

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>

The following website provides WHO Interim Guidance "Diagnostic testing for SARS-CoV-2":
<https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2>

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 componants 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 TGA
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 Health Canada/Interim Order TGA
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
13279F	MassARRAY® SARS-CoV-2 Panel	960T/kit	NucliSENS® easyMAG® (bioMérieux)	MassARRAY System	Agena Bioscience, Inc.	N gene, ORF-1 and ORF-1ab gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
			KingFisher Flex Purification System (ThermoFisher)								
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)							

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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)								
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								
	Identity Pack SARS-CoV-2				Arkray Factory Co., Ltd.		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
	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)							

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iAMP-COVID19-100	iAMP® COVID-19 Detection Kit	100T/kit	not required	CFX96 Real-Time System (Bio-Rad) 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	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
	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

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MFG030010	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV	50T/kit	TIANamp Virus RNA extraction Kit (DP315-R) TIANGEN	Applied Biosystems 7500/7500 Fast Real-Time PCR 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
			QIAamp Virus RNA Mini Kit (cat. #52904).	Applied Biosystems QuantStudio 5 Real-Time PCR Systems							
			RNA extraction kit by MGI Tech (Wuhan) (No.20200167)	SLAN-96P PCR system							
				LightCycler® 480 System							
	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
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)								

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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
			Beijing Wantai Nucleic Acid Extraction Kit on KingFisher Flex 96 (ThermoFisher)	CFX96 Touch Real-Time PCR Detection System (Bio-Rad)							
			Beijing Wantai Nucleic Acid Extraction Kit on NEXOR 32 (Yantai Addcare Bio-Tec)								
			Beijing Wantai Nucleic Acid Extraction Kit on NEXOR 96 (Yantai Addcare Bio-Tec)								
			QIAamp Viral RNA Mini Kit QIAGEN (cat. # 52094)								
	qSanger-COVID-19 Assay	3072T/kit	Applied Biosystems Veriti Thermal Cyclers and Applied Biosystems 3730xl DNA Analyzer and Thermo Fisher (Invitrogen) DynaMag-96 Side Magnet	BillionToOne, Inc	Sars-Cov-2 Genome	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA	

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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	
423883	Biofire Respiratory Panel 2.1-EZ (RP2.1-EZ)		FilmArray® 2.0 EZ Systems	BioFire Diagnostics LLC	S Gene, M Gene, Influenza A and others	see IFU	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA

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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)									
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									

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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)							
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								
XPCOV2/FLU/RSV-10	Xpert Xpress SARS-CoV-2/Flu/RSV	10T/kit	GeneXpert Xpress System (Tablet and Hub Configurations)		Cepheid	Genes N2 and E and Influenza A/Influenza B/RSV RNA	see IFU (302-4419)	2 to 28°C	see IFU (302-4419)	For consumables and details of components refer to IFU	US FDA EUA
XPCOV2/FLU/RSV-10	Xpert Xpress SARS-CoV-2/Flu/RSV	10T/kit	GeneXpert Dx		Cepheid	Genes N2 and E and Influenza A/Influenza B/RSV RNA	see IFU (302-4421)	2 to 28°C	see IFU (302-4421)	For consumables and details of components refer to IFU	US FDA EUA
			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)							
	Clear Dx™ SARS-CoV-2 Test	192T/kit	Clear Dx™ system comprising Hamilton STAR robotic platform and Oxford Nanopore GridION Sequencer and ALPAQUA Magnum FLX on deck magnet		Clear Labs, Inc	Sars-Cov-2 Genome	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
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
	DirectDetect™ SARS-CoV-2 Detection Kit				Coyote Bioscience Co Ltd (China)		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	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

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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							
				Bio Molecular Systems Mic qPCR (IDEXX Laboratories)							
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 TGA
			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	see IFU	see IFU	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									

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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	Orfiab genes	12 months	see IFU	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
LMP401	Loopamp New Coronavirus 2019 (SARS-CoV-2) Detection Reagent Kit	48T/kit	see IFU		Eiken Chemical Co., Ltd.	Replicase 1B region	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
	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
			QIASymphony® SP (QIAGEN)	QuantStudio® 5 Real-Time PCR System (Applied Biosystems)							
			Manual								

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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
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

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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
EA001222	ePlex Respiratory Pathogen Panel 2 (ePlex RP2 Panel)	12T/kit	GenMark ePlex instrument and Software		GenMark Diagnostics, Inc	Sars-Cov-2 and other pathogenic RNA	see IFU	2 to 8°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
	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									

