

List of SARS-CoV-2 Diagnostic test kits and equipments eligible for procurement according to Board Decision on Additional Support for Country Responses to COVID-19 (GF/B42/EDP11)

The following emergency procedures established by WHO and the Regulatory Authorities of the Founding Members of the GHTF have been identified by the QA Team and will be used to determine eligibility for procurement of COVID-19 diagnostics. The product, to be considered as eligible for procurement with GF resources, shall be listed in one of the below mentioned lists:

- WHO Prequalification decisions made as per the Emergency Use Listing (EUL) procedure opened to candidate in vitro diagnostics (IVDs) to detect SARS-CoV-2;
- The United States Food and Drug Administration's (USFDA) general recommendations and procedures applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act;
- The decisions taken based on the Canada's Minister of Health interim order (IO) to expedite the review of these medical devices, including test kits used to diagnose COVID-19;
- The COVID-19 diagnostic tests approved by the Therapeutic Goods Administration (TGA) for inclusion on the Australian Register of Therapeutic Goods (ARTG) on the basis of the Expedited TGA assessment
- The COVID-19 diagnostic tests approved by the Ministry of Health, Labour and Welfare after March 2020 with prior scientific review by the PMDA

The following websites provide access to Instructions For Use of certain products:

- https://www.who.int/diagnostics_laboratory/EUL/en/
- <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|----------------------------|------------------|---|--|--|----------------------|---------------------------------|---------------------------------|---------------|--|--|
| 444213 | 1COPY COVID-19 QPCR KIT | 100T/kit | QIAamp Viral RNA Mini Kit RNA mini kit (QIAgen) | Light Cycler 480 (Roche) | 1DROP INC. (imported by Luminarie Canada Inc.) | E gene and RdRp gene | see IFU | lower than -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order |
| | | | | Rotor-Gene Q 5plex HRM (Qiagen) | | | | | | | |
| | | | | Applied Biosystems Quantstudio5 (Thermo Fisher Scientific) | | | | | | | |
| | | | | Applied Biosystems 7500 Real-Time PCR Instrument system (Thermo Fisher Scientific) | | | | | | | |
| | | | CFX96™ Real-Time PCR Detection system (BIO-RAD) | | | | | | | | |

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|---------------------------------------|---------------------------------------|------------------|--|--|---|---------------------|---------------------------------|---------------------------------|---------------|--|---|
| 3B304 | TRUPCR SARS-CoV-2 Kit | 100T/kit | TRUPCR® Viral RNA Extraction Kit (3B213V/3B214V) | Applied Biosystems Quantstudio3 (Thermo Fisher Scientific) | 3B Blackbio Biotech India Ltd (a Kilpest India Ltd company) | RdRp, N and E genes | see IFU | -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | Rotor-Gene Q 5plex HRM (Qiagen) | | | | | | | |
| 190-000 | ID NOW COVID-19 Test Kit | 96T/kit | ID NOW Instrument | | Abbott Diagnostics Scarborough Inc | RdRp segment | see IFU | 2 to 30 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order |
| 09N78-095 | Alinity m SARS-CoV-2 AMP Kit | 96T/kit | Alinity m System | | Abbott Molecular | RdRp and N genes | see IFU | -25 to -15 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| 09N77-090 | Abbott RealTime SARS-CoV-2 RT-PCR Kit | 96T/kit | Abbott m2000 | | Abbott Molecular | RdRp and N genes | see IFU | -25 to -15 °C | see IFU | For consumables and details of components refer to IFU | Health Canada/Interim Order TGA WHO EUL |
| 09N77-095 | Abbott RealTime SARS-CoV-2 RT-PCR Kit | 96T/kit | Abbott m2000 | | Abbott Molecular | RdRp and N genes | see IFU | -25 to -15 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| 821025 | RealStar® SARS-CoV-2 RT-PCR Kit U.S. | 384T/kit | AltoStar® Automation System AM16 | CFX96™ Touch Real-Time PCR Detection System (Bio-Rad) | Altona Diagnostics GmbH | | see IFU | -25 to -15 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | CFX96™ Touch Deep Well Real-Time PCR Detection System (BioRad) | | | | | | | |
| 64-C0304 | BioCode® SARS-CoV-2 Assay | 384T/kit | NucliSENS® easyMAG® (bioMérieux) | BioCode® MDx-3000 automated system | Applied BioCode Inc | N gene | see IFU | lower than -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | MagNA Pure 96 (Roche) | | | | | | | | |

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|---------------------------------------|---|------------------|---|--|-----------------------------------|-----------------------------|---------------------------------|---------------------------------|--|--|--|
| DX-1001-001-000 | Linea™ COVID-19 Real-Time PCR Assay Kit assay kit | 100T/kit | QIAamp® Viral RNA Mini Kit (Qiagen) | Applied Biosystems QuantStudio™ Dx Real-Time PCR system | Applied DNA Sciences | S genes | 6 months | lower than -20 °C | nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, and sputum | For consumables and details of components refer to IFU | US FDA EUA |
| DX-1001-002-000 | | 500T/kit | TRIZOL™ RNA Extraction Kit (Invitrogen) | Applied Biosystems QuantStudio 5 Real-Time PCR System | | | | | | | |
| DX-1001-003-000 | | | 1000T/kit | Mag-Bind Viral RNA Xpress Kit (Omega Bio-Tek) automated on the Hamilton STARlet system | | | | | | | |
| | Assurance SARS-CoV-2 Panel | see IFU | Zymo Quick-RNA Viral Kit RNA Extraction Kit | CFX96™ Touch Real-Time PCR Detection System (Bio-Rad) | Assurance Scientific Laboratories | N gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | CFX384™ Touch Deep Well Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| iAMP-COVID19-100 | iAMP® COVID-19 Detection Kit | 100T/kit | not required | CFX96 Real-Time System (Bio-Rad) | Atila BioSystems, Inc. | N gene and the ORF-1ab gene | 12 months | lower than -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | Roche LightCycler 480 Instrument II Real-Time PCR System | | | | | | | |
| | | | | Atila PowerGene 9600 Plus Real-Time PCR System | | | | | | | |
| | | | | Applied Biosystems 7500 Fast Real-Time PCR System | | | | | | | |

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|---------------------------------------|--|------------------|--|--|------------------------------------|----------------------------|---------------------------------|---------------------------------|----------------------|--|---|
| | AusDiagnostics respiratory virus panel (including SARS-CoV-2) test | | | | AusDiagnostics Pty Ltd (Australia) | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | TGA |
| 445003-01 | BD SARS-CoV-2 Reagents | 24T/kit | BD MAX™ System | | Becton, Dickinson and Company | N gene (N1 and N2 regions) | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order |
| 444213 | BioGX SARS-CoV-2 Reagents | 24T/kit | BD MAX™ System | | Becton, Dickinson and Company | N gene (N1 and N2 regions) | 6 months | 15 to 30°C | nasopharyngeal swabs | For consumables and details of components refer to IFU | US FDA EUA |
| MFG030010 | Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV | 50T/kit | TIANamp Virus RNA extraction Kit (DP315-R) TIANGEN QIAamp Virus RNA Mini Kit (cat. #52904). RNA extraction kit by MGI Tech (Wuhan) (No.20200167) | Applied Biosystems 7500/7500 Fast Real-Time PCR System Applied Biosystems QuantStudio 5 Real-Time PCR Systems SLAN-96P PCR system LightCycler® 480 System | BGI Europe A/S | ORF1ab | 6 months | lower than -18 °C | throat swabs or BALF | For consumables and details of components refer to IFU | WHO EUL |
| | Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV | 50T/kit | QIAamp Virus RNA Mini Kit (cat. #52904 or 52906). | Applied Biosystems 7500 Real-Time PCR System | BGI Genomics Co. Ltd | ORF1ab | 12 months | lower than -18 °C | throat swabs or BALF | For consumables and details of components refer to IFU | US FDA EUA |

