



Laboratory services

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. Customers benefit from comprehensive lab services backed by our 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



5700+

Employees bending the cost and time curve of drug development



Bioanalytical Lab

Analyzes 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 Capabilities

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

- Unique, integrated approach across bioanalytical and central lab provides regulatory flexibility
- Broad expertise to deliver comprehensive support for biomarker studies

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



Central Lab

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

- Innovative Preclarus database reduces data discrepancies by up to 80%
- We deliver cleaner data, faster through real-time integration of lab and clinical development databases

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



GMP Lab

Analyzes and stability-tests drug substance, drug product, intermediates, raw materials, container/closure systems

- 30 years of chemistry, manufacturing and controls (CMC) development expertise
- An industry leader in analytical services for small molecules and biologics

Middleton, Wisconsin;
Athlone, Ireland



Vaccine Sciences Lab

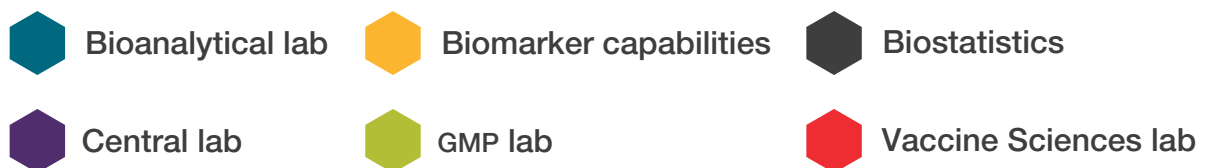
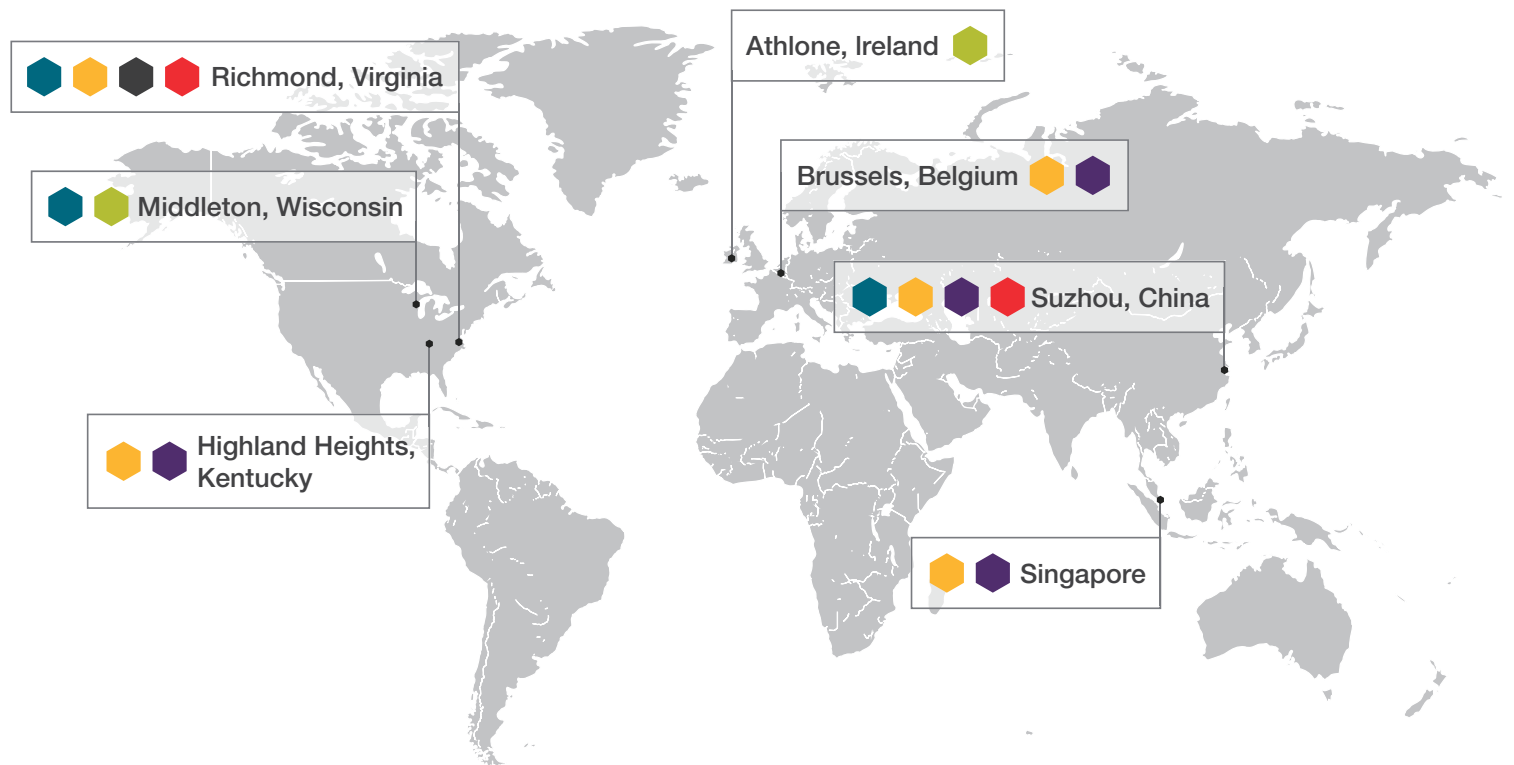
Develops vaccines with well-defined assays