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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
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™)							
	BKit Virus Finder Covid-19				Hyrus Ltd.		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	Health Canada/Interim Order
	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											

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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
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
JC10223-1NW-50T JC10223-1NW-25T	COVID-19 Coronavirus Real Time PCR Kit	50T/kit 25T/kit	Viral nucleic acid isolation kit (Bioperfectus Technologies)	Applied Biosystems QuantStudio5 instrument	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
			QIAamp® Viral RNA Mini Kit (Qiagen)	7500 Real-Time PCR instrument (Applied Biosystems)							
	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
KF2019CoV01	KimForest SARS-CoV-2 Detection Kit v1	96T/kit	QIAamp Virus RNA Mini Kit (Qiagen)	StepOne/StepOnePlus Real-Time PCR Systems (Applied Biosystems)	KimForest Enterprise Co., Ltd.	RdRp genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA

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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
R6900TD	PowerChek™ 2019-nCoV Real-time PCR Kit		QIAamp® DSP Viral RNA Mini Kit (QIAGEN)	CFX96 Real-Time PCR Detection System (Bio-Rad)	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
				7500 Real-Time PCR instrument (Applied Biosystems)							
				7500 Fast Real-Time PCR instrument (Applied Biosystems)							
	Curative SARS-Cov-2 Assay		Total RNA Purification 96-Well Kit (Norgen Biotek Corporation) manually or using Tecan Resolvex A200	BioRad CFX 96 Touch	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
				BioRad CFX Connect Real-Time PCR systems							
				Roche LightCycler 480 II Real-Time PCR systems							
	LabGun™ COVID-19 RT-PCR Kit	96T/kit	QIAamp® DSP Viral RNA Mini Kit (Qiagen)	7500 Fast Dx Real-Time PCR instrument (Applied Biosystems)	LabGenomics	RdRp and N genes	see IFU	see IFU	nasopharyngeal swab, anterior nasal swab and midturbinate nasal swab	For consumables and details of components refer to IFU	US FDA EUA TGA
				CFX96 Touch Real-Time PCR Detection System (Bio-Rad)							
	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	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA Health Canada/Interim Order

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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
I054C0463	NxTAG® CoV Extended Panel Assay	96T/kit	bioMérieux® NucliSENS® easyMAG® System	Luminex® MAGPIX® instrument including xPONENT	Luminex Molecular Diagnostics, Inc.	ORF1ab, N Gene and E Gene	see IFU	see IFU	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)	Roche LightCycler 480 II	LumiraDx UK Ltd	ORF1a Gene	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 (Applied Biosystem)	Applied Biosystems 7500 Fast Dx							
			QIAamp Viral RNA Mini Kit (Qiagen)	Applied Biosystems QuantStudio 5							
				Agilent AriaMx RT-PCR Instruments							
				Agilent Stratagene Mx3005P RT-PCR Instruments							

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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
L018180130096	LumiraDx SARS-CoV-2 RNA STAR Complete		n/a	Roche LightCycler 480 II	LumiraDx UK Ltd	ORF1a Gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
				Applied Biosystems 7500 Fast Dx							
				Applied Biosystems QuantStudio 5							
				Agilent AriaMx RT-PCR Instruments							
				Agilent Stratagene Mx3005P RT-PCR Instruments							
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

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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
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
	Veri-Q PCR 316 COVID-19 Detection Kit				MiCoBioMed Co Ltd		see IFU	see IFU	see IFU		TGA
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 TGA
XC25073	Sars-Cov-2 Virus Detection Diagnostic Kit	50T/kit	TAN Bead® extract system (Taiwan Advanced Nanotech)	Applied Biosystems 7500 & 7500 Fast Real-Time PCR System	Ningbo Health Gene Technologies Co., Ltd (China)	ORF1ab, N and S genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	Health Canada/Interim Order TGA WHO EUL
			RNeasy Mini Kit (Qiagen)								
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)							

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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
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)							
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).	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
			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)								

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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
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
02.01.1019	<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>
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 Bio-Rad CFX Connect™ Real-Time PCR Detection System Roche® LightCycler 480 II	Primerdesign Ltd	Orf1 ab gene	12 months	lower than -20 °C	see IFU	For consumables and details of components refer to IFU	WHO EUL TGA
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 Bio-Rad CFX Connect™ Real-Time PCR Detection System Roche® LightCycler 480 II	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

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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
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 componants refer to IFU	US FDA EUA
			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)								

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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	

