



PPD® LABORATORIES
BIOMARKER LAB



Biomarker Lab Capabilities Overview

PPD® Laboratories' biomarker lab works closely with clients to shape **biomarker strategy** and **drive projects to completion** even where uncertainty exists.

Selecting the best analytical technology or method and the best regulatory strategy requires significant discussion and investigation. PPD Laboratories takes a collaborative cross-functional approach to each project in order to provide the flexibility needed to develop customized solutions.

Our lab works with clients to:

- Identify the appropriate biomarker
- Select the right regulatory approach from fit-for-purpose to full compliance
- Choose the best analytical methodology
- Develop and validate the specific assay(s)
- Confirm intended useful purpose through clinical trials

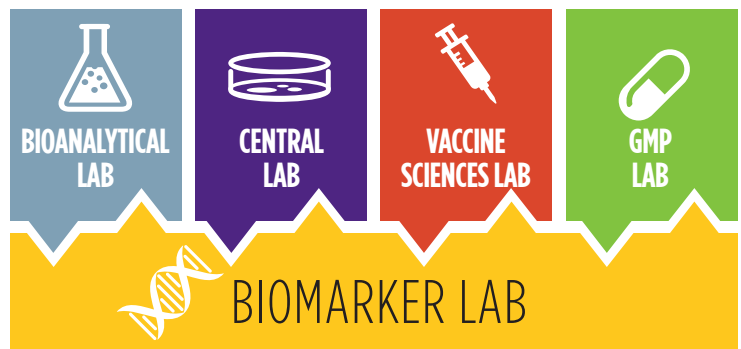
Integrated Approach

Our biomarker lab is committed to helping clients identify the right strategy for each development phase so that they can efficiently achieve their end goals. To do this, PPD Laboratories has a dedicated biomarker lab and additional capacity integrated into our bioanalytical lab and our central lab.

An integrated approach:

- Provides flexibility
- Leverages the operational experience of PPD Laboratories' bioanalytical and central labs
- Allows the biomarker team to provide a customized development strategy for each project
- Enables the biomarker lab to apply a tiered regulatory strategy from fit-for-purpose and GLP to GCLP and CLIA

AN INTEGRATED AND FLEXIBLE APPROACH TO BIOMARKER DEVELOPMENT



Our cross-laboratory model of support includes:

- Working with clients to select the right development approach
- Helping clients select the best technology platform to meet the unique requirements of each project
- Developing and validating methods under the appropriate regulatory guidelines at each stage of drug development
- Transferring and cross-validating assays to different/multiple locations or under multiple regulatory requirements
- Providing insight into how to effectively integrate safety and efficacy biomarkers into clinical development
- Global coverage for studies of all sizes

Biomarker Lab Capabilities Overview

Discipline/Methodology	Expertise and Experience	Key Instrumentation
Flow Cytometry Assays	<ul style="list-style-type: none"> Immunophenotyping, receptor occupancy, intracellular and phospho-flow assays Research to fully validated assays with CAP/CLIA, GLP and GCLP compliance Training for clinical sites on proper sample processing for complex procedures such as phospho-flow and activation assays Experience with multiple sample types including whole, frozen and lysed blood and PBMCs 	<ul style="list-style-type: none"> BD FACSCanto™ II
Ligand Binding	<ul style="list-style-type: none"> Traditional enzyme-linked immunosorbent assay (ELISA) Electrochemiluminescence Microfluidics based ligand binding assays Ultra sensitivity ligand binding assays Enzymatic activity assays Customized, tiered approach to validation Integration across lab locations to ensure seamless transitions of assays and technologies 	<ul style="list-style-type: none"> Meso Scale Discovery® (MSD®) Technology ELISA ProteinSimple Ella Simple Plex™ System Gyros Gyrolab™ xP workstation Bioplex® 200 Quanterix™ Simoa HD-1 Analyzer™
Immunohistochemistry	<ul style="list-style-type: none"> More than 60 years of combined experience in anatomic pathology services and research Continuous addition of new immunohistochemistry (IHC) and special stains in response to project and client needs 	<ul style="list-style-type: none"> Thermo Scientific™ HistoStar™ Embedding Workstation Leica® RM2245 Microtome Leica® ST5020 Multistainer Ventana® BenchMark ULTRA Aperio® AT2 Digital pathology scanner Dako Autostainer 48
Liquid Chromatography/ Mass Spectrometry (LC-MS)	<ul style="list-style-type: none"> Experienced scientists familiar with current perspectives in biomarker assay validation Novel and routine biomarker assays Multiple LC-MS technologies available including latest generation triple quadrupoles for ultrasensitive selected reaction monitoring (SRM) and Q-Orbitrap systems for high resolution parallel reaction monitoring (PRM), targeted selected ion monitoring (tSIM) or full scan HRMS techniques HPLC, UHPLC and multi-dimensional chromatography High throughput sample preparation 	<ul style="list-style-type: none"> Sciex Triple Quad™ LC-MS systems - 4000, 5000, 5500, 6500 Shimadzu Nexera UHPLC systems with 2-D capabilities Waters Acquity UPLC systems with 2-D capabilities Hamilton® MICROLAB® STARlet automatic pipetting workstations Waters Xevo® TQ-S systems Thermo Scientific™ UHPLC systems with 3-D and nanoflow capabilities Thermo Scientific™ Aria® multiplexing systems Thermo Scientific™ Quantiva™ Triple Quadrupole LC-MS systems Thermo Scientific™ Q Exactive™ Plus (HRMS)
Molecular/Genomics	<ul style="list-style-type: none"> Cutting-edge molecular genomics suite DNA and RNA purification PCR, Sanger sequencing and NextGen Sequencing Engineering and procedural controls to minimize risk of reagent and sample contamination including: <ul style="list-style-type: none"> Restricted access main entrance Directional airflow and pressure control Full (clean room style) gowning Whole room UV decontamination system State-of-the-art environmental monitoring system 	<ul style="list-style-type: none"> Agilent Mx3005P qPCR System Agilent TapeStation 2200 Bioanalyzer Applied Biosystems® 3730xl Genetic Analyzer Applied Biosystems 7500 Applied Biosystems QuantStudio 6 BioMérieux NucliSENS® easyMag® BioRad Gel Doc XR+ Imaging System BioRad QX200 Droplet Digital PCR (ddPCR™) System Illumina® MiSeq Qiagen BioRobot Universal System Qiagen QIASymphony® SP TECAN EVO®

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