

LISTED COVID-19 NAT ASSAYS

Jurisdiction	Date Listed	Product name	Product code(s)	Manufacturer	Link to IFU
WHO	3-Apr-20	cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems	09175431190 and 09175440190	Roche Molecular Systems, Inc	https://www.who.int/diagnostics_laboratory/eu/0504-046-00_cobas_sars_cov2_qu
WHO	7-Apr-20	Z-Path COVID-19-CE IVD	Z-Path-COVID-19-CE	Primerdesign Ltd.	https://www.who.int/diagnostics_laboratory/eu/0489_185_00_path_covid19_ce_ivd_ifu_issue_2.0.pdf?ua=1
WHO	9-Apr-20	Abbott Realtime SARS-Cov-2 Assay	09N77-090 and 09N77-080	Abbott Molecular Inc.	https://www.who.int/diagnostics_laboratory/eu/0503_027_00_abbott_realtime_sars_cov2.pdf?ua=1
WHO	24-Apr-20	PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay	SY580	SYM-BIO LiveScience Co., Ltd	https://www.who.int/diagnostics_laboratory/eu/eu/0501_192_00_PerkinElmer_kit_ifu.pdf?ua=1
WHO	7-May-20	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	MFG030011	BGI Europe A/S	https://www.who.int/diagnostics_laboratory/eu/eu/0498_191_00_real_time_fluorescent_rt_pcr_kit_for_detecting_2019_ncov.pdf?ua=1
WHO	14-May-20	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR- Fluorescence Probing)	DA0930, DA0931 and DA0932	Da An Gene Co., Ltd. Of Sun Yat-sen University	https://www.who.int/diagnostics_laboratory/eu/eu/0493_141_00_detection_kit_for_2019_ncov_rna_pcr_flourescence_probing.pdf?ua=1

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WHO	19-May-20	Multiple Real-Time PCR Kit for Detection of 2019-nCoV	CT8233-48T	Beijing Applied Biological Technologies Co. Ltd., (XABT	https://www.who.int/diagnostics_laboratory/eul/eul_0491_187_00_m
WHO	21-May-20	FTD SARS-CoV-2 (FTD-114-32)	11416300	Fast Track Diagnostics Luxembourg S.à r.l.	https://www.who.int/diagnostics_laboratory/eul/eul_0502_193_00_ftd_sars_cov_2_ftd_114_32_ifu.pdf?ua=1
WHO	22-May-20	Novel Coronavirus (SARS-CoV-2) Real Time Multiplex RT-PCR Kit	RR-0485-02	Shanghai ZJ Bio-Tech Co., Ltd	https://www.who.int/diagnostics_laboratory/eul/eul_0486_139_00_novel_coronavirus_sars_cov_2_real_time_multiple_x_rt_pcr_kit_ifu.pdf?ua=1
WHO	8-Jun-20	Diagnostic kit for SARS-CoV-2 Nucleic acid (Real-time PCR)	KH-G-M-574-48	Shanghai Kehua Bio-engineering Co., Ltd.	https://www.who.int/diagnostics_laboratory/eul/eul_0493_141_00_detection_kit_for_2019_ncov_na_pcr_flourescence_probing.pdf?ua=1
WHO	11-Jun-20	Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR)	GZ-D2RM25	Shanghai GeneoDx Biotechnology Co., Ltd	To be updsted
WHO	15-Jun-20	COVID-19 Real-Time PCR Kit	HBRT-COVID-19	Chaozhaou HybriBio Biochemistry Ltd.	https://www.who.int/diagnostics_laboratory/eul/eul_0535_196_00_covid19_real_time_pcr_kit_ifu.pdf?ua=1
WHO	23-Jun-20	Xpert® Xpress SARS-CoV-2	XPRSARS-COV2-10	Cepheid AB	https://www.who.int/diagnostics_laboratory/eul/200724_final_pgpr_eul_0511_070_00_xpert_xpress.pdf?ua=1

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WHO	6-Jul-20	Simplexa COVID-19 Direct and Simplexa COVID-19 Positive control Pack	MOL4150, MOL4160	DiaSorin	https://www.who.int/diagnostics_laboratory/eul/200717_final_pgpr_eul_0526_212_00_simplexa.pdf?ua=1
WHO	9-Jul-20	COVID-19 Coronavirus Real Time PCR Kit	JC10223-1NW-50T	Jiangsu Bioperfectus Technologies Co.,Ltd	https://www.who.int/diagnostics_laboratory/eul/200728_final_pgpr_eul_0515_202_00_covid19_real_time_pcr_kit.pdf?ua=1
WHO	14-Aug-20	Wantai SARS-CoV-2 RT-PCR	WS-1248	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd	https://www.who.int/diagnostics_laboratory/eul/eul_0500_005_00_wantai_sars_cov2_rt_pcr_ifu.pdf?ua=1
WHO	14-Aug-20	TaqPath COVID-19 CE-IVD RT-PCR Kit	A48067	Thermo Fisher Scientific	https://www.who.int/diagnostics_laboratory/eul/eul_0525_156_00_taqpath_covid19_ce_ivd_rt_pcr_kit_ifu.pdf?ua=1
WHO	28-Aug-20	SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method)	XC25073	Ningbo Health Gene Technologies Co., Ltd.	https://www.who.int/diagnostics_laboratory/eul/eul_0494_189_00_sars_cov2_virus_detection_diagnostic_kit_rt_qpcr_method.pdf?ua=1
WHO	2-Sep-20	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit (commercial name: Fosun 2019-nCoV qPCR)	PCSYHF	Shanghai Fosun Long March Medical Science Co., Ltd.	https://www.who.int/diagnostics_laboratory/eul/eul_0494_189_00_sars_cov2_virus_detection_diagnostic_kit_rt_qpcr_method.pdf?ua=1

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https://www.who.int/diagnostics_laboratory/200908_eul_sars_cov2_product_list.pdf?ua=1

Jurisdiction/ Country	SAHPRA Licence Holder	Product Name	Product Description	Original Manufacturer
S Africa	Abbott Laboratories South Africa (Pty) Ltd	Abbott RealTime SARS-CoV-2 Assay	RT-PCR	Abbott Molecular Inc
S Africa	ACS Pharma Access Health Solutions (Pty)Ltd	ACS 2019-nCovid Nucleic acid-based diagnostic reagent kit	PCR	Sansure Biotech Inc
S Africa	BECTON DICKINSON PTY LTD	Viasure SARS-CoV-2 S gene Real Time PCR Detection Kit	RT-PCR	CerTest BIOTEC S.L.
S Africa	BECTON DICKINSON PTY LTD	BD SARS-CoV-2 reagents for BD MAXTM system	RT-PCR	GeneOhm Sciences Canada Inc. t/a bd diagnostics
S Africa	Biomerieux South Africa (Pty) Ltd	SARS-CoV-2-R-GENE, SARS-CoV-2 nucleic acid IVD, kit, nucleic acid technique (NAT), 120 tests	RT-PCR	bioMérieux SA
S Africa	Biomerieux South Africa (Pty) Ltd	ARGENE® SARS-COV-2 R-GENE	RT-PCR	bioMérieux SA
S Africa	Biomerieux South Africa (Pty) Ltd	BioFire COVID-19 Test	RT-PCR	BioFire Defense, LLC
S Africa	Biomerieux South Africa (Pty) Ltd	Biofire respiratory panel	PCR	Biofire Diagnostics, LLC
S Africa	Celtic Molecular Diagnostics (Pty) Ltd	Genesig RT PCR Assay	PCR	Primerdesign Ltd
S Africa	CEPHEID	Xpert® Xpress SARS-CoV-2	RT- PCR	Cepheid
S Africa	EUROIMMUN Medical Laboratory Diagnosti	cSsASRoSu-tChoAVf-r2icRae(aPltyti)mLetdPCR	RT-PCR	Medizinische Labordiagnostika AG, Deutschland
S Africa	HAIN LIFESCIENCES SA (Pty) Ltd	Genesig Real-Time PCR Coronavirus (COVID-19) CE IVD	PCR	Primer Design Ltd
S Africa	Hea.IT (Pty) Ltd	iAMP COVID-19 Detection Kit	RT -PCR	ATILA BIOSYSTEMES INC
S Africa	Humor Diagnostica (Pty) Ltd	GeneFinder COVID 19 PLUS	Reagents	Osang Healthcare Co., Ltd
S Africa	Imperial Logistics South Africa (Pty) Ltd	COVID-19 (SARS-CoV-2) nucleic acid test kit	:Multiple PCR	Wuhan EasyDiagnosis Biomedicine Co., Ltd