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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
#1110 with #1105	Clarifi COVID-19 Test Kit	480T/kit	Quick-RNA Viral 96 Kit	CFX96 Touch Real-Time Detection System (Biorad)	Quadrant Biosciences Inc.	RdRp genes	see IFU	see IFU	saliva swab specimen	For consumables and details of components refer to IFU	US FDA EUA
				CFX384 Touch Real-Time Detection System (Biorad)							
				QuantStudio 5 instrument (Applied Biosystems)							
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

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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
	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
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 PMDA TGA WHO EUL
9211101190	cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test	96T/kit	cobas Liat System		Roche Molecular Systems, Inc.	ORF1 a/b and nucleocapsid protein gene with matrix gene of Influenza A, and non-structural protein gene of Influenza B	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
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								

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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
RX7038 (RX7048)	ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (Multiplex option)	96T/kit	Viral RNA Isolation Kit (ScienCell)	LightCycler® 96 Real-Time PCR System (Roche)	ScienCell	RdRp gene, N Gene	see IFU	see IFU	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)	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
				Applied Biosystems 7500 & 7500 Fast Real-Time PCR System							
				Roche LightCycler 480 Real-Time PCR systems							
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 and 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								

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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-9940	AQ-TOP COVID-19 Rapid Detection Kit PLUS	96T/kit	QIAamp DSP Virus Kit (Qiagen)	CFX96 Real-Time PCR Instrument (Biorad)	Seasun Biomaterials	ORF1ab and N Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
				Applied Biosystems 7500 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								

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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	100T/kit 124T/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									
PCSYHF	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit (commercial name: Fosun 2019-nCoV qPCR)				Shanghai Fosun Long March Medical Science Co Ltd (China)	ORF1ab, N and E genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	WHO EUL
GZ-D2RM25	Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real-time PCR)	50T/kit	GenAct NE-48 (Shanghai GeneoDx) QIAamp DSP Viral RNA Mini Kit (Qiagen)	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
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 CFX96 Real-Time PCR Instrument (Biorad) Tianlong Gentier 96E	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
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
	Ampdirect 2019-nCoV detection kit				Shimadzu Corporation		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA

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
	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
	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
PGA4102P1 (liquid) / PGA4102P2 (lyophilized form)	SARS-CoV-2 Nucleic acid detection kit based on Real-Time PCR platform				Tellgen Corporation		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	WHO EUL
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 Flex 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
	TaqPath New Coronavirus (SARS-CoV-2) Real-Time PCR Detection Kit				Thermo Fisher Scientific Inc (see also Life Technologies Corporation)		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
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 Flex 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 CFX96 Touch Real-Time PCR Detection System (Bio-Rad)	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
	TRCReady SARS-CoV-2		TRCReadyR-80 and Chipset for TRCRR detection reagent		Tosoh Corporation		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
	Gene Cube SARS-CoV-2	48T/kit	QIAmp Viral RNA Mini Kit (Qiagen)		Toyobo Co., Ltd.	N genes	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 TGA
				Applied Biosystems® 7500 Fast Dx Real-Time PCR System							
301068	ViroKey™ SARS-CoV-2 RT-PCR Test v2.0	8x48T/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							
	SARS-CoV-2 RT-qPCR Reagent Kit				Wallac Oy (Finland)		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	TGA
	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

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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)

A new technology for COVID-19 detection has become available that is much simpler and faster to perform than currently-recommended nucleic acid amplification tests (NAAT), like PCR. This method relies on direct detection of SARS-CoV-2 viral proteins in nasal swabs and other respiratory secretions using a lateral flow immunoassay (also called an RDT) that gives results in < 30 minutes. Though these antigen detection RDTs (Ag-RDTs) are substantially less sensitive than NAAT, they offer the possibility of rapid, inexpensive and early detection of the most infectious COVID-19 cases in appropriate settings. For more detailed technical advice please consult the WHO Interim guidance available at: <https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays>

SARS-CoV-2 Antigen 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
195-000	BinaxNOW COVID-19 Ag Card	40T/kit	n/a	Abbott Diagnostics Scarborough, Inc.	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	US FDA EUA
41FK10	Panbio COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	25T/kit	n/a	Abbott Rapid Diagnostics Jena GmbH	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	Health Canada/Interim Order TGA WHO EUL
	Sampinute COVID-19 Antigen MIA		SAMPINUTE™ Analyzer	BBB Inc. (distributed by Celltrion USA, Inc.)	SARS-CoV-2 receptor binding domains (RBDs) spike proteins	see IFU	see IFU	see IFU	magnetic force-assisted electrochemical sandwich immunoassay	US FDA EUA
256082	BD Veritor System for Rapid Detection of SARS-CoV-2	30T/kit	BD Veritor™ Plus Analyzer	Becton, Dickinson and Company	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	chromatographic digital immunoassay	US FDA EUA Health Canada/Interim Order TGA
	NowCheck COVID-19 Antigen Test			BioNote Inc		see IFU	see IFU	see IFU		TGA
	COVID-19 Antigen Rapid Test Cassette		n/a	BTNX Inc	SARS-CoV-2 antigen	see IFU	see IFU	see IFU	Visual Read	TGA

