



HELPING DELIVER LIFE-CHANGING THERAPIES



PPD Multi-Functional Lab In Suzhou (China)

PPD Laboratory Services

HELP MOVE YOUR DEVELOPMENT EFFORTS FORWARD

PPD® Laboratory Services combine high-quality scientific expertise with industry-leading technologies supported by a commitment to exceptional quality to deliver contract laboratory services to the pharmaceutical landscape. Our customers benefit from comprehensive lab services backed by PPD's more than 30 years' experience as a contract research organization. Our laboratory services and data integration capabilities accelerate pharmaceutical development for small molecules, biologics, vaccines and cell and gene therapies.



57,000+

Pharmaceutical development projects in the past five years



7,600+

Different compounds analyzed



4100+

Employees bending the cost and time curve of drug development



Bioanalytical Lab

Analysis of biological samples for drug, metabolite, biomarker concentrations and/or immune response

- Three decades of experience with both small molecules and biologics
- Lab excels at creating custom solutions for customers' most challenging problems
- High-throughput through extensive automation

Richmond, Virginia;
Middleton, Wisconsin;
Suzhou, China



Biomarker Lab

Measures changes in biological function or the concentration of desired biomarker molecule(s)

- Dedicated biomarker lab with largest variety of platforms and broad capabilities
- Unique, integrated approach across bioanalytical and central lab provides regulatory flexibility

Richmond, Virginia;
Highland Heights, Kentucky;
Brussels, Belgium;
Singapore;
Suzhou, China



Central Lab

Analysis of clinical samples for safety, efficacy, hematology, chemistry, biomarker, PD and genomic testing

- Innovative, single, global-database allows real-time integration of lab and clinical data and saves up to 400 hours per study
- Proprietary global laboratory assay standardization survey (GLASS) verifies accuracy and provides global standardization

Brussels, Belgium;
Highland Heights, Kentucky;
Singapore;
Suzhou, China



GMP Lab

Analysis and stability testing of drug substance, drug product, intermediates, raw materials, container/closure systems

- 25 years of chemistry, manufacturing and controls (CMC) development expertise
- Industry-leading capacity and proven ability to successfully grow organically
- An industry leader in inhalation-product testing

