THE GLOBAL FUND

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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)

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 COVID-19 diagnostic tests listed on the French government website and under the control of the French Health Authority ANSM

The following websites provide access to Instructions For Use of certain products:
- https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open
- 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

Important Note: The following lists are not exhaustive.

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	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	see IFU	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)							

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

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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) Rotor-Gene Q 5plex HRM (Qiagen)	3B Blackbio Biotech India Ltd (a Kilpest India Ltd company)	RdRp, N and E genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
3103010011	3DMed 2019-nCoV RT-qPCR Detection Kit	100T/kit	ANDiS Viral RNA Auto Extraction & Purification Kit Automated Nucleic Acid Extraction System ANDiS 350 Qiagen DSP Viral RNA Mini Kit	Applied Biosystems 7500 Real-Time PCR Instrument system (Thermo Fisher Scientific)	3D Biomedicine Science & Technology Co., Ltd.	N, E and ORF-1ab genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	WHO EUL
190-000	ID NOW COVID-19 Test Kit	96T/kit	ID NOW Instrument		Abbott Diagnostics Scarborough Inc	RdRp segment	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order PMDA TGA
09N78-090	Alinity m SARS-CoV-2 AMP Kit	192T/kit	Alinity m System		Abbott Molecular	RdRp and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA PMDA TGA
09N77-090	Abbott RealTime SARS-CoV-2 RT-PCR Kit	96T/kit	Abbott m2000		Abbott Molecular	RdRp and N genes	see IFU	see IFU	see IFU	For consumables and details of componants 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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

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	Resolute 2.0 SARS CoV-2 Detection Kit	see IFU	see IFU		Accelerate Technologies Pte Ltd (DxD Hub)	see IFU	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA
13279F 13278D 13281D	MassARRAY® SARS-CoV-2 Panel	960T/kit 3840T/kit 768T/kit	NucliSENS® easyMAG® (bioMérieux) KingFisher Flex Purification System (ThermoFisher)	MassARRAY System	Agena Bioscience, Inc.	N gene, ORF-1 and ORF-1ab gene	see IFU	see IFU	see IFU	For consumables and details of componants 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) CFX96™ Touch Deep Well Real-Time PCR Detection System (BioRad	Altona Diagnostics GmbH		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
	RESOLUTE 2.0				AMT Pte Ltd (Singapore)						TGA
64-C0304	BioCode® SARS-CoV-2 Assay	384T/kit	NucliSENS® easyMAG® (bioMérieux) MagNA Pure 96 (Roche)	BioCode® MDx-3000 automated system	Applied BioCode Inc	N gene	see IFU	see IFU	see IFU	Under risk assessment for Omicron variant	US FDA EUA

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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 gene	6 months	see IFU	see IFU	Under risk assessment for Omicron variant Note: See WHO Information Notice for IVD users 2021/01 with regards to mutations in SARS-CoV-2	US FDA EUA
DX-1001-002-000		500T/kit	TRIzol™ RNA Extraction Kit (Invitrogen)	Applied Biosystems QuantStudio 5 Real-Time PCR System							
			Mag-Bind Viral RNA Xpress Kit (Omega Bio-Tek)	Applied Biosystems 7500 Fast 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		BD MAX™ System		Arkray Factory Co., Ltd.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
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	see IFU	see IFU	For consumables and details of componants 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							
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	Under risk assessment for Omicron variant	US FDA EUA Health Canada/Interim Order

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**Manufacturer**	**Detection type**	**Anticipated Shelf life (months)**	**Recommended storage temperature**	**Specimen type**	**Comments**	**Eligibility criteria WHO EUL or others**
MFG030011	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	see IFU	see IFU	For consumables and details of componants 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-Cov-2 (2 gene)				BGI Europe A/S (distributed by BGI Health (AU) Company Pty Ltd)						TGA
	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	see IFU	see IFU	For consumables and details of componants 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	see IFU	see IFU	For consumables and details of componants 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
			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)								

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

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	qSanger-COVID-19 Assay	3072T/kit	Applied Biosystems Veriti Thermal Cycler 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 componants refer to IFU	US FDA EUA
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	see IFU	see IFU	For consumables and details of componants 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 BS-SY-SC2-1000	Bio-Speedy® Direct RT-qPCR SARS-CoV-2	100T/kit 1000T/kit		LightCycler 96 (Roche)	Bioeksen R&D Technologies Ltd	ORF1ab gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
				CFX96 Touch Real-Time PCR Detection System (Bio-Rad)							
				Rotor-Gene Q (Qiagen)							

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BS-SY-SC2-100 BS-SY-SC2-1000	Bio-Speedy® Direct RT-qPCR SARS-CoV-2 rebranded to BioeXsen SARS-CoV-2 RT PCR	100T/kit 1000T/kit		LightCycler 96 (Roche) CFX96 Touch Real-Time PCR Detection System (Bio-Rad) Rotor-Gene Q (Qiagen)	Bioeksen R&D Technologies Ltd (distributed by BioeXsen GmbH)	ORF1ab gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
BS-SY-WCOR-304-100	Bio-Speedy® Direct RT-qPCR SARS-CoV-2	100T/kit	RINA M14 Nucleic Acid Extraction Robot (Cat No: RINA-M14-01)	LightCycler 96 (Roche) CFX96 Touch Real-Time PCR Detection System (Bio-Rad) Rotor-Gene Q 5plex (Qiagen)	Bioeksen R&D Technologies Ltd	ORF1ab gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	WHO EUL
423745 423744	BioFire® COVID-19 Test	6T/kit 30T/kit	FilmArray® 2.0 and/or the FilmArray® Torch Instrument Systems		BioFire Defense, LLC	ORF1ab and ORF8	see IFU	see IFU	nasopharyngeal swabs	For consumables and details of componants refer to IFU	US FDA EUA
423738	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 componants refer to IFU	(US FDA EUA replaced by DeNovo approval) Health Canada/Interim Order TGA
500-003-XMP	BioGX Xfree COVID-19 Direct RT-PCR	104T/kit	n/a 	Applied Biosystems QuantStudio 5 Applied Biosystems 7500 Fast Dx Bio-Rad CFX96 Touch	BioGX, Inc.	N gene	see IFU	see IFU	see IFU	Under risk assessment for Omicron variant	US FDA EUA

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				Bio-Rad CFX384 Touch							
	Biomeme SARS-CoV-2 Real-Time RT-PCR	96T/kit	MagMax Viral/Pathogen on KingFisher Flex Purification System (ThermoFisher)	Bio-Rad CFX96	Biomeme Inc.	ORF1ab and S gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
			Biomeme M1 Sample Prep Cartridge Kit for RNA 2.0	QuantStudio 5							

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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 componants 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)	BioMérieux SA	N gene and RdRp gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	revoked US FDA EUA Health Canada/Interim Order
				QuantStudio12 Flex (QS12) instrument (Applied Biosystems)							
			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)							
	SARS-COV-2 R-GENE®				BioMérieux SA	see IFU	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA

