

California COVID-19 Testing Task Force PCR Test Analysis, As of May, 2020

This version is updated as of May, 2020. The information was obtained from FDA EUA IFU's and there may be copying errors, and, some items, such as estimated run time, are estimates and not statements from the manufacturers.

Category	System	Extraction needs	Throughput	PCR enzyme	PCR Unit	Limit of detection (LOD) Note ul = 1/1000 ml	Gene targets	Internal Control?	Specimen types	Sample Volume	PCR Run Time	Swabs?	VTM?
Automated high throughput	Hologic Inc. (Panther Fusion SARS-CoV-2)	All in one system	up to 335 specimens/8 hours •samples can be added continuously	Included	Panther fusion	0.010 TCID50/mL	ORF1ab target 1 ORF1ab target 2	IC-S	•nasopharyngeal •oropharyngeal	500uL	3 hr	Yes	Yes
Automated high throughput	Roche Molecular Systems Inc. (Cobas SARS-CoV-2)	All in one system	up to 384/960 specimens/8 hours	Included	Cobas Omni 6800/8800	0.009 TCID50/mL	ORF1, E	Internal control	•nasopharyngeal •oropharyngeal •nasal	600uL	3.5 hr	Yes	Yes
Automated high throughput	Abbott Molecular (Abbott RealTime SARS-CoV-2 assay) M2000/M200RT	All in one system	up to 282 specimens/8 hours	Included	M2000/M200RT	100 copies/mL	RdRp, N	hydroxypyruvate reductase gene of Cucurbita pepo	•nasopharyngeal •oropharyngeal •nasal	500uL	3 hr	Yes	Yes
Automated high throughput	NeuMoDx Molecular, Inc. (NeuMoDx SARS-CoV-2 Assay)	All in one system	up to 96 - 288 samples •samples can be added continuously	Included	•NeuMoDx™ 288 Molecular System [REF 500100] -or- •NeuMoDx™ 96 Molecular System [REF 500200]	150 copies/mL	Nsp2-gene, N-gene	Internal Control	•nasopharyngeal •oropharyngeal •nasal swab •mid-turbinate nasal	≥ 500 - ≥ 1000 µL	80 min	Yes	Yes
Automated medium throughput	BD BioGx SARS-CoV-2 Reagents for BD MAX System	All in one system	24 samples	Included	BD Max all-in-one instrument		N1, N2 (CDC P/P)		•nasopharyngeal •oropharyngeal				
Rapid	Cepheid (Xpert Xpress SARS-CoV-2 test)	All in one system	1 to 80 tests (depends on size of instrument)	Included	GeneXpert instrument	250 copies/mL	N2, E	SPC PCC	•nasopharyngeal •nasal swab •mid-turbinate nasal	300uL	45 min	Yes	Yes
Rapid	BioFire Defence LLC (BioFire COVID-19 Test)	All in one system	1-12 samples per instrument	Included	FilmArray® 2.0/Torch Instrument System	330 copies/mL	ORF1ab target a ORF1ab target b ORF8	Internal control	•nasopharyngeal	300uL	50 min	Yes	Yes
Rapid	DiaSorin Molecular LLC (Simplexa™ COVID-19 Direct Assay)	All in one system	8 wells	Included	LIAISON® MDX	500 copies/ml	S, ORF1ab	Internal Control	•nasopharyngeal	50uL	<1 hour	Yes	Yes
Rapid	Qiagen GmbH (QIAGEN QIAstat-Dx Respiratory SARS-CoV-2 Panel Assay)	All in one system	1-4 tests	Included	QIAstat-Dx Analyzer	500 copies/mL	Orf1b poly gene, E	Internal Control	•nasopharyngeal	300uL	1 hr	Yes	Yes
Rapid	Mesa Biotech Inc. (Accula SARS-CoV-2 Test)	All in one system	1 test	Included	•Accula Dock (Catalog # D2000) or •Silaris Dock (Catalog #1026)	200 copies/reaction	N gene	Internal control	•throat swab & •nasal swab <u>combined</u>	Swab placed directly in pre-aliquotted buffer (5 mL)	30 min	NO	NO

