



PPD® LABORATORIES  
BIOANALYTICAL LAB

# Capabilities and Expertise Overview

At PPD Laboratories, more than **1,000 scientists** and staff provide bioanalytical services for pharmaceuticals, biomarkers and vaccines. Together, they provide the **scientific and regulatory expertise** necessary to ensure you receive reliable data. Our senior management team averages more than **20 years of industry experience**. Our bioanalytical lab with locations in Richmond, Virginia and Middleton, Wisconsin, provides comprehensive services for both **small molecules and biologics**.

## Scientific and technical expertise

- Method feasibility
- Method development and optimization
- Method validation
- Cutpoint determination
- Sample analysis
- Long-term matrix stability

## Small molecule expertise

- Liquid chromatography, mass spectrometry (LC/MS)
- Multi-dimensional chromatography
- High performance liquid chromatography (HPLC), ultra-highperformance liquid chromatography (UPLC)
- Derivatization and metabolite identification
- Chiral assays
- Sample analysis in multiple biological species and matrices
- First-to-file generic pharmaceuticals experience

## Extensive biologics expertise

- Extensive LC-MS/MS experience with biologics
- Assay platforms include: enzyme-linked immunosorbent assay (ELISA), cell-based assays (CBA) and other ligand-binding assays (LBA)
- Custom design and validation of assays
- Immunogenicity/anti-drug antibody testing (ADA)

## Broad-ranging biologics experience

- CAP/CLIA, GLP, and fit-for-purpose assays
- LC/MS, CBA, LBA, flow cytometry, and immunohistochemistry (IHC)
- Companion diagnostics
- Genomics and molecular assays

## 25 years of vaccine experience

- CBA, molecular, neutralization and, viral and bacterial functional assays
- Antigen detection
- Dedicated biostatistics team
- Cell-mediated immunity methods

## Specialized veterinary pharmaceutical offering

- Customized/proprietary assays
- Discovery analysis, formulation development, studies for final product specifications
- Study protocol, sample analysis plan to streamline the pre-concurrence process

## Cell and gene therapy expertise

- Immunogenicity/ADA assays
- Target identification and confirmation
- Metabolite analysis and quantification
- PCR and sequencing
- Oligonucleotide analysis

### BIOANALYTICAL LAB SERVICES AT ANY PHASE

Preclinical Development	Development Strategy / Regulatory Guidance
Phase I	Targeted Studies / Safety Evaluations
Phase II-III	Established Product / Efficacy
Pre-Approval	Regulatory Filing Strategy / Submission
Post-Approval	Risk Management / Long Term Safety

# Comprehensive Services for Small Molecules and Biologics

Discipline/Methodology	Example Biomarkers/Types of Assays	Key Instrumentation/Platform
<b>Cell-based Assays</b>	<ul style="list-style-type: none"> <li>• &gt; 80 cell-based assays validated</li> <li>• Drug-specific Nab assays (including biosimilars)</li> <li>• Biomarkers</li> <li>• Toxin neutralization assay (TNA)</li> <li>• Virus-specific Nab assays</li> </ul>	<ul style="list-style-type: none"> <li>• MSD® Sector® S 600 reader</li> <li>• BioTek Cytation™ reader</li> <li>• Beckman Coulter Vi-CELL™ analyzer</li> <li>• Biosafety cabinets</li> <li>• CO<sub>2</sub> incubators</li> </ul>
<b>Chromatography/ Mass Spectrometry</b>	<ul style="list-style-type: none"> <li>• Highly diverse range of analytes from small to large</li> <li>• Difficult endogenous, reactive or unstable analytes</li> <li>• Ultrahigh sensitivity assays with sub-pg/ml lower limits of quantification (LLOQ)</li> <li>• Metabolite identification using Q-ToF/Q-Trap systems</li> <li>• High-resolution mass spectrometry</li> </ul>	<ul style="list-style-type: none"> <li>• Hamilton® MICROLAB® STAR and STARlet</li> <li>• Sciex Triple Quad™ 6500 and Sciex Q-Trap</li> <li>• Shimadzu Nexera UHPLC system with 2-D capabilities</li> <li>• Thermo Scientific™ Q Exactive™ Plus (HRMS)</li> <li>• Thermo Scientific™ Aria® multiplexing system</li> <li>• Waters Xevo® TQ-S (triple quad)</li> <li>• Waters Acquity UHPLC system with 2-D capabilities</li> </ul>
<b>Flow Cytometry</b>	<ul style="list-style-type: none"> <li>• Assay development and validation CAP/CLIA, GLP and/or GCLP regulations</li> <li>• Intracellular cytokine assays</li> <li>• Platelet, neutrophil and basophil activation assays</li> <li>• Receptor occupancy</li> <li>• Complex phosph-flow assays</li> <li>• Peripheral blood mononuclear cell (PBMC) enumeration</li> </ul>	<ul style="list-style-type: none"> <li>• BD FACSCanto™ II flow cytometers</li> </ul>
<b>Immunochemistry</b>	<ul style="list-style-type: none"> <li>• &gt; 400 immunogenicity/ADA assays</li> <li>• &gt; 200 oligonucleotide methods</li> <li>• &gt; 40 plate-based neutralizing antibody assays</li> <li>• Quantitation and validation of endogenous analytes</li> <li>• Robotic liquid handling to support high-volume testing needs and improve precision/accuracy</li> <li>• Automated immunogenicity screening</li> </ul>	<ul style="list-style-type: none"> <li>• TECAN EVO® automated liquid-handler</li> <li>• Hamilton MICROLAB® STAR</li> <li>• ELISA</li> <li>• Meso Scale Discovery (MSD)® ECL technology</li> <li>• Gyros Gryolab™ Xp workstation</li> <li>• Quanterix® Simoa HD-1 analyzer</li> <li>• Fluorescence</li> </ul>
<b>Molecular Genomics</b>	<ul style="list-style-type: none"> <li>• Development, qualification, validation, and sample analyzation for assays</li> <li>• Viral and bacterial detection, quantification and typing by PCR</li> <li>• SNP detection</li> <li>• Copy number variation</li> <li>• Gene expression and sequencing</li> <li>• Vector (transgene) copy number and persistence</li> <li>• Epigenetics</li> </ul>	<ul style="list-style-type: none"> <li>• Agilent Mx3005 Qpcr</li> <li>• Agilent TapeStation 2200 bioanalyzer</li> <li>• Applied Biosystems (AB)® 3730xl genetic analyzer</li> <li>• AB® 7500 and QuantStudio6</li> <li>• BioRad Gel Doc XR+ imaging system</li> <li>• BioRad QX200 ddPCR®</li> <li>• Illumina® MiSeq next generation sequencer</li> <li>• Qiagen BioRobot Universal System</li> <li>• Qiagen QIAsmphony® SP nucleic acid extraction</li> <li>• TECAN EVO® automated liquid handler</li> </ul>

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