

Table 1. Molecular detection of SARS-CoV-2 with FDA emergency use authorization (EUA)

| Manufacturer | Diagnostic Test | Technology | Manufacturer Estimated Testing Time | 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 |
|---|--|--------------------|-------------------------------------|--|------------------------|---|---|--|---|---|----------------|
| Quidel Corporation | Sofia 2 SARS Antigen FIA | Antigen FIA | 15 min | NPS, nasal swab | 1 | Sofia 2 SARS Antigen FIA Cassette | | Quidel Sofia 2 | N | Procedural control | 5/8/2020 |
| Gnomegen LLC | Gnomegen COVID-19-RT-qPCR Detection Kit | qRT-PCR | Not specified | NPS, OPS | 94 | Qiagen QIAmp (DSP) Viral RNA Mini Kit | Gnomegen COVID-19 RT-qPCR Detection Kit and ABI TaqPath 1-Step RT-PCR, CG | ABI 7500 FAST DX Real-Time PCR System | Two regions of N (CDC N1 and N2) | RNase P | 5/8/2020 |
| Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University | Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay** | qRT-PCR | Not specified | NPS, OPS, anterior/ mid-turbinate nasal swab, BALF, saliva | 94 | PerkinElmer Chemagic Viral DNA/RNA 300 Kit H96 and PerkinElmer Chemagic 360 extraction instrument | 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) or ABI ViiA7 Real-Time PCR System | Orf1ab, N, and S | MS2 bacteriophage | 5/7/2020 |
| Zymo Research Corporation | Quick SARS-CoV-2 RT-PCR Kit | qRT-PCR | Not specified | NPS, OPS, nasal/mid-turbinate swab, sputum, tracheal aspirate, BALF | 94 | Thermo Scientific King Fisher Flex and Zymo Research Quick-DNA/RNA Viral MagBead | Quick SARS-CoV-2 rRT-PCR kit | Bio-Rad CFX96 Touch Real-Time PCR Detection System | Three regions of N (CDC N1, N2, and N3) | RNase P | 5/7/2020 |
| OPTI Medical Systems, Inc. | OPTI SARS-CoV-2 RT PCR Test | qRT-PCR | Not specified | NPS, OPS, nasal swab, sputum, BALF | 93 | Thermo Scientific King Fisher Flex and IDEXX RealPCR DNA/RNA Magnetic Bead Kit or Thermo Scientific King Fisher DuoPrime and Macherey Nagel NucleoMag VET Magnetic Extraction Kit | OPTI RNA Master Mix | ABI 7500 FAST or ABI QuantStudio 5 or Agilent MX3005P or IDEXX Laboratories BioMolecular Systems Mic qPCR or Roche LightCycler 480 Real-Time PCR Systems | Two regions of N (CDC N1 and N2) | RNase P | 5/6/2020 |
| Sherlock BioSciences, Inc. | Sherlock CRISPR SARS-CoV-2 Kit | RT LAMP and CRISPR | 1 hour | NPS, OPS, nasal swab/aspirate, NP wash/aspirate, BALF | 94 | Thermo Fisher Scientific PureLink Viral RNA/ DNA Mini Kit | Sherlock CRISPR SARS-CoV-2 | BioTek Plate Reader | ORF1ab, N | RNase P | 5/6/2020 |
| BioMérieux SA | SARS-COV-2 R-GENE | qRT-PCR | Not specified | NPS, OPS, anterior/mid-turbinate nasal swab, nasal aspirate/wash, BALF | 94 | bioMérieux EMAG, NucliSENS® easyMAG or Qiagen QIASymphony SP or Roche MagNA Pure 96 | SARS-COV-2 R-GENE Test | ABI 7500 FAST/ FAST DX or ABI Quantbio 5 Dx or Roche LightCycler 480 (System II) or Bio-Rad CFX96 or Qiagen Rotor-Gene Q Real-Time PCR Systems | N, RdRp | RNA IC, E gene of Sarbecovirus, HPRT1 gene | 5/6/2020 |
