

PPD[®] Laboratories Assays for COVID-19 Trials

NAME	CATEGORY	ASSAY	ABOUT	REGULATORY DETAIL	LABORATORY
Abbott M2000 RealTime SARS-CoV-2 Assay	Molecular	RT-PCR	Automated with dual-target RdRp and N-genes	CAP/CLIA, EUA, Qualitative/Diagnostic	Central Lab
BioFire [®] Torch Respiratory 2 (RP2) Panel	Molecular	Alternative Upper Resp. Infection Nucleic Acid Amplification Test (NAAT)	Targets related molecules*	CAP/CLIA, Qualitative/Diagnostic	Central Lab
PPD SARS-CoV-2 Assay (Qualitative)	Molecular	RT-PCR	Targets SARS-CoV-2 Nucleocapsid protein (N), Spike protein (S), ORF1ab and MS2 phage	GCLP/exploratory, Qualitative	Bioanalytical Lab/ Central Lab
PPD SARS-CoV-2 Assay (Quantitative)	Molecular	RT-qPCR	Targets SARS-CoV-2 Nucleocapsid (N1) and human RNase P	GCLP/exploratory Quantitative	Bioanalytical Lab
PPD ACE2 Binding Inhibition Assay (spike)	Serology/Functional	Cut-point/plate-based neutralizing antibody (NAb) assay	Detects anti-spike antibodies that can disrupt ACE2 to SARS-CoV-2 spike binding	Fit-for-purpose Semi-quantitative	Bioanalytical Lab
Microneutralization	Serology/Functional	Pseudoneutralization assay	Detects virus-specific neutralizing antibodies to SARS-CoV-2	Pending available BSL2 vector	Vaccine Lab
PPD SARS-CoV-2 IgG (spike)	Serology	ELISA cut-point assay	Targets SARS-CoV-2 full length spike protein (S) recombinant protein (aa16-1214, S1+ S2)	Fit-for-purpose Semi-quantitative	Vaccine Lab/ Bioanalytical Lab
PPD SARS-CoV-2 IgA and IgM (spike)	Serology	ELISA cut-point assay	Targets SARS-CoV-2 full length spike protein (S) recombinant protein (aa16-1214, S1+ S2)	Fit-for-purpose Semi-quantitative	Vaccine Lab/ Bioanalytical Lab
PPD SARS-CoV-2 IgG (nucleocapsid)	Serology	ELISA cut-point assay	Targets SARS-CoV-2 full length nucleocapsid recombinant protein	Fit-for-purpose Semi-quantitative	Vaccine Lab/ Bioanalytical Lab
Clarity Diagnostics SARS-CoV-2 IgG/IgM	Serology	ELISA Kit Evaluation	Variable antigens	Point-of-care Qualitative/diagnostic	Central Lab
Roche cobas [®] 8000 SARS-CoV-2 antibodies (including IgG)	Serology	Electrochemiluminescent (ECL) assay	Recombinant protein representing the nucleocapsid (N) antigen for the determination of antibodies against SARS-CoV-2	EUA Qualitative/Diagnostic	Central Lab
T and B Cell ELISPOT	Biomarker/Functional	ELISPOT	Tests frequency of immunoglobulin-secreting B cells/identification of specific cytokine-secreting T cells	Quantitative	Biomarker Lab/ Vaccine Lab
Cardiac Troponin (CT)	Biomarker	ELISA	Tests the level of cardiac-specific troponin in the blood	CAP/CLIA, Quantitative	Central Lab
Coagulopathy Tests/Prothrombin Time/Platelet Count/Fibrinogen Activity	Biomarker	ELISA	Tests level of proteins essential for blood clot formation	Fit-for-purpose Quantitative monitoring	Biomarker Lab
C-Reactive Protein (CRP)	Biomarker	Immunochemiluminescent assay	Tests for CRP level in blood	CAP/CLIA, Quantitative	Central Lab
Cytokine Release Assay	Biomarker	Flow cytometry	Targets pro-inflammatory cytokines	Has CAP/CLIA potential Quantitative	Biomarker Lab
D-Dimer	Biomarker	ELISA	Test protein fragment level in blood, higher levels signify the formation and subsequent breakdown of blood clots	GCLP/exploratory, Quantitative	Biomarker Lab
Ferritin	Biomarker	ECL assay	Tests for amount of ferritin released/circulating in the blood	Fit-for-purpose Quantitative monitoring	Biomarker Lab
Immune Cell Profiling	Biomarker	Flow cytometry	Monitors changes in inflammatory biomarkers and immune cell composition	CAP/CLIA, Quantitative	Central Lab
Lactate dehydrogenase (LDH)	Biomarker	Cytotoxicity assay	Tests level of LDH in the blood/bodily fluids released by tissues	CAP/CLIA, Quantitative	Central Lab
Lymphocyte Count	Biomarker	Flow cytometry	Measures percentage in blood (B-cells, T-cells, and natural killer cells)	GCLP/exploratory, Quantitative	Biomarker Lab
Meso Scale Discovery V-PLEX Panels	Biomarker	Cytokine/Ligand binding	Cytokine Panel 1, Proinflammatory Panel 1, Chemokine Panel 1, Vascular Injury Panel 2, Angiogenesis Panel 1	GCLP/exploratory, Quantitative	Biomarker Lab
Procalcitonin	Biomarker	ECL assay	Tests level in response to tissue injury or bacterial infection	CAP/CLIA, Quantitative	Central Lab
Protein Simple ELLA	Biomarker	Cytokine/Ligand binding	Kits available for independent Cytokines or as a 4-plex panel	CAP/CLIA, Quantitative	Central Lab
Quanterix SiMoA	Biomarker	Cytokine/Ligand binding	Kits available for independent Cytokines or as a 6-plex panel	Pending CE mark	Central Lab
Roche cobas IL-6 Assay	Biomarker	Dual-target assay	Measures levels of IL-6 in serum	GCLP/exploratory Quantitative	Biomarker Lab
TBNK Safety Panel (T-cell, B-cell, NK-cell)	Biomarker	Flow cytometry	Surface marker panel (CD45,CD3,CD4,CD8, CD19,CD16/CD56)	CAP/CLIA, Quantitative	Central Lab
T-cell Activation and Proliferation Markers	Biomarker	Flow cytometry	CD45, CD3, CD4, CD8, CD56, Ki-67, HLA-DR, CD38	Fit-for-purpose, Quantitative monitoring	Biomarker Lab
T-reg and Functional Markers	Biomarker	Flow cytometry	CD45, CD3, CD4, CD25, FoxP3, CD8, PD-1, NKG2A	Fit-for-purpose, Quantitative monitoring	Biomarker Lab
Additional Biomarkers	Biomarker	Multiple platforms	IL1-ra, MCP-3, IL-18, HGF, MIG (monokine induced gamma interferon), M-CSF, G-CSF, MIG-1a, CTACK (cutaneous T-cell-attracting chemokine)	Fit-for-purpose, Quantitative monitoring	Biomarker Lab

BIOMARKER
 SEROLOGY
 MOLECULAR
 SEROLOGY/ FUNCTIONAL
 BIOMARKER/ FUNCTIONAL
 PATHOLOGY

*Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, including subtypes H1, H1-2009, and H3, Influenza, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, Bordetella parapertussis (IS1001), Bordetella pertussis (ptxP), Chlamydia pneumoniae, Mycoplasma pneumoniae