- 30 years' experience in vaccines from preclinical to post-licensure
- Extensive regulatory experience including 21 FDA/EMA approved vaccines

Richmond, Virginia;
Suzhou, China

A Global Network of Laboratories

More than **1,000,000** SQ. FT.



SuZhou Multi-Functional Lab:

Integrated capabilities and services

With global expertise and local operations, our 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)
- Cellular Immunoassays: ELISPOT, Intracellular Cytokine Staining
- 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 Service



- 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 sa. 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 more than 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™

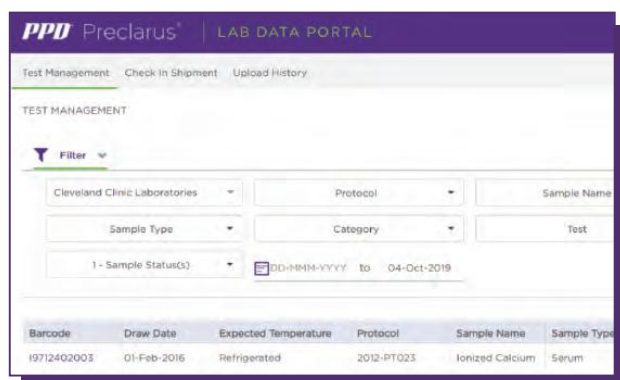
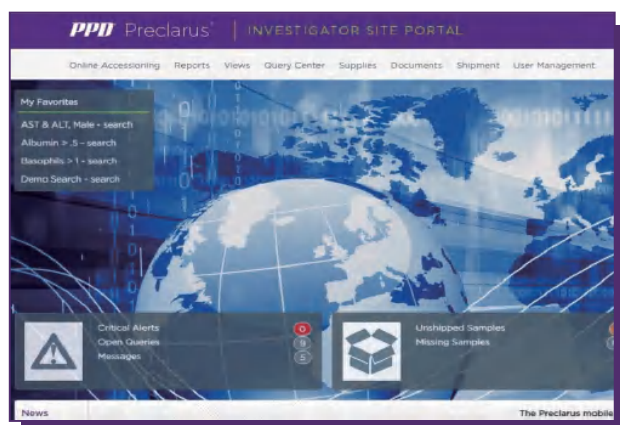
Key Instrumentation

| | |
|-------------------|---|
| Chemistry | Roche Cobas® 6000 and 8000 |
| Hematology | Beckman Coulter DXH600 Sysmex XN 1000 |
| Urinalysis | Beckman Coulter® Iricell |
| Coagulation | IL ACL TOP 500/550 |
| HbA1c-Level1NGSP | Tosoh G8 HPLC |
| Flow Cytometry | BD FACSCanto™/BD Lyric |
| EIA/ELISA | SpectraMax 190 |
| PCR | Biofire FilmArray Torch ABI QuantStudio 7 Roche Cobas® 4800 |
| 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

Our bioanalytical lab utilizes LC-MS/MS platforms to support highly sensitive quantitative analysis of small molecule drugs and large molecule drugs such as ADCs, bispecific antibodies, and monoclonal antibodies in preclinical and clinical biological samples. It conducts pharmacokinetics, immunogenicity, neutralizing antibody, and biomarker assays through ELISA, ECL, Ella, SIMOA, and cell-based technology platforms. Multiple high-throughput automated platforms are employed to enhance sample analysis efficiency. Adhering to GLP, GCP, and GCLP regulations, the laboratory provides high-quality, reproducible bioanalytical data, offering comprehensive preclinical and clinical sample analysis services to global partners.