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12013743	Bio-Rad SARS-CoV-2 ddPCR Kit	200T/kit	ThermoFisher MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (Cat No. A48310, 1000 reactions)	QX200™ PCR Systems	Bio-Rad Laboratories Inc	P and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
			QIAamp Virus RNA Mini Kit (cat. # 52906)								
			ThermoFisher MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (Cat No. A48310, 1000 reactions) on KingFisher Flex system	QXDx™ Droplet Digital™ PCR Systems							
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 componants 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)							
			RNeasy Mini kit (Qiagen)	7500 Real-Time PCR System (Applied Biosystems)							

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TD1100	COVID-19 RT-PCR PNA kit	24T/kit		7500 Fast Real-Time PCR System (Applied Biosystems)	BioTNS	RdRp gene and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
				CFX96 Touch 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)	see IFU	see IFU (302-3750)	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order TGA
XPRSARS-COV2-10	Xpert® Xpress SARS-CoV-2	10T/kit	GeneXpert Dx with 6- and 10-color optical modules)		Cepheid	Genes N2 and E	see IFU (302-3562)	see IFU	see IFU (302-3562)	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order TGA
			GeneXpert Infinity Systems								

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XPRSARS-COV2-10	Xpert® Xpress SARS-CoV-2	10T/kit	GeneXpert Dx with 6-color optical modules	GeneXpert Infinity Systems	Cepheid	Genes N2 and E	see IFU (302-3562)	see IFU	see IFU (302-3562)	For consumables and details of componants refer to IFU	WHO EUL

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	VIASURE SARS-CoV-2 Real Time PCR Detection Kit		Viasure RNA-DNA Extraction kit (VIASURE)	Applied Biosystems 7500 Fast Real-Time PCR System	CerTest Biotec SL / Abacus dx	ORF1ab and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA
			Maxwell® 16 Viral Total Nucleic Acid Purification Kit, using the Maxwell® 16 instrument (Promega)	Applied Biosystems StepOne™ Real-Time PCR System							
			Total Nucleic Acid Isolation (TNAI) Kit, using COBAS® AmpliPrep (ROCHE)	Bio-Rad CFX96™ Real-Time PCR System							
			MagDEA Dx SV kit, using the magLEAD® 12gC instrument (Precision System Science Co.)	Agilent Technologies AriaMx Real-Time PCR System							
			MagCore® Viral Nucleic Acid Extraction kit, using the MagCore® HF16 automated Nucleic Acid Extractor System	DNA-Technology Detection DTprime Real-time Detection Thermal Cycler							
			EZ1 Virus Mini Kit, using EZ1 instrument (Qiagen)	DNA-Technology DTlite Real-Time PCR System							
			mSample Preparation Systems RNA, using the Abbott m2000 RealTime System (Abbott Molecular)	Rotor-Gene® Q (Qiagen)							

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				SmartCycler (Cepheid)							
				Roche Molecular Diagnostics Cobas z480 Analyzer							
				VIASURE 48 Real Time PCR System							
				VIASURE 96 Real Time PCR System							
	VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit				CerTest Biotec SL / Becton Dickensen		see IFU	see IFU	nasopharyngeal swabs	For consumables and details of componants refer to IFU	TGA
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	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA 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 componants refer to IFU	US FDA EUA

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TR-US-01	Clinomics TrioDx RT-PCR COVID-19 Test	100T/kit	QIAamp Viral RNA Mini Kit	ABI QuantStudio 6 Flex	Clinomics USA Inc.	RdRp gene and N and E genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
			Maxwell RSC Viral Total Nucleic Acid Multi-Pack Kitwith the Maxwell RSC 48 instrument								
			MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit with KingFisher Flex instrument								
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	see IFU	nasopharyngeal swabs	For consumables and details of componants 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 componants refer to IFU	TGA
	Aridia COVID-19 Real-Time PCR Test				CTK Biotech Inc (United States Of America)		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA
C1020	Cue COVID-19 Test		Cue Health Monitoring System		Cue Health Inc	N Gene	see IFU	see IFU	see IFU	Under risk assessment for Omicron variant	US FDA EUA Health Canada/Interim Order

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
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	see IFU	see IFU	Under risk assessment for Omicron variant	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)							
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	see IFU	see IFU	For consumables and details of componants refer to IFU	WHO EUL TGA
			QIAamp Viral RNA Mini Kit, 52906	Roche LightCycler480 II							
	QuickNavi-Flu+COVID19 Ag				Denka Co., Ltd.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
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 componants 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 componants 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									

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
DC-11-0017	QuantiVirus SARS-CoV-2 Mulitplex 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	see IFU	nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, and sputum	For consumables and details of componants 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 CXF 384 Real-Time PCR Instrument							
MOL4150	Simplexa™ COVID-19 Direct	24T/kit	LIAISON® MDX		DiaSorin Molecular	ORF1ab and S gene	see IFU	see IFU	see IFU	For consumables and details of componants 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 componants refer to IFU	PMDA
ENZ-GEN215-0096	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	Under risk assessment for Omicron variant	US FDA EUA
			QIAsymphony® SP (QIAGEN)	QuantStudio® 5 Real-Time PCR System (Applied Biosystems)							
			Manual								

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
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 componants refer to IFU	Health Canada/Interim Order 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	Chemagic Viral DNA/RNA 300 Kit H96	CFX96 Touch Real-Time PCR Detection System (Bio-Rad)							
MP 2606-0100		100T/kit		qTOWER3 (Analytik Jena)							
MP 2606-0200		200T/kit									
MP 2606-1000		1000T/kit									
11416302 (FTD-114-96)	FTD SARS-CoV-2	96T/kit	NucliSENS® easyMAG® System (bioMéreux)	7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems™)	Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company)	ORF1ab and N gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA PMDA
			VERSANT® kPCR Molecular System (Siemens Healthineers)								
11416300 (FTD-114-32)	FTD SARS-CoV-2	32T/kit	NucliSENS® easyMAG® System (bioMéreux)	7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems™)	Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company)	ORF1ab and N gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	WHO EUL
11416284 (FTD-114-96)		96T/kit									
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	Under risk assessment for Omicron variant	US FDA EUA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
	µTASWako SARS-CoV-2		see IFU		FUJIFILM Wako Pure Chemical Corporation		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
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 componants refer to IFU	US FDA EUA
			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)								
	NeoPlex COVID-19 Detection Kit	96T/kit	QIAamp DSP Viral RNA Mini Kit (Qiagen)	7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems™)	GeneMatrix, Inc.	RdRp and N gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
4PCO052E	GB SARS-CoV-2 Real Time RT-PCR	100T/kit	QIAamp DSP Viral RNA Mini Kit (Qiagen)	QIAGEN Rotor-Gene® Q real-time PCR cycler	General Biologicals Corp	ORF1ab and E gene	see IFU	see IFU	see IFU	For consumables and details of componants 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 componants 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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
EA008212	ePlex® SARS-CoV-2 Test	12T/kit	GenMark ePlex instrument and Software		GenMark Diagnostics, Inc		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	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	see IFU	see IFU	For consumables and details of componants 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	see IFU	nasal, nasopharyngeal, and oropharyngeal swab	For consumables and details of componants refer to IFU	US FDA EUA
	Procleix SARS-CoV-2 Assay	250T/kit	Procleix Panther System with Procleix Reagent Preparation Incubator 250		Grifols Diagnostic Solutions Inc		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
NAT-01	RT-PCR IVD MEDICAL DEVICE FOR 2019 NOVEL CORONAVIRUS (SARS-COV-2) NUCLEIC ACID DETECTION	see IFU	see IFU		HA TECH PTY LTD	ORF1ab Region 1 ORF1ab Region 2	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA
PRD-06419	Aptima SARS-CoV-2 assay	250T/kit	Panther System		Hologic Inc	ORF1ab Region 1 ORF1ab Region 2	see IFU	see IFU	see IFU	For consumables and details of componants 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	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA Health Canada Interim Order TGA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
				QuantStudio 5 RT PCR System (Applied Biosystems™)							
	BKit Virus Finder Covid-19				Hyris Ltd.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	Health Canada/Interim Order
see IFU	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 componants refer to IFU	Health Canada/Interim Order US FDA EUA PMDA
			NextSeq 500 Sequencing System								
			NextSeq 550 Sequencing System								
			NextSeq 550Dx Sequencing System								

