

Q² Solutions[®]

Laboratory Solutions to Support Global COVID-19 Clinical Trials

As a leading laboratory services organization for trials across the globe, Q² Solutions is proud to partner in support of upcoming COVID-19 clinical trials.

Our global network of state-of-the-art laboratories offer Central Laboratories located in Valencia (CA, United States), Edinburgh (United Kingdom), Mumbai (India), Singapore, Beijing (China) and Tokyo (Japan) with partner laboratories in South America and South Africa. Our Centers of Excellence for Vaccines, Genomics and Bioanalytical/ADME are strategically located to offer worldwide testing solutions.

We provide cutting-edge technologies, including detection of SARS-CoV-2 virus and antibodies; vaccine neutralization testing; immunologic profiling (flow cytometry and cytokine detection); immunogenicity analysis; bioanalytic techniques for pharmacodynamics and pharmacokinetics and human and SARS-CoV-2 virus genomic analysis. Q² Solutions has the global capacity and high-quality infrastructure to support your COVID-19 clinical trials.

SARS-CoV-2/COVID-19 testing portfolio

Global regulatory readiness for COVID-19 sample handling and testing. Representative laboratory services offered:

SARS-CoV-2 PCR tests	 Qualitative to support patient enrollment (inclusion/exclusion) Quantitative to support efficacy endpoint
Serological antibody tests	 Qualitative total immunoglobulin (lg) to support patient enrollment (inclusion/exclusion) Qualitative and quantitative lgM and lgG to identify early versus late infection Quantitative lgM and lgG titers to assess drug off-target effects
Vaccine assays	 Immunogenicity: Spike and nucleocapsid antigen specific quantitative ELISA antibody measurement Developing a neutralization assay through a collaboration with <u>University of Texas Medical Branch</u> SARS-CoV-2 specific T-cell response assessment SARS-CoV-2 surrogate neutralization assay, used under license from the Albert Einstein College of Medicine
Cytokine panels	 Detection of cytokines including IL-1β, IL-2, IL-4, IL-6, IL-7, IL-10, IFN-γ, GCSF, IP-10, MCP-1, MIP-1α, TNF-α to monitor cytokine storm
Comprehensive portfolio of genomic assays	 SARS-CoV-2 complete viral genome sequencing by NGS Host transcriptomic analysis by RNA sequencing and targeted analyses Host genomic analysis by whole exome sequencing and targeted genotyping Host metagenomic analysis by 16S RNA metagenomic sequencing DNA and RNA sequencing Gene expression panels for inflammatory and immune response monitoring

SARS-CoV-2/COVID-19 testing portfolio continued

Comprehensive flow cytometry panels utilizing cutting-edge next-generation instruments

- T cells: CD3+CD4+CD8-/CD3+CD4-CD8+ ratio, CD3+CD4+IFN- γ +, CD3+CD8+CD38+HLA-DR+, Th, Th1, Th2, Th17, T-Follicular helper, Treg naïve/memory and intracellular staining: IL-2, IL-4, IL-6, IL-17A, IFN- γ GM-CFS, Granulysin, Granzyme B, Perforin, and TNF- α
- B cells: Plasmablasts, plasma cells short-lived/long-lived, and memory B cells
- Monocytes: Blood monocyte shift to inflammatory phenotype
- Macrophages: Broncho-alveolar lavage
- · Monocyte-derived dendritic cell analysis

Conventional safety markers for prognostic evaluation

- Chemistry: Ferritin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), hyper-sensitive troponin I, lactate dehydrogenase (LDH), C-reactive protein (CRP), procalcitonin, albumin
- Hematology: WBC, neutrophils, lymphocytes and platelets counts
- Disseminated intravascular coagulation (DIC): Prothrombin time (PT), partial thromboplastin time (aPTT), and D-dimer

Bioanalytical services

- Large molecule PK, immunogenicity/anti-drug antibody ligand-binding assays
- Small molecule PK and drug-drug interaction including Remdesivir, Chloroquine, HCQ and DesethylHCQ, Azithromycin, and Ritinovir



Study delivery and logistics

- Expedited study set-up: Rapid set-up, flexibility and commitment to support COVID-19 studies
- Global kit production and logistics capabilities:
 Navigating change through robust supply chain infrastructure, flexible kitting solutions and agile logistics support
- Near patient collection and local lab data management:
 Supporting patients and sites with trial continuity solutions including home nurses and phlebotomists
- Business continuity: Proactive and coordinated approach in place to minimize impact on our staff and business operations — Read message from our CEO

 Q^2 Solutions is a leading clinical trial laboratory services organization with end-to-end laboratory services and secure, enterprise-wide biospecimen and consent management solutions. With a relentless focus on quality and innovation, Q^2 Solutions uses its global experience and scientific expertise to transform science and data into actionable medical insights that help customers improve human health.

Contact us

Toll free: +1 855.277.9929 **Direct:** +1 919.998.7000

International: +44 (0) 1506 814000 **Website:** www.Q2LabSolutions.com

