

*Schedule 1 amended*

2. Schedule 1 to the Principal Regulations is amended in item 4, paragraph (d) by deleting “\$55” and substituting “\$50 (VAT Exclusive)”.

*Schedule 3 amended*

3. Schedule 3 to the Principal Regulations is amended by deleting “one year” and substituting “..... year(s)”.

*Schedule 4 amended*

4. The Principal Regulations are amended by deleting Schedule 4 and substituting the following—

“SCHEDULE 4  
(*Regulation 7*)

FEES PAYABLE ON GRANT OR RENEWAL OF LICENCE

<i>Number of beds</i>	<i>1-year licence (VAT Exclusive)</i>	<i>2-year licence (VAT Exclusive)</i>	<i>3-year licence (VAT Exclusive)</i>	<i>4-year licence (VAT Exclusive)</i>	<i>5-year licence (VAT Exclusive)</i>
1 - 50	\$250	\$500	\$750	\$1,000	\$1,250
51 - 300	\$500	\$1,000	\$1,500	\$2,000	\$2,500
301 and above	\$1,000	\$2,000	\$3,000	\$4,000	\$5,000

Made this 3rd day of December 2021.

A. SAYED-KHAIYUM  
Attorney-General

[LEGAL NOTICE NO. 132]

MEDICINAL PRODUCTS ACT 2011

## Medicinal Products (Exceptions to Licensing Requirements) Regulations 2021

In exercise of the powers conferred on me by section 35(1), (2) and (4) of the Medicinal Products Act 2011, I hereby make these Regulations—

*Short title and commencement*

1.—(1) These Regulations may be cited as the Medicinal Products (Exceptions to Licensing Requirements) Regulations 2021.

(2) These Regulations come into force on 4 December 2021.

*Schedule*

2. For the purposes of section 35(1), (2) and (4) of the Medicinal Products Act 2011, the products specified in the Schedule are safe for general use and a licence from the Fiji Medicinal Products Board is not required.

Made this 3rd day of December 2021.

I. WAQAINABETE  
Minister for Health and Medical Services

## SCHEDULE (Regulation 2)

### LIST OF PRODUCTS SAFE FOR GENERAL USE

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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
444213	iCOPY COVID-19 QPCR KIT	100T/kit	QIAamp Viral RNA Mini Kit RNA mini kit (QIAgen)	Light Cycler 480 (Roche)	iDROP INC. (imported by Luminarie Canada Inc.)	E gene and RdRp gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA Health Canada/Interim Order
				Rotor-Gene Q 5plex HRM (Qiagen)							
				Applied Biosystems Quantstudio05 (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 components refer to IFU	US FDA EUA
3103010011	3DMed 2019-nCoV RT-qPCR Detection Kit	100T/kit	ANDiS Viral RNA Auto Extraction & Purification 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 components refer to IFU	WHO EUL
			Automated Nucleic Acid Extraction System ANDiS 350								
			Qiagen DSP Viral RNA Mini Kit								
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 components refer to IFU	US FDA EUA Health Canada/Interim Order TGA
09N78-095	Alinity m SARS-CoV-2 AMP Kit	96T/kit	Alinity m System		Abbott Molecular	RdRp and N genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA Health Canada/Interim Order PMDA TGA
09N79-096	Alinity m Resp-4-Plex	96T/kit	Alinity m System		Abbott Molecular	RdRp and N genes and Influenza A & B and RSH	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA Health Canada/Interim Order
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 components refer to IFU	Health Canada/Interim Order TGA WHO EUL
09N77-095	Abbott RealTime SARS-CoV-2 RT-PCR Kit	96T/kit	Abbott m2000		Abbott Molecular	RdRp and N genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA

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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 components refer to IFU	TGA
13279F 13278D 13281D	MassARRAY® SARS-CoV-2 Panel	960T/kit 3840T/kit 768T/kit	NucliSENS® easyMAG® (bioMérieux)	MassARRAY System	Agena Bioscience, Inc.	N gene, ORF-1 and ORF-1ab gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
			KingFisher Flex Purification System (ThermoFisher)								
821025	RealStar® SARS-CoV-2 RT-PCR Kit U.S.	384T/kit	AltoStar® Automation System AM16	CFX96™ Touch Real-Time PCR Detection System (Bio-Rad)	Altona Diagnostics GmbH		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
				CFX96™ Touch Deep Well Real-Time PCR Detection System (BioRad)							
	RESOLUTE 2.0				AMT Pte Ltd (Singapore)						TGA
64-Co304	BioCode® SARS-CoV-2 Assay	384T/kit	NucliSENS® easyMAG® (bioMérieux)	BioCode® MDx-3000 automated system	Applied BioCode Inc	N gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
			Magna Pure 96 (Roche)								