| Fast Track Diagnostics Luxembourg S.à.r.l. (a Siemens Healthineers Company) | FTD SARS-CoV-2 | qRT-PCR | Not specified | NPS, OPS, nasal swab/aspirates, NP wash/aspirates | 93 | bioMérieux NucliSENS® easyMAG | FTD SARS-CoV-2 | ABI 7500 Standard Real-Time PCR System | ORF1ab, N | Equine arteritis virus | 5/5/2020 |
| Sansure BioTech, Inc. | Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) | qRT-PCR | Not specified | NPS, OPS, anterior nasal/mid-turbinate swabs, nasal washes/aspirates | 94 | Qiagen QIAmp (DSP) Viral RNA Mini Kit | Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) | ABI 7500 Standard Real-Time PCR System | ORF1ab, N | RNase P | 5/4/2020 |
| Bio-Rad Laboratories, Inc | Bio-Rad SARS-CoV-2 ddPCR Test | qRT-ddPCR | 7hr 45 min | NPS, anterior nasal/mid-turbinate swab, NP/nasal wash/aspirate | 94 | ThermoFisher MagMAX Viral/ Pathogen Nucleic Acid Isolation Kit | SARS-CoV-2 ddPCR Test | Bio-Rad QX200 or QXDx Auto DG Droplet Digital PCR Systems | Two regions of N (CDC N1 and N2) | RNase P | 5/1/2020 |
| BioFire Diagnostics, LLC | BioFire Respiratory Panel 2.1 (RP2.1) | qRT-PCR | 45 min | NPS | 1 | | BioFire RP2.1 | BioFire FilmArray System | S, M | RNA transcript (<i>Schizosaccharomyces pombe</i>) | 5/1/2020 |

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|---------------------------------|---|------------|-------------------------------------|---|------------------------|---|---|---|----------------------------------|--------------------------------------|----------------|
| LabGenomics Co., Ltd. | LabGun COVID-19 RT-PCR Kit | qRT-PCR | Not specified | NPS, OPS, anterior/mid-turbinate nasal swab, NP/nasal wash/aspirates, sputum | 94 | QIAamp Viral RNA Mini Kit | LabGun COVID-19 RT-PCR Kit | ABI 7500 Standard or BioRad CX96 Real-Time PCR Detection Systems | RdRp, E | MS2 bacteriophage | 4/29/2020 |
| Rheonix, Inc. | Rheonix COVID-19 MDx Assay | qRT-PCR | < 5 hours | NPS, OPS, anterior/mid-turbinate nasal swab, nasal wash/aspirates, BALF | 22 | | Rheonix CARD cartridge | Rheonix Encompass MDx Workstation | N1 (CDC) | RNase P | 4/29/2020 |
| SEASUN BIOMATERIALS | U-TOP COVID-19 Detection Kit | qRT-PCR | Not specified | NPS, OPS, anterior/mid-turbinate nasal swab, NP/nasal wash/aspirates, sputum | 94 | Qiagen QIAamp DSP Viral RNA Mini Kit | U-Top COVID-19 Detection Kit | ABI 7500 or BioRad CX96 Real-Time PCR Detection Systems | ORF1ab, N | RNase P | 4/27/2020 |
| SD Biosensor, Inc. | STANDARD M nCoV Real-Time Detection Kit | qRT-PCR | Not specified | NPS, OPS, nasal/mid-turbinate swab, sputum | 94 | Qiagen QIAamp Viral RNA Mini Kit | STANDARD M nCoV Real-Time Detection Kit | Roche LightCycler 480 or BioRad CX96 Dx or ABI 7500 Real-Time PCR Instrument Systems | ORF1ab (RdRp), E | Pseudovirus | 4/23/2020 |
| altona Diagnostics GmbH | RealStar SARS-CoV2 RT-PCR Kits U.S. | qRT-PCR | Not specified | NPS, OPS, anterior nasal/mid-turbinate swab, nasal wash/aspirate | 93 | AltoStar Automation System AM16 | RealStar SARS-CoV-2 RT-PCR Kit | BioRad CFX96 Touch or CFX96 Touch Deep Well Real-time PCR Detection Systems | E, S | RNA IC | 4/22/2020 |
| Seegene, Inc. | Allplex 2019-nCoV Assay | qRT-PCR | Not specified | NPS, OPS, anterior nasal/mid-turbinate swab, sputum | 94 | Microlab STARlet IVD or Seegene STARlet | Allplex 2019-nCoV Assay | BioRad CFX96 or CFX96 TouchReal-time PCR Detection Systems IVD | E, N, RdRp | MS2 bacteriophage | 4/21/2020 |
