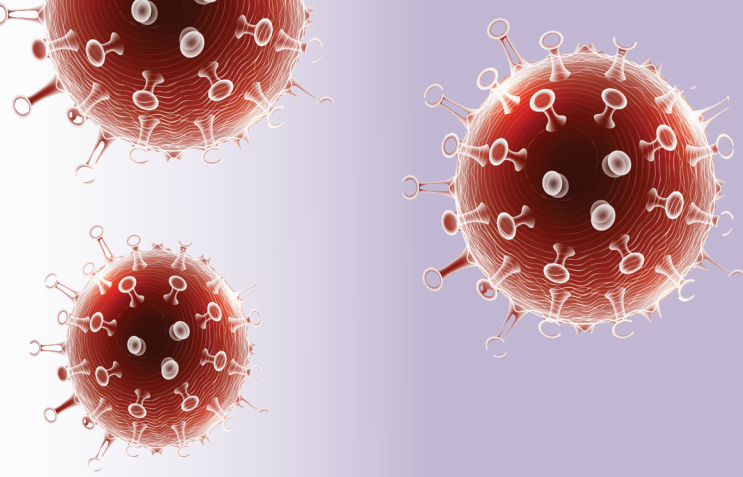




PPD® LABORATORIES

Accelerating COVID-19 Trials With Specialized Lab Services



Our vaccine sciences, bioanalytical, biomarker, GMP and central laboratories are **leveraging innovation and high-quality services** to aid in bringing **COVID-19 therapeutics and vaccines** to fruition.

PPD Laboratories' vaccine sciences lab is prepared and equipped to support COVID-19 trials

- 25+ years of experience
 - A wide variety of vaccines for respiratory pathogens
 - Vaccine efficacy and immunogenicity
 - Microneutralization, ELISPOT, RT-PCR, sequencing, serology and multiplexed assays
 - Data analysis
- Fit-for-purpose SARS-CoV-2 molecular and serology assays
- Method development, qualification/validation and transfer
- High-throughput capabilities
- Globally standardized safety testing

Our biomarker lab is ready to provide fit-for-purpose PCR assays for vector shedding and viral load

- An experienced R&D team that can develop and transfer assays
- Expertise in multiple regulatory environments
- A comprehensive menu includes immunoassays, flow cytometry, molecular and anatomic pathology
- Customizable, high-touch lab concierge services
 - Attentive to sample management for studies with low patient/specimen numbers
 - Frequent and proactive communication between study teams to confirm sample receipt, accelerate testing and coordinate rapid data transfers

The bioanalytical lab experience you need to accelerate your COVID-19 therapeutic to market

- 30 years of experience and more than 1,500 qualified methods
- R&D expertise for multiple assays
 - Method development, optimization, qualification, validation and transfer
 - Strong history of collaboration with regulatory agencies
 - Pharmacokinetic, pharmacodynamic, immunochemistry, ligand binding, LC-MS/MS, molecular and flow cytometry,
 - Experience with 20+ therapeutics being assessed for COVID-19
- Customizable serology assays available
 - Semi-quantitative assay with specificity to SARS-CoV-2 proteins and antibody isotyping
 - ACE2 binding inhibition assay to assess the ability of antibodies to block SARS-CoV-2 spike binding to host cell receptors
 - Specialized assays for inflammatory response, cytokines and vascular injury

PPD Laboratories has developed drug characterization **methods**, bioanalytical, molecular and serology **assays**, and analysis tools for **SARS-CoV-2** so we can support **therapeutic** trials, **vaccine** trials and **CMC** development

PPD LABORATORIES HAS **EXPERIENCE WITH 25+ THERAPEUTIC AGENTS** THAT ARE CURRENTLY BEING ASSESSED FOR USE **AGAINST COVID-19**

- Abacavir
- Bevacizumab
- Etravirine
- Lamivudine
- Raltegravir
- Ruxolitinib
- Acalabrutinib
- CD24-Fc
- Famotidine
- Lopinavir
- Retrovir
- Tenfovir
- Apremilast
- Cobicistat
- Fingolimod
- Losartan
- Ribavirin
- Zidovudine
- Azithromycin
- Darunavir
- Hydroxychloroquine
- Nevirapine
- Rilpivirine
- Baricitinib
- Emtricitabine
- Ivermectin
- Oseltamivir
- Ritonavir

The central lab supports clinical trials across all phases and offers a complete menu of testing