Rapid	Abbott Diagnostics Scarborough, Inc. (ID NOW COVID-19 kit)	All in one system	1 test	Included	ID NOW Instrument	125 Genome Equivalents/mL	RdRp	Procedural Control, Positive & Negative Control Swabs	<ul style="list-style-type: none"> •nasopharyngeal •nasal •throat 	200uL	13 min or less	NO	NO
Traditional PCR	CDC (CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel)	Qiagen, Roche, Easymag - various kits	21 - 29 specimens per PCR run	<ul style="list-style-type: none"> ThermoFisher TaqPath, Quantabio qScript XLT One-Step RT-qPCR ToughMix, Quantabio UltraPlex 1-Step ToughMix (4X),Promega GoTaq® Probe 1-Step RT-qPCR System 	ABI7500 Fast Dx Real-Time PCR Instrument	1-3 copies/uL	N1, N2	RNaseP	<ul style="list-style-type: none"> •nasopharyngeal •oropharyngeal •brochoalveolar lavage (BAL) •nasal aspirate •sputum 	20uL	44 min	Yes	Yes
Traditional PCR	Perkin Elmer (PE New Coronavirus Nucleic Acid Detection Kit)	Nucleic Acid Extraction Kit (KN0212) and automatic extraction instrument Pre-NAT II can be used with PerkinElmer chemagic™ Viral DNA/ RNA 300 Kit H96 (cat # CMG-1033-S) and the chemagic™ 360 instrument	48 tests per kit	Included: nCoV enzyme mix TaqMan	ABI TM 7500 Real-Time PCR System	9.3 cp/mL Pre-NAT II 7.142 cp/mL Chemagic	N, ORF1ab	MS2 phage	<ul style="list-style-type: none"> •nasopharyngeal •oropharyngeal 	60uL	1.6 hrs	Yes	Yes
Traditional PCR	Thermo Fisher Scientific Inc. (TaqPath COVID Combo kit)	ThermoFisher KingFisher™ Flex Magnetic Particle Processor with 96 DeepWell Head instrument and its reagents	93 specimens per PCR run	Included: TaqPath™ COVID-19 Combo Kit	<ul style="list-style-type: none"> •ABI7500 Fast Dx Real-Time PCR Instrument -or- •QuantStudioDx 	500 copies/mL	ORF1ab, N, S	MS2 phage	<ul style="list-style-type: none"> •nasopharyngeal •nasopharyngeal aspirate •bronchoalveolar lavage (BAL) •oropharyngeal •nasal •mid-turbinate 	400uL into 550uL extraction; 25uL	<3 hr	Yes	Yes
Traditional PCR	Quidel Corporation (Lyra SARS-CoV-2 assay)	<ul style="list-style-type: none"> •bioMerieux NucliSENS® easyMAG® system -or- •EMAG® system 	93 specimens per PCR run	Included: Lyra SARS-CoV-2 Master Mix Part M5150	<ul style="list-style-type: none"> •Applied Biosystems 7500 Fast Dx, •Applied Biosystems 7500 Standard, •Roche 93 LightCycler 480, or •Qiagen Rotor-Gene Q •Bio-Rad CFX96 Touch •ThermoFisher QuantStudio 7 Pro 	8.00E-01 copies/uL	pp1ab	Process control	<ul style="list-style-type: none"> •nasopharyngeal •oropharyngeal •nasal 	180uL	<3 hr	Yes	Yes

DNA hybridization and electrochemical detection	GenMark Diagnostic, Inc. (ePlex SARS-CoV-2 Test)	All in one system	96 tests in an 8-hour period	Included: Single-use cartridges; ePlex SARS-CoV-2 Test kit	GenMark ePlex instrument	1 X 10 ⁴ copies/mL	not stated	Internal control	•nasopharyngeal	200µL	<2 hr	Yes	Yes
