Testing Solutions to Advance Your COVID-19 Clinical Trials

Developing a vaccine or therapeutic in response to the outbreak of the 2019 Novel Coronavirus (COVID-19) requires a laboratory with significant technical and cross-functional experience. Covance Central Laboratories is prepared to support your COVID-19 studies.

Capabilities Specific to COVID-19

Several assays that are specific to COVID-19 are undergoing expedited validation to meet clinical trial testing standards:

- **COVID-19 Screening/Rapid Detection by PCR**
  - Validation will begin immediately following FDA approval of the GeneXpert® assay from Cepheid
  - Expected availability for clinical trials 3 weeks following reagent kit availability

- **Viral Load Testing by qPCR**
  - Built on the LabCorp Emergency Use Authorization Diagnostics, which was made available in early March
  - Now available for clinical trials

- **Viral Neutralization Assay**
  - Expected availability for clinical trials in early Q3 2020

- **Antibody Detection by ELISA**
  - Validation has been initiated for IgG and IgA; expected availability for clinical trials in June 2020
  - Additional evaluations of IgM and quantitative serology tests will begin immediately upon availability of kits and reagents and be completed within 6-8 weeks

Assay panels that can be used to exclude other respiratory illnesses are already validated to meet clinical trial testing standards.

- BioFire® FilmArray® Respiratory Panel rules out 21 different respiratory illnesses. BioFire Diagnostics is adding COVID-19 to the panel; expanded panel expected to be available for clinical trials 3-4 weeks following reagent kit availability.

Protocol-Specific Assay Customization

Expedited customization of existing assays as required for your protocol and/or molecule:

- Viral functional assays
- Flow cytometry
- ELISpot
- Infectivity
Extensive Assay Menu

Comprehensive immunology and safety test menu already available for clinical trials:
▶ Cytokine panels
▶ Kidney function
▶ Liver function

Experience in China

▶ Access a full suite of immunology, flow cytometry and safety testing at the new, state-of-the-art Shanghai R&D Center that opened in 2019
▶ Receive global guidance and local expertise that draws on 20+ years of experience
▶ Expect both scientific and operational support

World-Class Global Logistics

Ensure on-time, in-stability transportation and draw on the expertise of 50+ global logistics experts. With multi-layer contingency plans in place, we work around the clock so samples arrive on time.

Covance Global Vaccine Experience and Capabilities

In the past 5 years:

65 protocols
45 countries
1,049 sites
38,453 patients

Clinical Indications/Target Pathogens

Respiratory
(diphtheria, pandemic flu, pertussis, pneumococcal, RSV, seasonal flu, strep AB, tuberculosis)

Enteric
(cholera, C. difficile, E. coli, norovirus, rotavirus, Shigella, typhoid)

Sexually Transmitted
(chlamydia, CMV, hepatitis B, herpes, HIV, HPV)

Vector/Zoonotic
(Chikungunya, dengue, malaria, West Nile, Zika, various genetically modified vectors)

Other
(hepatitis, HIB, meningococcal, MMRV, rubella, Staph. aureus, tetanus)

Learn more at www.covance.com

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