PhenoPath provides anatomic pathology services for Phase I–III clinical trials. Our team adapts its service delivery to reflect your project design, management and implementation requirements. PhenoPath is experienced in working with third-party vendors to ensure timely and trackable specimen management, either directly from sponsor sites or another CRO.

PhenoPath understands the need for timely results on entrance criteria testing, and provides rapid turnaround time for biomarker-testing assays. Board-certified pathologists and/or scientists evaluate all assays. Report formats are customizable to reflect either individual case or cumulative case formats.

**PATHOLOGY SERVICES**

**DIAGNOSIS & INTERPRETATION**
- Solid tumor diagnosis and subtyping, including breast, colon, lung, sarcoma, etc.
- Hematopathology diagnosis and subtyping including, lymphoid, myeloid, plasma cell disorders, etc.
- Tissue biomarker quantification, including flow cytometry, immunohistochemistry (IHC), immunofluorescence (IF), cytogenetics, fluorescence in situ hybridization (FISH), chromogenic in situ hybridization (CISH), DNA/RNA in situ hybridization (ISH), and polymerase chain reaction (PCR)
- Tissue macrodissection for downstream assay(s)
- Tissue microarray construction
- Over 450 tests available

**EXPERT CONSULTATION**
- Consultation on therapeutic target selection and quantification in the pre-clinical setting
- Consultation on all pathology-related aspects of clinical trial design, including optimized therapeutic target quantification
- Second opinion consultation on complex cases, including clinical correlation

**CONTINUOUS EDUCATION**
- PhenoPath pathologists follow the latest developments in cancer diagnosis and treatment
- PhenoPath pathologists publish extensively in scientific peer-reviewed journals
- PhenoPath Pathology Reference Guide available
- PhenoPath pathologists are available to present on-site at investigator meetings

**ENTRANCE & ENROLLMENT**

**RAPID ENTRANCE CRITERIA SCREENING**
- Rapid pathology testing and evaluation by board-certified pathologists and scientists
- Close coordination with each sponsor’s clinical trial organizers

**REPORTING CAPABILITIES**
- Custom report formats
- Scalable and configurable results reporting database
- Virtual pathology reporting capabilities
- Secure and encrypted data transfer and archiving

**SPECIMEN MANAGEMENT**
- End-to-end specimen acquisition and tracking
- Rapid-turnaround time for enrollment criteria

PD-L1 by IHC
### Expertise

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<td>Amyloid subtyping</td>
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### Quality

- PhenoPath has an independent, on-site Quality Assurance Unit (QAU) with several decades of combined experience in CLIA, GLP and GCP environments
- Comprehensive Quality Management System, including:
  - All processes governed by SOPs
  - Change control process
  - Procedures for preventative and corrective actions (CAPA)
  - Quality metrics
  - Competency assessments of technical staff

### Regulatory Compliance

- CAP accreditation for high-complexity testing under CLIA
- Licensed laboratory in CA, FL, MD, NY*, RI, and WA (*subset of services)
- Studies performed in accordance with GLP/GCP, as applicable
- Clinical Trial activities at PhenoPath will be conducted according to PhenoPath’s Standard Operating Procedure (SOPs) and the following:
  - ICH Guideline for Good Clinical Practice (E6)
  - Good Clinical Laboratory Practices as outlined in the WHO "Good Clinical Laboratory Practices Guideline"
  - European Medicines Agency (EMA) "Reflection Paper for Laboratories that Perform the Analysis or Evaluation of Clinical Trial Specimens."

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If you would like more information about PhenoPath’s BioPharma services, please visit our web site at [www.phenopath.com](http://www.phenopath.com), contact any of our pathologists (888-927-4366), or contact your sales representative to request a quote.