



RESEARCH & DEVELOPMENT

PhenoPath's scientific team strives to create an environment of collaboration with our clients. Our team stands ready to support the client's projects including development, optimization and validation of specialty pathology assays for use in biomarker discovery, drug development, diagnosis, and clinical trial applications.

METHOD DEVELOPMENT

VALIDATION

- Carefully selected antibodies target tissue-specific markers, tumor prognostic and predictive markers, surrogate markers of chromosomal translocations, and a broad range of esoteric antigens
- Validation protocols include testing for specificity, sensitivity and reproducibility. Accuracy, precision, reportable range, reference intervals, co-localization, or concordance are evaluated, if relevant
- Technology transfers include development of detailed procedures and creation of project-specific SOPs, if applicable
- Controls and/or tissues are tested with alternative technology, when appropriate
- Technology transfers include verification and/or validation of the procedures and creation of project-specific SOPs, if applicable
- Comprehensive validation reports are provided
- PhenoPath commonly uses human, animal, xenografts, and patient-derived xenografts in our clinical studies

METHOD DEVELOPMENT - IHC

- Antigen retrieval methods, antibody titer and detection systems are optimized
- Antibodies can be tested on whole tissue sections, tissue microarrays, cell culture pellets, or xenografts

METHOD DEVELOPMENT - FLOW CYTOMETRY

- Up to 10-color custom assays may be designed for surface or intracellular antigens
- Internal positive and negative control populations are generally used, but if not available, isotype-matched controls can be utilized

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