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S Africa	Inqaba Biotechnical Industries (Pty) Ltd	Allplex 2019-NCoV Assay	PCR	Seegene Inc.	
S Africa	LABOTEC (Pty) Ltd	Novel Corona virus (2019-nCov) Realtime multiplex RT PCR KIT	RT- PCR	Liferiver -Shanghai ZJ Biotech	
S Africa	LTC Tech SA (Pty) Ltd	TaqPath™ COVID-19 CE-IVD RT-PCR Kit	PCR	Life Technologies Corporation (Pleasanton)	
S Africa	LTC Tech SA (Pty) Ltd	TaqPath™ COVID-19 Combo Kit 1000	PCR	Life Technologies Corporation (Pleasanton)	
S Africa	LTC Tech SA (Pty) Ltd	TaqPath™ COVID-19 Combo Kit 100	PCR Novel	Life Technologies Corporation (Pleasanton)	
S Africa	Mbabala Consulting (Pty) Ltd	Multiple respiratory virus nucleic acid IVD kit, nucleic acid technique (NAT)	Coronavirus	Shanghai ZJ Bio-Tech	
S Africa	PerkinElmer South Africa Pty Ltd	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	RT- PCR	Suzhou SYM-BIO Lifescience Co. Ltd	
S Africa	Roche Diagnostics (Pty) Ltd	cobas SARS-CoV-2	RT-PCR	Roche Diagnostics GmbH	
S Africa	RX MEDICAL	Logix Smart Coronavirus Disease 2019 (COVID-19) ki	RT -PCR	Co-Diagnostics, Inc	
S Africa	South Africa Seaways	GeneFinder COVID-19 Plus RealAmp Kit	PCR	Osang Healthcare Co Ltd	
S Africa	Supra Healthcare Johannesburg (Pty) Ltd	SARS-CoV-2 Nucleic Acid Detection Kit	RT-PCR	Bioer Technology Co., Ltd.	
S Africa	Supra Healthcare Johannesburg (Pty) Ltd	(Fluorescence RT-PCR)	RT-PCR	Xi'an TianLong Science and Technology corporate limited.	
S Africa	Supra Healthcare Johannesburg (Pty) Ltd	RT-PCR kit for detecting 2019-nCoV	RT-PCR	BGI Europe A/S	
S Africa	Supra Healthcare Johannesburg (Pty) Ltd	abTESTM COVID-19 qPCR I Kit	RT-PCR	AIT Biotech Pte. Ltd.	
S Africa	Supra Healthcare Johannesburg (Pty) Ltd	COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit	RT-PCR	Wuhan EasyDiagnosis Biomedicine Co., Ltd	
S Africa	Tokabio (Pty) Ltd	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	PCR	Sansure Biotech Inc	
S Africa	Trendline Trading (Pty) Ltd	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	RT-PCR	BGI Biotechnology (Wuhan) Co., Ltd.	

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S Africa	Whitehead Scientific (Pty) Ltd	2019-nCoV CDC EUA Kit, 500 rxn	RT-PCR	Integrated DNA Technologies Inc	
S Africa	Whitehead Scientific (Pty) Ltd	Mag-Bind® Viral DNA/RNA 96 Kit, 12 x 96 Preps (#M6246-03)	RT-PCR	Omega BioTek Inc	
S Africa	Whitehead Scientific (Pty) Ltd	CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	RT-PCR	QuantaBio	
S Africa	Vertice (Pty) Ltd	Ultra gene Combo2screen SARS cov2 assay	RT-PCR	Advanced Biological Laboratories (ABL) S.A.,	
S Africa	PerkinElmer South Africa Pty Ltd	PerkinElmer SARS-CoV-2 Real-time RT-PCR assay	RT-PCR	Wallac Oy	
S Africa	Abafazi Healthcare Services (Pty) Ltd	PCLMD™ nCoV one step RT-PCR kit	RT-PCR	PCL Inc.	
S Africa	Optical Data (Pty) Ltd	Labgun Covid 19 Real Time PCR Test Kit	PCR	Labgenomics Co Ltd	
S Africa	Qhayisa 2014 Trading & Projects (Pty) Ltd t/a GDR Pharma (Pty)Ltd	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	PCR	Sansure BioTech Inc.	
S Africa	Call Tech Technologies (Pty)Ltd	Liferiver Novel Coronavirus (SARS-CoV-2) Real Time Multiplex RT-PCR kit	PCR	Shanghai ZJ Bio-Tech Co., Ltd.	

<http://www.sahpra.org.za/be-prepared-for-covid-19/>

Jurisdiction/ Country	Product name	Marketing Authorization Holder	Type	Date of Authorization	
Japan	2019-nCoV Fluorescence Detection Real-time RT-PCR Kit	Sysmex Corporation	Nucleic acid (RT-PCR)	March 27, 2020	
Japan	Loopamp Novel Coronavirus 2019 (SARS-CoV-2) Detection Kit	Eiken Chemical Co., Ltd.	Nucleic acid (LAMP)	March 31, 2020	
Japan	cobas SARS-CoV-2	Roche Diagnostics K.K.	Nucleic acid (RT-PCR)	April 7, 2020	

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Japan	TaqPath Real Time PCR Reagent Kit for SARS-CoV-2	Life Technologies Japan Ltd.	Nucleic acid (RT-PCR)	April 20, 2020	
Japan	Xpert Xpress SARS-CoV-2 'Cepheid'	Beckman Coulter, Inc	Nucleic acid (RT-PCR)	May 8, 2020	
Japan	MEBRIGHT SARS-CoV-2 Kit	AL LABORATORIES CO., LTD.	Nucleic acid (RT-PCR)	May 21, 2020	
Japan	FilmArray Respiratory Panel 2.1	bioMérieux Japan Ltd.	Nucleic acid (RT-PCR)	June 2, 2020	
Japan	GENECUBE SARS-CoV-2	TOYOBO CO., LTD.	Nucleic acid (RT-PCR)	July 2, 2020	
Japan	TRCReady SARS-CoV-2	TOSOH CORPORATION	Nucleic acid (TRC)	July 31, 2020	
Japan	SmartAmp SARS-CoV-2	K.K. DNAFORM	Nucleic acid (SmartAmp)	August 17, 2020	
Japan	Aptima SARS-CoV-2	Hologic Japan, Inc.	Nucleic acid (TMA)	August 18, 2020	
Japan	Ampdirect 2019-nCoV Detection Kit	SHIMADZU CORPORATION	Nucleic acid (RT-PCR)	September 8, 2020	
Japan	i-densy Pack SARS-CoV-2	ARKRAY Factory, Inc.	Nucleic acid (RT-PCR)	September 8, 2020	

https://www.mhlw.go.jp/stf/newpage_11332.html

Updated 22 September

Jurisdiction/ Country	Date EUA Issued	Manufacturer	Diagnostic (Letter of Author	Technology	Authorized Setting(s) ¹
USFDA	9/9/20	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	Wantai SARS-CoV-2 RT-PCR Kit	Molecular	H
USFDA	8/9/20	Verily Life Sciences	Verily COVID-19 RT-PCR Test	Molecular, Pooling	H
USFDA	4/9/20	BillionToOne, Inc.	qSanger-COVID-19 Assay	Molecular	H
USFDA	3/9/20	Roche Molecular Systems, Inc.	cobas SARS-CoV-2 & Influenza A/B	Molecular, Multi-analyte	H, M
USFDA	2/9/20	Bioeksen R&D Technologies Ltd.	Bio-Speedy Direct RT-qPCR SARS-CoV-2	Molecular	H
USFDA	1/9/20	Detectachem Inc.	MobileDetect Bio BCC19 (MD-Bio BCC19) Test Kit	Molecular	H
USFDA	1/9/20	OPTOLANE Technologies, Inc.	Kaira 2019-nCoV Detection Kit	Molecular	H

