

Table 2 High complexity molecular-based laboratory developed tests for detection of SARS-CoV-2 with FDA emergency use authorization (EUA)

Manufacturer	Diagnostic Test	Technology	Sample Types	No. Samples / Test Run	RNA Extraction	RT-qPCR Master Mix	Instrument(s)/ System(s)	SARS-CoV-2 Gene Target(s)	Internal Control (IC) Gene Target(s)	EUA Issue Date
Biocollections Worldwide, Inc.	BioCollections Worldwide SARS-CoV-2 Assay	qRT-PCR	NPS, OPS, nasal swab/ aspirate, NP wash/ aspirate, BALF	93	Abbott <i>m</i> Sample Preparation System <i>DNA</i>	SARS-CoV-2 Assay and Invitrogen SuperScript III RT/Platinum Taq Mix	Abbott m2000 System	Three regions of N (CDC N1, N2, N3)	RNase P	5/7/2020
UTMG Pathology Laboratory	UTHSC/UCH SARS-CoV-2-RT-PCR Assay	qRT-PCR	Nasal swabs	93	Promega Maxwell RSC	ABI TaqPath 1-Step Multiplex Master Mix, CG (No ROX)	Agilent Technologies AriaMx Real Time PCR System	Two regions of N (CDC N1 and N2)	RNase P	5/3/2020
Altru Diagnostic, Inc.	Altru Dx SARS-CoV-2 RT-PCR assay	qRT-PCR	NPS, OPS, nasal/ mid-turbinate swab	94	ThermoFisher MagMAX Viral/ Pathogen Nucleic Acid Isolation Kit	ABI TaqPath COVID-19 Combo Kit and ABI TaqPath 1-Step Multiplex Master Mix, CG (No ROX)	ABI QuantStudio12K Flex Real-Time PCR System (QS12)	Orf1ab, N, and S	MS2 bacteriophage	4/30/2020
Biocerna	SARS-CoV-2 Test	qRT-PCR	NPS, OPS, nasal/ mid-turbinate swab, BALF	94	ThermoFisher MagMAX Viral/ Pathogen Nucleic Acid Isolation Kit	ABI TaqPath COVID-19 Combo Kit and ABI TaqPath 1-Step Multiplex Master Mix, CG (No ROX)	ABI QuantStudio 5 Real-Time PCR System (QS5)	Orf1ab, N, and S	MS2 bacteriophage	4/28/2020
Nationwide Children's Hospital	SARS-CoV-2 Assay	qRT-PCR	NPS, OPS, nasal/ mid-turbinate swab, NP/ nasal wash/aspirates, BALF, LRT aspirates, sputum	92	bioMérieux NucliSENS EasyMAG	ABI TaqPath 1-Step Multiplex Master Mix	ABI QuantStudio 7 Real-Time PCR System (QS7)	Two regions of N (CDC N1 and N2)	RNase P	4/27/2020
Ultimate Dx Laboratory	UDX SARS-CoV-2 Molecular Assay	qRT-PCR	NPS, OPS, nasal swab	94	ThermoFisher MagMAX Viral/ Pathogen Nucleic Acid Isolation Kit	BGI Biotechnology UltimateDx SARS-CoV-2 Assay	ABI QuantStudio12K Flex Real-Time PCR System (QS12)	ORF1ab	□-Actin	4/24/2020
AIT Laboratories	SARS-CoV-2 Assay	qRT-PCR	NPS, OPS, anterior/ mid-turbinate nasal swab, BALF, sputum	94	Omega Bio-Tek Mag-Bind Universal Pathogen Kit	ABI TaqPath COVID-19 Combo Kit and ABI TaqPath 1-Step Multiplex Master Mix, CG (No ROX)	ABI QuantStudio12K Flex Real-Time PCR System (QS12)	ORF1ab, N, S	MS2 bacteriophage	4/24/2020
Southwest Regional PCR Laboratory LLC. dba MicroGen DX	COVID-19 Key	qRT-PCR	NPS, OPS, anterior/ mid-turbinate nasal swab	94	Zymo BioScience Viral RNA Mag Bead Kit	Quanta BioScience UltraPlex 1-Step RT-PCR Mastermix	Roche LightCycler 480II	Three regions of N (CDC N1, N2, N3)	RNase P	4/23/2020
Diatherix Eurofins Laboratory	SARS-CoV-2 PCR Test	qRT-PCR	NPS, OPS, nasal/throat swab, BALF, sputum	93	Qiagen ClearMag or Omega Bio-tek MagBind Viral DNA/RNA	New England Biolabs Luna Universal One-Step qRT-PCR Kit	ABI GeneAmp 9700 or Thermo Fisher Scientific Veriti 96-well Thermal Cycler and Sensovation SensoSpot Fluorescence Low Density Microarray Analyzer	S	RNA IC	4/22/2020
Mayo Clinic Laboratories, Rochester, MN	SARS-CoV-2 Molecular Detection Assay	qRT-PCR	NPS, OPS, throat/nasal swabs, sputum	94	bioMérieux easyMAG and EMAG	Invitrogen SuperScript III Platinum One-Step qRT-PCR Kit	Roche LightCycler 480	N, ORF1ab	RNA IC	4/20/2020