| Trax Management Services Inc. | PhoenixDx 2019-CoV | qRT-PCR | Not specified | NPS, OPS, nasal swab, BALF | 94 | RTA Viral RNA Extraction Kit | PhoenixDx 2019-CoV | BioRad CFX-96 IVD Marked Instrument | RdRp, E | RNase P | 4/20/2020 |
| OSANG Healthcare | GeneFinder COVID-19 Plus RealAmp Kit | qRT-PCR | Not specified | NPS, OPS, nasal/mid-turbinate swab, BALF, sputum | 94 | Qiagen QIAamp Viral RNA Mini Kit or Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit | GeneFinder COVID-19 Plus RealAmp Kit | ABI 7500 standard/Fast or BioRad CFX96 Real-Time PCR Systems | RdRp, E, N | RNase P | 4/18/2020 |
| Fosun Pharma USA Inc. | Fosun COVID-19 RT-PCR Detection Kit | qRT-PCR | Not specified | Anterior/mid-turbinate nasal swab, NPS, OPS, sputum, LRT aspirate, BALF, NP/nasal wash/aspirate | 94 | Qiagen QIAamp Viral RNA Mini Kit | Fosun COVID-19 RT-PCR Detection Kit | ABI 7500 Standard Real-Time PCR System | ORF1ab, E, N | Lentivirus | 4/17/2020 |
| KorvaLabs Inc. | Curative-Korva SARS-Cov-2 Assay** | qRT-PCR | Not specified | NPS, OPS, nasal swab | 94 | Norgen Biotek Corporation Total RNA Purification 96-Well Kit | ABI TaqPATH 1-Step RT-PCR | BioRad CFX 96 Touch or BioRad CFX Connect or Roche LightCycler 480 II Real-Time PCR Systems | Two regions of N (CDC N1 and N2) | RNase P | 4/16/2020 |
| GenoSensor, LLC | GS™ COVID-19 RT-PCR KIT | qRT-PCR | Not specified | NPS, OPS | 22 | Qiagen QIAamp DSP Viral RNA Mini Kit | GS COVID-19 RT-PCR KIT | ABI 7500 Fast DX Real-Time PCR System | ORF1ab, N, E | GUSB control | 4/16/2020 |
| Maccura Biotechnology (USA) LLC | SARS-CoV-2 Fluorescent PCR Kit | qRT-PCR | Not specified | NPS, OPS, nasal/mid-turbinate swab | 94 | Maccura Manual or Fast Nucleic Acid Extraction Kit | SARS-CoV-2 Fluorescent PCR Kit | ABI 7500 Standard Real-Time PCR System | ORF1ab, N, E | MS2 bacteriophage | 4/15/2020 |

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| Atila BioSystems, Inc. | iAMP COVID-19 Detection Kit | Isothermal qRT-PCR | 1.5 hrs | NPS, OPS, nasal swab | 94 | iAMP COVID-19 Sample Buffer | iAMP COVID-19 Detection Kit | BioRad CFX Real-Time System or Real-Time PCR system with FAM/ HEX fluorescence channels | N, ORF1ab | GAPDH | 4/10/2020 |
| DiaCarta, Inc. | QuantiVirus SARS-CoV-2 Test kit | qRT-PCR | Not specified | NPS, OPS, nasal swab, sputum | 93 | ThermoFisher PureLink viral RNA/ DNA mini kit | ABI TaqPATH 1-Step RT-PCR, CG | ABI QuantStudio 5 (QS5) or ABI 7500 Fast Dx Real-Time PCR System | ORF1ab, E, N | RNase P | 4/8/2020 |
| Becton, Dickinson & Company | BD SARS-CoV-2 Reagents for BD MAX System | qRT-PCR | 3 hrs | NPS, OPS, nasal swab | 24 | BD MAX ExK TNA-3 kit | BD MAX TNA MMK | BD MAX System | Two regions of N (CDC N1 and N2) | RNase P | 4/8/2020 |
| InBios International, Inc. | Smart Detect SARS-CoV-2 rRT-PCR Kit | qRT-PCR | Not specified | NPS, anterior/mid-turbinate nasal swab | 93 | Qiagen QIAamp DSP Viral RNA Mini Kit | ABI TaqPATH 1-Step RT-PCR, CG | ABI 7500 Fast DX Real-Time PCR System | E, N, RdRp | RNase P | 4/7/2020 |