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USFDA	08/31/2020	T2 Biosystems, Inc.	T2SARS-CoV-2 Panel	Molecular	H
USFDA	08/31/2020	MiraDx	MiraDx SARS-CoV-2 RT-PCR assay	Molecular	H
USFDA	08/31/2020	Mammoth Biosciences, Inc.	SARS-CoV-2 DETECTR Reagent Kit	Molecular	H
USFDA	08/31/2020	BayCare Laboratories, LLC	BayCare SARS-CoV-2 RT PCR Assay	Molecular	H
USFDA	08/31/2020	Color Genomics, Inc.	Color COVID-19 Test Unmonitored Collection Kit	Home Collection Kit	
USFDA	08/28/2020	Patients Choice Laboratories, LLC	PCL SARS-CoV-2 Real-Time RT-PCR Assay	Molecular	H
USFDA	08/28/2020	DxTerity Diagnostics, Inc.	DxTerity SARS-CoV-2 RT PCR CE Test	Molecular, Home Collection, Screening, Saliva	H
USFDA	08/26/2020	Cuur Diagnostics	Cuur Diagnostics SARS-CoV-2 Molecular Assay	Molecular	H
USFDA	08/25/2020	Fluidigm Corporation	Advanta Dx SARS-CoV-2 RT-PCR Assay	Molecular	H
USFDA	08/25/2020	QDx Pathology Services	QDX SARS-CoV-2 Assay	Molecular, Home Collection	H
USFDA	08/21/2020	Texas Department of State Health Services, Laboratory Services Section	Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay	Molecular	H
USFDA	08/17/2020	ZhuHai Sinochips Bioscience Co., Ltd.	COVID-19 Nucleic Acid RT-PCR Test Kit	Molecular	H
USFDA	08/15/2020	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	SalivaDirect	Molecular	H
USFDA	08/13/2020	Pro-Lab Diagnostics	Pro-AmpRT SARS-CoV-2 Test	Molecular	H
USFDA	11/8/20	Biomeme, Inc.	Biomeme SARS-CoV-2 Real-Time RT-PCR Test	Molecular	H
USFDA	11/8/20	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 RNA STAR	Molecular	H
USFDA	10/8/20	Solaris Diagnostics	Solaris Multiplex SARS-CoV-2 Assay	Molecular	H
USFDA	7/8/20	George Washington University Public Health Laboratory	GWU SARS-CoV-2 RT-PCR Test	Molecular	H

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US FDA	6/8/20	Helix OpCo LLC (dba Helix)	Helix COVID-19 NGS Test	Molecular	H
US FDA	5/8/20	Vela Operations Singapore Pte Ltd	ViroKey SARS-CoV-2 RT-PCR Test	Molecular	H
US FDA	3/8/20	Wren Laboratories LLC	Wren Laboratories COVID-19 PCR Test	Molecular	H
US FDA	3/8/20	Ethos Laboratories	Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay	Molecular, Home Collection	H
US FDA	3/8/20	Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute	Cleveland Clinic SARS-CoV-2 Assay	Molecular	H
US FDA	3/8/20	Poplar Healthcare	Poplar SARS-CoV-2 TMA Pooling assay	Molecular, Sample Pooling	H
US FDA	3/8/20	ISPM Labs, LLC dba Capstone Healthcare	Genus SARS-CoV-2 Assay	Molecular	H
US FDA	07/31/2020	Xiamen Zeesan Biotech Co., Ltd.	SARS-CoV-2 Test Kit (Real-time PCR)	Molecular	H
US FDA	07/31/2020	University of California San Diego Health	UCSD RC SARS-CoV-2 Assay	Molecular, Pooling	H
US FDA	07/30/2020	Clinical Reference Laboratory, Inc.	CRL Rapid Response	Molecular, Home Collection	H
US FDA	07/27/2020	Eli Lilly and Company	Lilly SARS-CoV-2 Assay	Molecular	H
US FDA	07/27/2020	Sandia National Laboratories	SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay	Molecular	H
US FDA	07/24/2020	Jiangsu CoWin Biotech Co., Ltd.	Novel Coronavirus (SARS-CoV-2) Fast Nucleic Acid Detection Kit (PCR-Fluorescence Probing)	Molecular	H
US FDA	07/23/2020	Helix OpCo LLC (dba Helix)	Helix COVID-19 Test	Molecular	H
US FDA	07/21/2020	DiaCarta, Inc.	QuantiVirus SARS-CoV-2 Multiplex Test Kit	Molecular	H
US FDA	07/17/2020	Access Genetics, LLC	OraRisk COVID-19 RT-PCR	Molecular	H
US FDA	07/16/2020	Boston Heart Diagnostics	Boston Heart COVID-19 RT-PCR Test	Molecular	H

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US FDA	07/15/2020	Quest Diagnostics Infectious Disease, Inc.	Quest Diagnostics HA SARS-CoV-2 Assay	Molecular, Home Collection	H
US FDA	07/13/2020	KogeneBiotech Co., Ltd.	PowerChek 2019-nCoV Real-time PCR Kit	Molecular	H
US FDA	07/13/2020	Trax Management Services Inc.	PhoenixDx SARS-CoV-2 Multiplex	Molecular	H
US FDA	07/13/2020	Compass Laboratory Services, LLC	Compass Laboratory Services SARS-CoV2 Assay	Molecular, Home Collection	H
US FDA	10/7/20	Boston Medical Center	BMC-CReM COVID-19 Test	Molecular	H
US FDA	9/7/20	UCSF Health Clinical Laboratories, UCSF Clinical Labs at China Basin	SARS-CoV-2 RNA DETECTR Assay	Molecular	H
US FDA	9/7/20	BioSewoom, Inc.	Real-Q 2019-nCoV Detection Kit	Molecular	H
US FDA	8/7/20	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay	Molecular	H
US FDA	7/7/20	Enzo Life Sciences, Inc.	AMPIPROBE SARS-CoV-2 Test System	Molecular	H
US FDA	7/7/20	Access Bio, Inc.	CareStart COVID-19 MDx RT-PCR	Molecular	H
US FDA	7/7/20	Gene By Gene	Gene By Gene SARS-CoV-2 Detection Test	Molecular	H
US FDA	2/7/20	Centers for Disease Control and Prevention (CDC)	Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay	Molecular, Multi-analyte	H
US FDA	1/7/20	CENTOGENE US, LLC	Centofast-SARS-CoV-2 RT-PCR Assay	Molecular	H
US FDA	06/30/2020	Psomagen, Inc.	Psoma COVID-19 RT Test	Molecular	H
US FDA	06/30/2020	TNS Co., Ltd (Bio TNS)	COVID-19 RT-PCR Peptide Nucleic Acid (PNA) kit	Molecular	H