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Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory	CDI Enhanced COVID-19 Test	qRT-PCR	NPS, OPS, NP wash/aspirate	93	Roche MagNA Pure 24 System	Takara One Step PrimeScript RT-PCR Kit <u>and</u> Bioline SensiFAST Probe No-ROX One-Step Kit	Bio Molecular Mic PCR cycler	N (CDC N2), E	RNase P	4/15/2020
CirusDx Laboratories	CirusDx SARS-CoV-2 Assay	qRT-PCR	NPS, OPS, BALF	92	Qiagen QIAamp Viral Mini Kit <u>or</u> ABI MagMAX Viral/ Pathogen Nucleic Acid Isolation Kit	Seegene Technologies Allplex 2019 nCoV Assay	ABI QuantStudio 5 or 7 Real-Time PCR System (QS5/7)	E, N, RdRp	MS2 bacteriophage	4/15/2020
Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital	Childrens-Altona-SARS-CoV-2 Assay	qRT-PCR	NPS, OPS	93	Qiagen Virus MiniElute Spin Kit <u>and</u> Qiagen QIAcube	Altona Diagnostics RealStar SARS-CoV-2 RT-PCR Kit 1.0	Invitrogen Rotor-Gene Q 5Plex RT-PCR System	S, E (B-βCoV)	RNA IC	4/14/2020
Exact Sciences Laboratories	SARS-CoV-2 Assay	qRT-PCR	NPS, OPS, nasal swab	93	Promega Maxwell RSC Viral Total Nucleic Acid Purification Kit	Seegene AllPlex (Novaplex) 2019-nCoV Assay Kit	ABI QuantStudio 5 Real-Time PCR System (QS5)	E, N, RdRp	MS2 bacteriophage	4/13/2020
Integrity Laboratories	SARS-CoV-2 Assay	qRT-PCR	NPS, OPS	93	ThermoFisher MagMAX Viral/ Pathogen Nucleic Acid Isolation Kit <u>and</u> MagMax Expression 96	ABI TaqPath 1-Step Multiplex Master Mix (No ROX), CG	ABI QuantStudio12K Flex Real-Time PCR System (QS12)	Two regions of N (CDC N1 and N2)	RNase P	4/13/2020
Pathology/Laboratory Medicine Lab of Baptist Hospital Miami	COVID-19 RT-PCR Test	qRT-PCR	NPS, OPS	93	Promega Maxwell RSC Viral Total Nucleic Acid Purification Kit <u>and</u> Promega Maxwell CSC Instrument	ABI TaqPath 1-Step Multiplex Master Mix (No ROX), CG	ABI QuantStudio 7 Real-Time PCR System (QS7)	N (CDC N2)	RNase P	4/13/2020
Orig3n, Inc.	Orig3n 2019 Novel Coronavirus (COVID-19) Test	qRT-PCR	NPS, OPS	93	Omega Bio-Tek Mag-Bind Viral DNA/ RNA 96 Kit	Sigma Aldrich KiCqStart One-Step Probe RT-qPCR ReadyMix	ABI QuantStudio 7 Real-Time PCR System (QS7)	Three regions of N (CDC N1, N2, N3)	RNase P	4/10/2020
Specialty Diagnostic (SDI) Laboratories	SDI SARS-CoV-2 Assay	qRT-PCR	NPS, OPS	94	AUSdiagnostics AusDx extraction cartridges <u>and</u> AUSdiagnostics AusDx MT-Prep Extraction System	BGI Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV	ABI Real-Time PCR System 7500	ORF1ab	□-Actin	4/10/2020
University of North Carolina Medical Center	UNC Health SARS-CoV-2 real-time RT-PCR test	qRT-PCR	NPS, OPS, NP wash/aspirate, BALF, tracheal aspirates	93	Roche MagNAPure 24 system <u>or</u> the bioMerieux EasyMag system	SuperScriptIII OneStep RT-PCR System <u>and</u> Platinum Taq DNA Polymerase kit <u>and</u> UNC SARS-CoV-2 real-time RT-PCR kit	ABI PRISM 7500 Sequence Detection System	E	Albumin/ MRC-5 cells	4/10/2020