Traditional PCR	Primerdesign Ltd. (Primerdesign Ltd COVID-19 genisig Real-time PCR assay)	•GXT DNA/RNA Extraction kit (GenoXtract®, Bruker-HAIN Lifescience GmbH) •QIAamp Viral RNA Mini kit	96 well	Included: Oasig™ OneStep 2X RT-qPCR Master Mix	•Applied Biosystems® 7500 Real-Time PCR System; •Bio-Rad CFX Connect™ Real-Time PCR Detection System; •Roche® LightCycler 480 II	0.33 copies/µl	ORF1ab	Internal Control	•oropharyngeal •nasal	700µL	Depends upon instrument used (1.5 - 3 hr)	Yes	Yes
Traditional PCR	BGI Genomics Co. Ltd (Real-time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV)	QIAamp Virus RNA Mini Kit (cat. #52904 or 52906)	96 well	Included: Real-Time Fluorescent RT-PCR Kit	•ABI7500 Fast Dx Real-Time PCR Instrument -or- •QuantStudioDx	100 - 150 copies/mL	ORF1ab	human Beta-actin	•nasopharyngeal •throat •bronchoalveolar lavage (BAL) •Nasal •mid-turbinate nasal	100 - 140µL	3.5 hr	Yes	Yes
Traditional PCR - Bead-based detection	Luminex Molecular Diagnostics, Inc. (NxTAG CoV Extended Panel Assay)	bioMérieux®NucliSE NS® easyMAG® -or- EMAG® System	1 - 96 tests	Included: NxTAG® CoV Extended Panel (NxTAG CoV) Plate w/ Lyophilized Bead Reagents	•ABI 9700 thermal cyclers (or other thermalcycler without adjustable lids;E&KScientific,Cat.No.E K-64088) -AND- •Luminex® instrument (MAGPIX®) including xPONENT® Software	5.00E+03 Genomic Copy Equivalents/mL	ORF1ab, N Gene, E Gene	Internal Control	•nasopharyngeal	200µL	3.5 hr	Yes	Yes
Traditional PCR	Co-Diagnostics, Inc. (Logix Smart™ COVID-19 Detection Kit (CE-IVD))	QIAamp RNA Viral Mini Kit	96 well	Logix Smart COVID-19 test kit	CoDx Box, BMS, Bio Molecular Systems, distributed by Co-Diagnostics, Inc.	4,290 copies/mL	RdRp	RNaseP	•nasopharyngeal •oropharyngeal •bronchoalveolar lavage •sputum •tracheal aspirate	140 µl	63-90 min not including extraction	Yes	Yes
Rapid	Luminex Corporation (ARIES SARS-CoV-2 Assay)	All in one system	up to 6 or 12 cassettes	Included: ARIES® SARS-CoV-2 Assay Kit	Luminex® 6-unit and 12-unit ARIES® Systems	7.5E+04 GCE/mL	ORF1ab, N Gene	RNase P	•nasopharyngeal	200 µL	2 hr	Yes	Yes
Traditional PCR	ScienCell Research Laboratories (ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit)	QIAamp® DSP Viral RNA Mini kit (Qiagen; catalog #61904)	28 tests/plate	One-Step TaqProbe RT-qPCR Master Mix (ScienCell; catalog #MB802)	Roche LightCycler® 96 Real-Time PCR System	10 ⁴ .5 copies/µL	N1, N2 (CDC P/P)	human RPP30 gene	•nasopharyngeal •nasal •oropharyngeal •bronchoalveolar lavage	140 µL	3 hr	Yes	Yes
RT-Digital PCR	Gnomegen LLC (Gnomegen COVID-19 RT-Digital PCR Detection Kit)	QIAamp® DSP Viral RNA Mini Kit	24 samples	SuperScript™ II Reverse Transcriptase	QuantStudio™ 3D Digital PCR System	8 genomic copies/ rxn	N1 and N2	RNase P	•nasopharyngeal •oropharyngeal •nasal	140 uL	2 hr + Extraction	Yes	Yes
Traditional PCR	InBios International, Inc (Smart Detect SARS-CoV-2 rRT-PCR Kit)	QIAamp Viral RNA Mini Kit (QIAGEN, catalog # 52904 or 52906)	96 well	TaqPath™ 1-Step RT-qPCR Master Mix	•Applied Biosystems® 7500 Real-Time PCR System -or- •Bio-Rad CFX96 Touch Real-Time PCR Detection System	12.5 GE/rxn or 1.1E+03 GE/mL	ORF1ab, N Gene, E Gene	RNase P	•nasopharyngeal •anterior nasal •mid-turbinate nasal	140 uL	45 min + Extraction	Yes	Yes