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| CT8233-48T | Multiple Real-Time PCR Kit for Detection of 2019-nCoV | 48T/kit | Nucleic acid extraction Kit (XABT, Cat. # CN8033) | Applied Biosystems 7500 Real-Time PCR System | Beijing Applied Biological Technologies Co. Ltd., (XABT) | ORF1ab and N gene and the E gene | see IFU | -25 to -15 °C | see IFU | For consumables and details of components refer to IFU | WHO EUL |
| | | | QIAamp Viral RNA Mini Kit (Qiagen, Cat. # 52904 or 52906) | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| | | | PURELINK VIRAL RNA/DNA KIT (Invitrogen, Cat. #12280050) | LightCycler 480 (System II) (Roche) | | | | | | | |
| | | | High Pure Viral RNA Kit (Roche, Cat. # 11858882001) | | | | | | | | |
| WS-1248 | Wantai SARS-CoV-2 RT-PCR Kit | 48T/kit | Beijing Wantai Nucleic Acid Extraction Kit (cat. # ZCT1246) | Applied Biosystem® 7500 Real-Time PCR system | Beijing Wantai Biological Pharmacy Enterprise Co., Ltd | ORF1ab and N gene | see IFU | see IFU | see IFU | See IFU | WHO EUL |
| | | | GenMagBio (cat. #NA007-1) | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| | | | QIAGEN (cat. #57704) | | | | | | | | |

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| BC-01-0099 BC-01-0099 x4 | BioCore 2019-nCoV Real Time PCR Kit | 100T/kit 400T/kit | QIAamp DSP Viral RNA Mini Kit (Qiagen; catalog #61904) | Applied Biosystems 7500 Real-Time PCR System | BioCore Co. Ltd. | N gene and RdRp gene | see IFU | lower than -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA TGA |
| | | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | | | |
| | | SLAN-96P (Shanghai Hongshi Medical Technology Co. Ltd) | | | | | | | | | |
| BS-SY-SC2-100 | Bio-Speedy® Direct RT-qPCR SARS-CoV-2 | 100T/kit | | LightCycler 96 (Roche) | Bioeksen R&D Technologies Ltd | ORF1ab gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | | | |
| | | Rotor-Gene Q (Qiagen) | | | | | | | | | |
| 423745 | BioFire® COVID-19 Test | 6T/kit | FilmArray® 2.0 and/or the FilmArray® Torch Instrument Systems | | BioFire Defense, LLC | ORF1ab and ORF8 | see IFU | 15 to 30°C | nasopharyngeal swabs | For consumables and details of components refer to IFU | US FDA EUA |
| 423744 | | 30T/kit | | | | | | | | | |
| | Biofire Respiratory Panel 2.1 (RP2.1) | | FilmArray® 2.0 and/or the FilmArray® Torch Instrument Systems | | BioFire Diagnostics LLC | see IFU | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | Health Canada/Interim Order TGA |

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| | Biomeme SARS-CoV-2 Real-Time RT-PCR | 96T/kit | Biomeme M1 Sample Prep Cartridge Kit for RNA 2.0 | Bio-Rad CFX96 QuantStudio 5 | Biomeme Inc. | ORF1ab and S gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| 3000555 | Biomeme SARS-CoV-2 Go-Strips | | Biomeme's Franklin Real-Time PCR System | | Biomeme Inc. | ORF1ab and S gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA Health Canada/Interim Order |
| 423735 | ARGENE® SARS-COV-2 R-GENE® | 30 and 120T/kit (depending on PCR) | EMAG® (bioMérieux) | 7500 & 7500 Fast Real-Time PCR System (Applied Biosystems) QuantStudio12 Flex (QS12) instrument (Applied Biosystems) | BioMérieux SA | N gene and RdRp gene | see IFU | -31 to -15 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA TGA |
| | | NucliSENS easyMAG (bioMérieux) | LightCycler 480 (System II) (Roche) | | | | | | | | |
| | | QIASymphony SP (QIAGEN) | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | | |
| | | MagNA Pure 96 (Roche) | Rotor-Gene Q (Qiagen) | | | | | | | | |

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| BS7nCoV | Real-Q 2019-nCoV Detection Kit | 100T/kit | MagNA Pure 96 (Roche) or manual | 7500 Real-Time PCR System (Applied Biosystems) | BioSewoom | E gene and RdRp gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | 7500 Fast Real-Time PCR System (Applied Biosystems) | | | | | | | |
| | | | | QuantStudio5 realtime PCR instrument (Applied Biosystems) | | | | | | | |
| | | | | CFX96 DX Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| | | | | CFX96 Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| 12008202 | 2019-nCoV CDC ddPCR Triplex Probe Assay | 200T/kit | ThermoFisher MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (Cat No. A48310, 1000 reactions) | QX200™ PCR Systems | BioRad | P and N genes | see IFU | -25 to -15 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | QIAamp Virus RNA Mini Kit (cat. # 52906) | QXDx™ Droplet Digital™ PCR Systems | | | | | | | |
| XPRSARS-COV2-10 | Xpert® Xpress SARS-CoV-2 | 10T/kit | GeneXpert Xpress System (Tablet and Hub Configurations) | | Cepheid | Genes N2 and E | see IFU (302-3750) | 2 to 28°C | see IFU (302-3750) | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order TGA |
| XPRSARS-COV2-10 | Xpert® Xpress SARS-CoV-2 | 10T/kit | GeneXpert Dx | | Cepheid | Genes N2 and E | see IFU (302-3562) | 2 to 28°C | see IFU (302-3562) | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order TGA WHO EUL |
| | | | GeneXpert Infinity Systems | | | | | | | | |
| | VIASURE SARS-CoV-2 Real Time PCR Detection Kit | | | | CerTest Biotec SL / Abacus dx | | see IFU | see IFU | nasopharyngeal swabs | For consumables and details of components refer to IFU | TGA |

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|---------------------------------------|--|------------------|---|---|---|----------------------------|---------------------------------|---------------------------------|----------------------|---|--|
| HBRT-COVID-19 | COVID-19 Real-Time PCR Kit | 24T/kit | Thermo Scientific™ KingFisher™ Flex | 7500 Real-Time PCR System (Applied Biosystems) | Chaozhou HybriBio Biochemistry Ltd. | ORF1ab and N genes | see IFU | lower than -15 °C | see IFU | For consumables and details of components refer to IFU | WHO EUL |
| | | | Bioer GenePure Pro Nucleic Acid Purification System | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| | | | | 96S Real-Time PCR System (SLAN) | | | | | | | |
| COVID-K-001 | LOGIX SMART™ Coronavirus Disease 2019 (COVID-19) Kit | 100T/kit | QIAamp Virus RNA Mini Kit (Qiagen) | CoDx Box (BMS, Bio Molecular Systems) | Co-Diagnostics, Inc | | 12 months | lower than -20 °C | nasopharyngeal swabs | For consumables and details of components refer to IFU | US FDA EUA TGA |
| | <u>Aridia COVID-19 Real-Time PCR Test</u> | | | | <u>CTK Biotech Inc (United States Of America)</u> | | <u>see IFU</u> | <u>see IFU</u> | <u>see IFU</u> | <u>For consumables and details of components refer to IFU</u> | <u>TGA</u> |
| | Cue COVID-19 Test | | | Cue Health Monitoring System | Cue Health Inc | N Gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| 99-57003 | HDPCR™ SARS-CoV-2 Assay | 480T/kit | Thermo Scientific™ KingFisher™ Flex | 7500 Fast Real-Time PCR System (Applied Biosystems) | ChromaCode, Inc. | N gene (N1 and N2 regions) | see IFU | -25 to -15°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | QuantStudio7 (Fast Block) instrument (Applied Biosystems) | | | | | | | |
| | | | Roche MagNA Pure-24 | QuantStudio 12k Flex (96-well Fast Block) instrument (Applied Biosystems) | | | | | | | |
| | | | | Bio Molecular Systems Mic qPCR (IDEXX Laboratories) | | | | | | | |