- Testing for respiratory infections, inflammatory biomarkers, immune cell composition, inclusion testing, and safety and efficacy testing
- Innovative data solutions improve and accelerate decision-making during COVID-19 trials
 - Provides 24/7 access to studywide lab data
 - Delivers full visibility to all samples in real time
- The Preclarus® investigator site portal increases communication between investigators and sites
 - Assists with trial management and patient care
 - Electronic lab requisition (eReq) enhances specimen chain of custody
 - Improved visibility to all samples in real time to navigate unpredictable courier disruptions

Our GMP lab builds upon 20+ years of industry experience to deliver well-designed solutions for even the most complex programs

- Chemistry, manufacturing and controls (CMC) development services for small molecule, biologics, vaccines, and cell and gene therapies
- Global capacity, flexibility and advanced instrumentation
- Rapid release and stability testing of clinical trial and commercial drug products
- Customized assays for COVID-19 therapeutic and vaccine trials
 - Product characterization
 - Stability studies
 - Process and cleaning validations
 - Dose verification
 - Extractables and leachables testing
 - Bioequivalency testing
 - Quality control (QC) release testing

PPD Laboratories and PPD's global clinical development teams have activated internal working groups to **streamline our processes and expedite high-priority COVID-19 proposals** so trials can start more quickly, run more efficiently and get to database lock faster!

LEARN MORE about how we are committed to being part of the solution at PPD.com

PPD Laboratories Assays for COVID-19 Trials

BIOMARKER
SEROLOGY

MOLECULAR
PATHOLOGY

SEROLOGY/
FUNCTIONAL

BIOMARKER/
FUNCTIONAL

Name	Assay	Laboratory
Abbott M2000 RealTime SARS-CoV-2 Assay	RT-PCR	Central Lab
BioFire® Torch Respiratory 2 (RP2) Panel	Nucleic Acid Amplification Test (NAAT)	Central Lab
PPD SARS-CoV-2 Assay (Qualitative)	RT-PCR	Bioanalytical/ Central Lab
PPD SARS-CoV-2 Assay (Quantitative)	RT-qPCR	Bioanalytical Lab
PPD ACE2 Binding Inhibition Assay (spike)	Neutralizing antibody (NAb) assay	Bioanalytical Lab
Microneutralization	Pseudoneutralization assay	Vaccine Lab
PPD SARS-CoV-2 IgA and IgM (spike)	ELISA cut-point assays	Bioanalytical/Vaccine Lab
PPD SARS-CoV-2 IgG (nucleocapsid)	ELISA cut-point assay	Bioanalytical/Vaccine Lab
PPD SARS-CoV-2 IgG (spike)	ELISA cut-point assay	Bioanalytical/Vaccine Lab
Clarity Diagnostics SARS-CoV-2 IgG/IgM	ELISA kit evaluation	Central Lab
Roche cobas® 8000 SARS-CoV-2 antibodies (including IgG)	Electrochemiluminescent (ECL) assay	Central Lab
T and B Cell ELISPOT	ELISPOT	Biomarker/ Vaccine Lab
Cardiac Troponin (CT)	ELISA	Central Lab
Coagulopathy Tests/Prothrombin Time/ Platelet Count/Fibrinogen Activity	ELISA	Central Lab
C-Reactive Protein (CRP)	Immunochemiluminescent assay	Central Lab
Cytokine Release Assay	Flow cytometry	Biomarker Lab
D-Dimer	ELISA	Central Lab
Ferritin	ECL assay	Central Lab
Immune Cell Profiling	Flow cytometry	Biomarker Lab
Lactate Dehydrogenase (LDH)	Cytotoxicity assay	Central Lab
Lymphocyte Count	Flow cytometry	Central Lab
Meso Scale Discovery V-PLEX Panels	Cytokine/Ligand binding	Biomarker Lab
Other Useful Biomarkers	Multiple platforms	Biomarker Lab
Procalcitonin	ECL assay	Central Lab
ProteinSimple® ELLA	Cytokine/Ligand binding	Biomarker Lab
Quanterix SiMoA	Cytokine/Ligand binding	Biomarker Lab
Roche cobas IL-6 Assay	Dual-target assay	Central Lab
TBNK Safety Panel (T-cell, B-cell, NK-cell)	Flow cytometry	Central Lab
T-cell Activation and Proliferation Markers	Flow cytometry	Biomarker Lab
T-reg and Functional Markers	Flow cytometry	Biomarker Lab
Anatomic Pathology Testing	Multiple platforms	Central Lab