Automated medium throughput	Becton, Dickinson & Company (BD SARS-CoV-2 Reagents for BD MAX System)	BD MAX™ ExK™ TNA-3 kit	24 samples	BD MAX TNA MMK master mix	BD MAX System (BD Cat. No. 441916)	40 GE/mL	N1, N2	RNase P	<ul style="list-style-type: none"> nasopharyngeal nasal mid-turbinate nasal oropharyngeal swab 	750 µL	Not stated	Yes	Yes
Traditional PCR	DiaCarta, Inc (QuantiVirus SARS-CoV-2 Test kit)	Thermo Fisher PureLink™ viral RNA/DNA mini kit (cat# 122800500)	21 samples/96 well	Included: QuantiVirus™ SARS-CoV-2 Test kit	<ul style="list-style-type: none"> Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument -or- Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument 	<ul style="list-style-type: none"> 200 cp/mL for Quantstudio 100 cp/mL for ABI 7500 	N, Orf1ab, and E genes	RNase P	<ul style="list-style-type: none"> nasopharyngeal oropharyngeal nasal sputum 	200 µL	45 min + Extraction	Yes	Yes
Isothermal amplification	Atila BioSystems, Inc. (iAMP COVID-19 Detection Kit)	Atila COVID-19 Sample Buffer	96 well	Included: iAMP COVID-19 master mix	CFX96 Real-Time System	4 cp/µL	N, ORF1ab	Gapdh	<ul style="list-style-type: none"> nasopharyngeal oropharyngeal nasal swab 	350 µL	~1.5 hr	Yes	No
Traditional PCR	Maccura Biotechnology (USA) LLC (SARS-CoV-2 Fluorescent PCR Kit)	<ul style="list-style-type: none"> Maccura Nucleic Acid Extraction Kit, Manual Version Cat. No. GN7102903 Maccura Nucleic Acid Extraction Kit, Fast Version Cat. No. GN7101909 	extraction lower throughput, 96 well PCR	Included: SARS-CoV-2 Fluorescent PCR Kit	Applied Biosystems™ 7500 Real-Time PCR instrument	1.0x103 copies/mL	ORF1ab, N and E genes	MS2 based pseudo-virus	<ul style="list-style-type: none"> nasopharyngeal nasal mid-turbinate nasal oropharyngeal swab 	200 µL	~ 3 hr	Yes	Yes
Traditional PCR	GenoSensor, LLC (GST™ COVID-19 RT-PCR KIT)	QIAamp DSP Viral RNA Mini Kit	96 or 384 wells	Included: GSTM COVID-19 RT-PCR KIT	Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument	1 copy/µL	ORF1ab, E, and N genes	GUSB internal extraction control	<ul style="list-style-type: none"> nasopharyngeal oropharyngeal mid-turbinate nasal 	140 µL	~ 3 hr	Yes	Yes
Traditional PCR	Fosun Pharma USA Inc. (Fosun COVID-19 RT-PCR Detection Kit)	QIAamp® Viral RNA Mini Kit	96 well	Included: Fosun COVID-19 RT-PCR Detection Kit	Applied Biosystems® 7500 instrument	300 copies/mL	ORF1ab, E, and N genes	Internal Reference A	<ul style="list-style-type: none"> anterior nasal swabs mid-turbinate nasal nasopharyngeal oropharyngeal sputum lower respiratory tract aspirates bronchoalveolar lavage nasopharyngeal wash/aspirate nasal aspirate 	140 µL	~ 3 hr	Yes	Yes
Traditional PCR	OSANG Healthcare (GeneFinder COVID-19 Plus RealAmp Kit)	<ul style="list-style-type: none"> QIAamp® Viral RNA Mini Kit Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit 	96 well	Included: GeneFinder COVID-19 Plus RealAmp Kit	<ul style="list-style-type: none"> Applied Biosystems® 7500 Real-Time PCR Instrument (ABI 7500) OR ABI 7500 Fast CFX96 Real-Time PCR Instrument (CFX96) 	0.5 cp/µL	RdRp, E, and N genes	RNase P	<ul style="list-style-type: none"> nasopharyngeal nasal mid-turbinate nasal oropharyngeal swab sputum BAL 	140 µL or 250 µL	~ 3 hr	Yes	Yes