Middleton, Wisconsin;
Athlone, Ireland



Vaccine Sciences Lab

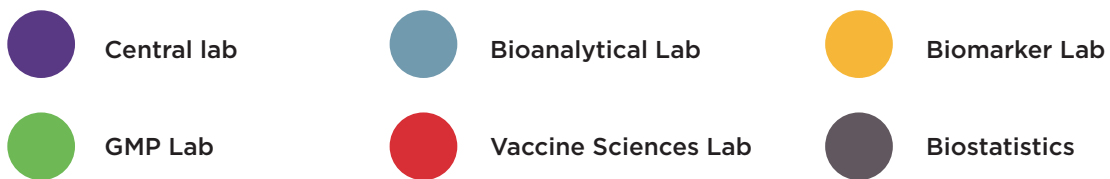
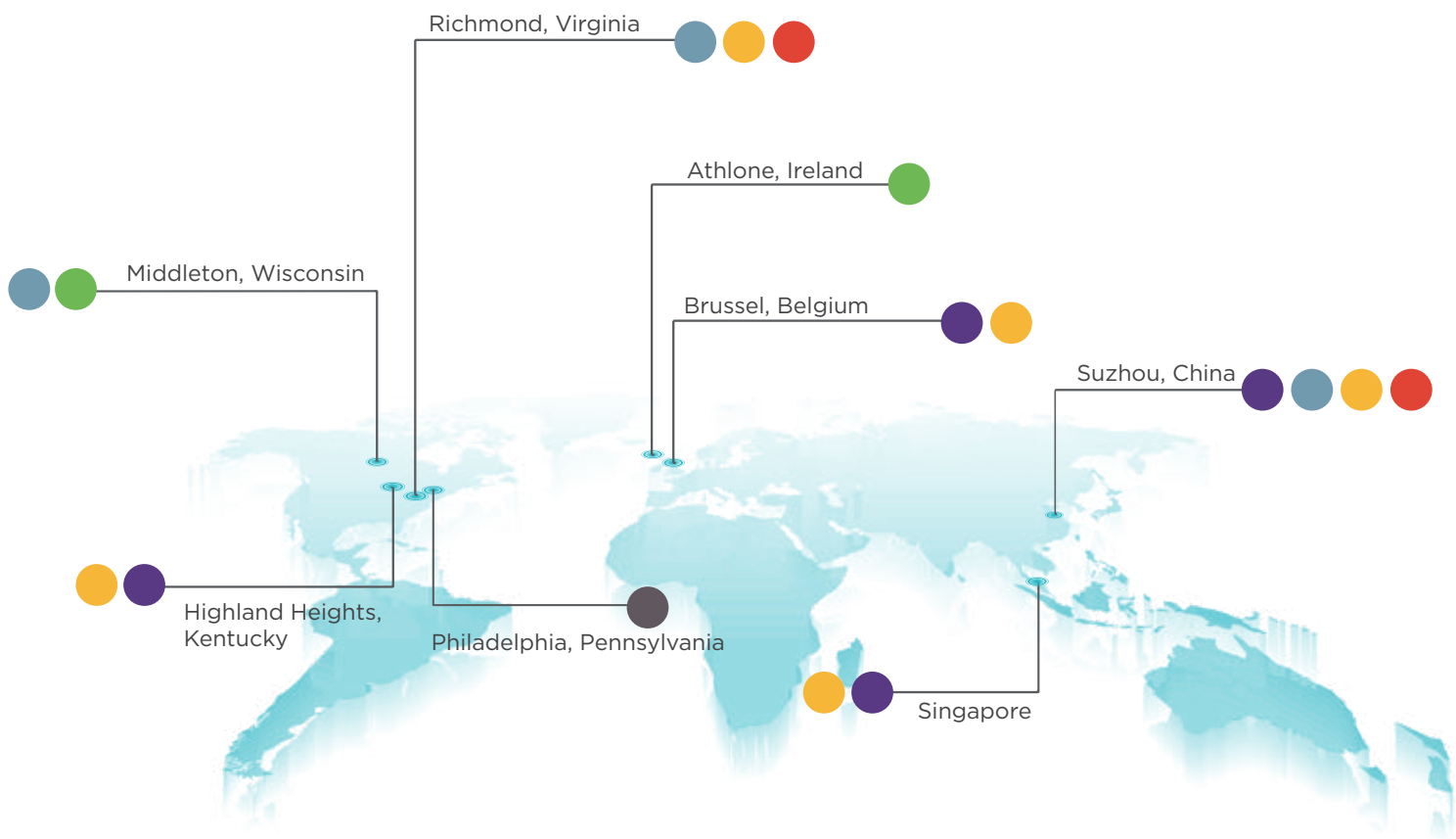
Comprehensive, centralized vaccine lab dedicated to vaccine development

- 25 years' experience in vaccines from preclinical to post-licensure
- Extensive regulatory experience including 15 FDA-approved vaccines

Richmond, Virginia;
Suzhou, China

A Global Network of Laboratories

More than 1,000,000 SQ. FT.



PPD SuZhou Multi-Functional Lab: Integrated capabilities and services

With global expertise and local operations, the PPD Suzhou Multi-Functional Laboratory provide global standard of high-quality data and convenient local services, to help customers make faster and more accurate decisions, and to accelerate the studies.

Central Lab



- Safety testing -chemistry, hematology, urinalysis
- Immunology testing
- Molecular testing
- Coagulation testing
- EIA/ELISA testing
- NGSP Certified HbA1c
- Special chemistry testing
- Flow cytometry

Bioanalytical Lab



- LC/MS for small molecules and biologics
- Immunochemistry ELISA, MSD platform for PK, ADA and plate-based Nab assay
- Cell-based Nab Assays
- Decision making biomarkers

Vaccine Sciences Lab



- Functional assay (MOPA,OPA,SBA)
- CMI-T cell ELISPOT, cytokines by flow cytometry
- Viral microneutralization assay (MNT)
- High-throughput serology testing by single or multiplex assay (MSD, Luminex, ELISA)
- Nucleic acid detection of pathogenic microorganisms: e.g. HPV genotyping

Biomarker Lab



- LC/MS and LBA formats
- Flow cytometry
- PCR/molecular

Locate in Hi-Tech park in Suzhou New District, Near highspeed railway, subway and highways

Three floors with 6200 sq.m. (~67,000 sq. ft.)