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| DA0930 DA0931 DA0932 | Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA, (PCR- Fluorescence Probing) | 24T/kit 48T/kit 96T/kit | YHXB No. 20170583, YHXB No. 20150302 (DAAN) | Applied Biosystems™ 7500 Dx Real-Time PCR Instrument | Da An Gene Co., Ltd. of Sun Yat-sen University | ORF1ab and N genes | 12 months | -25 to -15 °C | see IFU | For consumables and details of components refer to IFU | WHO EUL |
| | | | QIAamp Viral RNA Mini Kit, 52906 | Roche LightCycler480 II | | | | | | | |
| MOL4150 | MobileDetect-BIO BCC19 Test Kit | 24T/kit | MD-Bio BCC19 Heater | | DetectaChem LLC | N and E genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| DC-11-0007 | QuantiVirus SARS-CoV-2 Test kit | 24T/kit | Thermo Fisher PureLink™ viral RNA/DNA mini kit | Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument | DiaCarta, Inc | N, Orf1ab and E genes | 12 months | -25 to -15 °C | nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, and sputum | For consumables and details of components refer to IFU | US FDA EUA |
| DC-11-0008 | | 48T/kit | | Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument | | | | | | | |
| DC-11-0009 | | 480T/kit | | | | | | | | | |
| DC-11-0017 | QuantiVirus SARS-CoV-2 Multiplex Test kit | 24T/kit | Thermo Fisher PureLink™ viral RNA/DNA mini kit | Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument | DiaCarta, Inc | Orf1ab genes | 12 months | -25 to -15 °C | nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, and sputum | For consumables and details of components refer to IFU | US FDA EUA |
| DC-11-0018 | | 48T/kit | MGI MGISP960 High Throughput Automated Sample Preparation System | Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument | | | | | | | |
| DC-11-0019 | | 480T/kit | | Bio-Rad CFX 384 Real-Time PCR Instrument | | | | | | | |
| MOL4150 | Simplexa™ COVID-19 Direct | 24T/kit | LIAISON® MDX | | DiaSorin Molecular | ORF1ab and S gene | see IFU | -30 to -10 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order TGA WHO EUL |
| | Loopamp Novel Coronavirus 2019 (SARS-CoV-2) Detection Kit | | | | Eiken Chemical Co., Ltd. | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | PMDA |

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| | AMPIPROBE® SARS-CoV-2 Assay kit | | GENFLEX platform V1.0 | | Enzo Life Sciences, Inc. | N gene (N1 and N2 regions) | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | QIAasymphony® SP (QIAGEN) | QuantStudio® 5 Real-Time PCR System (Applied Biosystems) | | | | | | | |
| | | | Manual | | | | | | | | |
| MP 2606-0125 | EURORealTime SARS-CoV-2 | 25T/kit | QIAamp Virus RNA Mini Kit (Qiagen) | LightCycler® 480 II (Roche) | EUROIMMUN Medizinische Labordiagnostika AG (Germany) | ORF1ab and N gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA TGA |
| MP 2606-0225 | | 50T/kit | Prepito Viral DNA-RNA200 Kit (Chemagen) | 7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems™) | | | | | | | |
| MP 2606-0425 | | 100T/kit | | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| MP 2606-0100 | | 100T/kit | | | | | | | | | |
| MP 2606-0200 | | 200T/kit | | | | | | | | | |
| 11416302 (FTD-114-96) | FTD SARS-CoV-2 | 96T/kit | NucliSENS® easyMAG® System (bioMérieux) | 7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems™) | Fast Track Diagnostics Luxembourg S.à.r.l. (a Siemens Healthineers Company) | ORF1ab and N gene | see IFU | -30 to -10 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA TGA |
| 11416300 (FTD-114-32) | FTD SARS-CoV-2 | 32T/kit | NucliSENS® easyMAG® System (bioMérieux) | 7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems™) | Fast Track Diagnostics Luxembourg S.à.r.l. (a Siemens Healthineers Company) | ORF1ab and N gene | see IFU | -30 to -10 °C | see IFU | For consumables and details of components refer to IFU | WHO EUL |