Traditional PCR	Trax Management Services Inc (PhoenixDx 2019-CoV)	RTA Viral RNA Extraction Kit as extraction Kit (RTA Laboratories, Cat #09010100)	96 well	Included: PhoenixDx 2019-CoV kit	BioRad CFX-96 IVD marked instrument	100 cp/mL	RdRp and E genes	RNase P	<ul style="list-style-type: none"> nasal nasopharyngeal oropharyngeal swabs BAL 	unknown	estimated ~3 hr	Yes	Yes

Traditional PCR	Seegene, Inc (Allplex 2019-nCoV Assay)	<ul style="list-style-type: none"> •Microlab STARlet IVD (Cat. No. 173000-075, Hamilton Co.) -or- •Seegene STARlet (Cat. No. 65415-03, Seegene Inc.) -AND- •STARMag 96 X 4 Universal Cartridge Kit(Cat. No. 744300.4.UC384, Seegene Inc.) 	96 well	Included: Allplex™ 2019-nCoV Assay	<ul style="list-style-type: none"> •CFX96™ Real-time PCR Detection System-IVD (Bio-Rad) -or- •CFX96 Touch™ Real-Time PCR Detection System (Bio-Rad) 	1250 cp/mL (CFX96) 4167 cp/mL (CFX96 Touch)	RdRp, E, and N genes	MS2 phage	<ul style="list-style-type: none"> •nasopharyngeal •oropharyngeal •anterior nasal •mid-turbinate •sputum 	300 uL	~3 hr	Yes	Yes
Traditional PCR	altona Diagnostics GmbH (RealStar SARS-CoV02 RT-PCR Kits U.S.)	<ul style="list-style-type: none"> • AltoStar® Automation System AM16 (altona Diagnostics, Cat. No. AM16) - AltoStar® Connect software version 1.7.4 • AltoStar® Purification Kit 1.5 (altona Diagnostics, Cat. No. PK15-06) 	96 well	Included: RealStar® SARS-CoV-2 RT-PCR Kit	<ul style="list-style-type: none"> CFX96™ Touch Real-Time PCR Detection System (Bio-Rad) -or- CFX96™ Touch Deep Well Real-Time PCR Detection System (Bio-Rad) 	1.00E-01 PFU/mL	E and S genes	AltoStar® Internal Control 1.5	<ul style="list-style-type: none"> •nasopharyngeal •oropharyngeal •anterior nasal •mid-turbinate nasal •nasopharyngeal wash/ aspirate •nasal aspirate 	500 µL	~3 hr	Yes	Yes
Traditional PCR	SD Biosensor, Inc. (STANDARD M nCoV Real-Time Detection Kit)	QIAamp® Viral RNA Mini Kit, Qiagen, Cat.no. 52904	96 well	Included: STANDARD M nCoV Real-Time Detection Kit	<ul style="list-style-type: none"> LightCycler® 480 (S/W version 1.5.1.62, Roche) • CFX96™ Dx System (S/W version 3.1, Bio-Rad) • Applied Biosystems 7500 Real-Time PCR Instrument System (S/W version 2.0.6, Thermo Fisher Scientific) 	0.25 cp/µL	ORF1ab (RdRp) & E genes	Internal Control	<ul style="list-style-type: none"> •nasopharyngeal •oropharyngeal •anterior nasal •mid-turbinate nasal •sputum 	200 uL	~3 hr	Yes	Yes
Traditional PCR	SEASUN BIOMATERIALS (U-TOP COVID-19 Detection Kit)	QIAamp DSP virus kit (Qiagen, Cat. No 60704)	96 well		<ul style="list-style-type: none"> •CFX 96 real-time PCR detection system (Bio-Rad) -or- •Applied Biosystems real-time PCR system 7500 	10 copies/rxn (1 copy/µL)	ORF1ab and N gene	RNase P	<ul style="list-style-type: none"> •nasopharyngeal •oropharyngeal •anterior nasal •mid-turbinate nasal •nasopharyngeal wash/ aspirate •nasal aspirate •sputum 	300 uL	~3 hr	Yes	Yes