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	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	see IFU	see IFU	For consumables and details of componants 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)							
COV2-C	Smart Detect™ SARS-CoV-2 rRT-PCR Kit				InBios International, Inc		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	Health Canada/Interim Order
	COV-19 IDx assay	96T/kit	KingFisher Flex nucleic acid extraction systems QS12 instrument	Applied Biosystems QuantStudio12 Flex (QS12) instrument	Ipsum Diagnostics, LLC		see IFU	see IFU	see IFU	For consumables and details of componants 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 componants 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 componants refer to IFU	US FDA EUA
	KANEKA Direct RT-PCR kit SARS-CoV-2				KANEKA CORPORATION		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
RV008	RADI COVID-19 Detection Kit	100T/kit	QIAamp® DSP Viral RNA Mini Kit (Qiagen)	CFX96 Real-Time PCR Detection System (Bio-rad)	KH Medical Co. Ltd	S gene and RdRp gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	WHO EUL
	SmartAmp SARS-CoV-2				K.K. DNAFORM		see IFU	see IFU	see IFU	For consumables and details of componants 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 componants refer to IFU	US FDA EUA
R6900TD	PowerChek™ 2019-nCoV Real-time PCR Kit		QIAamp® DSP Viral RNA Mini Kit (QIAGEN)	CFX96 Real-Time PCR Detection System (Bio-Rad) 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 componants refer to IFU	US FDA EUA TGA
	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	see IFU	nasopharyngeal swab, anterior nasal swab and midturbinate nasal swab	For consumables and details of componants refer to IFU	US FDA EUA TGA
	Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCRTest	96T/kit		IntelliQube PCR System	LGC Biosearch Technologies		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
	TaqPath COVID-19 Combo Kit				Life Technologies Corporation (USA) (see also ThermoFisher)		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA PMDA
810055970056	Lucira COVID-19 All-In-One Test Kit	24T/kit	Disposable Lucira Device		Lucira Health, Inc.	N gene	see IFU	see IFU	see IFU	Under risk assessment for Omicron variant	US FDA EUA Health Canada/Interim Order
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 componants refer to IFU	US FDA EUA Health Canada/Interim Order
I054C0463	NxTAG® CoV Extended Panel Assay	96T/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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order
GCRNA-COVID-96R	Genecount Covid-19 Rt-Qpcr Assay Kit				Luminultra Technologies Ltd. (Canada)		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	Health Canada/Interim Order

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**Manufacturer**	**Detection type**	**Anticipated Shelf life (months)**	**Recommended storage temperature**	**Specimen type**	**Comments**	**Eligibility criteria WHO EUL or others**
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 componants 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							
L018180130096	LumiraDx SARS-CoV-2 RNA STAR Complete		n/a	Applied Biosystems 7500 Fast Dx	LumiraDx UK Ltd	ORF1a Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
				Applied Biosystems QuantStudio 5							
				Applied Biosystems QuantStudio 7 Flex							
				Roche LightCycler 480 II							
				Bio-Rad CFX96 Touch Real-Time PCR Detection System							
				Agilent AriaMx RT-PCR Instruments							
				Agilent Stratagene Mx3005P RT-PCR Instruments							

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
BUSGN7102109		64T/kit									
BUSGN7103109		96T/kit	QIAGEN QIAamp Viral RNA Mini 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 componants refer to IFU	US FDA EUA
ST-CV19-2SF	MatMaCorp COVID-19 2SF Test		MatMaCorp Solas 8 Instrument		Materials and Machines Corporation of America (DBA MatmaCorp, Inc.)	RdRp gene	see IFU	see IFU	see IFU	For consumables and details of componants 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 componants refer to IFU	PMDA
410700	Revogene SARS-CoV-2 assay		REVOGENE SYSTEM		Meridian	N gene	see IFU	see IFU	see IFU	Under risk assessment for Omicron variant	US FDA EUA
COV4100	Accula SARS-Cov-2 Test		Accula™ Dock or the Silaris™ Dock		Mesa Biotech Inc.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
7K105 7K111	Veri-Q PCR 316 COVID-19 Detection Kit	50 test/kit 100 test/kit	Veri-Q System		MiCoBioMed Co Ltd	ORF3a and N gene target	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA WHO EUL

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
	Smart Gene SARS-CoV-2				Mizuhomedy Co., Ltd.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
	MobileDetect Bio BCC19 (MD-Bio BCC19) Test Kit	12T/kit	MD-Bio heater		MobileDetect Bio Inc.	E and N gene target	see IFU	see IFU	see IFU	For consumables and details of componants 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	see IFU	see IFU	Under risk assessment for Omicron variant	US FDA EUA TGA
XC25073	Sars-Cov-2 Virus Detection Diagnostic Kit	50T/kit	TAN Bead® extract system (Taiwan Advanced Nanotech) RNeasy Mini Kit (Qiagen)	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 componants refer to IFU	Health Canada/Interim Order WHO EUL
DXTM67120 (500RXNS)	2019-NCoV Taqman Rt-PCR Kit Dx				Norgen Biotek Corp. (Canada)	RdRp and E Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	Health Canada/Interim Order
DXTM67100 (50RXNS)	2019-NCoV Taqman Rt-PCR Kit Dx				Norgen Biotek Corp. (Canada)	RdRp and E Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	Health Canada/Interim Order
DXTM67200	COVID-19 Taqman Rt-PCR Kit (e/rdrp Genes) Dx				Norgen Biotek Corp. (Canada)	RdRp and E Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	Health Canada/Interim Order

