## **Celerion's Bioanalytical COVID-19 Assays for Clinical Trials**

Celerion is proud to offer the most comprehensive suite of bioanalytical tests for COVID-19 research, and support our biotech and pharma partners reach **Closer to a Cure.** 

COVID-19

## **COVID-19 Assays:**

Assay Name	Technique	Assay Description	Matrix	Context of Use
SARS-CoV-2 RNA (Semi-quantitative	RT-qPCR e)	Semi-quantitative assay for subject enrollment; SARS-CoV-2 Nucleocapsid gene	Nasal swab, Saliva	Fit-for-purpose
SARS-CoV-2 RNA (Quantitative)	RT-qPCR	Quantitative assay for measuring viral RNA level during treatment period; SARS-CoV-2 Nucleocapsid gene	Nasal swab, Saliva	Fit-for-purpose
Viral components	LBA	Antigen detection; Spike proteins, RNA Binding Domain	Serum	Fit-for-purpose
Antibody titer (Qualitative)	LBA	Subject screening for past viral infection; IgG and IgM against Spike proteins and RNA Binding Domain	Serum	Fit-for-purpose
Antibody titer (Qualitative)	LBA	High throughput quantitative assay for measuring antibodies in response to vaccine or donor screening for passive vaccine; IgG and IgM	Serum	Fit-for-purpose
Neutralizing antibodies	ELISA	High throughput novel quantitative assay for measuring neutralizing antibodies in response to vaccine or donor screening for passive vaccine	Serum	Fit-for-purpose

Assay Name	Technique	Assay Description	Matrix	Context of Use
Neutralizing antibody assay	Cell based assay	High throughput quantitative assay for measuring antibodies in response to vaccine or donor screening for passive vaccine-requires BSL-3; managed through partnerships	Serum	Fit-for-purpose
Immune response	ELISpot	Cell-mediated cytokine-secreting T cells immune responses such as IFN-γ and granzyme B secretion, immunoglobulin-secreting B cells	Whole blood, PBMC	Fit-for-purpose
Cellular profiling	Flow cytometry	Profiles of T, B, NK cells and vaccine-induced T-cell response	Whole blood, PBMC	Fit-for-purpose
Ferritin	Roche COBAS 6000	Late phase biomarker of host immune response to SARS-CoV-2	Serum	GLP CLIA Lab
D-dimer	Roche COBAS 6000	Early phase biomarker of viral response and coagulopathy	Serum	GLP CLIA Lab
CRP	Roche COBAS 6000	Late phase biomarker of host immune response to SARS-CoV-2	Serum	GLP CLIA Lab
Fibrinogen	Roche COBAS 6000	Biomarker of coagulopathy in COVID-19 patients	Serum	GLP CLIA Lab

ELISA – enzyme-linked immunosorbent assay; LBA – ligand binding assays; RT-qPCR – Reverse transcription-quantitative polymerase chain reaction

## **Cytokine Biomarkers Multiplex Assays:**

Cytokine and chemokines can be determined by MSD Cytokine Panels with up to 10 cytokines and chemokines for quantification via automated electrochemiluminescence (ECL). The panels can be custom designed according to need while maintaining the performance of the assay.

MSD Panels	Cytokines
Panel 1	IFN-γ, IL-1b, IL-2, IL-4, IL-6, IL-8, IL-10, IL-12p70, IL-13, TNF-α
Panel 2	Eotaxin, Eotaxin-3, IL-8, IP-10, MCP-1, MCP-4, MDC, MIP-1a, MIP-1b, TARC
Panel 3	GM-CSF, IL-12/IL-23p40, IL-15, IL-16, IL-17A, IL-1α, IL-5, IL-7, TNF-β, VEGF-A

MSD – Meso Scale Discovery® V-Plex assay



Celerion offers a three-tiered approach for biomarker validation based on fit-for-purpose in a GLP environment that is consistent with all global regulatory guidelines.