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DX-1001-001-000	Linea™ COVID-19 Real-Time PCR Assay Kit assay kit	100T/kit	QIAamp® Viral RNA Mini Kit (Qiagen)	Applied Biosystems QuantStudio™ Dx Real-Time PCR system	Applied DNA Sciences	S genes	6 months	see IFU	see IFU	For consumables and details of components refer to IFU  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							
DX-1001-003-000			Mag-Bind Viral RNA Xpress Kit (Omega Bio-Tek) automated on the Hamilton STARlet system	Applied Biosystems 7500 Fast Real-Time PCR System							
		1000T/kit									
	Identity Pack SARS-CoV-2				Arkray Factory Co., Ltd.		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
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 components refer to IFU	US FDA EUA
				Roche LightCycler 480 Instrument II Real-Time PCR System							
				Atila PowerGene 9600 Plus Real-Time PCR System							
				Applied Biosystems 7500 Fast Real-Time PCR System							
	AusDiagnostics respiratory virus panel (including SARS-CoV-2) test				AusDiagnostics Pty Ltd (Australia)		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	TGA

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445003-01	BD SARS-CoV-2 Reagents	24T/kit	BD MAX™ System		Becton, Dickinson and Company	N gene (N1 and N2 regions)	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA Health Canada/Interim Order
445011	BD SARS-CoV-2/Flu Reagents	24T/kit	BD MAX™ System		Becton, Dickinson and Company	N gene (N1 and N2 regions) and Influenza A / Influenza B	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
444213	BioGX SARS-CoV-2 Reagents	24T/kit	BD MAX™ System		Becton, Dickinson and Company	N gene (N1 and N2 regions)	6 months	see IFU	nasopharyngeal swabs	For consumables and details of components refer to IFU	US FDA EUA
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 components refer to IFU	WHO EUL
			QLAamp 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	QLAamp 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 components refer to IFU	US FDA EUA

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CT8233-48T	Multiple Real-Time PCR Kit for Detection of 2019-nCoV	48T/kit	Nucleic acid extraction Kit (XABT, Cat. # CN8033)	Applied Biosystems 7500 Real-Time PCR System	Beijing Applied Biological Technologies Co. Ltd., (XABT)	ORF1ab and N gene and the E gene	see IFU	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 components 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 components refer to IFU	US FDA EUA TGA
				CFX96 Touch Real-Time PCR Detection System (Bio-Rad)							
				SLAN-96P (Shanghai Hongshi Medical Technology Co. Ltd)							
BS-SY-SC2-100 BS-SY-SC2-1000	Bio-Speedy® Direct RT-qPCR SARS-CoV-2	100T/kit 1000T/kit		LightCycler 96 (Roche)	Bioexen R&D Technologies Ltd	ORF1ab gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
				CFX96 Touch Real-Time PCR Detection System (Bio-Rad)							
				Rotor-Gene Q (Qiagen)							

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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)	Bioeksen R&D Technologies Ltd (distributed by BioeXsen GmbH)	ORF1ab gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
				CFX96 Touch Real-Time PCR Detection System (Bio-Rad)							
				Rotor-Gene Q (Qiagen)							
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)	Bioeksen R&D Technologies Ltd	ORF1ab gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	WHO EUL
				CFX96 Touch Real-Time PCR Detection System (Bio-Rad)							
				Rotor-Gene Q 5plex (Qiagen)							
423745	BioFire® COVID-19 Test	6T/kit	FilmArray® 2.0 and/or the FilmArray® Torch Instrument Systems		BioFire Defense, LLC	ORF1ab and ORF8	see IFU	see IFU	nasopharyngeal swabs	For consumables and details of components refer to IFU	US FDA EUA
423744		30T/kit									
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 components refer to IFU	(US FDA EUA replaced by DeNovo approval) Health Canada/Interim Order TGA
423883	Biofire Respiratory Panel 2.1-EZ (RP2.1-EZ)		FilmArray® 2.0 EZ Systems		BioFire Diagnostics LLC	S Gene, M Gene, Influenza A and others	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA

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500-003-XMP	BioGX Xfree COVID-19 Direct RT-PCR	104T/kit	n/a	Applied Biosystems QuantStudio 5	BioGX, Inc.	N gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
				Applied Biosystems 7500 Fast Dx							
				Bio-Rad CFX96 Touch							
				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							
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