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US FDA	06/29/2020	LifeHope Labs	LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel	Molecular	<u>H</u>
US FDA	06/29/2020	Acupath Laboratories, Inc.	Acupath COVID-19 Real-Time (RT-PCR) Assay	Molecular	<u>H</u>
US FDA	06/26/2020	Inform Diagnostics, Inc.	Inform Diagnostics SARS-CoV-2 RT-PCR Assay	Molecular	<u>H</u>
US FDA	06/25/2020	Diagnostic Solutions Laboratory, LLC	DSL COVID-19 Assay	Molecular	<u>H</u>
US FDA	06/25/2020	PreciGenome LLC	FastPlex Triplex SARS-CoV-2 detection kit (RT-Digital PCR)	Molecular	<u>H</u>
US FDA	06/25/2020	PlexBio Co., Ltd.	IntelliPlex SARS-CoV-2 Detection Kit	Molecular	<u>H</u>
US FDA	06/24/2020	University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory	MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay	Molecular	<u>H</u>
US FDA	06/23/2020	HealthQuest Esoterics	HealthQuest Esoterics TaqPath SARS-CoV-2 Assay	Molecular	<u>H</u>
US FDA	06/23/2020	University of Alabama at Birmingham Fungal Reference Lab	FRL SARS CoV-2 Test	Molecular	<u>H</u>
US FDA	06/23/2020	Gencurix, Inc.	GenePro SARS-CoV-2 Test	Molecular	<u>H</u>
US FDA	06/18/2020	Jiangsu Bioperfectus Technologies Co., Ltd.	COVID-19 Coronavirus Real Time PCR Kit	Molecular	<u>H</u>
US FDA	06/18/2020	3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.	TRUPCR SARS-CoV-2 Kit	Molecular	<u>H</u>
US FDA	06/17/2020	The Ohio State University Wexner Medical Center	OSUWMC COVID-19 RT-PCR test	<u>Molecular</u>	H
US FDA	06/17/2020	Omnipathology Solutions Medical Corporation	Omni COVID-19 Assay by RT-PCR	Molecular	<u>H</u>
US FDA	06/15/2020	Applied BioCode, Inc.	BioCode SARS-CoV-2 Assay	Molecular	<u>H</u>
US FDA	06/13/2020	Kaiser Permanente Mid-Atlantic States	KPMAS COVID-19 Test	Molecular, Home Collection	<u>H</u>

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US FDA	12/6/20	RTA Laboratories Biological Products Pharmaceutical and Machinery Industry	Diagnovital SARS-CoV-2 Real-Time PCR Kit	Molecular	<u>H</u>
US FDA	10/6/20	Tide Laboratories, LLC	DTPM COVID-19 RT-PCR Test	Molecular	<u>H</u>
US FDA	10/6/20	Cue Health Inc.	Cue COVID-19 Test	Molecular	<u>H, M, W</u>
US FDA	9/6/20	ChromaCode Inc.	HDPCR SARS-CoV-2 Assay	Molecular	<u>H</u>
US FDA	10/6/20	TBG Biotechnology Corp.	ExProbe SARS-CoV-2 Testing Kit	Molecular	<u>H</u>
US FDA	9/6/20	Illumina, Inc.	Illumina COVIDSeq Test	Molecular	<u>H</u>
US FDA	9/6/20	ChromaCode Inc.	HDPCR SARS-CoV-2 Assay	Molecular	<u>H</u>
US FDA	8/6/20	Euroimmun US, Inc.	<u>EURORealTime SARS-Cov- 2</u>	Molecular	<u>H</u>
US FDA	5/6/20	Genetron Health (Beijing) Co., Ltd.	<u>Genetron SARS-CoV-2 RNA Test</u>	Molecular	<u>H</u>
US FDA	06/04/2020	Phosphorus Diagnostics LLC	Phosphorus COVID-19 RT-	Molecular, Home Collection	<u>H</u>
US FDA	05/28/2020	PrivaPath Diagnostics, Inc.	LetsGetChecked	Molecular	<u>H</u>
US FDA	05/21/2020	dba SpectronRx	Hymon SARS-CoV-2 Test	Molecular	<u>H</u>
US FDA	05/21/2020	BioCore Co., Ltd.	BioCore 2019-nCoV Real	Molecular	<u>H</u>
US FDA	05/21/2020	SolGent Co., Ltd.	DiaPlexQ Novel	Molecular	<u>H</u>
US FDA	05/21/2020	Seasun Biomaterials, Inc.	AQ-TOP COVID-19 Rapid Detection Kit (395KB)	Molecular	<u>H</u>
US FDA	05/21/2020	P23 Labs, LLC.	P23 Labs TaqPath SARS- CoV-2 Assay (372KB)	Molecular	<u>H</u>
US FDA	05/18/2020	Quidel Corporation	Lyra Direct SARS-CoV-2 Assay (396KB)	Molecular	<u>H</u>
US FDA	05/15/2020	Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit (307KB)	Molecular	<u>H</u>
US FDA	05/15/2020	Fulgent Therapeutics, LLC	Fulgent COVID-19 by RT- PCR Test (288KB)	Molecular	<u>H</u>
US FDA	05/15/2020	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel (287KB)	Molecular	<u>H</u>
US FDA	05/14/2020	Hologic, Inc.	Aptima SARS-CoV-2 assay (131KB)	Molecular	<u>H</u>

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US FDA		GeneMatrix, Inc.	NeoPlex COVID-19 Detection Kit (135KB)	Molecular	<u>H</u>
US FDA	05/13/2020	Applied DNA Sciences, Inc.	Linea COVID-19 Assay Kit	Molecular	<u>H</u>
US FDA	11/5/20	1drop Inc.	1copy COVID-19 qPCR	Molecular	<u>H</u>
US FDA	11/5/20	Abbott Molecular Inc.	Alinity m SARS-CoV-2	Molecular	<u>H</u>
US FDA	6/5/20	Sherlock BioSciences, Inc.	<u>Sherlock CRISPR SARS-CoV-2 Kit</u>	Molecular	H
US FDA	6/5/20	BioMérieux SA	<u>SARS-COV-2 R-GENE</u>	Molecular	H
US FDA	5/5/20	Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company)	<u>FTD SARS-CoV-2</u>	Molecular	H
US FDA	4/5/20	Sansure BioTech Inc.	<u>Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)</u>	Molecular	H
US FDA	1/5/20	Bio-Rad Laboratories, Inc	<u>Bio-Rad SARS-CoV-2 ddPCR Test</u>	Molecular	H
US FDA	1/5/20	BioFire Diagnostics, LLC	<u>BioFire Respiratory Panel 2.1 (RP2.1) (400KB)</u>	Molecular, Multi-analyte	H, M
US FDA	04/29/2020	LabGenomics Co., Ltd.	<u>LabGun COVID-19 RT-PCR Kit</u>	Molecular	H
US FDA	04/29/2020	Rheonix, Inc.	<u>Rheonix COVID-19 MDx Assay</u>	Molecular	H
US FDA	04/27/2020	SEASUN BIOMATERIALS	<u>U-TOP COVID-19 Detection Kit</u>	Molecular	H
US FDA	04/23/2020	SD Biosensor, Inc.	<u>STANDARD M nCoV Real-Time Detection Kit</u>	Molecular	H
US FDA	04/22/2020	altona Diagnostics GmbH	<u>RealStar SARS-CoV02 RT-PCR Kits U.S.</u>	Molecular	H
US FDA	04/21/2020	Seegene, Inc.	<u>Allplex 2019-nCoV Assay</u>	Molecular	H

LISTED COVID-19 NAT ASSAYS

US FDA	04/20/2020	Trax Management Services Inc.	<u>PhoenixDx 2019-CoV</u>	Molecular	H
US FDA	04/18/2020	OSANG Healthcare	<u>GeneFinder COVID-19 Plus RealAmp Kit</u>	Molecular	H
US FDA	04/17/2020	Fosun Pharma USA Inc.	<u>Fosun COVID-19 RT-PCR Detection Kit</u>	Molecular	H
US FDA	04/16/2020	KorvaLabs Inc.	<u>Curative-Korva SARS-Cov-2 Assay</u>	Molecular	H
US FDA	04/16/2020	GenoSensor, LLC	<u>GS™ COVID-19 RT-PCR KIT</u>	Molecular	H
US FDA	4/15/2020	Maccura Biotechnology (USA) LLC	<u>SARS-CoV-2 Fluorescent PCR Kit</u>	Molecular	H
US FDA	10/4/20	Atila BioSystems, Inc.	<u>iAMP COVID-19 Detection Kit</u>	Molecular	H
US FDA	8/4/20	DiaCarta, Inc	<u>QuantiVirus SARS-CoV-2 Test kit</u>	Molecular	H
US FDA	8/4/20	Becton, Dickinson & Company	<u>BD SARS-CoV-2Reagents for BD MAX System</u>	Molecular	H, M
US FDA	7/4/20	InBios International, Inc	<u>Smart Detect SARS-CoV-2 rRT-PCR Kit</u>	Molecular	H
US FDA	6/4/20	Gnomegen LLC	<u>Gnomegen COVID-19 RT-Digital PCR Detection Kit</u>	Molecular	H
US FDA	3/4/20	Co-Diagnostics, Inc.	<u>Logix Smart Coronavirus Disease 2019 (COVID-19) Kit</u>	Molecular	H
US FDA	3/4/20	ScienCell Research Laboratories	<u>ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit</u>	Molecular	H
US FDA	3/4/20	Luminex Corporation	<u>ARIES SARS-CoV-2 Assay</u>	Molecular	H, M

