



PPD® LABORATORIES
HELPING DELIVER LIFE-CHANGING THERAPIES



BIOANALYTICAL LAB

PPD[®] LABORATORIES BIOANALYTICAL LAB: RAPID, ACCURATE ASSAY RESULTS TO KEEP YOUR STUDY ON TRACK

PPD Laboratories combines superior scientific expertise with industry-leading technologies supported by a commitment to exceptional quality. Our clients benefit from comprehensive lab services spanning bioanalytical, vaccine sciences, GMP, central lab testing and biomarkers. Our laboratory services accelerate pharmaceutical development for small molecules and biologics, allowing clients to make faster decisions about their compounds.

BIOANALYTICAL LAB SERVICES SUPPORT ALL PHASES OF DEVELOPMENT AND COMMERCIALIZATION



Richmond, Virginia

Middleton, Wisconsin

Innovation, expertise,
versatility and service to
provide you with answers

PPD Laboratories provides a comprehensive set of services in our dedicated bioanalytical laboratories for both small molecules and biologics including:

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

SOPHISTICATED INSTRUMENTATION TO GIVE YOU THE ADVANTAGE

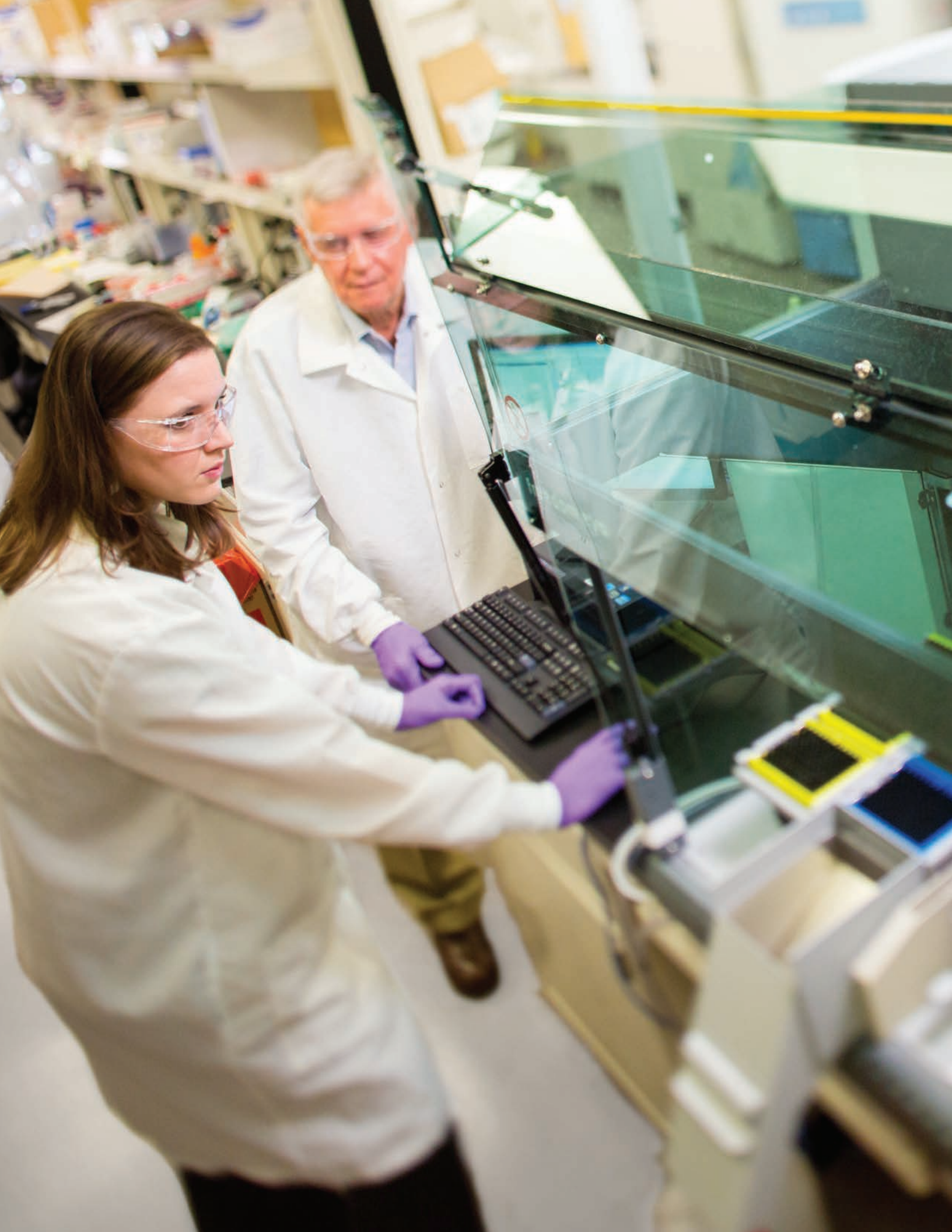
PPD Laboratories continues to remain focused on your study needs by investing in the latest technologies including:

