



## Summary Table of COVID-19 Testing From Test Kit Manufacturer's and Commercial Laboratories

This information is current and accurate as of April 22, 2020. This document will be updated on a weekly basis, if needed. For the most current information on COVID-19 tests with Emergency Use Authorizations (EUA), visit the FDA website:

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

The California Pharmacists Association (CPhA) does not endorse the use of any specific product or manufacturer.

Abbreviations: N – Nasal (nasopharyngeal, nasal, anterior nasal, and mid-turbinate nasal swab); O – Oral (oropharyngeal or throat swab); RS – Respiratory Specimens (sputum, bronchoalveolar lavage, tracheal aspirate, or nasal wash/aspirate); B – Blood specimens (serum, plasma, or whole blood); HC – High complexity test; MC – Moderate complexity test; W/PCS – Waived/Patient care settings (i.e, settings with CLIA Certificate of Waiver or Certificate of Compliance).

### Molecular Diagnostic – detecting nucleic acid

Test	Manufacturer	Specimen				Authorized Locations			Date Issued
		N	O	RS	B	HC	MC	W	
Abbot RealTime SARS-CoV-2 assay	Abbott Molecular	X	X			X			3/18/2020
Accula SARS-Cov-2 Test	Mesa Biotech Inc.	X	X			X	X	X	3/23/2020
Allplex 2019-nCoV Assay	Seegene, Inc.	X	X	X		X			4/21/2020
ARIES SARS-CoV-2 Assay	Luminex Corporation	X				X	X		4/3/2020
AvellinoCoV2 test	Avellino Lab USA, Inc.	X	X			X			3/25/2020
BD SARS-CoV-2 Reagents for BD MAX System	Becton, Dickinson & Company	X	X			X	X		4/8/2020
BioFire COVID-19 Test	BioFire Defense, LLC	X				X	X		3/23/2020



Test	Manufacturer	Specimen				Authorized Locations			Date Issued
		N	O	RS	B	HC	MC	W	
BioGX SARS-CoV-2 Reagents for BD MAX System	Becton, Dickinson & Company (BD)	X	X			X	X		4/2/2020
CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel (CDC)	CDC	X	X	X		X			2/4/2020
cobas SARS-CoV-2	Roche Molecular Systems, Inc. (RMS)	X	X			X			3/12/2020
COV-19 IDx Assay	Ipsium Diagnostics, LLC	X	X			X			4/1/2020
COVID-19 RT-PCR Test	Laboratory Corporation of America (LabCorp)	X	X	X		X			3/16/2020
Curative-Korva SARS-Cov-2 Assay	KorvaLabs Inc.	X	X	X		X			4/16/2020
Curative-Korva SARS-Cov-2 Assay	KorvaLabs Inc.	X	X	X		X			4/16/2020
ePlex SARS-CoV-2 Test	GenMark Diagnostics, Inc.	X				X	X		3/19/2020
Fosun COVID-19 RT-PCR Detection Kit	Fosun Pharma USA Inc.	X	X	X		X			4/17/2020
GeneFinder COVID-19 Plus RealAmp Kit	OSANG Healthcare	X	X	X		X			4/18/2020



Test	Manufacturer	Specimen				Authorized Locations			Date Issued
		N	O	RS	B	HC	MC	W	
Gnomegen COVID-19 RT-Digital PCR Detection Kit	Gnomegen LLC	X	X	X		X			4/6/2020
GS™ COVID-19 RT-PCR KIT	GenoSensor, LLC	X	X			X			4/16/2020
GS™ COVID-19 RT-PCR KIT	GenoSensor, LLC	X	X			X			4/16/2020
iAMP COVID-19 Detection Kit	Atila BioSystems, Inc.	X	X			X			4/10/2020
ID NOW COVID-19	Abbott Diagnostics Scarborough, Inc.	X	X			X	X	X	3/27/2020
Logix Smart Coronavirus Disease 2019 (COVID-19) Kit	Co-Diagnostics, Inc.	X	X	X		X			4/3/2020
Lyra SARS-CoV-2 Assay	Quidel Corporation	X	X			X			3/17/2020
NeuMoDx SARS-CoV-2 Assay	NeuMoDx Molecular, Inc.	X	X			X	X		3/30/2020
New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	CDC	X	X	X		X			2/29/2020
NxTAG CoV Extended Panel Assay	Luminex Molecular Diagnostics, Inc.	X				X			3/27/2020
Panther FUSion SARS-CoV-2	Hologic, Inc.	X	X			X			3/16/2020



Test	Manufacturer	Specimen				Authorized Locations			Date Issued
		N	O	RS	B	HC	MC	W	
PerkinElmer New Coronavirus Nucleic Acid Detection Kit	PerkinElmer, Inc	X	X			X			3/24/2020
PhoenixDx 2019-CoV	Trax Management Services Inc.	X	X	X		X			4/20/2020
Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Primerdesign Ltd.		X			X			3/20/2020
QIAstat-Dx Respiratory SARS-CoV-2 Panel	QIAGEN GmbH	X				X	X		3/30/2020
QuantiVirus SARS-CoV-2 Test kit	DiaCarta, Inc	X	X	X		X			4/8/2020
Quest SARS-CoV-2 rRT-PCR	Quest Diagnostics Infectious Disease, Inc.	X	X	X		X			3/17/2020
Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV	BGI Genomics Co. Ltd		X	X		X			3/26/2020
SARS-CoV-2 Fluorescent PCR Kit	Maccura Biotechnology (USA) LLC	X	X			X			4/15/2020
SARS-CoV-2 Fluorescent PCR Kit	Maccura Biotechnology (USA) LLC	X	X			X			4/15/2020



Test	Manufacturer	Specimen				Authorized Locations			Date Issued
		N	O	RS	B	HC	MC	W	
ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit	ScienCell Research Laboratories	X		X		X			4/3/2020
Simplexa COVID-19 Direct assay	DiaSorin Molecular LLC	X				X	X		3/19/2020
Smart Detect SARS-CoV-2 rRT-PCR Kit	InBios International, Inc	X				X			4/7/2020
TaqPath COVID-19 Combo Kit	Thermo Fisher Scientific, Inc.	X		X		X			3/13/2020
Xpert Xpress SARS-CoV-2 test	Cepheid	X		X		X	X	X	3/20/2020



**Serological Diagnostic** – detecting IgG and IgM antibodies

Test	Manufacturer	Specimen				Authorized Locations			Date Issued
		N	O	RS	B	HC	MC	W	
COVID-19 ELISA IgG Antibody Test	Mount Sinai Laboratory				X	X			4/15/2020
DPP COVID-19 IgM/IgG System	Chembio Diagnostic System, Inc				X	X	X		4/14/2020
qSARS-CoV-2 IgG/IgM Rapid Test	Cellex Inc.				X	X	X		4/1/2020
VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	Ortho Clinical Diagnostics, Inc.				X	X	X		4/14/2020