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| 102-0355 | Advanta Dx SARS-CoV-2 RT-PCR Assay | | Biomark HD in Conjunction with Juno or IFC Controller RX with Applied Biosystems Veriti 96-Well Thermal Cycler | | Fluidigm Corporation | N-gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| CV002 | GenePro SARS-CoV-2 Test | | QIAamp DSP Viral RNA Mini Kit (Qiagen) | QuantStudio™ DX (Applied Biosystems) | Gencurix, Inc. | N-gene and E-gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA TGA |
| | | | QIAamp Viral RNA Mini Kit (Qiagen) | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| | | | MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit automated on KingFisher™ Flex Purification System (KingFisher) | | | | | | | | |
| EA008212 | GB SARS-CoV-2 Real Time RT-PCR | | | | General Biologicals Corp | | | | | For consumables and details of components refer to IFU | TGA |
| | EasyScreen™ SARS-CoV-2 Detection Kit | | | | Genetic Signatures Ltd (Australia) | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | TGA |
| RPQ021 RPQ022 | Genetron SARS-CoV-2 RNA Test | 50T/kit 100T/kit | QIAamp DSP Viral RNA Mini Kit (Qiagen) | 7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems™) | Genetron Health (Beijing) Co., Ltd. | ORF1ab and N gene | 6 months | lower than -18 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| EA008212 | ePlex® SARS-CoV-2 Test | 12T/kit | GenMark ePlex instrument and Software | | GenMark Diagnostics, Inc | | see IFU | 2 to 8°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|---------------------------------------|------------------|---|---|------------------|------------------------------------|---------------------------------|---------------------------------|---|--|--|
| | GS COVID-19 RT-PCR KIT | 96T/kit | QIAamp DSP Viral RNA Mini Kit | 7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems™) | GenoSensor LLC | ORF1ab, N and E genes | see IFU | -20°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | 384T/kit | | | | | | | | | |
| CV0202 | COVID-19 RT-Digital PCR Detection Kit | 48T/kit | QIAamp® DSP Viral RNA Mini Kit (Qiagen) | QuantStudio™ 3D Digital PCR System (Applied Biosystems) | Gnomegen LLC | | see IFU | -10 to -30 °C | nasal, nasopharyngeal, and oropharyngeal swab | For consumables and details of components refer to IFU | US FDA EUA |
| PRD-06419 | Aptima SARS-CoV-2 assay | 250T/kit | Panther System | | Hologic Inc | ORF1ab Region 1 ORF1ab Region 2 | 2 months | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA TGA PMDA |
| | Panther Fusion SARS-CoV-2 Kit | 96T/kit | Panther/Panther Fusion System | | Hologic Inc | ORF1ab Region 1 ORF1ab Region 2 | 2 months | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order TGA |
| 351251 | Hymon™ SARS-CoV-2 Test Kit | 96T/kit | | 7500 Dx Real-Time PCR Instrument (Applied Biosystems™) | HymonBio Co. LTD | N and E genes | see IFU | -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | QuantStudio 5 RT PCR System (Applied Biosystems™) | | | | | | | |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|--------------------------------------|------------------|--|--|---------------------------|----------------------|---------------------------------|---------------------------------|---------------|--|--|
| | ILLUMINA® COVIDSeq™ Test | 3072T/kit | | NovaSeq 6000 Sequencing System | Illumina | Sars-Cov-2 Genome | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | NextSeq 500 Sequencing System | | | | | | | |
| | | | | NextSeq 550 Sequencing System | | | | | | | |
| | | | | NextSeq 550Dx Sequencing System | | | | | | | |
| COV2-E | Smart Detect™ SARS-CoV-2 rRT-PCR Kit | 48T/kit | QIAamp® DSP Viral RNA Mini Kit (Qiagen) | 7500 Fast Dx Real-Time PCR instrument (Applied Biosystems) | InBios International, Inc | ORF1b, N and E genes | see IFU | -10 to -30 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| | | | MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit Hamilton MagEx Star automated liquid handling system | CFX384 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| | COV-19 IDx assay | 96T/kit | KingFisher Flex nucleic acid extraction systems QS12 instrument | Applied Biosystems QuantStudio12 Flex (QS12) instrument | Ipsium Diagnostics, LLC | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|--|-------------------------------|--|--|--|-----------------------|---------------------------------|---------------------------------|---------------|--|--|
| JC10223-1NW-50T JC10223-1NW-25T | COVID-19 Coronavirus Real Time PCR Kit | 50T/kit 25T/kit | Viral nucleic acid isolation kit (Bioperfectus Technologies) QIAamp® Viral RNA Mini Kit (Qiagen) | Applied Biosystems QuantStudio5 instrument 7500 Real-Time PCR instrument (Applied Biosystems) | Jiangsu Bioperfectus Technologies Co Ltd (China) | ORF1ab and N genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA TGA WHO EUL |
| | Novel Coronavirus (SARS-CoV-2) Fast Nucleic Acid Detection Kit | 24T/kit 48T/kit 96T/kit | see IFU | 7500 Real-Time PCR instrument (Applied Biosystems) | Jiangsu CoWin Biotech Co., Ltd. (China) | ORF1ab and N genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | SmartAmp SARS-CoV-2 | | | | K.K. DNAFORM | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | PMDA |
| R6900TD | PowerChek™ 2019-nCoV Real-time PCR Kit | | QIAamp® DSP Viral RNA Mini Kit (QIAGEN) | CFX96 Real-Time PCR Detection System (BioRad) 7500 Real-Time PCR instrument (Applied Biosystems) 7500 Fast Real-Time PCR instrument (Applied Biosystems) | Kogene Biotech Co Ltd (Korea - Republic of) | RdRp and E genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA TGA |
| | Curative SARS-Cov-2 Assay | | Total RNA Purification 96-Well Kit (Norgen Biotek Corporation) manually or using Tecan Resolvex A200 | BioRad CFX 96 Touch BioRad CFX Connect Real-Time PCR systems Roche LightCycler 480 II Real-Time PCR systems | KorvaLabs, Inc. | ORF1ab, N and E genes | see IFU | -20°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|---------------------------------|------------------|--|---|---|---------------------------|---------------------------------|---------------------------------|--|--|---|
| | LabGun™ COVID-19 RT-PCR Kit | 96T/kit | QIAamp® DSP Viral RNA Mini Kit (Qiagen) | 7500 Fast Dx Real-Time PCR instrument (Applied Biosystems) CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | LabGenomics | RdRp and N genes | see IFU | -25 to -15 °C | nasopharyngeal swab, anterior nasal swab and midturbinate nasal swab | For consumables and details of components refer to IFU | US FDA EUA TGA |
| | TaqPath COVID-19 Combo Kit | | | | Life Technologies Corporation (USA) (see also ThermoFisher) | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | TGA PMDA |
| 50-10047 | ARIES® SARS-CoV-2 Assay Kit | 24T/kit | Luminex® ARIES® System | | Luminex Corporation | | see IFU | 15 to 30°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order |
| I054C0463 | NxTAG® CoV Extended Panel Assay | 12T/kit | bioMérieux® NucliSENS® easyMAG® System bioMérieux® EMAG® System | Luminex® MAGPIX® instrument including xPONENT | Luminex Molecular Diagnostics, Inc. | ORF1ab, N Gene and E Gene | see IFU | Store at 2°C to 8°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order |
| L018180030096 | LumiraDx SARS-CoV-2 RNA STAR | | Qiagen DSP Virus/Pathogen Kit on QIASymphony SP (Qiagen) MagMax Viral/Pathogen Nucleic Acid Isolation Kit (Applied) QIAamp Viral RNA Mini Kit (Qiagen) | Roche LightCycler 480 II Applied Biosystems 7500 Fast Dx Applied Biosystems QuantStudio 5 Agilent AriaMx RT-PCR Instruments Agilent Stratagene Mx3005P RT-PCR Instruments | LumiraDx UK Ltd | ORF1a Gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|---|------------------|---|--|--|-------------------------------|---------------------------------|---------------------------------|---------------|--|--|
| BUSGN7101109 | SARS-CoV-2 Fluorescent PCR Kit | 32T/kit | Nucleic Acid Extraction Kit, Manual Version or Nucleic Acid Extraction Kit, Fast Version | 7500 Real-Time PCR Systems with v2.3 software (Applied Biosystems) | Maccura Biotechnology (USA) LLC | ORF1ab, N and E genes | see IFU | -30 to -10°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| BUSGN7102109 | | 64T/kit | | | | | | | | | |
| BUSGN7103109 | | 96T/kit | | | | | | | | | |
| | SARS-CoV-2 DETECTR™ Reagent Kit | | EZ1 Virus Mini Kit v2.0 on EZ1 Advanced benchtop automated extraction instrument (Qiagen) | 7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems) | Mammoth Biosciences, Inc. | RP and N Gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | MEBRIGHT SARS-CoV-2 Kit | | | | Medical & Biological Laboratories Co., Ltd. | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | PMDA |
| COV4100 | Accula SARS-Cov-2 Test | | | Accula™ Dock or the Silaris™ Dock | Mesa Biotech Inc. | | see IFU | 15 to 30°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| 300800 | NeuMoDx™ SARS-CoV-2 Test Strip | 96T/kit | NeuMoDx™ 288 Molecular System [500100] or NeuMoDx™ 96 Molecular System [500200] | | NeuMoDx Molecular, Inc. | Nsp2 target and N gene target | see IFU | 4 to 28°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | Sars-Cov-2 Virus Detection Diagnostic Kit | | | | Ningbo Health Gene Technologies Co., Ltd (China) | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | TGA |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|---------------------------------------|------------------|---|--|-----------------------------|------------------------------|---------------------------------|---------------------------------|---------------|--|--|