- + Sciex API, 4000™, 5000™ and 6500™ LC-MS/MS
- + Waters Xevo® G2 and Micromass® Quadrupole Time of Flight (Q-ToF) systems
- + Electrochemiluminescence equipment (MSD® 6000)
- + Hamilton MICROLAB™ STAR systems
- + Tecan EVO® with 96-tip multichannel arm
- + Bio-plex® 200 (Luminex)
- + BD FACSCanto™ II 8-color flow cytometers
- + Biacore™
- + Gyrolab™ xP workstation

IMPROVING LAB OPERATIONS WITH AN ELN SYSTEM

Our innovative electronic laboratory notebook (ELN) system improves the efficiency, quality and security of lab operations. Based on VelQuest® SmartLab™ software customized to PPD Laboratories' specifications and needs, the ELN provides:

- + Automatic flagging of out-of-limit conditions
- + Real-time simultaneous data entry and access by multiple staff
- + Automated process and procedure tracking
- + Audit trails
- + Security measures
- + Ability to electronically search for information



PROVEN SCIENTIFIC AND TECHNICAL EXPERTISE LEAD TO RELIABLE DATA

PPD Laboratories delivers precise and timely analysis of your samples in our dedicated bioanalytical labs by providing accurate, high-quality results across a wide variety of platforms.

IMMUNOCHEMISTRY

Our ligand binding assay team has the expertise to successfully conduct testing, to include:

- + Three-tiered immunogenicity method development and testing
- + Enzyme-linked immunosorbent assay (ELISA) and electrochemiluminescence (ECL)
- + Biomarkers
- + Flow cytometry
- + Multiplexed assays
- + qPCR
- + Oligonucleotides (DNA, siRNA)
- + Cell and gene therapies

Cell-based bioanalytical assay services are provided by our dedicated scientists experienced in cell culture, bioassay development and validation, molecular biology, microbiology and neutralizing antibody testing.

VACCINE SCIENCES

For more than 20 years, PPD Laboratories has supported clients' vaccine development programs at every stage. We provide a full range of services, incorporating cost and operational efficiencies to move life-changing vaccines to market faster. Our vaccines lab provides:

- + A useful collection of commercial vaccine assays — including ELISA, the Luminex® platform, MSD®, PCR, ELISPOT, virus microneutralization, OPA/OPK, serum bactericidal assays and cell-based/functional assays
- + Therapeutic experience in neuroscience, infectious diseases and oncology
- + Scientific expertise in large molecules

CHROMATOGRAPHIC SCIENCES

We have extensive scientific and technical expertise on the LC-MS/MS platform to provide innovative, sensitive testing, including alternatives to typical ligand-binding assays:

- + Highly diverse range of analytes, from 1 to >15 kDa
- + Tissue, difficult endogenous, reactive or unstable types of analytes
- + Ultra-high sensitivity assays with sub-pg/ml lower limits of quantification (LLOQ)
- + Extensive list of non-proprietary assays available
- + Proprietary assays for MAb, Oligo and ADC molecules
- + 2D chromatographic separations
- + Dried blood spot (DBS) methodology
- + Biomarkers such as Abeta, salmon calcitonin and IGF-1
- + Duplex LC-MS/MS analysis using Thermo Scientific (Cohesive) Aria® Multiplexing system

BIOMARKER SERVICES

- + Biomarkers management team has an average of 20 years of experience across pertinent disciplines
- + Combination of expertise from bioanalytical lab, central lab and dedicated biomarkers team allows PPD Laboratories to identify and apply the most experienced team to each project
- + Scientific team collaborates closely with clinical translational medicine team to help clients select appropriate biomarkers
- + Extensive experience evaluating and implementing new technology
- + Association with industry and regulatory advisory groups



30 YEARS OF PROVIDING THE RELIABILITY AND SERVICE OUR CLIENTS TRUST

For three decades, we've been partnering with our clients during all phases of product development to accelerate timelines with high-quality procedures and assays.

BIOANALYTICAL LAB SERVICES ACROSS THE PHASES



YOU CAN TRUST OUR BIOANALYTICAL LABS:

- + Our independent quality assurance team ensures strict compliance with regulatory guidance and continual review of study data
- + Experience with more than 2,000 proprietary and non-proprietary validated assays to ensure high-quality science
- + Extensive off-the-shelf, non-proprietary validated methods that ensure efficient analysis
- + Clinical Laboratory Improvement Amendments (CLIA)-compliant assays for post-marketing studies
- + Experienced staff to rapidly develop and validate your proprietary, custom assays
- + Proactive communication tailored to your needs so you can have critical information on demand

BIOANALYTICAL LABS CAPACITY

- + More than 1 million samples received per year
- + More than 20 new validations completed each month
- + Capacity, depth and breadth of experience in virtually all therapeutic areas
- + Diverse range of analytes, assays and platforms lead to efficient analysis with accurate, high-quality results



For more information about how PPD Laboratories can partner with you, please contact us at labs@ppdi.com or +1 877 643 8773.

www.ppdi.com/labs

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