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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 components refer to IFU	US FDA EUA Health Canada/Interim Order
				QuantStudio12 Flex (QSt12) 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 components refer to IFU	TGA
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 components refer to IFU	US FDA EUA
			QLAmp 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							

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12015361	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit	200T/kit	QIAamp Virus RNA Mini Kit (cat. # 52906)	CFX Opus Real-Time PCR (Biorad)	Bio-Rad Laboratories Inc	P and N genes and Influenza A/ Influenza B	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA
				CFX96 Touch (Biorad)							
				CFX96 Dx (Biorad)							
				Applied Biosystems 7500 Fast Dx Real-Time PCR System							
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)							



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TD1100	COVID-19 RT-PCR PNA kit	24T/kit	RNeasy Mini kit (Qiagen)	7500 Real-Time PCR System (Applied Biosystems)	BioTNS	RdRp gene and N genes	see IFU	see IFU	see IFU	For consumables and details of compoanants refer to IFU	US FDA EUA
				7500 Fast Real-Time PCR System (Applied Biosystems)							
				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 compoanants 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 compoanants refer to IFU	US FDA EUA Health Canada/Interim Order TGA
			GeneXpert Infinity Systems								
XPRSARS-COV2-10	Xpert® Xpress SARS-CoV-2	10T/kit	GeneXpert Dx with 6-color optical modules)		Cepheid	Genes N2 and E	see IFU (302-3562)	see IFU	see IFU (302-3562)	For consumables and details of compoanants refer to IFU	WHO EUL
			GeneXpert Infinity Systems								
XPCOV2/FLU/RSV-10	Xpert Xpress SARS-CoV-2/Flu/RSV	10T/kit	GeneXpert Xpress System (Tablet and Hub Configurations)		Cepheid	Genes N2 and E and Influenza A/Influenza B/RSV RNA	see IFU (302-4419)	see IFU	see IFU (302-4419)	For consumables and details of compoanants refer to IFU	US FDA EUA TGA
XP3COV2/FLU/RSV-10	Xpert Xpress CoV-2/Flu/RSV plus	10T/kit	GeneXpert Xpress System (Tablet and Hub Configurations)		Cepheid	RdRp and Genes N and E and Influenza A/Influenza B/RSV RNA	see IFU (302-6991)	see IFU	see IFU (302-6991)	For consumables and details of compoanants refer to IFU	US FDA EUA
XPCOV2/FLU/RSV-10	Xpert Xpress SARS-CoV-2/Flu/RSV	10T/kit	GeneXpert Dx with 6- and 10-color optical modules)		Cepheid	Genes N2 and E and Influenza A/Influenza B/RSV RNA	see IFU (302-4421)	see IFU	see IFU (302-4421)	For consumables and details of compoanants refer to IFU	US FDA EUA TGA
			GeneXpert Infinity Systems								

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OMNISARS-COV2-10	Xpert® Omni SARS-CoV-2	10T/kit	GeneXpert Omni System		Cepheid	Genes N2 and E	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
	VIASURE SARS-CoV-2 Real Time PCR Detection Kit				CerTest Biotec SL / Abacus dx	ORF1ab and N gene	see IFU	see IFU	nasopharyngeal swabs	For consumables and details of components refer to IFU	TGA
	VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit				CerTest Biotec SL / Becton Dickinson		see IFU	see IFU	nasopharyngeal swabs	For consumables and details of components 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 components 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 components 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	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 equipment)	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 Multiplex Test kit	24T/kit	Thermo Fisher PureLink™ viral RNA/DNA mini kit	Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument	DiaCarta, Inc	Orfiab genes	12 months	see IFU	nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, and sputum	For consumables and details of components refer to IFU	US FDA EUA
DC-11-0018		48T/kit	MGI MGISP960 High Throughput Automated Sample Preparation System	Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument							
DC-11-0019		480T/kit		Bio-Rad CFX 384 Real-Time PCR Instrument							
MOL4150	Simplexa™ COVID-19 Direct	24T/kit	LIAISON® MDX		DiaSorin Molecular	ORF1ab and S gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA Health Canada/Interim Order TGA WHO EUL
LMP401	Loopamp New Coronavirus 2019 (SARS-CoV-2) Detection Reagent Kit	48T/kit	see IFU		Eiken Chemical Co., Ltd.	Replicase 1B region	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
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	For consumables and details of components refer to IFU	US FDA EUA
			QIAasymphony® 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 equipment)	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 Labor diagnostika AG (Germany)	ORF1ab and N gene	see IFU	see IFU	see IFU	For consumables and details of components 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 <sup>™</sup> )							
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 (bioMérieux)	7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems <sup>™</sup> )	Fast Track Diagnostics Luxembourg S.à.r.l. (a Siemens Healthineers Company)	ORF1ab and N gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
		VERSANT® kPCR Molecular System (Siemens Healthineers)									
11416300 (FTD-114-32)	FTD SARS-CoV-2	32T/kit	NucliSENS® easyMAG® System (bioMérieux)	7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems <sup>™</sup> )	Fast Track Diagnostics Luxembourg S.à.r.l. (a Siemens Healthineers Company)	ORF1ab and N gene	see IFU	see IFU	see IFU	For consumables and details of components 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	For consumables and details of components 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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
CV002	GenePro SARS-CoV-2 Test		QIAamp DSP Viral RNA Mini Kit (Qiagen)	QuantStudio™ DX (Applied Biosystems)	Gencurix, Inc.	N-gene and E-gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
			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 components 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 components refer to IFU	TGA
	EasyScreen™ SARS-CoV-2 Detection Kit				Genetic Signatures Ltd (Australia)		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	TGA
RPQ021 RPQ022	Genetron SARS-CoV-2 RNA Test	50T/kit 100T/kit	QIAamp DSP Viral RNA Mini Kit (Qiagen)	7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems™)	Genetron Health (Beijing) Co., Ltd.	ORF1ab and N gene	6 months	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
EA001222	ePlex Respiratory Pathogen Panel 2 (ePlex RP2 Panel)	12T/kit	GenMark ePlex instrument and Software		GenMark Diagnostics, Inc	Sars-Cov-2 and other pathogenic RNA	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
EA008212	ePlex® SARS-CoV-2 Test	12T/kit	GenMark ePlex instrument and Software		GenMark Diagnostics, Inc		see IFU	see IFU	see IFU	For consumables and details of components 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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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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
	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									
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	