| RDM101-X | Kaira 2019-nCoV Detection Kit | 100T/kit | QIASymphony DSP Virus/Pathogen Kit on QIASymphony SP (Qiagen) | 7500 Fast Real-Time PCR System (Applied Biosystems) | OPTOLANE Technologies, Inc. | RdRp and E Gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | QuantStudio5 Flex (QS5) instrument (Applied Biosystems) | | | | | | | |
| | | | | CFX96 Real-Time PCR Instrument (Biorad) | | | | | | | |
| IFMR-45 | GeneFinder™ COVID-19 Plus RealAmp Kit | 100T/kit | QIAamp viral RNA Mini Kit (Qiagen) | Applied Biosystems 7500 & 7500 Fast Real-Time PCR System | OSANG Healthcare Co., Ltd | RdRp gene, N Gene and E Gene | see IFU | -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order |
| | | | DNA and Viral NA Small Volume Kit (Roche MagNA Pure 96) | CFX96 Real-Time PCR Instrument (Biorad) | | | | | | | |
| 99-57003 | OPTI SARS-CoV-2 RT PCR Test | | Duo instrument (Thermo Scientific) | 7500 Fast Real-Time PCR System (Applied Biosystems) | OPTI Medical Systems, Inc. | N gene and RdRp gene | see IFU | -25 to -15°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | QuantStudio5 Flex (QS5) instrument (Applied Biosystems) | | | | | | | |
| | | | | LightCycler 480 (System II) (Roche) | | | | | | | |
| | | | Flex instrument (Thermo Scientific) | Agilent Mx3005P™ (Agilent) | | | | | | | |
| | | | | Bio Molecular Systems Mic qPCR (IDEXX Laboratories) | | | | | | | |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|---|------------------|--|--|---|-----------------------------|---------------------------------|---------------------------------|----------------------------|---|--|
| 2019-nCoV-PCR-AUS | PerkinElmer® New Coronavirus Nucleic Acid Detection Kit | 48T/kit | PerkinElmer® Nucleic Acid Extraction Kits (KNO212) and PreNAT II (SY61)(software version 1.00.06). chemagic™ Viral DNA/RNA 300 Kit special H96 (CMG-1033, CMG-1033-S) and chemagic™ 360 (2024-0020) with chemagic™ Rod Head Set 96 (CMG371) (chemagic MSM I software version 6.1.0.5) | Applied Biosystems 7500 Real-Time PCR System | PerkinElmer, Inc. / Suzhou Sym-Bio Lifescience Co Ltd | ORF1ab gene and N gene | see IFU | -25 to -15°C | see IFU | For consumables and details of components refer to IFU v3.0 | US FDA EUA Health Canada/Interim Order WHO EUL |
| 82303-U | IntelliPlex SARS-CoV-2 Detection Kit | 96T/kit | QIAmp Viral RNA Mini Kit (Qiagen) | Thermo Fisher MiniAmp Thermal cycler with IntelliPlex™ 1000 πCode Processor (PlexBio; Cat. No. 80033) and PlexBio 100 Fluorescent Analyzer (PlexBio; Cat. No. 80000) | PlexBio Co., Ltd. | RdRp gene, N and E Gene | 12 months | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| <u>02.01.1019</u> | <u>FastPlex Triplex SARS-CoV-2 detection kit</u> | <u>24T/kit</u> | <u>QIAmp Viral RNA Mini Kit (Qiagen)</u> | <u>DropX-2000 Digital PCR System</u> | <u>PreciGenome LLC</u> | <u>RdRp gene and N Gene</u> | <u>see IFU</u> | <u>-20 °C</u> | <u>nasopharyngeal swab</u> | <u>For consumables and details of components refer to IFU</u> | <u>US FDA EUA</u> |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|---------------------------------------|------------------|--|--|---|----------------------|---------------------------------|---------------------------------|---------------|--|--|
| Z-PATH-COVID-19-CE | COVID-19 genesig® Real-Time PCR assay | 96T/kit | GXT DNA/RNA Extraction kit (GenoXtract®, Bruker-HAIN Lifescience GmbH) | Applied Biosystems® 7500 Real-Time PCR System | Primerdesign Ltd | Orf1 ab gene | 12 months | lower than -20 °C | see IFU | For consumables and details of components refer to IFU | WHO EUL |
| | | | | Bio-Rad CFX Connect™ Real-Time PCR Detection System | | | | | | | |
| | | | | Roche® LightCycler 480 II | | | | | | | |
| Z-COVID-19 (US ONLY) | COVID-19 genesig® Real-Time PCR assay | 96T/kit | GXT DNA/RNA Extraction kit (GenoXtract®, Bruker-HAIN Lifescience GmbH) | Applied Biosystems® 7500 Real-Time PCR System | Primerdesign Ltd | Orf1 ab gene | 12 months | lower than -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | Bio-Rad CFX Connect™ Real-Time PCR Detection System | | | | | | | |
| | | | | Roche® LightCycler 480 II | | | | | | | |
| PCCSKU15261 | PhoenixDx® 2019-nCoV | 50T/kit | RTA Viral RNA Extraction Kit as extraction Kit (RTA Laboratories) | 7500 Fast Real-Time PCR System (Applied Biosystems) | Procomcure Biotech GmbH (Trax Management Services Inc.) | E gene and RdRp gene | see IFU | -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | QIAamp MinElute Virus Spin Kit (Qiagen) | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| | | | High Pure Viral RNA Kit (Roche) | Rotor-Gene Q (Qiagen) | | | | | | | |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|---|------------------|---|---|---|--------------------|---------------------------------|---------------------------------|--|--|--|
| PCCSKU15262 | PhoenixDx® SARS-CoV-2 Multiplex | 50T/kit | RTA Viral RNA Extraction Kit as extraction Kit (RTA Laboratories) | 7500 Fast Real-Time PCR System (Applied Biosystems) | Procomcure Biotech GmbH (Trax Management Services Inc.) | ORF1ab and N genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | MagMax Viral/Pathogen Nucleic Acid Isolation Kit (Thermo Fisher) | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| | | | QIAamp MinElute Virus Spin Kit (Qiagen) | Rotor-Gene Q (Qiagen) | | | | | | | |
| | | | High Pure Viral RNA Kit (Roche) | DTPPrime5 (DNA Technologie) | | | | | | | |
| | | | SphaeraMag DNA/RNA Isolation Kit (Procomcure) | qTower3G (Analytik Jena) | | | | | | | |
| | | | | Applied Biosystems™ QuantStudio 1 Real-Time PCR Instrument (ThermoFisher) | | | | | | | |
| | | | | Applied Biosystems™ QuantStudio 3 Real-Time PCR Instrument (ThermoFisher) | | | | | | | |
| | Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument (ThermoFisher) | | | | | | | | | | |
| 691223 | QIAstat-Dx Respiratory SARS-CoV-2 Panel | 6 Tests | QIAstat Dx Analyzer System | QIAGEN GmbH | Orf1b poly gene (Rdrp) and E genes | see IFU | 15 to 25°C | nasopharyngeal swab | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order TGA | |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|---|------------------|---|--|--|------------------------------------|---------------------------------|---------------------------------|--|---|---|
| 39433 | Quest SARS-CoV-2 rRT-PCR Kit | 96T/kit | Roche MagNA Pure-96 (MP96) | Applied Biosystems 7500 Real Time PCR System | Quest Diagnostics Infectious Disease Inc | Gene N1 & N3 | 12 months | -90 to -60°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | Mag-Bind Viral RNA Xpress Kit (Omega Bio-Tek, Cat. M6219-2304) with the MagEx STAR (Hamilton) | | | | | | | | |
| | Quest Diagnostics RC SARS-CoV-2 rRT-PCR Kit | 96T/kit | cobas 6800/8800 (Roche) | | Quest Diagnostics Infectious Disease Inc | ORF1 a/b | 12 months | -90 to -60°C | see IFU | Quest Diagnostics Self-Collection Kit for COVID-19 For consumables and details of components refer to IFU | US FDA EUA |
| | Quest Diagnostics HA SARS-CoV-2 rRT-PCR Kit | 96T/kit | Aptima (Hologic) | | Quest Diagnostics Infectious Disease Inc | ORF1ab Region 1 ORF1ab Region 2 | 12 months | -90 to -60°C | nasopharyngeal swabs, oropharyngeal swabs, sputum, BAL, and tracheal aspirates | Quest Diagnostics Self-Collection Kit for COVID-19 For consumables and details of components refer to IFU | US FDA EUA |
| | Quest Diagnostics PF SARS-CoV-2 rRT-PCR Kit | 96T/kit | Panther Fusion (Hologic) | | Quest Diagnostics Infectious Disease Inc | ORF1ab Region 1 ORF1ab Region 2 | 12 months | -90 to -60°C | nasopharyngeal swabs, oropharyngeal swabs, sputum, BAL, and tracheal aspirates | Quest Diagnostics Self-Collection Kit for COVID-19 For consumables and details of components refer to IFU | US FDA EUA |
| SKU # CE-M120 | Lyra SARS-CoV-2 rRT-PCR Kit | 96T/kit | bioMérieux NucliSENS easyMAG | Applied Biosystems 7500 Real Time PCR System | Quidel Corp. | Orf1ab | see IFU | 2 to 8°C | Nasopharyngeal or oropharyngeal specimens | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order TGA |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|--|------------------|--|--|-----------------------|--------------------|---------------------------------|---------------------------------|---------------------------------------|--|---|
| KCCOV19-24 | Rheonix COVID-19 MDx Assay | 96T/kit | Rheonix Encompass MDx® Workstation | | Rheonix | ORF1 a/b | see IFU | see IFU | nasopharyngeal and oropharyngeal swab | For consumables and details of components refer to IFU | US FDA EUA |
| 9175431190 | Cobas SARS-CoV-2 RT-PCR Kit | 96T/kit | cobas 6800/8800 | | Roche Diagnostics | ORF1 a/b | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order TGA WHO EUL |
| S3104E | Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) | 24T/kit | QIAamp Virus RNA Mini Kit (cat. # 52904) | Applied Biosystems 7500 Real-Time PCR System | Sansure Bio Tech Inc. | ORF1ab and N genes | see IFU | -25 to -15°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA TGA |
| | | 48T/kit | without Extraction | | | | | | | | |
