

# Laboratory Solutions to Advance Your COVID-19 Clinical Trials

Developing a vaccine or treatment for COVID-19 requires a laboratory partner with cross-functional, forward-thinking scientific expertise and the skill to conduct clinical trial testing during a global pandemic.

## Global Reach: Efficiency Without Compromise

Covance Central Laboratory Services (CLS) leverages innovation and automation to deliver solutions that support your COVID-19 studies. Five central labs are strategically located around the world, and use uniform SOPs, reagents and instrumentation to generate consistent, combinable data.

## COVID-19 Testing Capacity: Proactive Investments and Strategic Oversight That Anticipates Testing Volume

- ▶ Expanding menu of COVID-19 laboratory assays and expedited assay validation
- ▶ Multiple COVID-19 testing methodologies are supported by technology and platform investments
- ▶ Redundancy of key platforms helps ensure turnaround times are met
- ▶ Sample storage capacity increased to meet anticipated volume

## Accelerated Assay Development: A Comprehensive Testing Menu for COVID-19 Clinical Trials

### *Molecular and Genomic Testing*



- ▶ High-throughput quantitative RT-qPCR for viral load measurement (respiratory, saliva, plasma)
- ▶ Qualitative RT-PCR (respiratory, saliva)
- ▶ Cepheid GeneXpert® RT-PCR (qualitative detection of SARS-CoV-2)
- ▶ BioFire® RT-PCR (22 respiratory pathogen panel, including SARS-CoV-2)
- ▶ Sequencing assays (viral isolates, ACE2 variants, HLA genotyping)

### *Immunology Testing*



- ▶ Qualitative ELISA for seropositivity (available: IgG spike, IgA, IgM, IgM S1 protein)
- ▶ Quantitative ELISA (future: IgG)
- ▶ Semi-quantitative titer-based methods (future: Anti-SARS-CoV-2 IgG, IgM, IgA)
- ▶ Immunoassays for inflammation – cytokine panels
- ▶ ELISPOT to measure cytokine response

### *Cell-Based and Microbiology Assays*



- ▶ Viral culture
- ▶ Neutralizing antibody assays (available: pseudovirus; future: wild-type virus)
- ▶ ELISPOT: breadth, magnitude and specificity of B and IFN gamma T-cell responses directed against SARS-CoV-2 antigens or peptides; other cytokines available upon request
- ▶ BSL3 laboratory capability

## Flow Cytometry Assays



- ▶ Main lineage immunophenotyping and activation (Neutrophils, T, B, monocytes, MDSC, NK cells, regulatory cells, Tfh)
- ▶ Custom panels for activation/maturation markers, memory differentiation and exhaustion
- ▶ Panels for cellular activation and cycling (Ki67)
- ▶ Functional testing by intracellular cytokine staining following in vitro activation of PBMC (IFN gamma, IL-2, TNFa, Granzyme B, Perforin, CD107a, MIP1b, IL-17)

## Covance CLS is Committed to the Critical Search for COVID-19 Treatments and Vaccines

### Accelerated Study Startup

Rely on dedicated study startup teams that can decrease standard database creation timelines by up to 50%. With Covance CLS, you can get your study up and running, faster.

### Unparalleled Logistics Performance

Globally based, skilled logistics team monitors sample shipments and draws on unique courier relationships to implement contingency plans that support on-time and in-stability shipment.

**Kits received in stability | 99.2% (2019) | 97.3% (Q2 2020)\* | 98.3% (Nov YTD 2020)**

\*Q2 2020 characterized by worldwide flight cancellations, border closings due to global pandemic

### Alternative Sample Collection Sites

Reliable options for patients traveling to investigator sites are no longer merely a convenience. Patient-centric alternatives are becoming mandatory to address the needs of the most vulnerable patients. Covance offers several options for patients to choose from:

**Home Health Phlebotomists | Home Health Nurses | LabCorp Patient Service Centers (US)**

## Covance Experience

### COVID-19 Clinical Trial Awards

Covance Total	Central Lab	Bioanalytical Services
399	103	113

Covance internal metrics, 11/11/2020

### CLS Vaccine and Infectious Disease Experience

5-Year Experience	Studies	Patients	Sites	Countries
Vaccines	68	46,392	1,340	53
Infectious Disease	457	158,010	12,848	76

Covance internal metrics, 2015-2019

Learn more about our COVID-19 drug development and diagnostic solutions by visiting [www.covance.com/coronavirus-disease-covid-19.html](http://www.covance.com/coronavirus-disease-covid-19.html)

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