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US FDA	2/4/20	Becton, Dickinson & Company (BD)	<u>BioGX SARS-CoV-2 Reagents for BD MAX System</u>	Molecular	H, M
US FDA	1/4/20	Ipsium Diagnostics, LLC	<u>COV-19 IDx assay</u>	Molecular	H
US FDA	03/30/2020	QIAGEN GmbH	<u>QIAstat-Dx Respiratory SARS-CoV-2 Panel</u>	Molecular	H, M
US FDA	03/30/2020	NeuMoDx Molecular, Inc.	<u>NeuMoDx SARS-CoV-2 Assay</u>	Molecular	H, M
US FDA	03/27/2020	Luminex Molecular Diagnostics, Inc.	<u>NxTAG CoV Extended Panel Assay</u>	Molecular	H
US FDA	03/27/2020	Abbott Diagnostics Scarborough, Inc.	<u>ID NOW COVID-19</u>	Molecular	H, M, W
US FDA	03/26/2020	BGI Genomics Co. Ltd	<u>Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV</u>	Molecular	H
US FDA	03/25/2020	Avellino Lab USA, Inc.	<u>AvellinoCoV2 test</u>	Molecular	H
US FDA	03/24/2020	PerkinElmer, Inc.	<u>PerkinElmer New Coronavirus Nucleic Acid Detection Kit</u>	Molecular	H
US FDA	03/23/2020	Mesa Biotech Inc.	<u>Accula SARS-Cov-2 Test</u>	Molecular	H, M, W
US FDA	03/23/2020	BioFire Defense, LLC	<u>BioFire COVID-19 Test</u>	Molecular	H, M
US FDA	03/20/2020	Cepheid	<u>Xpert Xpress SARS-CoV-2 test</u>	Molecular	H, M, W
US FDA	03/20/2020	Primerdesign Ltd.	<u>Primerdesign Ltd COVID-19 genesig Real-Time PCR assay</u>	Molecular	H
US FDA	03/19/2020	GenMark Diagnostics, Inc.	<u>ePlex SARS-CoV-2 Test</u>	Molecular	H, M
US FDA	03/19/2020	DiaSorin Molecular LLC	<u>Simplexa COVID-19 Direct assay</u>	Molecular	H, M
US FDA	03/18/2020	Abbott Molecular	<u>Abbott RealTime SARS-CoV-2 assay</u>	Molecular	H
US FDA	03/17/2020	Quest Diagnostics Infectious Disease, Inc.	<u>Quest SARS-CoV-2 rRT-PCR</u>	Molecular	H

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US FDA	03/17/2020	Quidel Corporation	<u>Lyra SARS-CoV-2 Assay</u>	Molecular	H
US FDA	03/16/2020	Laboratory Corporation of America (LabCorp)	<u>COVID-19 RT-PCR Test</u>	Molecular	H
US FDA	03/16/2020	Hologic, Inc.	<u>Panther Fusion SARS-CoV-2</u>	Molecular	H
US FDA	03/13/2020	Thermo Fisher Scientific, Inc.	<u>TaqPath COVID-19 Combo Kit</u>	Molecular	H
US FDA	12/3/20	Roche Molecular Systems, Inc. (RMS)	<u>cobas SARS-CoV-2</u>	Molecular	H, M
US FDA	02/29/2020	Wadsworth Center, New York State Department of Public Health's (CDC)	<u>New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR</u>	Molecular	H
US FDA	4/2/20	Centers for Disease Control and Prevention's (CDC)	<u>CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC)</u>	Molecular	H

Authorized settings include the following:

H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.

W - Patient care settings operating under a CLIA Certificate of Waiver.

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-molecular>

Jurisdiction/ Country	Name of the assay	Manufacturer	Device type	Laboratory of point of Care test	Date authorized
Canada	aqPath™ COVID-19 Combo Kit	Thermo Fisher (United States)	Nucleic acid technology	Lab-based test	3/18/20
Canada	Xpert Xpress SARS-CoV-2	Cepheid (United States)	Nucleic acid technology	Lab-based test, Point of care test	3/24/20
Canada	Abbott Realtime SARS-CoV-2 Assay	Abbott Molecular Inc. (United States)	Nucleic acid Technology Lab-based test		3/25/20
Canada	LYRA SARS-COV-2 ASSAY	Diagnostic Hybrids, Inc. - Also trading as Quidel Corporation (United States)	Nucleic acid technology	Lab-based test	3/25/20
Canada	SARS-CoV-2 Assay (Panther Fusion System)	Hologic (United States)	Nucleic acid technology	Lab-based test	3/25/20

LISTED COVID-19 NAT ASSAYS

Canada	NxTAG COV Extended Panel	Luminex Molecular Diagnostics, Inc. (Canada)	Nucleic acid technology	Lab-based test	3/26/20
Canada	1copy COVID-19 QPCR Multi Kit	1DROP INC. (imported by Luminarie Canada Inc.) (South Korea)	Nucleic acid technology	Lab-based test	3/30/20
Canada	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	Solgent Co., Ltd. (South Korea)	Nucleic acid technology	Lab-based test	4/5/20
Canada	PerkinElmer New Coronavirus Nucleic Acid Detection Kit	PerkinElmer, Inc. (United States)	Nucleic Acid Technology	Lab-based test	4/7/20
Canada	Allplex 2019-NCov Assay	Seegene Inc. (Korea)	Nucleic Acid Technology	Lab-based test	4/9/20
Canada	DiaSorin Simplexa COVID-19 Direct Molecular Assay on the LIAISON MDX Instrument	DiaSorin Molecular LLC (United States)	Nucleic Acid technology	Lab-based test	4/9/20
Canada	BD SARS-CoV-2 Reagents For BD Max System	Becton Dickinson and Company (Canada)	Nucleic acid technology	Lab-based test	4/19/20
Canada	Genefinder CoVid-19 Plus Realamp Kit	Osang Healthcare Co., Ltd. (South Korea)	Nucleic Acid technology	Lab-based test	4/21/20
Canada	Biofire COVID - 19 Test & Biofire COVID - 19 External Control Test Kit (+)	Biofire Defense LLC (United States)	Nucleic Acid Technology	Lab-based test	5/4/20
Canada	Real-time Fluorescent RT-PCR Kit For Detecting SARS-2019-nCoV	BGI Americas Corp. (China)	Nucleic Acid Technology	Lab-based test	5/4/20
Canada	Biofire Respiratory Panel 2.1 (RP2.1)	Biofire Diagnostics, LLC. (United States)	Nucleic acid technology	Lab-based test	5/26/20
Canada	Qiasat-DX Respiratory SARS-CoV-2 Panel	Qiagen GmbH (Germany)	Nucleic acid technology	Lab-based test	5/27/20
Canada	Aries SARS-CoV-2 Assay	Luminex Corporation (United States)	Nucleic acid technology	Lab-based test	6/11/20