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**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) QuantStudio5 Flex (QS5) instrument (Applied Biosystems) CFX96 Real-Time PCR Instrument (Biorad)	OPTOLANE Technologies, Inc.	RdRp and E Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
IFMR-45	GeneFinder™ COVID-19 Plus RealAmp Kit	100T/kit	QIAamp viral RNA Mini Kit (Qiagen) DNA and Viral NA Small Volume Kit (Roche MagNA Pure 96)	Applied Biosystems 7500 & 7500 Fast Real-Time PCR System CFX96 Real-Time PCR Instrument (Biorad)	OSANG Healthcare Co., Ltd	RdRp gene, N Gene and E Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
99-57003 99-57004	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	see IFU	see IFU	For consumables and details of componants 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)							
	P23 Labs TaqPath SARS-CoV-2 Assay	see IFU	see ThermoFisher TaqPath COVID-19 Combo Kit		P23 Labs, LLC	see IFU	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
	DetectX-Rv	see IFU		MiniAmp A37834 (ThermoFisher)	PathogenDx, Inc.	see IFU	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	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 (KN0212) 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	see IFU	see IFU	For consumables and details of componants refer to IFU	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)	Applied Biosystems™ 7500 Fast Dx Real-Time PCR System							
				Applied Biosystems™ QuantStudio 3 Real-Time PCR System							
				Applied Biosystems™ QuantStudio 5 Real-Time PCR System							
				Analytik Jena qTower3 / qTower3G Real-Time PCR System							
				Analytik Jena qTower3 84 / qTower3 84 G Real-Time PCR System							

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**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 IntelliPlexTM 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 componants refer to IFU	US FDA EUA
02.01.1019	FastPlex Triplex SARS-CoV-2 detection kit	24T/kit	QIAmp Viral RNA Mini Kit (Qiagen)	DropX-2000 Digital PCR System	PreciGenome LLC	RdRp gene and N Gene	see IFU	see IFU	nasopharyngeal swab	For consumables and details of componants refer to IFU	US FDA EUA
	Triplelock SARS-Cov-2 Test Strips				Precision Biomonitoring Inc		see IFU	see IFU	nasopharyngeal swab	For consumables and details of componants refer to IFU	Health Canada/Interim Order
	ELITe MGB SARS-CoV-2 PCR Detection Kit				Precision System Science Co., Ltd.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
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	see IFU	see IFU	For consumables and details of componants refer to IFU	WHO EUL TGA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**Manufacturer**	**Detection type**	**Anticipated Shelf life (months)**	**Recommended storage temperature**	**Specimen type**	**Comments**	**Eligibility criteria WHO EUL or others**
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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
				Bio-Rad CFX Connect™ Real-Time PCR Detection System							
			QIAamp Viral RNA Mini kit	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	see IFU	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)								

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**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 componants 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)	DTPrime5 (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)							
				Applied Biosystems™ QuantStudio 7 Real-Time PCR Instrument (ThermoFisher)							

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
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	see IFU	nasopharyngeal swab	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order TGA
#1110 with #1105 #1154 with #1155	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 componants 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	see IFU	see IFU	For consumables and details of componants 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	see IFU	see IFU	Quest Diagnostics Self-Collection Kit for COVID-19 For consumables and details of componants refer to IFU	US FDA EUA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
	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	see IFU	nasopharyngeal swabs, oropharyngeal swabs, sputum, BAL, and tracheal aspirates	Quest Diagnostics Self-Collection Kit for COVID-19 For consumables and details of componants 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	see IFU	nasopharyngeal swabs, oropharyngeal swabs, sputum, BAL, and tracheal aspirates	Quest Diagnostics Self-Collection Kit for COVID-19 For consumables and details of componants 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	see IFU	Nasopharyngeal or oropharyngeal specimens	For consumables and details of componants refer to IFU	US FDA EUA Health Canada Interim Order
				Applied Biosystems 7500 Fast Dx Real-Time PCR System							
				Roche LightCycler 480							
				Qiagen Rotor-Gene Q							
				Bio-Rad CFX96 Touch							
				Thermofisher QuantStudio 7 Pro							
M313	Solana SARS-CoV-2 Assay	96T/kit	Solana Instrument		Quidel Corp.	Orf1ab	see IFU	see IFU	Nasopharyngeal or oropharyngeal specimens	For consumables and details of componants refer to IFU	US FDA EUA Health Canada Interim Order

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	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 componants refer to IFU	US FDA EUA
09175431190 09343733190	Cobas SARS-CoV-2 RT-PCR Kit	192T/kit 480T/kit	cobas 6800/8800		Roche Diagnostics	ORF1 a/b	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order PMDA WHO EUL
09408592190	cobas SARS-CoV-2	20T/kit	cobas Liat System		Roche Diagnostics	ORF1ab and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order PMDA
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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order TGA
		48T/kit	without Extraction								

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	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) QIAamp Virus RNA Mini Kit (Qiagen)	LightCycler® 96 Real-Time PCR System (Roche)	ScienCell	RdRp gene, N Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
SS-9930	U-TOP™ COVID-19 Detection Kit	96T/kit	QIAamp Virus RNA Mini Kit (Qiagen) PANAMAX Viral DNA/RNA Extraction Kit performed on the PANAMAX 48 Nucleic Acid Extraction System TOP Viral DNA/RNA Extraction Kit	CFX96 Real-Time PCR Instrument (Biorad) Applied Biosystems 7500 & 7500 Fast Real-Time PCR System	Seasun Biomaterials	ORF1ab and N Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order
SS-9920	AQ-TOP COVID-19 Rapid Detection Kit	96T/kit	QIAamp DSP Virus Kit (Qiagen)	CFX96 Real-Time PCR Instrument (Biorad) Applied Biosystems 7500 Real-Time PCR System	Seasun Biomaterials	ORF1ab and N Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**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								
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	see IFU	see IFU	For consumables and details of componants 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)								

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**Manufacturer**	**Detection type**	**Anticipated Shelf life (months)**	**Recommended storage temperature**	**Specimen type**	**Comments**	**Eligibility criteria WHO EUL or others**
			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)								
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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
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 componants refer to IFU	WHO EUL

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
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	see IFU	see IFU	For consumables and details of componants 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	see IFU	see IFU	For consumables and details of componants refer to IFU	WHO EUL
RR-0485-02	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	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	see IFU	see IFU	For consumables and details of componants refer to IFU	WHO EUL
RR-0479-02	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 genes)	25T/kit	nucleic acid extraction product and equipment of Shanghai ZJ Bio-Tech QIAamp Virus RNA Mini Kit (Qiagen) 	ABI Prism 7500 CFX96 Real-Time PCR Instrument (Biorad) SLAN MIC POC Dx48	Shanghai ZJ Bio-Tech Co Ltd (China)	ORF1ab and N genes and E genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
	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	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
	Ampdirect 2019-nCoV detection kit				Shimadzu Corporation		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
GNT2011-1	Ezplex SARS-CoV-2 G Kit	100T/kit	QIAamp Virus RNA Mini Kit (Qiagen)	CFX96 Real-Time PCR Instrument (Biorad)	SML GENETREE Co., Ltd.	RdRP and N genes	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							
	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 componants refer to IFU	Health Canada/Interim Order
ASM-00144	Spartan COVID-19 System Test Cartridge	see IFU	Spartan COVID-19 System		Spartan Bioscience Inc. (Canada)	see IFU	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	Health Canada/Interim Order
	PlexPCR® SARS-CoV-2				SpeeDx Pty Ltd (Australia)		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA
	SGNP nCoV/Flu PCR Detection Kit				SUDx-Biotec Corporation		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
	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 componants 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 componants refer to IFU	PMDA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
80-10284	T2SARS-CoV-2 Panel	12T/kit	T2Dx® Instrument		T2 Biosystems, Inc.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
	Takara SARS-CoV-2 Direct PCR detection kit				Takara Bio Inc.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
O11200-25	Talis One COVID-19 Cartridge Pack	25T/kit	Talis One Instrument		Talis Biomedical Corporation	ORF1ab and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
68020	ExProbeTM 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 componants refer to IFU	US FDA EUA
			EZbead Viral Extraction Kit with automated EZbead System-32 instrument	TBG Q6000 Real-Time PCR System							
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 componants refer to IFU	WHO EUL