| RX7038 | ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit | 96T/kit | Viral RNA Isolation Kit (ScienCell) | LightCycler® 96 Real-Time PCR System (Roche) | ScienCell | RdRp gene, N Gene | see IFU | lower than -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | QIAamp Virus RNA Mini Kit (Qiagen) | | | | | | | | |
| M-NCOV-01 | STANDARD M nCoV Real-Time Detection kit | 96T/kit | QIAamp Virus RNA Mini Kit (Qiagen) | CFX96 Real-Time PCR Instrument (Biorad) Applied Biosystems 7500 & 7500 Fast Real-Time PCR System Roche LightCycler 480 Real-Time PCR systems | SD Biosensor | ORF1ab, E genes | see IFU | -25 to -15°C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|-------------------------------|------------------|---|--|---------------------|----------------|---------------------------------|---------------------------------|---------------|--|--|
| SS-9930 | U-TOP™ COVID-19 Detection Kit | 96T/kit | QIAamp Virus RNA Mini Kit (Qiagen) | CFX96 Real-Time PCR Instrument (Biorad) | Seasun Biomaterials | ORF1ab, N Gene | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | Applied Biosystems 7500 & 7500 Fast Real-Time PCR System | | | | | | | |
| | | | PANAMAX Viral DNA/RNA Extraction Kit performed on the PANAMAX 48 Nucleic Acid Extraction System | | | | | | | | |
| | | | TOP Viral DNA/RNA Extraction Kit | | | | | | | | |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|------------------------------|------------------|--|---|--------------|------------------------------|---------------------------------|---------------------------------|---------------|--|--|
| RP10243X / RP10252W | Allplex™ 2019-nCoV Assay kit | 96T/kit | Microlab STARlet IVD (Cat. No. 173000-075, Hamilton Co.) | CFX96 Real-Time PCR Instrument (Biorad) | Seegene Inc | RdRp gene, N Gene and E Gene | see IFU | lower than -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | STARMag 96 X 4 Universal Cartridge Kit (Cat. No. 744300.4.UC384, Seegene Inc.) using Microlab NIMBUS IVD instrument (Microlab) | CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | |
| | | | QIAamp DSP Viral Mini Kit using QIAcube instrument (QIAgen) | Applied Biosystems 7500 & 7500 Fast Dx Real-Time PCR System | | | | | | | |
| | | | Ribospin vRD Viral RNA/DNA Extraction Kit (GeneAll) (manual) | | | | | | | | |
| | | | MagMAX Viral/Pathogen Nucleic Acid Isolation Kit using KingFisher Flex instrument | | | | | | | | |
| | | | MagNA Pure DNA and Viral NA Small Volume Kit using Roche MagNA Pure 96 | | | | | | | | |
| | | | AdvanSure NA EX Kit (extraction kit) using AdvanSure E3 Instrument System (LG Chem) | | | | | | | | |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|--|------------------|--|---|--|--------------------------------|---------------------------------|---------------------------------|---------------|--|--|
| PCSYHF02-a | Fosun COVID-19 RT-PCR Detection Kit | 48T/kit | QIAamp DSP Viral RNA Mini Kit (Qiagen) | 7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems™) | Shanghai Fosun Long March Medical Science Co Ltd (China) | ORF1ab, N and E genes | 12 months | -25 to -15 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA TGA |
| PCSYHF03-a | | 96T/kit | | | | | | | | | |
| GZ-D2RM25 | Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real-time PCR) | 50T/kit | GenAct NE-48 (Shanghai GeneoDx) | 7500 Real-Time PCR Instrument (Applied Biosystems™) | Shanghai GeneoDx Biotechnology Co., Ltd (China) | ORF1ab and N genes | see IFU | -25 to -15 °C | see IFU | For consumables and details of components refer to IFU | WHO EUL |
| | | | QIAamp DSP Viral RNA Mini Kit (Qiagen) | | | | | | | | |
| KH-G-M-574-48 | Diagnostic kit for SARS-CoV-2 Nucleic acid (Real-time PCR) | 48T/kit | nucleic acid extraction product and equipment of Shanghai Kehua bio-engineering Co., Ltd | Applied Biosystems 7500 Real-Time PCR System | Shanghai Kehua bio-engineering Co., Ltd | ORF1ab and N genes and E genes | 12 months | lower than -15 °C | see IFU | For consumables and details of components refer to IFU | WHO EUL |
| | | | | CFX96 Real-Time PCR Instrument (Biorad) | | | | | | | |
| | | | | Tianlong Gentier 96E | | | | | | | |
| RR-0485-02 | Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 genes) | 25T/kit | QIAamp Virus RNA Mini Kit (Qiagen) | Applied Biosystems 7500 & 7500 Fast Real-Time PCR System | Shanghai ZJ Bio-Tech Co Ltd (China) | ORF1ab and N genes and E genes | see IFU | -25 to -15°C | see IFU | For consumables and details of components refer to IFU | TGA WHO EUL |
| | Sherlock CRISPR SARS-CoV-2 Kit | 96T/kit | PureLink™ Viral RNA/DNA Mini Kit (Thermo Fisher Scientific) | Not required (RT-LAMP and CRISPR Technology used) | Sherlock BioSciences, Inc. | ORF1ab and N genes | 12 months | lower than -20 °C | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit | | | | SolGent Co., Ltd (represented by JK Toxpert) | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | Health Canada/Interim Order |
| | PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay | | | | Suzhou Sym-Bio Lifescience Co Ltd (China) (represented by PerkinElmer) | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | TGA |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|---|------------------|--|--|------------------------------|--------------------------|---------------------------------|---------------------------------|--|--|--|
| | 2019-nCoV Fluorescence Detection Real-time RT-PCR Kit | | | | Sysmex Corporation | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | PMDA |
| 80-10284 | T2SARS-CoV-2 Panel | 12T/kit | T2Dx® Instrument | | T2 Biosystems, Inc. | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | ExProbe™ SARS-CoV-2 Testing Kit | | QIAamp Virus RNA Mini Kit (Qiagen) | Applied Biosystems 7500 Real-Time PCR System | TBG Biotechnology Corp | RdRp gene, N and E genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| A47814 | TaqPath COVID-19 Combo Kit | 1000T/kit | MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit automated on KingFisher™ Flex Purification System (KingFisher) | Applied Biosystems 7500 & 7500 Fast Real-Time PCR System | Thermo Fisher Scientific Inc | ORF1ab, S and N genes | see IFU | see IFU | nasopharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage (BAL) | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order TGA |
| | | | MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit manual (KingFisher) | Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument | | | | | | | |
| | | | | Applied Biosystems™ QuantStudio 7 Real-Time PCR Instrument | | | | | | | |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|--|--|------------------|---|--|---|-----------------------|---------------------------------|---------------------------------|---------------|--|--|
| A48067 | TaqPath COVID-19 CE-IVD RT-PCR Kit | 1000T/kit | MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (manual) | Applied Biosystems 7500 & 7500 Fast & Fast Dx Real-Time PCR System | Thermo Fisher Scientific Inc | ORF1ab, S and N genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | WHO EUL |
| | | | MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (manual) | Applied Biosystems™ QuantStudio 5 & 5 Dx Real-Time PCR Instrument | | | | | | | |
| | | | | Applied Biosystems™ QuantStudio 7 Real-Time PCR Instrument | | | | | | | |
| TD1100 | COVID-19 RT-PCR PNA Kit | 100T/kit | RNeasy Mini kit (Qiagen) | Applied Biosystems 7500 & 7500 Fast Real-Time PCR System | TNS Co., Ltd (Bio TNS) | RdRp and N genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| CFX96 Touch Real-Time PCR Detection System (Bio-Rad) | | | | | | | | | | | |
| | TRCReady SARS-CoV-2 | | | | Tosoh Corporation | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | PMDA |
| | Gene Cube SARS-CoV-2 | | | | Toyobo Co., Ltd. | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | PMDA |
| | EasyNat Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay) | | | | Ustar Biotechnologies (Hangzhou) Co Ltd (China) | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | TGA |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|---|---------------------|--|---|--|--------------------|---------------------------------|---------------------------------|---------------|--|--|
| 300681 | ViroKey™ SARS-CoV-2 RT-PCR Test | 4x50T/kit | see IFU | Sentosa® SA201 Real-Time PCR Instrument | Vela Operations Singapore Pte Ltd | Orf1a and RdRp | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | | Applied Biosystems® 7500 Fast Dx Real-Time PCR System | | | | | | | |
| | COVID-19 (SARS-CoV-2) Nucleic Acid Test kit | | | | Wuhan EasyDiagnosis Biomedicine Co Ltd (China) | | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | TGA |
| 801301 | SARS-CoV-2 Test Kit (Real-time PCR) | 48T/kit | Virus RNA Extraction Kit (Xiamen Zeesan) | Applied Biosystems™ QuantStudio 3 real-time PCR | Xiamen Zeesan Biotech Co., Ltd. (China) | ORF1ab and N genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| SC-COVID19-20 SC-COVID19-100 | COVID-19 Nucleic Acid RT-PCR Test Kit | 20T/kit 100T/kit | QIAamp Virus RNA Mini Kit (Qiagen) | Applied Biosystems® 7500 Fast Real-Time PCR System | ZhuHai Sinochips Bioscience Co., Ltd | ORF1ab and N genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA |
| | | | MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit automated on KingFisher™ Flex Purification System (KingFisher) | Applied Biosystems® 7500 Fast Dx Real-Time PCR System | | | | | | | |