| Gnomegen LLC | Gnomegen COVID-19 RT-Digital PCR Detection Kit | qRT-dPCR | Not specified | NPS, OPS, nasal swab | 44 | Qiagen QIAamp DSP Viral RNA Mini Kit | SuperScript II Reverse Transcriptase and RNaseOUT Recombinant Ribonuclease Inhibitor and QuantStudio 3D Digital PCR Master Mix v2 | ABI QuantStudio 3D Digital PCR System Package, with Master Mix, Chip Kit v2 | Two regions of N (CDC N1 and N2) | RNase P | 4/6/2020 |
| Co-Diagnostics, Inc. | Logix Smart Coronavirus Disease 2019 (COVID-19) Kit | qRT-PCR | Not specified | NPS, OPS, NP/nasal wash/aspirate, BALF, sputum, tracheal aspirate | 94 | Qiagen QIAamp DSP Viral RNA Mini Kit | Logix Smart COVID-19 Test Kit | BMS CoDx Box | RdRp | RNase P | 4/3/2020 |
| ScienCell Research Laboratories | ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit | qRT-PCR | Not specified | NPS, OPS, nasal swab, BALF | 26 | Qiagen QIAamp DSP Viral RNA Mini Kit | ScienCell One-Step TaqProbe RT-qPCR Mater Mix, 4x | Roche LightCycler 96 Real-Time PCR System | Two regions of N (CDC N1 and N2) | RNase P | 4/3/2020 |
| Luminex Corporation | ARIES SARS-CoV-2 Assay | qRT-PCR | Not specified | NPS | 6 | ARIES SARS-CoV-2 Assay cassette sample chamber | | ARIES Instrument | ORF1ab and N | RNase P | 4/3/2020 |
| Becton, Dickson & Company (BD) | BioGX SARS-CoV-2 Reagents for BD MAX System | qRT-PCR | 3 hrs | NPS, OPS | 24 | BD MAX ExK TNA-3 kit | BD BioGX SARS-CoV-2 Reagents for BD MAX System | BD MAX System | Two regions of N (CDC N1 and N2) | RNase P | 4/2/2020 |
| Ipsium Diagnostics, LLC | COVID-19 IDx assay** | qRT-PCR | Not specified | NPS, OPS | 46 | Omega Bio-Tek Mag-Bind Viral DNA/ RNA 96 Kit | TaKarRa PrimeDirect™ Probe RT-qPCR Mix | ABI QuantStudio12Flex (QS12) Real-Time PCR System | One region of N (CDC N1) | RNase P | 4/1/2020 |
| QIAGEN GmbH | QIAstat-Dx Respiratory SARS-CoV-2 Panel | qRT-PCR | 1 hr; Walk-away (<1min hands-on) | NPS | 6 | QIAstat-Dx Respiratory SARS-CoV-2 Panel Cartridge | | QIAstat Dx Analyzer 1.0 System | RdRp and E | MS2 bacteriophage | 3/30/2020 |
| NeuMoDx Molecular, Inc. | NeuMoDx SARS-CoV-2 Assay | qRT-PCR | 80 min; Walk-away | NPS, OPS, nasal swab | 96-288 | NeuMoDx SARS-CoV-2 Test Strip and NeuMoDx Cartridge | | NeuMoDx 288/ 96 Molecular System | Nsp2 and N | Sample processing control | 3/30/2020 |
| Luminex Molecular Diagnostics, Inc. | NxTAG CoV Extended Panel Assay | qRT-PCR | Not specified | NPS | 94 | bioMérieux easy MAG or EMAG Systems | NxTAG CoV Extended Panel Kit | End-point ThermalCycler and Luminex NxTAG MAGPIX | ORF1ab, N, and E | MS2 bacteriophage | 3/27/2020 |
| Abbott Diagnostics Scarborough, Inc. | ID NOW COVID-19* | Isothermal NAAT | 5-13 min | NPS, nasal/throat swab | 1 | ID NOW COVID-19 Kit | | ID NOW Instrument | RdRp | Not specified | 3/27/2020 |
| BGI Genomics Co. Ltd | Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV | qRT-PCR | Not specified | Throat swab, BALF | 94 | Qiagen QIAamp DSP Viral RNA Mini Kit | Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV | ABI 7500 Standard Real-Time PCR System | ORF1ab | □-Actin | 3/26/2020 |