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**Manufacturer**	**Detection type**	**Anticipated Shelf life (months)**	**Recommended storage temperature**	**Specimen type**	**Comments**	**Eligibility criteria WHO EUL or others**
A47813	TaqPath COVID-19 Combo Kit Advanced	200T/kit	MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (manual) and 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	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
			MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)	Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument							
				Applied Biosystems™ QuantStudio 7 Flex Real-Time PCR Instrument							
A47814	TaqPath COVID-19 Combo Kit	1000T/kit	MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)	Applied Biosystems 7500 & 7500 Fast Real-Time PCR System	Thermo Fisher Scientific Inc (see also Life Technologies Corporation)	ORF1ab, S and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
			MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)	Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument							
				Applied Biosystems™ QuantStudio 7 Flex Real-Time PCR Instrument							

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
A49868	TaqPath COVID-19, FluA, FluB Combo Kit	1000T/kit		Applied Biosystems 7500 Fast Real-Time PCR System	Thermo Fisher Scientific Inc (see also Life Technologies Corporation)	ORF1ab, S and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
			MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)	Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument							
A47817	Taqpath COVID-19 Rt-PCR Kit				Thermo Fisher Scientific Inc		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	Health Canada/Interim Order
	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 componants refer to IFU	PMDA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**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) and automated on KingFisher™ Flex Purification System (KingFisher)	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 componants refer to IFU	WHO EUL
			MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)	Applied Biosystems™ QuantStudio 5 & 5 Dx Real-Time PCR Instrument							
				Applied Biosystems™ QuantStudio 7 Flex Real-Time PCR Instrument							
A49918	TaqPath™ COVID-19 Pooling Kit	384T/kit	MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)	Applied Biosystems™ QuantStudio 7 Flex Real-Time PCR Instrument	Thermo Fisher Scientific Inc (see also Life Technologies Corporation)	ORF1ab, S and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
			MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)								

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
A51333	TaqPath COVID-19 RNase P Combo Kit 2.0	1T/kit	MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)	Applied Biosystems™ QuantStudio 5 Flex Real-Time PCR Instrument	Thermo Fisher Scientific Inc (see also Life Technologies Corporation)	ORF1ab and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
				Applied Biosystems™ QuantStudio 7 Flex Real-Time PCR Instrument							
A51606	TaqPath COVID-19 FAST PCR Combo Kit 2.0	1T/kit	n/a	Applied Biosystems™ QuantStudio 5 Flex Real-Time PCR Instrument	Thermo Fisher Scientific Inc (see also Life Technologies Corporation)	ORF1ab and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
				Applied Biosystems™ QuantStudio 7 Flex Real-Time PCR Instrument							
A49869	Amplitude™ Solution with TaqPath COVID-19 High Throughput Combo Kit	20000/kit	Amplitude™ Solution automated on a Tecan™ Fluent™ 1080 Automation Workstation	Applied Biosystems™ QuantStudio 7 Flex Real-Time PCR Instrument	Thermo Fisher Scientific Inc (see also Life Technologies Corporation)	ORF1ab, S and N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA Health Canada/Interim Order

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
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 componants 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 componants refer to IFU	PMDA
	Gene Cube SARS-CoV-2	48T/kit	QIAmp Viral RNA Mini Kit (Qiagen)		Toyobo Co., Ltd.	N gene	see IFU	see IFU	see IFU	Under risk assessment for Omicron variant	PMDA
	Gene Cube HQ SARS-CoV-2				Toyobo Co., Ltd.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
102997	SARS-CoV-2 NGS Assay	96T/kit	NextSeq 500 Sequencing System NextSeq 550 Sequencing System NextSeq 550Dx Sequencing System		Twist Bioscience Corporation	Sars-Cov-2 Genome	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
	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 componants refer to IFU	TGA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**Manufacturer**	**Detection type**	**Anticipated Shelf life (months)**	**Recommended storage temperature**	**Specimen type**	**Comments**	**Eligibility criteria WHO EUL or others**
	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 componants refer to IFU	TGA
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 componants 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 componants refer to IFU	US FDA EUA
				Applied Biosystems® 7500 Fast Dx Real-Time PCR System							
PS-001541	Visby Medical COVID-19 Point of Care Test	1T/kit	n/a		Visby Medical		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
	SARS-CoV-2 RT-qPCR Reagent Kit				Wallac Oy (Finland)		see IFU	see IFU	see IFU	For consumables and details of componants 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 componants refer to IFU	TGA

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)											
Manufacturer Product Catalogue number	**Product Name** (IVD product)	**Reference detail**	**Platform (Extraction equipment)**	**Platform (amplification equipement)**	**Manufacturer**	**Detection type**	**Anticipated Shelf life (months)**	**Recommended storage temperature**	**Specimen type**	**Comments**	**Eligibility criteria WHO EUL or others**
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 componants refer to IFU	US FDA EUA
			Lab-Aid Virus RNA Extraction Kit on Lab-Aid 824s Nucleic Acid Extraction System	Bio-Rad CFX96 Real-Time System							
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 componants 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							
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 gene	see IFU	see IFU	see IFU	Under risk assessment for Omicron variant	US FDA EUA Health Canada/Interim Order
			MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit manual (KingFisher)	Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument							

SARS-CoV-2 Nucleic Acid Amplification Technologies (only sequencing equipment with the intended use to diagnoses acute infections are included)

Manufacturer Product Catalogue number	Product Name (IVD product)	Reference detail	Platform (Extraction equipment)	Platform (amplification equipement)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
N/A- NOT APPLICABLE											

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 advise 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
(Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)