SARS-CoV-2 Nuclear Acid Amplification Technologies

| Manufacturer Product Catalogue number | Product Name (IVD product) | Reference detail | Platform (Extraction equipment) | Platform (amplification equipment) | Manufacturer | Detection type | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility criteria WHO EUL or others |
|---------------------------------------|------------------------------|------------------|---|---|--------------------|----------------|---------------------------------|---------------------------------|---------------|---|--|
| R3011 R3011-1K R3011-10K | Quick SARS-CoV-2 rRT-PCR Kit | | MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit automated on KingFisher™ Flex Purification System (KingFisher) | Bio-Rad CFX96 Touch Real-Time PCR Detection System | Zymo Research Corp | N genes | see IFU | see IFU | see IFU | For consumables and details of components refer to IFU | US FDA EUA Health Canada/Interim Order TGA |
| | | | MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit manual (KingFisher) | Applied Biosystems™ QuantStudio 5 Real- Time PCR Instrument | | | | | | | |

N/A- NOT APPLICABLE

Disclaimer: The Global Fund does not endorse or warrant the fitness of any product on the List for a particular purpose. In addition, the Global Fund assumes no responsibility for any misstatement or omission from the list and directs Principal Recipients of Global Fund grants to conduct their own independent confirmation that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's quality assurance policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use in any particular country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of any product included in the list.

List of SARS-CoV-2 Diagnostic test kits and equipments eligible for procurement according to Board Decision on Additional Support for Country Responses to COVID-19 (GF/B42/EDP11)

Important Precautionary statements:

With the limited data now available, WHO does not currently recommend the use of antigen-detecting rapid diagnostic tests for patient care, although research into their performance and potential diagnostic utility is highly encouraged.

Based on current data, WHO does not recommend the use of antibody-detecting rapid diagnostic tests for patient care but encourages the continuation of work to establish their usefulness in disease surveillance and epidemiologic research. (<https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19>)

SARS-CoV-2 Rapid Diagnostic Tests

| Manufacturer Product Catalogue number | Product Name (IVD product) | Number of tests per kit | Platform (Calibrator and Equipment) | | Manufacturer | Analyte | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility WHO EUL or others |
|---------------------------------------|---|-------------------------|-------------------------------------|-----|--|---------|---------------------------------|---------------------------------|---------------|----------|-------------------------------|
| | Assure COVID-19 IgG/IgM Rapid Test Device | see IFU | n/a | n/a | Assure Tech. (Hangzhou Co., Ltd) | IgG/IgM | see IFU | see IFU | see IFU | | US FDA EUA |
| | NOVA Test® COVID-19 IgG/IgM Antibody Test (Colloidal Gold) | see IFU | n/a | n/a | Atlaslink Beijing Technology Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | AtomoRapid™ COVID-19 IgM/IgG Antibody Test | see IFU | n/a | n/a | Atomo Diagnostics Limited | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| WJ-2701, WJ-2710, WJ-2750 | Wantai SARS-CoV-2 Ab Rapid Test kit | see IFU 10 50 | n/a | n/a | Beijing Wantai Biological Pharmacy Enterprise Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | US FDA EUA TGA |
| B251C | Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test | | n/a | n/a | Biocan Diagnostics Inc. | IgG/IgM | see IFU | see IFU | see IFU | | US FDA EUA |