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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
	COV-19 IDx assay	96T/kit	KingFisher Flex nucleic acid extraction systems QS12 instrument	Applied Biosystems QuantStudio12 Flex (QS12) instrument	Ipsium Diagnostics, LLC		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
JC10223-1NW-50T JC10223-1NW-25T	COVID-19 Coronavirus Real Time PCR Kit	50T/kit 25T/kit	Viral nucleic acid isolation kit (Bioperfectus Technologies)	Applied Biosystems QuantStudio5 instrument	Jiangsu Bioperfectus Technologies Co Ltd (China)	ORF1ab and N genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA TGA WHO EUL
			QIAamp® Viral RNA Mini Kit (Qiagen)	7500 Real-Time PCR instrument (Applied Biosystems)							
	Novel Coronavirus (SARS-CoV-2) Fast Nucleic Acid Detection Kit	24T/kit 48T/kit 96T/kit	see IFU	7500 Real-Time PCR instrument (Applied Biosystems)	Jiangsu CoWin Biotech Co., Ltd. (China)	ORF1ab and N genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
	KANEKA Direct RT-PCR kit SARS-CoV-2				KANEKA CORPORATION		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
	SmartAmp SARS-CoV-2				K.K. DNAFORM		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
KF2019CoV01	KimForest SARS-CoV-2 Detection Kit v1	96T/kit	QIAamp Virus RNA Mini Kit (Qiagen)	StepOne/StepOnePlus Real-Time PCR Systems (Applied Biosystems)	KimForest Enterprise Co., Ltd.	RdRp genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA

