



BIOPHARMA SERVICES

For over 15 years, PhenoPath has collaborated with biopharma, biotechnology and academic institutions worldwide on the development of oncology focused therapies. PhenoPath BioPharma services support pre-clinical research, all phases of clinical trials, development of tests for cancer-associated biomarkers, drug and companion diagnostics development, and translational oncology research.

ABOUT PHENOPATH

EXTENSIVE DIAGNOSTIC ONCOLOGY EXPERIENCE

- PhenoPath is nationally recognized as a leader in solid tumor and hematologic cancer diagnostics
- PhenoPath pathologists have diagnosed and identified targeted therapy on over 200,000 clinical cases
- PhenoPath supports up to 200 research projects and clinical trials a year

EXPERT PATHOLOGY TEAM

- PhenoPath pathologists follow the latest developments in diagnostic oncology
- Collectively, PhenoPath pathologists have published over 450 peer-reviewed scientific publications
- Customer consultation and collaboration are PhenoPath's core commitments
- Pathology Reference Guide available

COMPREHENSIVE LABORATORY SERVICES

- PhenoPath offers an extensive array of fully validated assays including IVD, RUO, ASR, and LDT
- Tissue biomarker quantification capabilities are offered for applicable assays
- Histology support includes processing, embedding, and sectioning

QUALITY DRIVEN PROCESSES

- Standardization of methods, automation and quality control and use of an independent QAU ensures reproducible and accurate results
- Comprehensive quality system is built upon use of SOPs, regulatory training, job specific competency assessments, and process controls
- Each project is tailored to the client's requirements for testing methods, quality standards, and documentation

PhenoPath
BioPharma Pathology Services

EXPERTISE

SOLID TUMOR PATHOLOGY	HEMATOPATHOLOGY
Diagnosis and subtyping (breast, colon, lung, sarcoma, etc.)	Indolent B cell non-Hodgkin lymphoma
Undifferentiated malignant neoplasms	Prognostic and predictive markers
Carcinomas of unknown primary site	Aggressive B cell non-Hodgkin lymphoma
Spindle cell tumors/sarcoma subtyping	T cell non-Hodgkin lymphoma
Mesothelioma vs. adenocarcinoma	Lymphoblastic leukemia / lymphoma
Small, blue, round cell tumors	Hodgkin lymphoma
Germ cell neoplasms	Plasma cell neoplasms
Skin and mucosal immunofluorescence studies	Acute myeloid leukemias
Chronic myeloid neoplasms (MDS & MPN)	Rare hematolymphoid neoplasms
Hydatidiform mole evaluation	Benign hematolymphoid proliferations
Amyloid subtyping	

TESTING CAPABILITIES

IHC, IF, DNA/RNA ISH, RNAScope	IMAGING & QUANTIFICATION
Dako Link 48	Aperio AT2
Dako Omnis	PerkinElmer Nuance inForm Multispectral Imaging
Ventana Benchmark Ultra	PCR
Ventana Benchmark Discovery	Bio-Rad CFX96
BioCare Intellipath	Roche cobas z 480
Leica Bond-Max	Qiagen Rotor-Gene Q
10-color FLOW CYTOMETRY	FISH / CYTOGENETICS
Beckman Coulter Gallios™	MetaSystems Metafer 4

SERVICE DELIVERY

PROJECT MANAGEMENT	DATA MANAGEMENT
Central point of contact	Customized database development
Coordination of all delivery groups	Virtual pathology reporting capabilities
Structured processes	Secure and encrypted data transfer and archiving
GLOBAL LOGISTICS	REGULATORY COMPLIANCE
Sample integrity and security	CAP Accreditation / CLIA Certificate
International and domestic shipping capabilities	Permits and Licenses: NY, CA, MD, FL, RI
Long-term specimens storage	Studies performed in accordance with GLP/GCP, as applicable