SARS-CoV-2 Rapid Diagnostic Tests

| Manufacturer Product Catalogue number | Product Name (IVD product) | Number of tests per kit | Platform (Calibrator and Equipment) | | Manufacturer | Analyte | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility WHO EUL or others |
|---------------------------------------|--|-------------------------|-------------------------------------|-----|--|---------|---------------------------------|---------------------------------|--|----------|-------------------------------|
| RTA0203 | SARS-CoV-2 IgM/IgG Antibody Test Kit | 25 | n/a | n/a | Biohit Healthcare (Hefei) Co., Ltd. | IgG/IgM | see IFU | 2 to 30°C | see IFU | | US FDA EUA |
| 5515C025 | qSARS-CoV-2 IgG/IgM Rapid Test | 25 | n/a | n/a | Cellex Inc (United States of America) | IgG/IgM | 12 | 2 to 30°C | serum, plasma (EDTA or citrate), or venipuncture whole blood | | US FDA EUA TGA |
| 5515C050 | | 50 | | | | | | | | | |
| 5515C100 | | 100 | | | | | | | | | |
| | OnSite COVID-19 IgG/IgM Rapid Test | see IFU | n/a | n/a | CTK Biotech Inc (USA) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | GenBody COVID-19 IgM/IgG | see IFU | n/a | n/a | GenBody Inc (Korea - Republic of) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | SARS-CoV-2 Antibody Test (Lateral Flow Method) | see IFU | n/a | n/a | Guangzhou Wondfo Biotech Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| W195 | SARS-CoV-2 Antibody Test (Lateral Flow Method) | see IFU | n/a | n/a | Guanngzhou Wondfo Biotech Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| INCP-402 | 2019-n-CoV IgG/IgM Rapid Test Cassette | see IFU | n/a | n/a | Hangzhou Alltest Biotech Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |

SARS-CoV-2 Rapid Diagnostic Tests

| Manufacturer Product Catalogue number | Product Name (IVD product) | Number of tests per kit | Platform (Calibrator and Equipment) | | Manufacturer | Analyte | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility WHO EUL or others |
|---------------------------------------|---|-------------------------|-------------------------------------|-----|---|---------|---------------------------------|---------------------------------|---------------|------------|-------------------------------|
| | COVID-19 IgG/IgM Rapid Test Cassette | see IFU | n/a | n/a | Hangzhou Biotest Biotech Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | RightSign™ COVID-19 IgG/IgM Rapid Test Cassette | see IFU | n/a | n/a | Hangzhou Biotest Biotech Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | US FDA EUA |
| | RightSign™ COVID-19 IgG/IgM Rapid Test Cassette rebranded to CoronaCHEK COVID-19 IgG/IgM Rapid Test Cassette | see IFU | n/a | n/a | Hangzhou Biotest Biotech Co Ltd (China) distributed by CLIAwaived Inc. | IgG/IgM | see IFU | see IFU | see IFU | | US FDA EUA |
| | RightSign™ COVID-19 IgG/IgM Rapid Test Cassette rebranded to Premier Biotech COVID-19 IgG/IgM Rapid Test Cassette | see IFU | n/a | n/a | Hangzhou Biotest Biotech Co Ltd (China) distributed by Premier Biotech Inc. | IgG/IgM | see IFU | see IFU | see IFU | | US FDA EUA |
| | Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) | see IFU | n/a | n/a | Hangzhou Laihe Biotech Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| 303002 | LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) | see IFU | n/a | n/a | Hangzhou Laihe Biotech Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | IFU update | US FDA EUA |
| | 2019-nCoV/COVID-19 IgG/IgM Rapid Test Device | see IFU | n/a | n/a | Hangzhou Realy Tech Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |

SARS-CoV-2 Rapid Diagnostic Tests

| Manufacturer Product Catalogue number | Product Name (IVD product) | Number of tests per kit | Platform (Calibrator and Equipment) | | Manufacturer | Analyte | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility WHO EUL or others |
|---------------------------------------|---|-------------------------|-------------------------------------|-----|---|---------|---------------------------------|---------------------------------|---------------|---|-------------------------------|
| GCCOV-402a | COVID-19 IgG/IgM Rapid Test Cassette | 25 | n/a | n/a | Healgen Scientific Limited Liability Company (United States Of America) | IgG/IgM | see IFU | see IFU | see IFU | Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate or high complexity tests | US FDA EUA TGA |
| | InnoScreen™ COVID-19 IgG/IgM Rapid Test | see IFU | n/a | n/a | Innovation Scientific Pty Ltd (Australia) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | 2019-nCov Ab Test (Colloidal Gold) | see IFU | n/a | n/a | Innovita (Tangshan) Biological Technology Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | Rapid COVID-19 IgM/IgG Combo Test Kit | see IFU | n/a | n/a | Megna Health, Inc. | IgG/IgM | see IFU | see IFU | see IFU | | US FDA EUA |
| | COVID-19 IgG/IgM Rapid Test Kit | see IFU | n/a | n/a | Nantong Egens Biotechnology Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | COVID-19 IgG/IgM Rapid Test Cassette | see IFU | n/a | n/a | Newsen Coast Bio-Pharmaceutical Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |

SARS-CoV-2 Rapid Diagnostic Tests

| Manufacturer Product Catalogue number | Product Name (IVD product) | Number of tests per kit | Platform (Calibrator and Equipment) | | Manufacturer | Analyte | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility WHO EUL or others |
|---------------------------------------|---|-------------------------|-------------------------------------|-----|--|---------|---------------------------------|---------------------------------|---------------|----------|-------------------------------|
| | | | | | | | | | | | |
| | NTBIO One Step Rapid Test - COVID-19 IgG/IgM Antibody Test | see IFU | n/a | n/a | NTBIO Diagnostics Inc (Canada) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | PCL COVID19 IgG/IgM Rapid Gold | see IFU | n/a | n/a | PCL Inc (Korea - Republic of) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | SARS-CoV-2 IgM/IgG Antibody Rapid Test | see IFU | n/a | n/a | Qingdao Hightop Biotech Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette | see IFU | n/a | n/a | Salofa Oy | IgG/IgM | see IFU | see IFU | see IFU | | US FDA EUA |
| 20010 | TBG SARS-CoV-2 IgG / IgM Rapid Test Kit | see IFU | n/a | n/a | TBG Biotechnology Corp. | IgG/IgM | see IFU | see IFU | see IFU | | US FDA EUA |
| | VivaDiag™ COVID-19 IgM/IgG Rapid Test | see IFU | n/a | n/a | VivaCheck Biotech (Hangzhou) Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | SARS-CoV-2 IgM/IgG Antibody Test Kit | see IFU | n/a | n/a | Wuhan EasyDiagnosis Biomedicine Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test | see IFU | n/a | n/a | Xiamen Biotime Biotechnology Co., Ltd. (China) | IgG/IgM | see IFU | see IFU | see IFU | | US FDA EUA |

SARS-CoV-2 Rapid Diagnostic Tests

| Manufacturer Product Catalogue number | Product Name (IVD product) | Number of tests per kit | Platform (Calibrator and Equipment) | | Manufacturer | Analyte | Anticipated Shelf life (months) | Recommended storage temperature | Specimen type | Comments | Eligibility WHO EUL or others |
|---------------------------------------|--|-------------------------|-------------------------------------|-----|---|---------|---------------------------------|---------------------------------|---------------|----------|-------------------------------|
| ☐ GCCOV-402a | COVID-19 IgG/IgM Rapid Test Cassette | see IFU | n/a | n/a | Zhejiang Orient Gene Biotech Co Ltd (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |
| | Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow) | see IFU | n/a | n/a | Zhuhai Livzon Diagnostics Inc (China) | IgG/IgM | see IFU | see IFU | see IFU | | TGA |

N/A- NOT APPLICABLE

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**List of SARS-CoV-2 products deleted/delisted
Products not eligible for procurement**

| Manufacturer Product Catalogue number | Product Name | Number of tests per kit | Manufacturer | Deleted period | Reason for deletion/delisting |
|--|--|--------------------------------|--------------------------------------|-----------------------|--------------------------------------|
| 65-9569-0 | DPP® COVID-19 IgM/IgG System on DPP Micro Reader or DPP Micro Reader 2 | 20 | Chembio (USA) | Jul-20 | US FDA EUA revoked |
| RTA0203 | Anti-SARS-CoV-2 Rapid Test | 20 | Autobio Diagnostics Co., Ltd (China) | Aug-20 | US FDA EUA revoked |