CAP accredited, BSL2 certificated laboratories



Central Lab

Dedicate to providing comprehensive testing solutions for all phases of drug development, helping customers make faster and more accurate decisions

Our Central Lab is capable of providing a wide range of clinical sample testing services to both domestic and global clients, which including flow cytometry, chemistry, immunoassays, molecular testing, hematology, protein analysis and urinalysis. Moreover, Preclarus®, our innovative lab data management system developed by PPD, not only provides real-time laboratory data, but also combines laboratory and clinical data:

- Precise results, ensuring global consistency with instrumentation, reagents and SOPs
- Experience supporting >140 protocols with over 150 sites since 2015
- Providing safety and efficacy testing for all phases of clinical trials
- Delivering high-quality data across a wide range of technologies and applications
- In-country kitting services implemented
- Single global database - Preclarus®

Key Instrumentation	
Chemistry	Roche Cobas® 6000 and 8000
Hematology	Beckman Coulter DXH600 Sysmex XN 1000
Urinalysis	Beckman Coulter® Iricell
Coagulation	IL ACL TOP 500/550
HbA1c - Level 1 NGSP	Tosoh G8 HPLC
Flow Cytometry	BD FACSCanto™/BD Lyric
EIA/ELISA	SpectraMax 190
PCR	Roche Cobas® 4800
Autoimmune/inflammatory	Siemens Healthcare BN™ II
POC	FANhp
Special Chemistry	Diasorin® Liaison



Central Lab

Preclarus® Lab Solutions - An advanced suite of tools to streamline clinical trials

Central Lab Database

Our proprietary and award-winning enterprise and information management system is purposefully designed to manage every aspect of a central lab clinical trial

Investigator Site Portal

Secure clinical site access to manage study activities (e.g. sample/subject registration, kit supply ordering and query resolution) and provides 24\7 access to real time data for investigators

Lab Data Portal

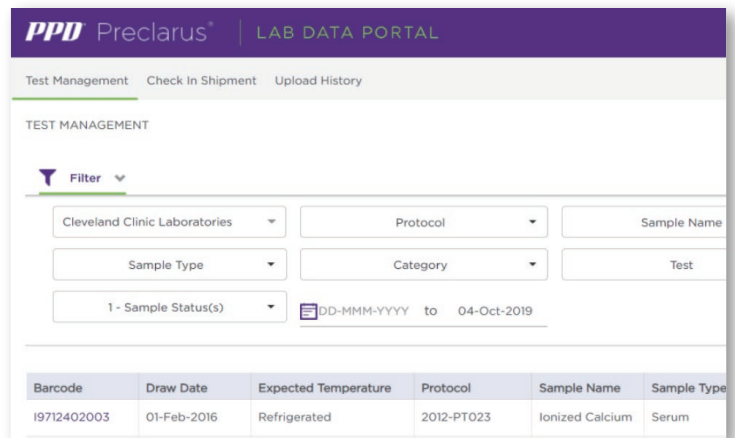
Secure access for customer project teams to real-time, studywide data including the ability to visualize, organize search and manage lab data

3PL (Third-Party Lab) Portal

Allows customers to easily track their specimens and results at partner labs

PM (Project Management) Dashboards

Real-time access for PPD project teams to program, region, site level data (labs results, quality data, budget)





Bioanalytical Lab

A trusted bioanalytical laboratory for more than 30 years

The Bioanalytical lab applies the LC-MS technology to support the quantitative analysis of small molecules, ADCs, bispecific antibodies, monoclonal antibodies and fusion proteins etc., through all phases of development. Pharmacokinetic characteristics, immunogenicity responses, neutralizing antibodies and biomarkers are analyzed through ELISA, ECL, Simoa and cell-based technology platforms. We also utilize high-throughput automated liquid handling platforms to improve the efficiency of sample analysis. We provide high quality and reproducible bioanalytical data in compliance with GLP regulations and offer a full range of preclinical and clinical sample analysis solutions to our global customers.