| Avellino Lab USA, Inc. | AvellinoCoV2 test** | qRT-PCR | Not specified | NPS, OPS | 93 | Qiagen QIAamp DSP Viral RNA Mini Kit | ABI TaqPATH 1-Step RT-PCR, CG | ABI 7500 Standard Real-Time PCR System | Two regions of N (CDC N1 and N2) | RNase P | 3/25/2020 |

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| PerkinElmer, Inc. | PerkinElmer New Coronavirus Nucleic Acid Detection Kit | qRT-PCR | Not specified | NPS, OPS | 94 | PerkinElmer Nucleic Acid Extraction Kit, PreNAT II (SY61) | PerkinElmer New Coronavirus Nucleic Acid Detection Kit | ABI 7500 Standard Real-Time PCR System | ORF1ab and N | MS2 bacteriophage | 3/24/2020 |
| Mesa Biotech Inc. | Accula SARS-Cov-2 Test* | PCR and Lateral Flow | 30 min | Nasal/throat swab | 1 | Accula SARS CoV-2 Test Cassette | | Accula Dock (Cat No. D2000) or Silaris Dock (Cat. No 1026) | N | RNA IC | 3/23/2020 |
| BioFire Defense, LLC | BioFire COVID-19 Test* | qRT-PCR | 50 min | NPS | 1 | BioFire COVID-19 Test | | FilmArray 2.0 or FilmArray Torch Systems | Two regions of ORF1ab and ORF8 | RNA transcript (<i>Schizosaccharomyces pombe</i>) | 3/23/2020 |
| Cepheid | Xpert Xpress SARS-CoV-2 test | qRT-PCR | 60 min; Walk-away | NPS, nasal wash/aspirate | 10 | Xpert Xpress SARS CoV-2 cartridge | | GeneXpert Dx System or GeneXpert Infinity Systems | N2 and E | Sample processing and probe check controls | 3/20/2020 |
| Primerdesign Ltd. | Primerdesign Ltd COVID-19 genesis Real-Time PCR assay | qRT-PCR | Not specified | OPS | 93 | GenoExtract, Bruker-HAIN Lifesciences Gmb GX DNA/RNA Extraction Kit | Primerdesign LTD COVID-19 genesis Real Time PCR Assay | ABI 7500 Standard or Roche LightCycler 480 II or Bio-Rad CFX Connect Real-Time PCR Detection Systems | ORF1ab | RNA internal extraction control | 3/20/2020 |
| GenMark Diagnostics, Inc. | ePlex SARS-CoV-2 Test | qRT-PCR | Walk-away (2 mins hands-on) | NPS | 12 | The True Sample-to-Answer Solution ePlex SARS-CoV 2 Test | | GenMark ePlex Instrument | Not specified | DNA and RNA IC | 3/19/2020 |
| DiaSorin Molecular LLC | Simplexa COVID-19 Direct assay | qRT-PCR | 60 min | NPS | 24 | Simplexa COVID-19 Direct Assay | | LIAISON® MDX | ORF1ab and S | RNA IC | 3/19/2020 |
| Abbott Molecular | Abbott RealTime SARS-CoV-2 assay | qRT-PCR | 87-141 min | NPS, OPS, nasal swab | 94 | Abbott mSample Preparation System/DNA | Abbott RealTime SARS-CoV-2 Assay | Abbott m2000rt Instrument | RdRp and N | RNA IC | 3/18/2020 |
| Quest Diagnostics Infectious Disease, Inc. | Quest SARS-CoV-2 rRT-PCR** | qRT-PCR | Not specified | NPS, OPS, sputum, tracheal aspirate, BALF | 94 | Roche MagNA Pure 96 DNA and Viral NA, Small Volume Kit | Quest SARS-CoV-2 rRT-PCR | ABI 7500 Standard/FAST Real-Time PCR System | Two regions of N (CDC N1 and N3) | RNA IC | 3/17/2020 |
| Quidel Corporation | Lyra SARS-CoV-2 Assay | qRT-PCR | Not specified | NPS, OPS | 93 | bioMérieux easyMAG; EMAG Systems, NucliSENS | Lyra SARS-CoV-2 Assay | ABI 7500 Standard/Fast Dx or Roche LightCycler 480 Instrument II or Qiagen Rotor-Gene Q Real-Time PCR Systems | ORF1ab | Processing Control | 3/17/2020 |