Automated medium throughput	Rheonix, Inc. (Rheonix COVID-19 MDx Assay)	All in one system	24 samples (4 per Rheonix CARD® cartridge X 6 CARDS per instrument)	Included: target gene is amplified in the presence of biotin-tagged primers and the resulting amplicons denatured and flowed over the low-density array of capture probes contained within the CARD cartridge	Rheonix Encompass MDx Workstation	625 genomic equivalents/mL	N1 gene	RNase P	<ul style="list-style-type: none"> •nasopharyngeal •oropharyngeal •anterior nasal •mid-turbinate nasal •nasopharyngeal wash/aspirate •nasal aspirate •bronchoalveolar lavage (BAL) 	200 uL	?	Yes	Rheonix 4X Sample Buffer
Traditional PCR	LabGenomics Co., Ltd. (LabGun COVID-19 RT-PCR Kit)	QIAamp Viral RNA Mini kit (QIAGEN, Cat. No. 52904)	96 well	Included: LabGun COVID-19 RT-PCR Kit	<ul style="list-style-type: none"> •Applied Biosystems™ 7500 Real-time PCR Instrument system -or- •Bio-Rad CFX96™ Real-time PCR detection system 	20 genomic copies/μL	RdRp and E genes	MS2	<ul style="list-style-type: none"> •nasopharyngeal •oropharyngeal •anterior nasal •mid-turbinate nasal •nasopharyngeal wash/aspirate •nasal aspirate •sputum 	140 uL	~3.5 hr		
Rapid	BioFire Diagnostics, LLC (BioFire Respiratory Panel 2.1 (RP2.1))	All in one system		Included	<ul style="list-style-type: none"> BioFire® FilmArray® 2.0 -or- BioFire® FilmArray® Torch Systems 		Targets S & M genes	Internal control	•nasopharyngeal swabs	300 μL		Yes	Yes
Traditional PCR	Sansure BioTech Inc. (Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing))	Centrifugation & Lysis -or- QIAamp Viral RNA Mini Kit (50, Catalogue No. 52904)	96 well	2019-nCoV-PCR master mix (2019-nCoV-PCR Mix + 2019-nCoV-PCR-Enzyme Mix)	ABI 7500 Real-Time PCR System	200 copies/mL	ORF1ab and N genes	RNase P	<ul style="list-style-type: none"> •nasopharyngeal •nasal •mid-turbinate nasal •oropharyngeal swab 	200 μL -or- 140 μL (Qiagen)	~3.5 hr	Yes	Yes
Digital Droplet PCR	Bio-Rad Laboratories, Inc (Bio-Rad SARS-CoV-2 ddPCR Test)	ThermoFisher MagMAX Viral/Pathogen Nucleic Acid Isolation Kit -or- QIAamp Viral Mini Kit	96 well	Bio-Rad One-Step RT-ddPCR Advanced Kit for Probes	QX200 Droplet Reader, IVD -or- QXDx Droplet Reader; QXDx Automated Droplet Generator; C1000 Touch Thermal Cycler with 96-Deep Well Reaction Module	625 cp/mL	N1, N2 (CDC P/P)	RNase P	<ul style="list-style-type: none"> •nasopharyngeal •anterior nasal •mid-turbinate nasal •nasopharyngeal wash/aspirate •nasal aspirate 	100μl (TF) -or- 140 μL (Qiagen)	6 hr	Yes	Yes
Traditional PCR	Fast Track Diagnostics Luxembourg S.à.r.l. (a Siemens Healthineers Company) (FTD SARS-CoV-2)	NucliSENS® easyMAG® (bioMérieux)	96 well	Included:FTD SARS-CoV-2 kit	Applied Biosystems® 7500 Real-Time PCR System	0.0023 TCID50/mL	N gene and ORF1ab	equine arteritis virus (EAV) IC	<ul style="list-style-type: none"> •anterior nasal •nasopharyngeal •oropharyngeal •bronchoalveolar lavage •nasopharyngeal wash/aspirate •nasal aspirate 	200 uL	~3 hr	Yes	Yes