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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
R6900TD	PowerChek™ 2019-nCoV Real-time PCR Kit		QIAamp® DSP Viral RNA Mini Kit (QIAGEN)	CFX96 Real-Time PCR Detection System (Bio-Rad)	Kogene Biotech Co Ltd (Korea - Republic of)	RdRp and E genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA TGA
				7500 Real-Time PCR instrument (Applied Biosystems)							
				7500 Fast Real-Time PCR instrument (Applied Biosystems)							
	LabGun™ COVID-19 RT-PCR Kit	96T/kit	QIAamp® DSP Viral RNA Mini Kit (Qiagen)	7500 Fast Dx Real-Time PCR instrument (Applied Biosystems)	LabGenomics	RdRp and N genes	see IFU	see IFU	nasopharyngeal swab, anterior nasal swab and midturbinate nasal swab	For consumables and details of components refer to IFU	US FDA EUA TGA
				CFX96 Touch Real-Time PCR Detection System (Bio-Rad)							
	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 components refer to IFU	US FDA EUA
	TaqPath COVID-19 Combo Kit				Life Technologies Corporation (USA) (see also ThermoFisher)		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	TGA PMDA
810055970056	Lucira COVID-19 All-In-One Test Kit	24T/kit	Disposable Lucira Device		Lucira Health, Inc.	N genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	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 components 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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
I054C0463	NxTAG® CoV Extended Panel Assay	96T/kit	bioMérieux® NucliSENS® easyMAG® System	Luminex® MAGPIX® instrument including xPONENT	Luminex Molecular Diagnostics, Inc.	ORF1ab, N Gene and E Gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA Health Canada/Interim Order
			bioMérieux® EMAG® System								
I056C0468	NxTAG Respiratory Pathogen Panel + SARS-CoV-2	96T/kit	bioMérieux® NucliSENS® easyMAG® System	Luminex® MAGPIX® instrument including xPONENT	Luminex Molecular Diagnostics, Inc.	ORF1ab, N Gene and E Gene and Influenza A & B and RSH and others	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
			bioMérieux® EMAG® System								
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 components refer to IFU	Health Canada/Interim Order
L018180030096	LumiraDx SARS-CoV-2 RNA STAR		Qiagen DSP Virus/Pathogen Kit on QIAasymphony SP (Qiagen)	Roche LightCycler 480 II	LumiraDx UK Ltd	ORF1a Gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
			MagMax Viral/Pathogen Nucleic Acid Isolation Kit (Applied Biosystem)	Applied Biosystems 7500 Fast Dx							
			QIAamp Viral RNA Mini Kit (Qiagen)	Applied Biosystems QuantStudio 5							
				Agilent AriaMx RT-PCR Instruments							
				Agilent Stratagene Mx3005P RT-PCR Instruments							

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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
L018180130096	LumiraDx SARS-CoV-2 RNA STAR Complete		n/a	Applied Biosystems 7500 Fast Dx	LumiraDx UK Ltd	ORF1a Gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
				Applied Biosystems 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							
BUSGN7101109	SARS-CoV-2 Fluorescent PCR Kit	32T/kit	Nucleic Acid Extraction Kit, Manual Version or	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 components refer to IFU	US FDA EUA
BUSGN7102109		64T/kit	Nucleic Acid Extraction Kit, Fast Version								
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 components 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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
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 components refer to IFU	US FDA EUA
	MEBRIGHT SARS-CoV-2 Kit				Medical & Biological Laboratories Co., Ltd.		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
COV4100	Accula SARS-Cov-2 Test		Accula™ Dock or the Silaris™ Dock		Mesa Biotech Inc.		see IFU	see IFU	see IFU	For consumables and details of components 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 components refer to IFU	TGA WHO EUL
	Smart Gene SARS-CoV-2				Mizuhomedy Co., Ltd.		see IFU	see IFU	see IFU	For consumables and details of components 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 components refer to IFU	US FDA EUA
300800	NeuMoDx™ SARS-CoV-2 Test Strip	96T/kit	NeuMoDx™ 288 Molecular System [500100] or NeuMoDx™ 96 Molecular System [500200]		NeuMoDx Molecular, Inc.	Nsp2 target and N gene target	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA TGA
300800	NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay	96T/kit	NeuMoDx™ 288 Molecular System [500100] or NeuMoDx™ 96 Molecular System [500200]		NeuMoDx Molecular, Inc.	Nsp2 target and N gene target and Influenza A/B and RSV M genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
XC25073	Sars-Cov-2 Virus Detection Diagnostic Kit	50T/kit	TAN Bead® extract system (Taiwan Advanced Nanotech)	Applied Biosystems 7500 & 7500 Fast Real-Time PCR System	Ningbo Health Gene Technologies Co., Ltd (China)	ORF1ab, N and S genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	Health Canada/Interim Order WHO EUL
			RNeasy Mini Kit (Qiagen)								