LISTED COVID-19 NAT ASSAYS

Canada	Biomeme SARS-CoV-2 Go-Strips for use with Biomeme's Franklin Real-Time PCR System	Biomeme Inc. (United States)	Nucleic acid technology	Lab-based test	6/30/20
Canada	Lyra Direct Sars-Cov-2 Assay	Diagnostic Hybrids, Inc. - Also Trading as Quidel Corporation (United States)	Nucleic acid technology	Lab-based test	7/21/20
Canada	FTD SARS-COV-2	Fast Track Diagnostics Luxembourg S.A.R.L. (Luxembourg)	Nucleic acid technology	Lab-based test	7/23/20
Canada	cobas SARS-CoV-2	Roche (United States)	Nucleic acid technology	Lab-based test	Initial authorization - 2020-03-18 Amended authorization 2020-04-09
Canada	Sars-Cov-2 Virus Detection Diagnostic Kit (Rt-Qpcr Method)	Ningbo Health Gene Technologies Co., Ltd (China)	Nucleic Acid Technology	Lab-based test	8/10/20
Canada	Aptima Sars-Cov-2 Assay Kit And Controls Kit, Aptima Multitest Swab Specimen Collection Kit For Sars-Cov-2 Specimen Collection	Hologic, Inc. (United States)	Nucleic Acid Technology	Lab-based test	8/14/20

<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html#wb-auto-5>



Jurisdiction/ Country	Name of the test	Laboratory or point of care	Type of the Test	Australian sponsor	Manufacturer
Australia	genesig® Real-Time PCR Coronavirus COVID-19	Laboratory	Nucleic Acid Test	Pacific Laboratory Products Pty Ltd	Primer Design Limited (United Kingdom)
Australia	NeuMoDx™ SARS-CoV-2 Assay	Laboratory	Nucleic Acid Test	Qiagen Pty Ltd	NeuMoDx Molecular Inc (United States Of America)

LISTED COVID-19 NAT ASSAYS

Australia	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing)	Laboratory	Nucleic Acid Test		Da An Gene Co Ltd of Sun Yat-sen University (China)
Australia	SARS-CoV-2 RT-qPCR Reagent Kit	Laboratory	Nucleic Acid Test	PerkinElmer	Wallac Oy (Finland)
Australia	eri-Q PCR 316 COVID-19 Detection Kit	Laboratory	Nucleic Acid Test	Covid Solutions Pty Ltd	MiCoBioMed Co Ltd (Korea - Republic of)
Australia	Alinity m SARS-CoV-2 AMP Kit	Laboratory	Nucleic Acid Test	Abbott Australasia Pty Ltd Molecular Division	Abbott Molecular Inc (United States Of America)
Australia	CareStart™ COVID-19 MDx RT-PCR	Laboratory	Nucleic Acid Test	Pantonic Health Pty Ltd	Access Bio Inc (United States Of America)
Australia	ViroKey™ SARS-CoV-2 RT-PCR Test v2.0	Laboratory	Nucleic Acid Test	Vela Diagnostics Australia Pty Ltd	Vela Operations Singapore Pte Ltd (Singapore)
Australia	Logix Smart™ Coronavirus Disease 2019 (COVID-19) Kit	Laboratory	Nucleic Acid Test	Gene Target Solutions Pty Ltd	Co-Diagnostics Inc (United States Of America)
Australia	Simplexa™ COVID-19 Direct	Laboratory	Nucleic Acid Test	DiaSorin Australia Pty Ltd	DiaSorin Molecular LLC (United States Of America)
Australia	SARS-COV-2 R-GENE®	Laboratory	Nucleic Acid Test	Biomerieux Australia Pty Ltd	Biomerieux SA (France)
Australia	BioFire Respiratory Panel 2.1 plus (RP2.1plus)	Laboratory	Nucleic Acid Test	Biomerieux Australia Pty Ltd	BioFire Diagnostics LLC
Australia	GeneFinder™ COVID-19 Plus RealAmp Kit	Laboratory	Nucleic Acid Test	Elitechgroup Australia Pty Ltd	OSANG Healthcare Co Ltd (Korea - Republic of)
Australia	Bio-Core 2019-nCoV Real Time PCR Kit	Laboratory	Nucleic Acid Test		BioCore Co Ltd (Korea - Republic of)

LISTED COVID-19 NAT ASSAYS

Australia	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Laboratory	Nucleic Acid Test	Allsafe Medical Pty Ltd	Sansure Biotech Inc (China)
Australia	Aptima® SARS-CoV-2 Assay	Laboratory	Nucleic Acid Test	Hologic (Australia & New Zealand) Pty Ltd	Hologic Inc (United States Of America)
Australia	GB SARS-CoV-2 Real Time RT-PCR	Laboratory	Nucleic Acid Test	Labtest Medical Pty Ltd	General Biologicals Corp (Taiwan)
Australia	LabGun™ COVID-19 RT-PCR Kit	Laboratory	Nucleic Acid Test	Viso Aesthetics Pty Ltd	Labgenomics Co Ltd (Korea - Republic of)
Australia	Allplex™ SARS-CoV-2 Assay	Laboratory	Nucleic Acid Test	Integrated Sciences Pty Ltd	Seegene Inc (Korea - Republic of)
Australia	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	Laboratory	Nucleic Acid Test	PerkinElmer	Suzhou Sym-Bio Lifescience Co Ltd (China)
Australia	Elecsys Anti-SARS-CoV-2	Laboratory	Nucleic Acid Test	Roche Diagnostics Australia Pty Limited	Roche Diagnostics GmbH (Germany)
Australia	COVID-19 (SARS-CoV-2) Nucleic Acid Test kit	Laboratory	Nucleic Acid Test	Australian Trefoil Health Technologies Pty Ltd	Wuhan EasyDiagnosis Biomedicine Co Ltd (China)
Australia	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit	Laboratory	Nucleic Acid Test	Alma Lasers Australia Pty Ltd	Shanghai Fosun Long March Medical Science Co Ltd (China)
Australia	QIAstat-Dx® Respiratory SARS-CoV-2 Panel	Laboratory	Nucleic Acid Test	Qiagen Pty Ltd	Qiagen GmbH
Australia	COVID-19 Coronavirus Real Time PCR Kit	Laboratory	Nucleic Acid Test	Sonictec	Jiangsu Bioperfectus Technologies Co Ltd (China)
Australia	Aridia COVID-19 Real-Time PCR Test	Laboratory	Nucleic Acid Test	MD Solutions Australasia Pty Ltd	CTK Biotech Inc (United States Of America)

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Australia	EasyNat Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal	Laboratory	Nucleic Acid Test	Ustar Biotechnologies (Hangzhou) Co Ltd (China)	Ustar Biotechnologies (Hangzhou) Co Ltd (China)
Australia	Abbott RealTime SARS-CoV-2	Laboratory	Nucleic Acid Test	bbott Australasia Pty Ltd	Molecular Division Abbott Molecular Inc (United States Of America)
Australia	BD SARS-CoV-2 Reagents for BD MAX™ System	Laboratory	Nucleic Acid Test	Becton Dickinson Pty Ltd	Becton Dickinson and Company (United States Of America)
Australia	PowerChek™ 2019-nCoV Real-time PCR Kit	Laboratory	Nucleic Acid Test	World Systems Corporation Pty Ltd	Kogene Biotech Co Ltd (Korea - Republic of)
Australia	EasyScreen™ SARS-CoV-2 Detection Kit	Laboratory	Nucleic Acid Test	Genetic Signatures Ltd	Genetic Signatures Ltd (Australia)
Australia	Real-time fluorescent RT-PCR kit for detecting SARS-CoV-2	Laboratory	Nucleic Acid Test	BGI Health (AU) Company Pty Ltd	BGI Europe A/S (Denmark)
Australia	Allplex™ 2019-nCoV Assay	Laboratory	Nucleic Acid Test	Integrated Sciences Pty Ltd	Seegene Inc (Korea - Republic of)
Australia	AusDiagnostics respiratory virus panel (including SARS-CoV-2) test	Laboratory	Nucleic Acid Test	AusDiagnostics Pty Ltd	AusDiagnostics Pty Ltd (Australia)
Australia	cobas® SARS-CoV-2	Laboratory	Nucleic Acid Test	Roche Diagnostics Australia Pty Limited	Roche Molecular Systems Inc (USA)
Australia	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 genes)	Laboratory	Nucleic Acid Test	Icon International Pty Ltd t/a Icon Medipharm	Shanghai ZJ Bio-Tech Co Ltd (China)

