—or work with companies in optimization and validation, IHC is an area of expertise at Precision. Our labs are equipped with the leading platforms in the industry, with multiple instances of these instruments within and across our labs to provide you with the best solutions.

- Dako Link 48
- Dako Omnis
- Ventana BenchMark ULTRA
- Leica BOND RX
- Leica BOND-III

## Sequencing: Platforms and Assays

Precision's labs offer custom and off-the-shelf NGS assays on different platforms for a variety of characterization in both cfDNA and any tissue type.

### Illumina

- TSO 500
- Whole Genome
- Whole Exome
- RNA-Seq

### Thermo Fisher

- Oncomine Precision Assay
- TCR-Seq

## Digital Pathology Services

Our digital pathology solutions are designed to bring you the right samples at the right time. Having invested in multiple on-site scanners to ensure our solutions are platform agnostic, and onboarding the necessary technologies, such as HALO AP and Proscia Concentriq®, to develop a seamless workflow for delivery, storage, and analysis of your samples. These platforms also allow for flexibility in sample review and collaboration, while accelerating your sample procurement timelines.

- Use of software-based image analysis for better and faster quantification of WSIs using solutions like HALO from Indica Lab or Visiopharm
- WSI scanning platforms:
  - Leica Aperio GT 450
  - 3DHISTECH
- Training of complex AI algorithms for tumor and/or cell classification
- Real-time collaboration with other pathologists with online collaboration and image management tools like HALO AP

## Whole Slide Images (WSIs)

Thousands of digital H&E tissue slides with IHC and genomic characterization alongside 3 million FFPE blocks ready to be scanned and annotated upon QC – ensuring delivery of curated samples that meet your exact needs.

### High-Resolution Digital Images, H&E-Stained FFPE Tissue

- Cancer and benign indications
  - Custom scans available upon request
  - Slides with NGS and IHC characterization readily available
- FFPE blocks, slides, or curls available alongside images
  - Residual extracted DNA and RNA available

### Proscia Concentriq®: Cloud-Based Delivery

Capable of storing and delivering thousands of digital H&E tissue slide images to you instantaneously—cloud-based delivery allows for real-time collaboration with other pathologists for IHC optimization and scoring methods, and instant retrieval of images for pathologist annotation anywhere in the world, serving as a powerful tool for quantitative pathology, development of predictive AI models, and other digital pathology uses.

### Characterization of Digital H&E Images

- Generic pathology report with quality indicators and tissue metrics
- Custom pathology report or annotation (necrosis, fat, tumor) available upon request

### Additional Characterization

- IHC, Multiplex Immunofluorescence, RNAscope, FISH, and other services available
- Next-generation sequencing (NGS)
- Standard and special stains; companion diagnostic stains

# Tissue Biospecimens

Our combined repository of FFPE samples and histology slides, containing a wide variety of disease-state tissue and healthy normal tissue, undergo extensive pathologist review to ensure only the highest-quality samples are delivered to you for downstream applications. Precision's network of partner hospitals and laboratories allow us to prospectively collect samples for indications not in our repository.

Oncology Indications*				
Breast	Colon	Colorectal-MSS	Endometrial	GIST
Lung-NSCLC	Melanoma	Ovarian	Prostate	Thyroid

\*other indications available upon request

## Formalin-Fixed Paraffin-Embedded (FFPE) Tissue

CAP-graduated clinical FFPE tissue samples are obtained from high-caliber CLIA- and CAP-certified laboratories and hospitals. Our samples are of the highest quality, suitable for varied downstream analysis and assay utilization or TMA preparation.



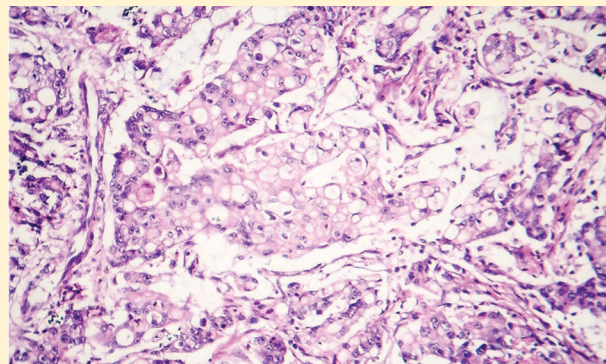
- Excisions, resections, and biopsies available
- Tissue formats:
  - Blocks
  - Slides
  - Curls
  - TMAs
- Clinical data:
  - Patient age, sex
  - Date of collection
  - Diagnosis, subdiagnosis
  - TNM and stage, grade
- Additional data available at pathologist QC

## Histology Slides

- Hematoxylin & eosin (H&E)-stained slides
- Special stains
- Custom stains available upon request

### Slide Characterization

- Cancer and benign indications
- Pathologist QCed
- FFPE blocks and curls available alongside slides

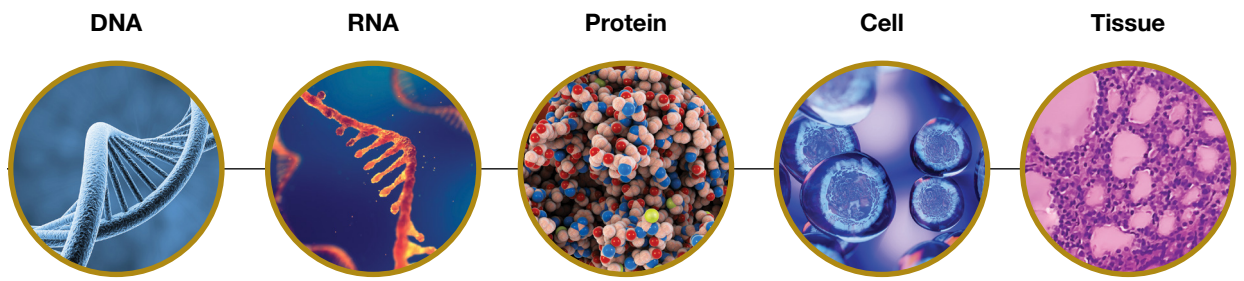


# Solving the most complex challenges in biomarker-driven and precision therapeutic development

Precision for Medicine is the first clinical research services organization engineered to support life sciences companies in the use of biomarkers essential to targeting patient treatments more precisely and effectively. Combining deep scientific expertise, clinical trial excellence, and advanced approaches for data science, Precision accelerates therapeutic development from the late preclinical phase through commercialization.

- 7 specialty labs throughout North America and Europe
- Sample processing labs on 5 continents
- Central lab services, including custom kitting, logistics, processing, and storage
- Assays available under GxP, CLIA, CLSI, CAP, ISO 9001/13485

Comprehensive suite of technologies, capabilities, and proprietary approaches to interrogate any sample type



- DNA**
- PCR—ddPCR, qPCR
  - NGS—whole exome and targeted resequencing

- RNA**
- Gene expression profiling—NanoString
  - CAR T and virus (ie, gene therapy) biodistribution
  - rtPCR
  - MicroRNA analysis

- 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)

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

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



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