SARS-CoV-2 Antigen 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
	QuickNavi-COVID19 Ag			Denka Co., Ltd.		see IFU	see IFU	see IFU		PMDA
	Lumipulse SARS-CoV-2 Ag			Fujirebio Inc		see IFU	see IFU	see IFU		PMDA
	Lumipulse Presto SARS-CoV-2 Ag			Fujirebio Inc		see IFU	see IFU	see IFU		PMDA
	ESPLINE SARS-CoV-2			Fujirebio Inc		see IFU	see IFU	see IFU		PMDA
	InnoScreen COVID-19 Antigen Rapid Test Device			Innovation Scientific Pty Ltd (Australia)		see IFU	see IFU	see IFU		TGA
	LumiraDx SARS-CoV-2 Ag Test	25T/kit	LumiraDx Platform	LumiraDx UK Ltd.	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Reader required	US FDA EUA
20374	Sofia SARS Antigen FIA	25T/kit	Sofia and Sofia 2 instrument	Quidel Corporation	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Reader required	US FDA EUA TGA
	Sofia 2 Flu + SARS Antigen FIA	25T/kit	Sofia and Sofia 2 instrument	Quidel Corporation	SARS-CoV-2 nucleocapsid protein antigen and Influenza A	see IFU	see IFU	see IFU	Reader required	US FDA EUA

SARS-CoV-2 Antigen 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
09COV30D	STANDARD Q COVID-19 Ag Test		n/a	SD Biosensor Inc.	SARS-CoV-2 antigen	see IFU	see IFU	see IFU	Visual Read	TGA WHO EUL
	Immuno Ace SARS-CoV-2 / Capilia SARS-CoV-2			Towns Co., Ltd.		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA

N/A- NOT APPLICABLE

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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:

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 Antibody 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
	Assure COVID-19 IgG/IgM Rapid Test Device rebranded as Ecotest 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
	Assure COVID-19 IgG/IgM Rapid Test Device rebranded as Fastep 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
	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 Antibody 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 TGA
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									
R0180C	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
W195	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
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
	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

SARS-CoV-2 Antibody 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
	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
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		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
	Orawell IgM/IgG Rapid Test	see IFU	n/a	n/a	Jiangsu Well Biotech Co., Ltd.	IgG/IgM	see IFU	see IFU	see IFU		US FDA EUA

SARS-CoV-2 Antibody 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
	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	Newscen Coast Bio-Pharmaceutical Co Ltd (China)	IgG/IgM	see IFU	see IFU	see IFU		TGA
NBPC-0001-xx	Nirmidas COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	see IFU	n/a	n/a	Nirmidas Biotech, Inc	IgG/IgM	see IFU	see IFU	see IFU		US FDA EUA
	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

SARS-CoV-2 Antibody 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
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
	SGTi-flex COVID-19 IgG	see IFU	n/a	n/a	Sugentech, Inc.	IgG/IgM	see IFU	see IFU	see IFU		US FDA EUA
VID35-08-011 VID35-08-012 VID35-08-013 VID35-08-014	VivaDiag™ COVID-19 IgM/IgG Rapid Test	40T/kit	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	25T/kit	n/a	n/a	Xiamen Biotime Biotechnology Co., Ltd. (China)	IgG/IgM	see IFU	see IFU	see IFU		US FDA EUA
☐ 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
	COVID-19 IgG/IgM Rapid Test Kit	see IFU	n/a	n/a	Zhongshan Chuangyi Biochemical Engineering 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

SARS-CoV-2 Antibody 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
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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
	NOVA Test® COVID-19 IgG/IgM Antibody Test (Colloidal Gold)		Atlaslink Beijing Technology Co Ltd (China)	Oct-20	TGA delisted
RTA0203	Anti-SARS-CoV-2 Rapid Test	20	Autobio Diagnostics Co., Ltd (China)	Aug-20	US FDA EUA revoked
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
	GenBody COVID-19 IgM/IgG		GenBody Inc (Korea - Republic of)	Oct-20	TGA delisted