Chromatographic sciences

- ▶ **Ultra-sensitive LC-MS/MS methods for small molecules**
 - Parent drug and metabolites
 - Chiral assays
 - Liposome
 - Peptide
 - Reactive or endogenous compounds
 - Analyte interference checks with non-proprietary drugs
- ▶ **Broad capabilities for biologics bioanalysis with LC-MS/MS**
 - Monoclonal Antibody (mAb)
 - Antibody-Drug Conjugates (ADC)
 - Bispecific or co-dosed mAbs
 - Fragment antigen binding (Fab)
 - Fusion proteins
 - Oligonucleotides
 - Oligosaccharide

Immunochemistry

- ▶ **A wide range of immunoassay platforms**
 - Chromogenic, chemiluminescent, and fluorescent, ELISA
 - Electrochemiluminescence—MSD®
- ▶ **Assays supporting tests**
 - PK/biomarker
 - 3 Tier antidrug antibody tests
 - Screening
 - Confirmatory
 - Titration
 - Plate based Neutralizing antidrug antibody tests
- ▶ **Automated assistance, including Tecan Freedom EVO®**
- ▶ **Electronic laboratory notebooks (ELN)**

Cell-based assays

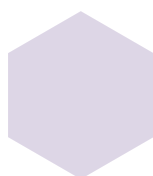
- ▶ **Deep expertise in assay development and validation**
- ▶ **115 cell-based assays available for transferring**
 - Drug-specific neutralizing antibody (Nab) assays (including Biosimilars)
 - PK assays
 - Vector (AAV) NAb detection in support of CGT
 - Toxin neutralization assays
- ▶ **Various platforms and end-point methods**
 - Receptor phosphorylation (ECL), cellular proliferation (cATP, cAMP), cell signaling pathways (STAT3, SMAD)
 - Cytokine production/detection, reporter gene products (fluorescence)
 - Flow cytometry (receptor binding)



Biomarker Lab

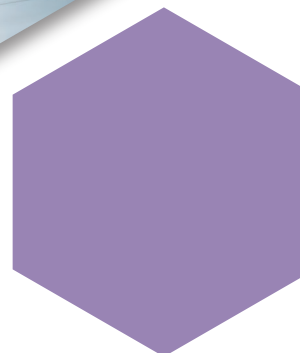
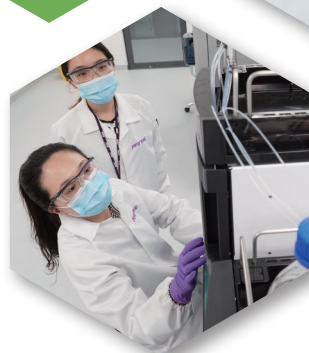
Helping customers identify the right strategy for each development phase complemented by end-to-end services that span multiple lab disciplines

The Biomarker lab provides a range of services that are applicable to different regulatory environments and fit-for-purpose research. We can develop customized biomarker strategies using molecular genomics, flow cytometry analysis, ligand binding and liquid chromatography-tandem mass spectrometry methods to analyze samples.



Services

- Flow cytometry and cell-based assays
- Ligand-binding assays
- Immunoassays
- LC-MS
- Molecular testing
- Companion diagnostics



Laboratory Operations

- Dedicated laboratories with expertise in GCP/GLP, CAP/CLIA and fit-for-purpose assays
- Experience with multiple sample types
- Novel and routine biomarker assays

Integrated Approach

- Develop and validate methods with a customized strategy for each project
- Allows for the transfer and cross-validation of assays to different locations under multiple regulatory requirements