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	15 months	see IFU	see IFU	Visual read	US FDA EUA
195-005	BinaxNOW COVID-19 Ag 2 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 41FK20	Panbio COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	25T/kit	n/a	Abbott Rapid Diagnostics Jena GmbH	SARS-CoV-2 nucleocapsid protein antigen	24	see IFU	see IFU	Visual read	Health Canada/Interim Order TGA WHO EUL
41FK11 41FK21	Panbio COVID-19 Ag Rapid Test Device (NASAL)	25T/kit	n/a	Abbott Rapid Diagnostics Jena GmbH	SARS-CoV-2 nucleocapsid protein antigen	24	see IFU	see IFU	Visual read	Health Canada/Interim Order TGA WHO EUL
	Arsonic COVID-19 Ag		n/a	Alfresa Pharma Corporation	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU		PMDA
PN-0003KT40	NIDS COVID-19 Antigen Rapid Test Kit	40T/kit	n/a	ANP Technologies, Inc.	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	US FDA EUA

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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**
	ARISTA™ COVID-19 Antigen Rapid Test		n/a	Arista Biotech Pte Ltd (Singapore)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	TGA
A03-50-422	Artron COVID-19 Antigen Test			Artron Laboratories Inc. (Canada)	SARS-CoV-2 nucleocapsid protein antigen	18	see IFU	see IFU		Health Canada/Interim Order
	COVID-19 Antigen Rapid Test Device	25T/kit	n/a	Assure Tech (Hangzhou) Co Ltd (China)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	Health Canada/Interim Order TGA
	Ecotest COVID-19 Antigen Saliva Test Kit		n/a	Assure Tech (Hangzhou) Co Ltd (China)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU		TGA
	Ecotest COVID-19 Antigen Nasal Test Kit		n/a	Assure Tech (Hangzhou) Co Ltd (China)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU		TGA
	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
256091 256113 256114	Bd Kit For Rapid Detection Of SARS-CoV-2		see IFU	Becton, Dickinson and Company	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU		Health Canada/Interim Order
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 PMDA TGA

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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**
	Wantai SARS-CoV-2 Ag Rapid Test (Colloidal Gold)			Beijing Wantai Biologicalpharmacy Enterprise Co Ltd (China)	see IFU	see IFU	see IFU	see IFU		TGA
	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method)			BIOHIT HealthCare (Hefei) Co Ltd (China)	see IFU	see IFU	see IFU	see IFU		TGA
RG1901DG	NowCheck COVID-19 Antigen Test			BioNote Inc	see IFU	see IFU	see IFU	see IFU		TGA
SW40006	BIOSYNEX COVID-19 Ag BSS	see IFU	n/a	Biosynex Swiss SA	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	ANSM
SW40010 SW40010F	BIOSYNEX COVID-19 Ag+	see IFU	n/a	Biosynex Swiss SA	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	ANSM
2070088301	Rapid Response™ COVID-19 Antigen Rapid Test Device		n/a	BTNX Inc	SARS-CoV-2 antigen	see IFU	see IFU	see IFU	Visual Read	Health Canada
2070089201	Rapid Response™ COVID-19 Antigen Rapid Test Device		n/a	BTNX Inc	SARS-CoV-2 antigen	see IFU	see IFU	see IFU	Visual Read	Health Canada
SWB-19	Rapid Response™ COVID-19 Antigen Rapid Test Device		n/a	BTNX Inc	SARS-CoV-2 antigen	see IFU	see IFU	see IFU	Visual Read	Health Canada

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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 Response COV-19C25	Rapid Response™ COVID-19 Antigen Rapid Test Device		n/a	BTNX Inc	SARS-CoV-2 antigen	see IFU	see IFU	see IFU	Visual Read	TGA Health Canada
	Surescreen Diagnostics COVID-19 Antigen Rapid Test Cassette		n/a	BTNX Inc	SARS-CoV-2 antigen	see IFU	see IFU	see IFU	Visual Read	TGA
	SARS Coronavirus Antigen Kit Rapiim SARS-CoV-2-N PRT-C2N01A			Canon Medical Systems Corporation	SARS-CoV-2 antigen	see IFU	see IFU	see IFU		PMDA
	Quampas COVID-19 Antigen Test Kit			Cellspect Co.,Ltd.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
	OnSite® COVID-19 Ag Point of care test / Aria® COVID-19 Ag Rapid Test		n/a	CTK Biotech Inc	SARS-CoV-2 antigen	see IFU	see IFU	see IFU	Visual Read	TGA
	QuickNavi-COVID19 Ag			Denka Co., Ltd.		see IFU	see IFU	see IFU		PMDA
311500	LIAISON® SARS-CoV-2 Ag	see IFU	see IFU	DiaSorin	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Reader required	US FDA EUA
	Ellume COVID-19 Home Test		see IFU	Ellume Ltd	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Reader required	US FDA EUA

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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**
ATG 900-207 ATG 900-208 ATG 900-210	CovClear COVID-19 Antigen Test			Empowered Diagnostics LLC (United States Of America)		12				Health Canada/Interim Order TGA
	Fuji Dry Chem IMMUNO AG Handy COVID-19 Ag			Fujifilm Corporation		see IFU	see IFU	see IFU		PMDA
	Accuraseed SARS-CoV-2Ag			FUJIFILM Wako Pure Chemical Corporation		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
231906	ESPLINE SARS-CoV-2	100T/kit	n/a	Fujirebio Inc	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU		PMDA
COVAG025-U COVAG025-NU	GenBody COVID-19 Ag	25T/kit		GenBody Inc (Korea - Republic of)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	US FDA EUA TGA
	2019-nCoV Ag Saliva Rapid Test Card			Guangzhou Decheng Biotechnology Co Ltd (China)						TGA

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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**
	2019-nCoV Antigen Test (Lateral Flow Method)			Guangzhou Wondfo Biotech Co Ltd (China)						TGA
	GSD NovaGen SARS CoV-2 Rapid Test			Hangzhou Alltest Biotech Co Ltd						TGA
ICOV-802	COVID-19 Antigen Rapid Test (Oral Fluid) ICOV-802			Hangzhou Alltest Biotech Co Ltd						TGA
ICOV-502	COVID-19 Antigen Rapid Test (swab) ICOV-502			Hangzhou Alltest Biotech Co Ltd						TGA
	COVID-19 Antigen Rapid Test Cassette			HANGZHOU BIOTEST BIOTECH NO LTD (China)						TGA
	Clungene Covid-19 Antigen Rapid Test			Hangzhou Clongene Biotech Co Ltd						TGA
	LYHER Novel Coronavirus (Covid-19) Antigen Test Kit (Colloidal Gold)			Hangzhou Laihe Biotech Co Ltd (China)						TGA
	Novel Coronavirus (SARS-COV-2) Antigen Rapid test cassette (swab)			Hangzhou Realy Tech Co Ltd (China)						TGA

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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**
	Cellife Covid-19 Antigen Test Cassette			Hangzhou Testsea Biotechnology Co Ltd (China)						TGA
	Testsea SARS-CoV-2 Antigen Test Kit			Hangzhou Testsea Biotechnology Co Ltd (China)						TGA
CT-P60 D-2 02	Celltrion DiaTrust™ COVID-19 Ag Rapid Test	25T/kit	n/a	Humasis, Co Ltd. (distributed by Celltrion USA, Inc)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual Read	US FDA EUA
COVAG-RC	SCoV-2 Ag Detect Rapid Test	50T/kit	n/a	InBios International, Inc.	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	US FDA EUA
	InnoScreen COVID-19 Antigen Rapid Test Device			Innovation Scientific Pty Ltd (Australia)		see IFU	see IFU	see IFU		TGA
	PixoTest® COVID-19 AG Test Kit			iXensor Co Ltd (Taiwan)						TGA
	SARS-CoV-2 antigen Test Kit (LFIA)		n/a	Jiangsu Medomics medical technology Co Ltd (China)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU		TGA
	KBM line check nCoV (stick type)		n/a	Kojin Bio Co., Ltd.	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	PMDA

