

# Biomarker Lab Overview

Supporting customers with comprehensive biomarker capabilities from study startup through data delivery.

PPD® Laboratory Services

Our **biomarker lab** is committed to helping **our customers** identify the right strategy for **each development phase** complemented by **end-to-end services** that span **multiple lab disciplines**.

PPD® Laboratory services takes a collaborative cross-functional approach to each project in order to provide the flexibility needed to develop customized solutions for our customers.



Develop and validate methods under appropriate regulatory guidelines at each stage of development per customer need



Identify the appropriate biomarker, development approach and best analytical methodology



Transfer and cross-validate assays to different or multiple locations



Provide insights that effectively integrate safety/efficacy biomarkers into clinical development

## Benefits of an integrated biomarker development approach

- Access to clean lab data in real time
- Provides flexibility needed to meet customer's unique program needs
- 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 approach from fit-for-purpose (FFP) characterization to GLP/GCLP to CAP/CLIA
- Allows PPD Laboratories to provide global coverage for studies of all sizes

## Lab Concierge

Concierge is a "named" individual who is an experienced, ultra-attentive, and specialized person who provides attentive project management and proactive engagement — specifically in the areas of sample management and logistics. These professionals are supported by internal PPD teams and are empowered to make independent decisions.

Your lab concierge can:

- Streamline communication with sponsor, central lab project manager, sites, shippers, data management, other PPD laboratory and third-party labs (3PLs) if necessary to ensure sample receipt, testing and initiate and coordinate data transfers
- Track samples to protect integrity of critical collections by communicating and coordinating sample shipments globally, from shipment through receipt. Our concierges receive automatic status notifications on their mobile device and have direct access to all sites and 3PLs
- Streamline query and discrepancy resolution (through early notifications and continuous reminders emailed hourly) to ensure critical samples are shipped on time for uninterrupted downstream testing

Bioanalytical Lab



Central Lab



GMP Lab



Vaccine Sciences Lab



PPD® Laboratory Services  
Biomarker Lab

We are there every step of the way with customized support options including ancillary services such as a biorepository, sample, data and project management, logistics and kitting.

Discipline/ Methodology	Expertise and Experience	Key Instrumentation
Flow Cytometry	<ul style="list-style-type: none"> <li>Immune profiling assays</li> <li>Receptor occupancy assays</li> <li>CAR-T cell enumeration assays</li> <li>Intracellular phospho-flow assays</li> <li>Research to fully validated assays with CAP/CLIA, GLP and GCLP compliance</li> <li>Experience with multiple sample types including whole blood, lysed frozen blood, bone marrow and PBMCs</li> <li>Cellular immune response assays: Intracellular cytokine secreting cells by flow cytometry and ELISpot</li> </ul>	<ul style="list-style-type: none"> <li>BD FACSCanto™ II</li> <li>BD FASCLytic™</li> <li>CTL Immunospot Reader</li> <li>BD FACSCanto™ II</li> <li>BD FASCLytic™</li> <li>Cytek® Northern Lights</li> <li>CTL Immunospot Reader</li> </ul>
Ligand Binding	<ul style="list-style-type: none"> <li>Traditional Enzyme-Linked Immunosorbent assays (ELISA)</li> <li>Electrochemiluminescence (ECL) mode of detection to enhance the dynamic range of quantitation</li> <li>Microfluidics based ligand binding assays to enhance throughput and minimize variability</li> <li>Ultrasensitive ligand binding assays for detection in the sub-picomolar/femtomolar ranges</li> <li>Enzymatic activity assays to mimic physiological levels</li> <li>Customized multiplex assays (up to 13plex) in 384 well format to resolve constraints around throughput, rare matrices, and limited sample volume</li> <li>Quantification from Non-Liquid Matrices (NLM) such as tissue homogenate, PBMCs, RBCs, reticulocytes, CTCs and so on to support cell and gene therapeutics</li> <li>Customized, tiered approach to assay qualification that fits the Context of Use (CoU) for a specific clinical trial</li> <li>QC'd data and QA involvement to support PD markers and GLP-like studies</li> <li>Integration across lab locations to ensure seamless transitions of methods and technologies</li> </ul>	<ul style="list-style-type: none"> <li>Meso Scale Discovery® (MSD®) Technology</li> <li>ELISA - Molecular devices Spectramax</li> <li>Protein Simple Ella Simple Plex™ System</li> <li>Quanterix™ SiMoA HD-X Analyzer™</li> <li>SMCxPro - Single Molecule Counting</li> <li>Tecan Spark multimode reader (Abs/Lum/Flu)</li> <li>Bioplex 200</li> <li>Tecan EVO and Hamilton instruments</li> </ul>
Liquid Chromatography/ Mass Spectrometry (LC-MS)	<ul style="list-style-type: none"> <li>Experienced scientists familiar with current perspectives in biomarker assay development and FFP qualification</li> <li>Novel and routine biomarker assays including both large and small molecules</li> <li>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</li> <li>HPLC, UHPLC and multi-dimensional chromatography</li> <li>High throughput sample preparation</li> </ul>	<ul style="list-style-type: none"> <li>Sciex Triple Quad™ LC-MS systems - 6500+</li> <li>Shimadzu Nexera UHPLC systems with 2-D capabilities</li> <li>Hamilton® Nimbus automatic pipetting workstations</li> <li>Thermo Scientific™ UHPLC systems with 3-D capabilities</li> <li>Thermo Scientific™ Quantiva™ and Altis™ Triple Quadrupole Systems LC-MS systems</li> <li>Thermo Scientific™ Q Exactive™ Plus (HRMS)</li> </ul>
Molecular/ Genomics	<ul style="list-style-type: none"> <li>Support development and validation of methods for analyzing molecular markers in preclinical and clinical samples from multiple matrices such as stool, plasma, serum, urine, tissue etc.</li> <li>Assays validation is performed based on the development phase and purpose with both exploratory and CAP/CLIA, GLP or GCLP compliance.</li> <li>Multiple platforms to perform gene expression, vector copy number, mutational and/or methylation analysis.</li> <li>Comprehensive bio-informatic capabilities for data analytics.</li> <li>Support for Companion/Complementary Diagnostics Development</li> <li>PCR Clean™ suite to prevent sample contamination.</li> </ul>	<ul style="list-style-type: none"> <li>Agilent TapeStation 4200 Bioanalyzer</li> <li>Applied Biosystems® 3500 and 3730xl Genetic Analyzer</li> <li>Applied Biosystems 7500 and Dx</li> <li>Applied Biosystems QuantStudio 6, 12 and Dx</li> <li>BioRad Gel Doc XR+ Imaging System</li> <li>BioRad QX200 Droplet Digital PCR (ddPCR™) System</li> <li>Illumina® MiSeq and MiSeqDx</li> <li>QiaCube HT</li> <li>Qiagen QIAasymphony® SP</li> <li>TECAN EVO®</li> <li>Kingfisher Flex</li> </ul>

For more information: <https://www.ppd.com/our-solutions/ppd-laboratories/biomarker-lab/contact-biomarker-lab/>