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Australia	Panther Fusion® SARS-CoV-2 Assay (Panther Fusion® System)	Laboratory	Nucleic Acid Test	Hologic (Australia & New Zealand) Pty Ltd	Hologic Inc (USA)
Australia	TaqPath COVID-19 Combo Kit	Laboratory	Nucleic Acid Test	Life Technologies Australia Pty Ltd	Life Technologies Corporation (USA)
Australia	VIASURE SARS-CoV-2 Real Time PCR Detection Kit	Laboratory	Nucleic Acid Test	Abacus dx Pty Ltd	CerTest Biotec SL (Spain)
Australia	VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit	Laboratory	Nucleic Acid Test	Becton Dickinson Pty Ltd	CerTest Biotec SL (Spain)
Australia	Xpert® Xpress SARS-CoV-2	Laboratory/POCT	Nucleic Acid Test	Cepheid Holdings Pty Ltd	Cepheid (USA)

<https://www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia>

Jurisdiction/ Country	Applicant	Name of test	Date approved	Information Link	
Singapore	Diagnostics Development Hub (DxD)	FORTITUDE KIT 2.0	7-Feb-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/dxd-hub_fortitude-kit-2-0e_provisional-authorisation-for-covid-19-tests_02062020.pdf	
Singapore	Veredus Laboratories Pte Ltd	VereCoV™ Detection Kit	18-Feb-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/veredus-laboratories-pte-ltd.pdf	
Singapore	AITbiotech Pte Ltd	abTES™ COVID-19 qPCR I Kit	5-Mar-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/aitbiotech-ltd.pdf	
Singapore	DSO National Laboratories	Real-Time PCR Assay for the Detection of SARS-CoV-2 Virus	10-Mar-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/dso-national-laboratories.pdf	

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Singapore	Roche Diagnostics Asia Pacific Pte Ltd	Cobas® SARS-CoV-2	19-Mar-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/roche_provisional-authorisation-for-covid-19-tests_17042020.pdf	
Singapore	JN Medsys Pte Ltd	ProTect™ COVID-19 RT-qPCR Kit	19-Mar-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/jn-medsys_provisional-authorisation-for-covid-19_17042020.pdf	
Singapore	Life Technologies Holdings Pte Ltd	TaqPath™ COVID-19 Combo Kit	20-Mar-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/life-technologies_provisional-authorisation-for-covid-19-tests_12052020.pdf	
Singapore	Biowalker Pte Ltd	Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)	24-Mar-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biowalker-pte-ltd.pdf	
Singapore	SPD Scientific Pte Ltd	Cepheid® Xpert® Xpress SARS-CoV-2	26-Mar-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/spd-scientific-pte-ltd.pdf	
Singapore	MIRXES Pte Ltd	MIRXES FORTITUDE KIT 2.0	30-Mar-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/mirxes_provisional-authorisation-for-covid-19-tests_17042020.pdf	
Singapore	Acumen Research Laboratories	Acu-Corona™ 2.0	31-Mar-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/acumen-research-laboratories-pte-ltd.pdf	

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Singapore	Credo Diagnostics Biomedical Pte Ltd	VitaPCR™ SARS-CoV-2 Assay	1-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/credo-diagnostics-biomedical-pte-ltd.pdf	
Singapore	Abbott Laboratories (Singapore) Pte Ltd	Abbott RealTime SARS-CoV-2 assay	1-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/abbott-laboratories-(singapore)-pte-ltd.pdf	
Singapore	All Eights (Singapore) Pte Ltd	Seegene Allplex™ 2019-nCoV Assay	2-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/all-eights-(singapore)-pte-ltd.pdf	
Singapore	Acumen Research Laboratories Pte Ltd	Acu-Corona 3.0	13-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/acumen-research-laboratories-pte-ltd---acu-corona-3-0.pdf	
Singapore	Vela Operations Singapore Pte Ltd	ViroKey SARS-CoV-2 RT-PCR Test	15-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-15 April 2020mdb/vela provisional- authorisation-for-covid-19- tests 17042020.pdf	
Singapore	PerkinElmer Singapore Pte Ltd	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	20-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/perkinelmer provisional- authorisation-for-covid-19- tests 24042020.pdf	
Singapore	BioWalker Pte Ltd	BioWalker SARS-CoV-2 Assay	20-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biowalker provisional- authorisation-for-covid-19- tests 24042020.pdf	

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Singapore	Medicell Pharmaceutical (S) Pte Ltd	Sansure Biotech Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit	23-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/medicell_provisional-authorisation-for-covid-19-tests_24042020.pdf	
Singapore	Diagnostics Development Hub (DxD)	Fortitude™ Kit 2.1	30-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/dxd_provisional-authorisation-for-covid-19-tests_05052020.pdf	
Singapore	Abbott SARS-CoV-2 IgG – ARCHITECT assay	Abbott Laboratories (S) Pte Ltd	30-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/genomax_provisional-authorisation-for-covid-19-tests_05052020.pdf	
Singapore	Genomax Technologies Pte Ltd	Allplex 2019-nCoV Assay	30-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/genomax_provisional-authorisation-for-covid-19-tests_05052020.pdf	
Singapore	BioWalker Pte Ltd	BioWalker SARS-CoV-2 Assay 2.0	30-Apr-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biowalker_provisional-authorisation-for-covid-19-tests_05052020.pdf	
Singapore	Liferiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	Tanglin Cardiology Pte Ltd	4-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/tanglin_provisional-authorisation-for-covid-19-tests_05052020.pdf	

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Singapore	Becton Dickinson Holding Ptd Ltd	BD SARS-CoV-2 Reagents for BD MAXTM System	6-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/becton-dickinson_provisional-authorisation-for-covid-19-tests_06052020.pdf	
Singapore	Biomed Diagnostics Pte Ltd	Liferiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	6-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biomed_provisional-authorisation-for-covid-19-tests_06052020.pdf	
Singapore	Biomed Diagnostics Pte Ltd	Luminex NxTAG® CoV Extended Panel Assay	8-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biomed_luminex_provisional-authorisation-for-covid-19-tests_12052020.pdf	
Singapore	MiRXES Pte Ltd	MiRXES Fortitude Kit 2.1	8-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/mirxes_fortitude-2-1_provisional-authorisation-for-covid-19-tests_12052020.pdf	
Singapore	BioMérieux Singapore Pte Ltd	BioFire® Respiratory Panel 2.1 (RP2.1)	14-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biomérieux_provisional-authorisation-for-covid-19-tests_15052020.pdf	
Singapore	SPD Scientific Pte Ltd	GeneFinder™ COVID-19 Plus RealAmp Kit	14-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/spd_genefinder_provisional-authorisation-for-covid-19-tests_15052020.pdf	

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Singapore	SDT Molecular Pte Ltd	altona Diagnostics RealStar™ SARS-CoV-2 RT-PCR Kit 1.0	15-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/sdt_provisional-authorisation-for-covid-19-tests_19052020.pdf	
Singapore	AMT Pte Ltd	AMT RESOLUTE 1.0	20-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/amt_provisional-authorisation-for-covid-19-tests_22052020.pdf	
Singapore	Novena Global Healthcare Pte Ltd	Fosun Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit	27-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/novena_fosun_provisional-authorisation-for-covid-19-tests_28052020.pdf	
Singapore	Siemens Healthcare Pte Ltd	FTD™ SARS-CoV-2	27-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/siemens_ftd_provisional-authorisation-for-covid-19-tests_28052020.pdf	
Singapore	Qiagen Singapore Pte. Ltd.	QIAstat-Dx® Respiratory SARS-CoV-2 Panel	28-May-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/qiagen_qiastat_provisional-authorisation-for-covid-19-tests_02062020.pdf	
Singapore	Veredus Laboratories Pte Ltd	VereRTCoV™ SARS-CoV-2 Real-Time RT-PCR 2.0	3-Jun-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/veredus_verertcov_provisional-authorisation-for-covid-19-tests_08062020.pdf	