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Stanford Health Care Clinical Virology Laboratory	Stanford SARS-CoV-2 assay	qRT-PCR	NPS, OPS	93	Qiagen EZ1 Virus Mini Kit and Qiagen EZ1 XL or QIAasymphony DSP Virus/Pathogen Midi Kit and QIAasymphony SP/AS	Superscript III One Step RT-PCR	Qiagen Rotor-Gene Q thermocycler	E	RNase P	4/8/2020
Viracor Eurofins Clinical Diagnostics	Viracor SARS-CoV-2 assay	qRT-PCR	NPS, OPS, NP wash/aspirate, BALF	92	bioMerieux NucliSENS easyMAG or eMAG instrument with bioMerieux NucliSENS nucleic acid extraction reagents	Viracor Eurofins COV2 Assay Oligo Mix and ABI TaqPath 1-Step Multiplex Master Mix, CG (No ROX)	ABI Real-Time PCR System 7500	Two regions of N (CDC N1 and N2)	MS2 bacteriophage	4/6/2020
Massachusetts General Hospital	MGH COVID-19 qPCR assay	qRT-PCR	NPS, OPS, BALF	93	Qiagen QIAamp Viral RNA Mini Kit	MGH SARS-CoV-2 RT-PCR and ABI TaqPath 1-Step Multiplex Master Mix, CG (No ROX)	Cobas Z 480 real-time PCR analyzer or ABI QuantStudio 7 Real-Time PCR System (QS7) or ABI ViiA7 Real-Time PCR System	Two regions of N (CDC N1 and N2)	RNase P	4/3/2020
Diagnostic Molecular Laboratory – Northwestern Medicine	SARS-Cov-2 Assay	qRT-PCR	NPS, OPS, BALF	94	Qiagen QIAamp MinElute Virus Spin Kit	ABI TaqPath 1-Step Multiplex Master Mix, CG (No ROX)	ABI QuantStudio 6 Real-Time PCR System (QS6)	N (CDC N1)	RNase P	4/2/2020
Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia	SARS-CoV-2 RT-PCR test	qRT-PCR	NPS, OPS, NP wash/aspirate, BALF, tracheal aspirates	93	Roche MagNA Pure LC Total Nucleic Acid extraction platform	QuantaBio UltraPlex 1-Step ToughMix Low ROX	ABI QuantStudio DX automated PCR platform	N (CDC N2)	□-Actin	4/2/2020
Yale New Haven Hospital, Clinical Virology Laboratory	SARS-CoV-2 PCR test	qRT-PCR	NPS, OPS, BALF, sputum	93	NUCLISENS EASYMAG from BioMerieux	IDT 2019-nCoV CDC qPCR Probe primer/probe mix and ABI TaqPath 1-Step Multiplex Master Mix, CG (No ROX)	ABI QuantStudio 6 Real-Time PCR System (QS6)	Two regions of N (CDC N1 and N2)	RNase P	3/31/2020

Adapted from FDA Website: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>

PCR, polymerase chain reaction; qRT-PCR, real-time reverse transcriptase polymerase chain reaction; NAAT, nucleic acid amplification test; NPS, nasopharyngeal swab; OPS, oropharyngeal swab, NP, nasopharyngeal; BALF, bronchoalveolar lavage liquid; S, spike; E, envelope; N, nucleocapsid; ORF, open reading frame; RdRp, RNA dependent RNA polymerase; LRT, Lower respiratory tract; B-βCoV, SARS-like coronavirus; N/A, Not applicable.

Online version accessible at: <https://tmclinicallab.jabsom.hawaii.edu/lab-services/fda-emergency-use-authorizations-euas-for-covid-19-diagnostics/>