Bioanalytical and Biomarker Labs

Key Instrumentation	
LC-MS/MS	<p>Shimadzu LC-40 SCIEX 7500</p>
Immunoassays	<p>MSD Meso Sector S 600 Tecan Spark® Molecular Device 384 plus Synergy HTX Cytation 5 Envision Quanterix™ HD-X Analyzer™ Protein Simple® Ella LUMINEX® 200™ System Gyros</p>
Others	<p>Automation</p> <ul style="list-style-type: none"> • Tecan Freedom EVO® • Hamilton® Microlab STAR • Hamilton® Firefly Nimbus <p>Flow Cytometry</p> <ul style="list-style-type: none"> • BD FACSCanto II™ • BD FACSLyric™ <p>Molecular Testing</p> <ul style="list-style-type: none"> • Bio-Red PCR C1000 • AB PCR VeritiPro™ 96-Well ThermalCycler • Bio-Red qPCR CFX 96 • Abbott qPCR M2000RT • Bio-Red ddPCR QX200





Vaccine Sciences Lab

Supporting the clinical evaluation of vaccines for multiple pathogens and provide a full range of analytical tests for vaccine clinical trial sample

The Vaccine Sciences lab provides various sample testing services for vaccine clinical trials to evaluate humoral and cellular immune response, and uses nucleic acid testing for a variety of pathogens. Our services include, functional antibody assessment, high-throughput MSD and Luminex methods for antibody detection, pseudoviral methods for neutralizing antibodies detection, ELISPOT and flow cytometry methods to measure cellular immune response, Real-time fluorescent PCR assay and Molecular hybridization method for detection of nucleic acids of various pathogens.

- Comprehensive, centralized vaccine lab dedicated to vaccine development
- High-throughput, automated and/or multiplex assays
- Enables regulatory approaches from fit-for-purpose to GCLP/GMP
- 25 years' experience in vaccines from preclinical to post-licensure
- Extensive regulatory experiences including 15 FDA-approved vaccines

Services:

► Functional Assays

- Opsonophagocytic killing assay (OPA, OPK, MOPA)
- Serum bactericidal assays, SBA
- CMI-T cell ELISPOT
- Automated liquid handling

► Viral Microneutralization Assay (MNT)

- WT virus MNT (BSL2)
- Reporter virus particle MNT
- Automated liquid handling

► Serology

- >40 custom single or multiplex assays
- ELISA, MSD and Luminex expertise
- Automated liquid handling

► Molecular Testing

- Nucleic acid detection of pathogenic organisms, qPCR, RT-PCR, ddPCR
- HPV genotyping by INNO-LiPA





Vaccine Sciences Lab

Supported licensure of eight new vaccines and quality support for 15 FDA-licensed vaccines

Bacterial Agents

- Streptococcus pneumoniae
- Staphylococcus aureus
- Clostridium difficile
- Diphtheria-Tetanus-Pertussis
- Escherichia coli
- Group B Streptococcus
- Haemophilus influenza type B
- Neisseria meningitidis



Viral Agents

- SARS-CoV-2
- Epstein-Barr virus
- Human metapneumovirus
- Cytomegalovirus (CMV)
- Dengue virus
- Respiratory Syncytial Virus (RSV)
- Hepatitis A, Hepatitis B
- Herpes Simplex Virus (HSV)
- Human Immunodeficiency Virus (HIV)
- Human Papilloma Virus (HPV)
- Influenza
- Measles, Mumps, Rubella (MMR)
- Norovirus
- Varicella Zoster
- Lymphocytic Choriomeningitis



Key Instrumentation

Artel MVS® Plate Reader	QIAGEN QIAcube HT
CTL ImmunoSpot®S6	ThermoFisher Scientific VeritiPro™ 96-Well Thermal Cycler
Tecan Freedom EVO	Bio-Rad CFX96 Real-Time PCR System
Hamilton® Microlab STAR	FujireBio Auto-LiPA™48
ThermoFisher Scientific F/B Incubator	Bio-rad QX200 Droplet Digital PCR
BioTek® 405™ LS Microplate Washer	Eppendorf Centrifuge 5810R
Meso Scale Discovery	PerkinElmer Envision®2105
CO2incubator (Thermo Fisher3111)	Beckman Cell Viability Analyzer



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