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

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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 equipment)	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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
2019-nCoV-PCR-AUS	PerkinElmer® New Coronavirus Nucleic Acid Detection Kit	48T/kit	PerkinElmer® Nucleic Acid Extraction Kits (KNo212) and PreNAT II (SY61)(software version 1.00.06).	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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
82303-U	IntelliPlex SARS-CoV-2 Detection Kit	96T/kit	QIAmp Viral RNA Mini Kit (Qiagen)	Thermo Fisher MiniAmp Thermal cycler with IntelliPlex™ 1000 µCode Processor (PlexBio; Cat. No. 80033) and PlexBio 100 Fluorescent Analyzer (PlexBio; Cat. No. 80000)	PlexBio Co., Ltd.	RdRp gene, N and E Gene	12 months	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
<u>02.01.1019</u>	<u>FastPlex Triplex SARS-CoV-2 detection kit</u>	<u>24T/kit</u>	<u>QIAmp Viral RNA Mini Kit (Qiagen)</u>	<u>DropX-2000 Digital PCR System</u>	<u>PreciGenome LLC</u>	<u>RdRp gene and N Gene</u>	<u>see IFU</u>	<u>see IFU</u>	<u>nasopharyngeal swab</u>	<u>For consumables and details of components refer to IFU</u>	<u>US FDA EUA</u>
	Triplelock SARS-Cov-2 Test Strips				Precision Biomonitoring Inc		see IFU	see IFU	nasopharyngeal swab	For consumables and details of components 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 components 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 components 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 equipment)	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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
PCCSKU15262	PhoenixDx® SARS-CoV-2 Multiplex	50T/kit	RTA Viral RNA Extraction Kit as extraction Kit (RTA Laboratories)	7500 Fast Real-Time PCR System (Applied Biosystems)	Procomcure Biotech GmbH (Trax Management Services Inc.)	ORF1ab and N genes	see IFU	see IFU	see IFU	For consumables and details of 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)	DTPPrime5 (DNA Technologie)							
			SphaeraMag DNA/RNA Isolation Kit (Procomcure)	qTower3G (Analytik Jena)							
				Applied Biosystems™ QuantStudio 1 Real-Time PCR Instrument (ThermoFisher)							
				Applied Biosystems™ QuantStudio 3 Real-Time PCR Instrument (ThermoFisher)							
				Applied Biosystems™ QuantStudio 5 Real-Time PCR Instrument (ThermoFisher)							
				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 equipment)	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 components 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 components refer to IFU	US FDA EUA	
				CFX384 Touch Real-Time Detection System (Biorad)								
				QuantStudio 5 instrument (Applied Biosystems)								
39433	Quest SARS-CoV-2 rRT-PCR Kit	96T/kit	Roche MagNA Pure-96 (MP96)	Applied Biosystems 7500 Real Time PCR System	Quest Diagnostics Infectious Disease Inc	Gene N1 & N3	12 months	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA	
			Mag-Bind Viral RNA Xpress Kit (Omega Bio-Tek, Cat. M6219-2304) with the MagEx STAR (Hamilton)									
	Quest Diagnostics RC COVID-19 +Flu RT-PCR	96T/kit	cobas 6800/8800 (Roche)			Quest Diagnostics Infectious Disease Inc	Gene N1 & N3	12 months	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
	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 components 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 equipment)	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 components refer to IFU	US FDA EUA
	Quest Diagnostics PF SARS-CoV-2 rRT-PCR Kit	96T/kit	Panther Fusion (Hologic)		Quest Diagnostics Infectious Disease Inc	ORF1ab Region 1 ORF1ab Region 2	12 months	see IFU	nasopharyngeal swabs, oropharyngeal swabs, sputum, BAL, and tracheal aspirates	Quest Diagnostics Self-Collection Kit for COVID-19 For consumables and details of components refer to IFU	US FDA EUA
SKU # CE-M120	Lytra SARS-CoV-2 rRT-PCR Kit	96T/kit	bioMérieux NucliSENS easyMAG	Applied Biosystems 7500 Real Time PCR System	Quidel Corp.	Orfiab	see IFU	see IFU	Nasopharyngeal or oropharyngeal specimens	For consumables and details of components 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.	Orfiab	see IFU	see IFU	Nasopharyngeal or oropharyngeal specimens	For consumables and details of components 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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
KCCOV19-24	Rheonix COVID-19 MDx Assay	96T/kit	Rheonix Encompass MDx® Workstation		Rheonix	ORF1 a/b	see IFU	see IFU	nasopharyngeal and oropharyngeal swab	For consumables and details of components refer to IFU	US FDA EUA
09175431190 0934373190	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 components refer to IFU	US FDA EUA Health Canada/Interim Order PMDA WHO EUL
09233474190	cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test	96T/kit	cobas 6800/8800		Roche Molecular Systems, Inc.	ORF1 a/b and nucleocapsid protein gene with matrix gene of Influenza A, and non-structural protein gene of Influenza B	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA Health Canada/Interim Order PMDA TGA
09211101190	cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test	20T/kit	cobas Liat System		Roche Molecular Systems, Inc.	ORF1 a/b and nucleocapsid protein gene with matrix gene of Influenza A, and non-structural protein gene of Influenza B	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA 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 components 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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others							
RX7038 (RX7048)	ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (Multiplex option)	96T/kit	Viral RNA Isolation Kit (ScienCell)	LightCycler® 96 Real-Time PCR System (Roche)	ScienCell	RdRp gene, N Gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA							
			QIAamp Virus RNA Mini Kit (Qiagen)															
M-NCOV-01	STANDARD M nCoV Real-Time Detection kit	96T/kit	QIAamp Virus RNA Mini Kit (Qiagen)	CFX96 Real-Time PCR Instrument (Biorad)	SD Biosensor	ORF1ab, E genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA							
				Applied Biosystems 7500 & 7500 Fast Real-Time PCR System														
				Roche LightCycler 480 Real-Time PCR systems														
SS-9930	U-TOP™ COVID-19 Detection Kit	96T/kit	QIAamp Virus RNA Mini Kit (Qiagen)	CFX96 Real-Time PCR Instrument (Biorad)	Seasun Biomaterials	ORF1ab and N Gene	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA Health Canada/Interim Order							
				Applied Biosystems 7500 & 7500 Fast Real-Time PCR System														
			PANAMAX Viral DNA/RNA Extraction Kit performed on the PANAMAX 48 Nucleic Acid Extraction System															
			TOP Viral DNA/RNA Extraction Kit															
SS-9920	AQ-TOP COVID-19 Rapid Detection Kit	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 components refer to IFU	US FDA EUA							
				Applied Biosystems 7500 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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others	
SS-9940	AQ-TOP COVID-19 Rapid Detection Kit PLUS	96T/kit	QIAamp DSP Virus Kit (Qiagen)	CFX96 Real-Time PCR Instrument (Biorad)	Seasun Biomaterials	ORF1ab and N Gene	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	US FDA EUA	
				Applied Biosystems 7500 Real-Time PCR System								
			PANAMAX Viral DNA/RNA Extraction Kit performed on the PANAMAX 48 Nucleic Acid Extraction System									
			TOP Viral DNA/RNA Extraction Kit									