| Laboratory Corporation of America | COVID-19 RT-PCR Test** | qRT-PCR | Not specified | NPS, OPS, sputum, LRT aspirate, BALF, NP/nasal wash/aspirate | 93 | Roche DNA and Viral Small Volume Kit | ABI TaqPATH 1-Step RT-PCR, CG | ABI QuantStudio7Flex (QS7) Real-Time PCR System | Three regions of N (CDC N1, N2, and N3) | RNase P | 3/16/2020 |
| Hologic, Inc. | Panther Fusion SARS-CoV-2 | qRT-PCR | 2.4 hrs; Walk away | NPS, OPS | 120 | Panther Fusion SARS-CoV-2 Assay | | Panther Fusion System | Two regions of ORF1ab | RNA IC | 3/16/2020 |
| Thermo Fisher Scientific, Inc. | TaqPath COVID-19 Combo Kit | qRT-PCR | Not specified | NPS, OPS, 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 7500 FAST/ DX Real-Time PCR System | Orf1ab, N, and S | MS2 bacteriophage | 3/13/2020 |
| Roche Molecular Systems, Inc. | cobas SARS-CoV-2 | qRT-PCR | 4 hrs; Walk away | NPS, OPS, nasal swab | 192 | Roche cobas SARS-CoV-2 | | cobas® 6800/8800 Systems | ORF1ab and E | RNA IC | 3/12/2020 |
| Wadsworth Center, New York State Department of Public Health's | New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel** | qRT-PCR | Not specified | NPS, OPS, Sputa | 20 | Qiagen EZ1 Advanced XL EZ1 DSP Virus Kit or bioMérieux easyMAG or EMAG Systems, NucliSENS | ABI TaqPATH 1-Step RT-PCR, CG | ABI 7500 FAST DX Real-Time PCR System | Two regions of N (CDC N1 and N2) | RNase P | 2/29/2020 |

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| Centers for Disease Control and Prevention's | CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC) | qRT-PCR | Not specified | NPS, OPS, Sputum, LRT aspirate, BALF, NP/nasal wash/aspirate | 20 | Qiagen QIAcube, QIAamp (DSP) Viral RNA Mini Kit or Qiagen EZ1 Advanced XL EZ1 DSP Virus Kit or Roche MagNA Pure Total Nucleic Acid Kit/ Nucleic Acid Isolation Kit I/ DNA and Viral RNA Mini Kit or bioMérieux easyMAG/ EMAG System, NucliSENS | Quantabio qScript XLT One-Step RT-qPCR ToughMix or Quantabio UltraPlex 1-Step ToughMix (4x) or Promega GoTaq Probe 1-Step RT-qPCR System or ABI TaqPATH 1-Step RT-PCR, CG | ABI 7500 FAST DX Real-Time PCR System | Two regions of N (CDC N1 and N2) | RNase P | 2/4/2020 |
| Adapted from FDA Website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus | | | | | | | | | | | |
| *Rapid Point-of-Care (POC) diagnostics; ** Restricted use to specific commercial CLIA Laboratories | | | | | | | | | | | |
| PCR, polymerase chain reaction; qRT-PCR, real-time reverse transcription polymerase chain reaction; qRT-ddPCR, real-time reverse transcription droplet digital polymerase chain reaction; NAAT, nucleic acid amplification test; RT-LAMP, reverse transcriptio loop-mediated isothermal amplification; CRISPR, clustered regularly interspaced short palindromic repeats; Antigen FIA, lateral flow immunofluorescent sandwich assay; NPS, nasopharyngeal swab; OPS, oropharyngeal swab, NP, nasopharyngeal; BALF, bronchoalveolar lavage liquid; LRT, Lower respiratory tract; S, spike; E, envelope; N, nucleocapsid; ORF, open reading frame; RdRp, RNA dependent RNA polymerase; M, membrane; N/A, Not applicable. | | | | | | | | | | | |
| Online version accessible at: https://tmclinlab.jabsom.hawaii.edu/lab-services/fda-emergency-use-authorizations-euas-for-covid-19-diagnostics/ | | | | | | | | | | | |