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 Antibody Assay

► 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)
- Vector(AAV)Nab detection in support of CGT
- Toxin neutralization assays

► Various platforms and end-point methods

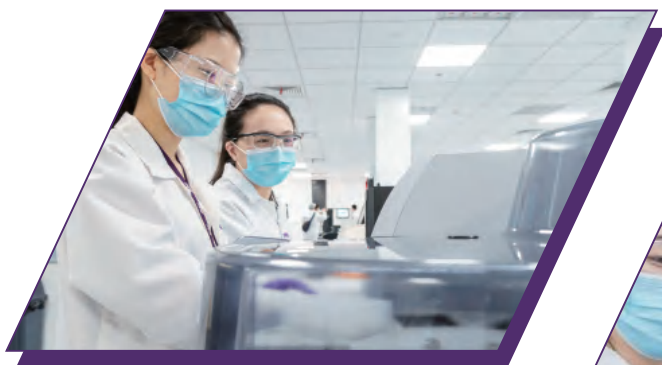
- Receptor phosphorylation(ECL), cellular proliferation (cATP, cAMP), cell signaling pathways(STAT3, SMAD)
- Cytokine production/detection, reporter gene products (fluorescence)
- Flow Cytometry-based Receptor Binding and Immunophenotyping Assays



Biomarker Capability

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

Our Biomarker service 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 etc 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/GCLP, CAP/CLIA and fit-for-purpose assays
- Experience with multiple sample types
- Novel and routine biomarker assays



Integrated Approach

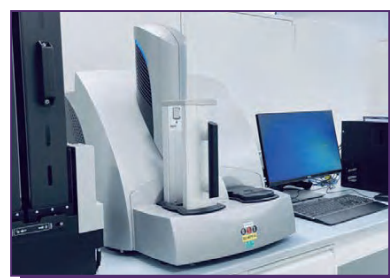
- Develop and validate methods with a customized strategy for each project
- Allows for the transfer and cross-validation of assays to different locations under multiple regulatory requirements





Bioanalytical Lab and Biomarker Capability

| Key Instrumentation | |
|---------------------|---|
| LC-MS/MS | Shimadzu LC-40 SCIEX 7500 |
| Immunoassays | <ul style="list-style-type: none"> • 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 |
| 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 FACSLytic™ <p>Molecular Testing</p> <ul style="list-style-type: none"> • AB PCR VeritiPro™ • 96-Well ThermalCycler • Bio-Red qPCR CFX 96 • Abbott qPCR M2000RT • Bio-Red ddPCR QX200 • QIAcube HT® • KingFisher™ Flex • Purification system |



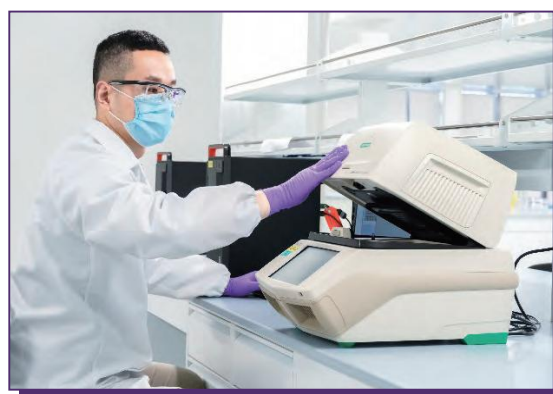


Vaccine Sciences Lab

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

Our 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 GCP/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 cel 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 | Sorenson Benchtop Pipettor |
| Meso Scale Discovery | PerkinElmer Envision®2105 |
| Bio-Plex 200 Luminex | Beckman Cell Viability Analyzer |
| Bravo Workstation | Attune NxT Flow Cytometer |
| Cytation 5 | |

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representative or visit
[ppd.com/our-solutions/ppd laboratories/china/](https://ppd.com/our-solutions/ppd-laboratories/china/)
to learn more about **our Suzhou**
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