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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
RP10243X / RP10252W	Allplex™ 2019-nCoV Assay kit	100T/kit 124T/kit	Microlab STARlet IVD (Cat. No. 173000-075, Hamilton Co.)	CFX96 Real-Time PCR Instrument (Biorad)	Seegene Inc	RdRp gene, N Gene and E Gene	see IFU	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)								
			MagMAX Viral/Pathogen Nucleic Acid Isolation Kit using KingFisher Flex instrument								
			MagNA Pure DNA and Viral NA Small Volume Kit using Roche MagNA Pure 96								
			AdvanSure NA EX Kit (extraction kit) using AdvanSure E3 Instrument System (LG Chem)								

SARS-CoV-2 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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
	Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay		see IFU		Seegene Inc	RdRp gene, N Gene and E Gene and Influenza A/B	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	TGA
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
GZ-D2RM25	Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real-time PCR)	50T/kit	GenAct NE-48 (Shanghai GeneoDx)	7500 Real-Time PCR Instrument (Applied Biosystems™)	Shanghai GeneoDx Biotechnology Co., Ltd (China)	ORF1ab and N genes	see IFU	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	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
				CFX96 Real-Time PCR Instrument (Biorad)							
				Tianlong Gentier 96E							
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

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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
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	ABI Prism 7500	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 components refer to IFU	TGA
			QIAamp Virus RNA Mini Kit (Qiagen)	CFX96 Real-Time PCR Instrument (Biorad)							
				SLAN							
				MIC POC Dx48							
	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 components refer to IFU	US FDA EUA
	Ampdirect 2019-nCoV detection kit				Shimadzu Corporation		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
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 components 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 components 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 components 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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
	PlexPCR® SARS-CoV-2				SpeedX Pty Ltd (Australia)		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	TGA
	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay				Suzhou Sym-Bio Lifescience Co Ltd (China) (represented by PerkinElmer)		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	TGA
	2019-nCoV Fluorescence Detection Real-time RT-PCR Kit				Sysmex Corporation		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
80-10284	T2SARS-CoV-2 Panel	12T/kit	T2Dx® Instrument		T2 Biosystems, Inc.		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EU/A
	Takara SARS-CoV-2 Direct PCR detection kit				Takara Bio Inc.		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	PMDA
68020	ExProbe™ SARS-CoV-2 Testing Kit		QIAamp Virus RNA Mini Kit (Qiagen)	Applied Biosystems 7500 Real-Time PCR System	TBG Biotechnology Corp	RdRp gene, N and E genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EU/A
			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 components 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 equipment)	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 components 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							
			MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)	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 components 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							
			MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)	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 equipment)	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 components 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 components 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 components 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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
A48067	TaqPath COVID-19 CE-IVD RT-PCR Kit	1000T/kit	MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (manual) 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							
			MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (manual) and automated on KingFisher™ Flex Purification System (KingFisher)	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 equipment)	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	iT/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 components 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	iT/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 components 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 components 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 equipment)	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	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
				CFX96 Touch Real-Time PCR Detection System (Bio-Rad)							
	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 genes	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		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
			NextSeq 550 Sequencing System								
			NextSeq 550Dx Sequencing System								
	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
	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