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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**
	KBM LineCheck nCoV/Flu		n/a	Kojin Bio Co., Ltd.	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	PMDA
	Clip COVID Rapid Antigen Test	25T/kit	Clip Analyzer	Luminostics, Inc	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Reader required	US FDA EUA
	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
CP0023	COVIDx-SARS-CoV-2 Rapid Antigen Test Kit	25T/kit	LumiraDx Platform	Lumos Diagnostics Ata Rapid Pathogen Screening Inc Ata Lumos Diagnostics Inc (United States)	SARS-CoV-2 nucleocapsid protein antigen	12	see IFU	see IFU		Health Canada/Interim Order
	STANDARD Q COVID-19 Ag Test			MALCOM COMPANY LIMITED		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
	Fuji Dry Chem IMMNO AG Cartridge COVID-19 Ag		n/a	Mizuhomedy Co., Ltd.	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	PMDA
	Quick Chaser Auto SARS-CoV-2		n/a	Mizuhomedy Co., Ltd.	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Reader required	PMDA
	Rapid SARS-CoV-2 Antigen Test Card			MP Biomedicals Asia Pacific Pte Ltd (Singapore)						TGA

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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**
ND-MD8147	Nano-Check COVID-19 Antigen Test	20T/kit	n/a	Nano-Ditech Corp		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
	Immunofine SARS-COV-2			Nichirei Biosciences Inc		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
1001-0614 1001-0615	InteliSwab COVID-19 Rapid Test Pro	25T/kit 100T/kit	n/a	OraSure Technologies, Inc.	SARS-CoV-2 nucleocapsid protein antigen	9	see IFU	see IFU	Visual read	US FDA EUA
1001-0614.001	InteliSwab COVID-19 Rapid Test Pro		n/a	OraSure Technologies, Inc.	SARS-CoV-2 nucleocapsid protein antigen	9	see IFU	see IFU	Visual read	Health Canada Interim Order
619 9949	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack	100T/kit	VITROS 3600 Immunodiagnostic System and the VITROS 5600/XT 7600 Integrated Systems	Ortho Clinical Diagnostics, Inc	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Analyzer required	US FDA EUA Health Canada/Interim Order PMDA
COV05	Pcl COVID19 AG Rapid Fia		Pcl Immunofluorescence Analyzer Pclok Ez	Pcl Inc.	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Analyzer required	Health Canada Interim Order TGA
	INDICAID COVID-19 Rapid Antigen Test	25T/kit	n/a	PHASE Scientific International Limited	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	US FDA EUA
SS03P25	Sure Status COVID-19 Antigen Card Test	25T/kit	n/a	Premier Medical Corporation Private Limited	SARS-CoV-2 nucleocapsid protein antigen	24	see IFU	see IFU	Visual read	WHO EUL

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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**
	Simoa® SARS-COV-2 N Protein Antigen Test	25T/kit	Simoa HD-X Analyzer	Quanterix Corporation	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Reader required	US FDA EUA
20387	QuickVue SARS Antigen Test	25T/kit	n/a	Quidel Corporation	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	US FDA EUA
20396	QuickVue SARS Antigen Test	25T/kit	n/a	Quidel Corporation	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	Health Canada Interim Order
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
QPR8302	Omnia SARS-CoV-2 Antigen Test	20T/kit	Qorvo Biotechnologies Omnia System (Catalog number # QPR9002)	Qorvo Biotechnologies, LLC	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Reader required	US FDA EUA
	Eclusis Reagent SARS-CoV-2 Ag		n/a	Roche Diagnostics Co., Ltd	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	see IFU	PMDA
	SARS-Cov-2 Rapid Antigen Test		n/a	Roche Diagnostics Co., Ltd	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual Read	PMDA
CLA-COV19AG-VIS/ 102241	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette		n/a	Salofa Oy	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual Read	US FDA EUA

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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**
	Clarity COVID-19 Antigen Rapid Test Cassette		n/a	Salofa Oy	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual Read	US FDA EUA
	OVIOS COVID-19 Antigen Rapid Test Cassette		n/a	Salofa Oy	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual Read	US FDA EUA
	Spring Health COVID-19 Antigen Rapid Test Cassette		n/a	Salofa Oy	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual Read	US FDA EUA
	Salocor COVID-19 Antigen Rapid Test Cassette		n/a	Salofa Oy	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual Read	US FDA EUA
09COV30D	STANDARD Q COVID-19 Ag Test		n/a	SD Biosensor Inc.	SARS-CoV-2 nucleocapsid protein antigen	24	see IFU	see IFU	Visual Read	TGA WHO EUL
9901-NCOV-01G	SARS-Cov-2 Rapid Antigen Test		n/a	SD Biosensor Inc. (distributed by Roche Diagnostics Australia)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual Read	TGA
9901-NCOV-04G	SARS-Cov-2 Rapid Antigen Test		n/a	SD Biosensor Inc. (distributed by Roche Diagnostics Australia)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual Read	Health Canada Interim Order
9901-NCOV-06G	SARS-Cov-2 Rapid Antigen Test		n/a	SD Biosensor Inc. (distributed by Roche Diagnostics Australia)	SARS-CoV-2 nucleocapsid protein antigen	24	see IFU	see IFU	Visual Read	Health Canada Interim Order

SARS-CoV-2 Antigen Rapid Diagnostic Tests (Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)										
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**
	RapidTesta SARS-CoV-2			SEKISUI MEDICAL CO., LTD.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
	HISCL SARS-CoV-2 Ag Assay Kit			Sysmex Corporation		see IFU	see IFU	see IFU		PMDA
	AFIAS COVID-19 Ag Test Cartridge			TOKYO BOEKI MEDISYS INC		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
	CL AIA-PACK SARS-CoV-2-Ag			TOSOH CORPORATION		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
	Immuno Ace SARS-CoV-2 / Capilia SARS-CoV-2			TAUNS LABORATORIES, INC.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
	ImmunoArrow SARS-CoV-2			TOYOBO CO., LTD.		see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	PMDA
61254	Rapid SARS-CoV-2 Antigen Test Card		n/a	Xiamen Boson Biotech Co., Ltd. (China)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	Health Canada Interim Order
9167	Rapid SARS-CoV-2 Antigen Test Card		n/a	Xiamen Boson Biotech Co., Ltd. (China)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	Health Canada Interim Order
1N40C5	Rapid SARS-CoV-2 Antigen Test Card		n/a	Xiamen Boson Biotech Co., Ltd. (China)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	Health Canada Interim Order

SARS-CoV-2 Antigen Rapid Diagnostic Tests
(Important note: Antigen tests do detect the omicron variant but may have reduced sensitivity and are therefore currently under risk assessment)

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
1N40T0	Rapid SARS-CoV-2 Antigen Test Card		n/a	Xiamen Boson Biotech Co., Ltd. (China)	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	Health Canada Interim Order
XH-100-110	SPERA COVID-19 Ag Test	10T/kit	n/a	Xtrava Health	SARS-CoV-2 nucleocapsid protein antigen	see IFU	see IFU	see IFU	Visual read	US FDA EUA

N/A- NOT APPLICABLE

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
L031-11711	ACON SARS-CoV-2 IgG/IgM Rapid Test	see IFU	n/a	n/a	ACON Laboratories, Inc	IgG/IgM	see IFU	see IFU	see IFU		US FDA EUA
A-RAPCOV01	RapCov™ Rapid COVID-19 Test	see IFU	n/a	n/a	Advaite	IgG	see IFU	see IFU	see IFU		US FDA EUA
COV-W23M	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		Health Canada/Interim Order 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

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
	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-2710, WJ-2750	Wantai SARS-CoV-2 Ab Rapid Test kit	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
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
90-1092 90-1098	Insti COVID-19 Antibody Test	see IFU	n/a	n/a	Biolytical Laboratories Inc. (Canada)	IgG/IgM	12	see IFU	see IFU		Health Canada/Interim Order
COV-13C25	Rapid Response COVID-19 IgG/IgM Rapid Test Device	see IFU	n/a	n/a	Btnx Inc. (Canada)	IgG/IgM	see IFU	see IFU	see IFU		Health Canada/Interim Order
	COVID-19 IgG/IgM Rapid Test	see IFU	n/a	n/a	Btnx Inc. (Canada)	IgG/IgM	see IFU	see IFU	see IFU		TGA

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
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		TGA revoked US FDA EUA
5515C050		50									
5515C100		100									
R0180C	OnSite COVID-19 IgG/IgM Rapid Test (Aria 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 revoked US FDA EUA
2039	CovAb SARS-CoV-2 Ab Test	see IFU	n/a	n/a	Diabetomics, Inc.	IgG/IgA/IgM	see IFU	see IFU	see IFU		US FDA EUA
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 removed from US FDA EUA
	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 removed from US FDA EUA
	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
	COVID-19 IgG/IgM Rapid Test Cassette	see IFU	n/a	n/a	Hangzhou Clongene 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
	LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) rebranded to QUICKKIT Novel Coronavirus (2019-nCov) IgM/IgG Antibody Combo Test Kit	see IFU	n/a	n/a	Hangzhou Laihe Biotech Co Ltd (China) distributed by Unisources Group LLC.	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 removed from US FDA EUA
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
	InnoScreenTM 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

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
YF319C	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		US FDA EUA TGA
B25-CSER1001	Lumivi Diagnostics SARS-CoV-2 IgG Rapid Test Kit	see IFU	n/a	n/a	International Point Of Care, Inc. (Canada)	IgG/IgM	see IFU	see IFU	see IFU		Health Canada/Interim Order
	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
	INDICAID COVID-19 IgM/IgG Rapid Test rebranded by Phase Scientific International Limited	see IFU	n/a	n/a	Jiangsu Well Biotech Co., Ltd. distributed by Phase Scientific International Limited	IgG/IgM	see IFU	see IFU	see IFU		US FDA EUA
	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
243001N-10 243001N-20 243001N-50 243001N-100	Nadal COVID-19 IgG/IgM Test (pack Of 10)	10 20 50 100	n/a	n/a	Nal Von Minden Gmbh (Germany)	IgG/IgM	see IFU	see IFU	see IFU		Health Canada/Interim Order
	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 removed from US FDA EUA
	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 removed from 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
8075	ADEXUSDx COVID-19 Test	50	n/a	n/a	NOWDiagnostics, Inc	Total Ig	see IFU	see IFU	see IFU		US FDA EUA
NBPC-0007	MidaSpotTM COVID-19 Antibody Combo Detection Kit	25	n/a	n/a	Nirmidas Biotech, Inc	IgG/IgM	see IFU	see IFU	see IFU		US FDA EUA
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
	SARS-CoV-2 IgM/lgG Antibody Rapid Test	see IFU	n/a	n/a	Qingdao Hightop Biotech Co Ltd (China)	IgG/IgM	see IFU	see IFU	see IFU		TGA
CD-COV19CW/102223/ 102224	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
COGT025E, COGT005E	SGTi-flex COVID-19 IgG	25T/kit 5T/kit	n/a	n/a	Sugentech, Inc	IgG	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

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
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) distributed by O'Neill Medical LLC, HORIBA instrument incorporated, Lifesaving Global LLC, THE RUHOF CORPORATION, Marlan's Group Us Inc, and JEMF Pharma	IgG/IgM	see IFU	see IFU	see IFU		US FDA EUA
	rebranded by Telepoint Medical Services, LLC	25T/kit	n/a	n/a	Xiamen Biotime Biotechnology Co., Ltd. (China) distributed by Telepoint Medical Services, LLC	IgG/IgM	see IFU	see IFU	see IFU		US FDA EUA
☐	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		TGA
☐ 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

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
	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

N/A- NOT APPLICABLE

THE GLOBAL FUND

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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
OMNISARS-COV2-10	Xpert® Omni SARS-CoV-2	10T/kit	Cepheid	Jan-22	US FDA EUA revoked
	Multiplex NAAT and Ag tests (Sars-Cov-2/RSV, Sars-Cov-2/Influenza, etc)		Multi	Jan-22	WHO does not recommend Multiplex assays
444213	BioGX SARS-CoV-2 Reagents	24	Becton, Dickinson and Company	Dec-21	US FDA EUA revoked
	BIOCREDIT COVID-19 Ag		RapiGEN Inc	Nov-21	Global Fund delisted
	Novel Coronavirus (SARS-CoV-2) Antigen rapid test		Hangzhou Realy Tech Co Ltd (China)	Nov-21	Global Fund delisted
A51329	TaqPath™ COVID-19 MS2 Combo Kit 2.0	1	Thermo Fisher Scientific Inc (see also Life Technologies Corporation)	Oct-21	US FDA EUA revoked
RTA0203	Anti-SARS-CoV-2 Rapid Test	20	Autobio Diagnostics Co., Ltd (China)	Aug-21	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
	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)		Hangzhou Laihe Biotech Co Ltd (China)	Feb-20	TGA delisted
	PCL COVID19 IgG/IgM Rapid Gold		PCL Inc (Korea - Republic of)	Feb-20	US FDA EUA revoked TGA delisted
	SGTi-flex COVID-19 IgM/IgG		Sugentech Inc	Oct-20	US FDA EUA revoked
	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)		Zhuhai Livzon Diagnostics Inc (China)	Jan-21	US FDA EUA revoked TGA delisted

N/A- NOT APPLICABLE