**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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
300681	ViroKey™ SARS-CoV-2 RT-PCR Test	4x50T/kit	see IFU	Sentosa® SA201 Real-Time PCR Instrument	Vela Operations Singapore Pte Ltd	Orfia and RdRp	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA TGA
				Applied Biosystems® 7500 Fast Dx Real-Time PCR System							
301068	ViroKey™ SARS-CoV-2 RT-PCR Test v2.0	8x48T/kit	see IFU	Sentosa® SA201 Real-Time PCR Instrument	Vela Operations Singapore Pte Ltd	Orfia and RdRp	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
				Applied Biosystems® 7500 Fast Dx Real-Time PCR System							
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 components 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 components refer to IFU	TGA
	COVID-19 (SARS-CoV-2) Nucleic Acid Test kit				Wuhan EasyDiagnosis Biomedicine Co Ltd (China)		see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	TGA
801301	SARS-CoV-2 Test Kit (Real-time PCR)	48T/kit	Virus RNA Extraction Kit (Xiamen Zeesan)	Applied Biosystems™ QuantStudio 3 real-time PCR	Xiamen Zeesan Biotech Co., Ltd. (China)	ORF1ab and N genes	see IFU	see IFU	see IFU	For consumables and details of components refer to IFU	US FDA EUA
			Lab-Aid Virus RNA Extraction Kit on Lab-Aid 824s Nucleic Acid Extraction System	Bio-Rad CFX96 Real-Time 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 equipment)	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility criteria WHO EUL or others
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-iK R3011-10K	Quick SARS-CoV-2 rRT-PCR Kit		MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit automated on KingFisher™ Flex Purification System (KingFisher)	Bio-Rad CFX96 Touch Real-Time PCR Detection System	Zymo Research Corp	N genes	see IFU	see IFU	see IFU	For consumables and details of componants refer to IFU	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 Antigen Rapid Diagnostic Tests

	Product Name	Name of Manufacturer/ Supplier	Country of Manufacture	WHO- EUL/TGA APPROVAL
1	CareStart™ COVID-19 Antigen	ACCESS BIO INC, 65 CLYDE RD, SUITE A, SOMERSET NJ 08873, USA	USA	TGA
2	InnoScreen Covid-19 Antigen Rapid Test Device	Innovation Scientific Pty Ltd	Australia	TGA
3	InnoScreen COVID-19 Antigen Rapid Test Device	Innovation Scientific Pty Ltd	Australia	TGA
4	Panbio Covid-19 Ag Rapid Test Device (Nasal)	ABBOTT RAPID DIAGNOSTICS-Jena GmbH	Korea	WHO-EUL
5	Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal)	ABBOTT RAPID DIAGNOSTICS-Jena GmbH	Korea	WHO-EUL
6	SARS COV-2 Antigen rapid Test kits	Biohit Healthcare (Hefei) Co., Ltd	China	TGA
7	SARS-CoV-2 Antigen Quantitative Assay Kit (Enzyme-linked Immunoassay)	Biohit Healthcare (Hefei) Co., Ltd	China	TGA
8	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method)	Biohit Healthcare (Hefei) Co., Ltd	China	TGA
	SARS-CoV-2 Antigen Self-Test Nasal	SD Biosensor, INC., C-4/5 Floor 16, Deogyong-daero	Korea	TGA

	<b>Product Name</b>	<b>Name of Manufacturer/ Supplier</b>	<b>Country of Manufacture</b>	<b>WHO- EUL/TGA APPROVAL</b>
9		1556 beong-gil, Yeongtong-10gu, Suwon-si Gyeonggi-do 16690.		
10	SARS-CoV-2 Rapid Antigen Test	SD Biosensor, INC	Korea	TGA
11	STANDARD™ Q COVID-19 Ag Test	SD Biosensor, INC	Korea	WHO EUL /TGA
12	Sure Status Covid-19 Antigen Card Test	Premier Medical Corporation Private Limited	India	WHO-EUL
13	VivaDiag™ SARS-CoV-2 Ag Rapid Test	VivaChek Biotrch (Hangzhou) Co. Ltd, Level 2 Block 2 146 EastChaofeng Road Yuhang Economy Development Zone, Hangzhou Zhejiang, 311100	China	TGA