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Singapore	XIN Pte Ltd	Fosun Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit	16-Jun-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/xin_fosun_provisional-authorisation-for-covid-19-tests_19062020.pdf	
Singapore	Credo Diagnostics Biomedical Pte Ltd	VitaPCR™ SARS-CoV-2 Gen 2 Assay	16-Jun-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/credo_vitapcr_provisional-authorisation-for-covid-19-tests_19062020.pdf	
Singapore	Biomed Diagnostics Pte Ltd	Luminex ARIES® SARS-CoV-2 Assay	16-Jun-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biomed_luminex-aries_provisional-authorisation-for-covid-19-tests_19062020.pdf	
Singapore	TODOS MEDICAL SINGAPORE Pte Ltd	Kaira 2019-nCoV Detection Kit	22-Jun-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/todos_kaira_provisional-authorisation-for-covid-19-tests_25062020.pdf	
Singapore	All Eights (Singapore) Pte Ltd	Hologic Aptima® SARS-CoV-2 assay	22-Jun-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/all-eights_hologic_provisional-authorisation-for-covid-19-tests_25062020.pdf	
Singapore	Accelerate Technologies Pte Ltd (DxD Hub)	Accelerate Technologies Resolute 2.0 assay	23-Jun-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/accelerate-technologies_resolute_provisional-authorisation-for-covid-19-tests_25062020.pdf	

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Singapore	All Eights (Singapore) Pte Ltd	genesig® Real-Time PCR Coronavirus COVID-19	23-Jun-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/all-eights_genesig_provisional-authorisation-for-covid-19-tests_25062020.pdf
Singapore	Andaman Medical Pte Ltd	Seegene Allplex™ SARS-CoV-2 Assay	24-Jun-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/andaman_seegene_provisional-authorisation-for-covid-19-tests_25062020.pdf
Singapore	DSO National Laboratories	RESOLUTE 1.0 LITE	25-Jun-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/dso_resolute-1-0-lite_provisional-authorisation-for-covid-19-tests_03072020.pdf
Singapore	EMERGO by UL	AccuraDTect SARS-CoV-2 RT-qPCR Kit	1-Jul-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/emergo_accuradtect_provisional-authorisation-for-covid-19-tests_03072020.pdf
Singapore	Vela Operations Singapore Pte Ltd	ViroKey™ SARS-CoV-2 RT-PCR Test v2.0	1-Jul-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/vela_virokey_provisional-authorisation-for-covid-19-tests_03072020.pdf
Singapore	Biotrilance Pte Ltd	Novel Coronavirus (2019-nCoV) Nucleic Acid Detection Kit (PCR-Fluorescence Probing)	7-Jul-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biotrilance_novel_provisional-authorisation-for-covid-19-tests_09072020.pdf

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Singapore	N Medsys Pte Ltd	ProTect COVID-19 RT-qPCR Kit 2.0	7-Jul-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/in-medsys_protect_provisional-authorisation-for-covid-19-tests_09072020.pdf	
Singapore	AMT Pte Ltd	AMT Resolute 2.0 assay	7-Jul-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/amt_resolute-2-0_provisional-authorisation-for-covid-19-tests_09072020.pdf	
Singapore	An Xin Home Care	genesig® Real-Time PCR Coronavirus COVID-19	24-Jul-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/an-xin_genesig_provisional-authorisation-for-covid-19-tests_28072020.pdf	
Singapore	Life Technologies Holdings Pte Ltd	TaqPath™ COVID 19 CE IVD RT PCR Kit	27-Jul-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/life-technologies_taqpath_provisional-authorisation-for-covid-19-tests_28072020.pdf	
Singapore	BioMérieux Singapore Pte Ltd	BioFire® Respiratory Panel 2.1 plus (RP2.1plus)	28-Jul-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/biomérieux_biofire_provisional-authorisation-for-covid-19-tests_28072020.pdf	
Singapore	All Eights (Singapore) Pte Ltd	StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit	28-Jul-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/all-eights_strongstep_provisional-authorisation-for-covid-19-tests_28072020.pdf	

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Singapore	-DNA Biotechnology Pte Ltd	Maccura SARS-CoV-2 Fluorescent PCR	5-Aug-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/i-dna_maccura_provisional-authorisation-for-covid-19-tests_06082020.pdf	
Singapore	Cheung Yong Sam Investment Private Limited	COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit	5-Aug-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/cheung-yong-sam_covid-19_provisional-authorisation-for-covid-19-tests_06082020.pdf	
Singapore	Restalyst Pte Ltd	genesig® Real-Time PCR COVID-19 (Swab Use)	11-Aug-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/restalyst_genesig_provisional-authorisation-for-covid-19-tests_18082020.pdf	
Singapore	Gaia Science Pte Ltd	genesig® Real-Time PCR COVID-19 (Swab Use)	11-Aug-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/gaia_genesig_provisional-authorisation-for-covid-19-tests_18082020.pdf	
Singapore	Veredus Laboratories Pte Ltd	VereRTCoV™ 3.0 ZeroStep Real-Time RT-PCR	14-Aug-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/veredus_verertcov_provisional-authorisation-for-covid-19-tests_18082020.pdf	
Singapore	Link Trust Laboratories Pte Ltd	DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection kit	14-Aug-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/linktrust_diaplexq_provisional-authorisation-for-covid-19-tests_18082020.pdf	

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Singapore	Illumina Singapore Pte Ltd	Illumina COVIDSeq Test	3-Sep-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/illumina_covidseq-test_provisional-authorisation-for-covid-19-tests_08092020.pdf	
Singapore	INEX Innovate Pte Ltd	GenoAmp Real-Time RT-PCR SARS-CoV-2	3-Sep-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/inex_genoamp_provisional-authorisation-for-covid-19-tests_08092020.pdf	
Singapore	AGSG	COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit	7-Sep-20	https://www.hsa.gov.sg/docs/default-source/hprg-mdb/agsg_covid-19-(sars-cov-2)_provisional-authorisation-for-covid-19-tests_08092020.pdf	

<https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation>

Jurisdiction/ Country	Name of the kit	Name of the Manufacturer	Type of the Test	Local Agent	
Saudi FDA	Roche Molecular Systems	cobas SARS-CoV-2 test	RT-PCR	HIGH STANDARD MEDICAL INC	
Saudi FDA	Genekam	Novel Coronavirus 2020 (Wuhan Strain specific) Realtime PCR	RT-PCR	Medical Supplies and Services Co Ltd	
Saudi FDA	Primerdesign Ltd.	genesig Real-Time PCR COVID-19	RT-PCR	Cigalah group warehouse for Drug	
Saudi FDA	BGI	Real-Time Fluorescent RT-PCR kit for detecting SARS-CoV-2	RT-PCR	BGI HEALTH (HK) CO. LTD/ Fetal Care Medical expired AR	
	altona-RealStar® SARS-CoV-2	altona-diagnostic		Abdulla Fouad Company	
Saudi FDA	Kogene Biotech	2019 Novel Coronavirus Real-time PCR Kit	RT-PCR	HIGH STANDARD MEDICAL INC	
Saudi FDA	Becton Dickinson and Company	SARS-COV-2 s Gen realtime	RT-PCR	Becton Dickinson BV Saudi Limited Company	

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Saudi FDA	Abbott Molecular Division	Abbott RealTime SARS- CoV-2 Amplification Reagent Kit Abbott RealTime SARS- CoV-2 Control Kit	RT-PCR	Medical Supplies and Services Co Ltd	
Saudi FDA	KogeneBiotech Co., Ltd.	PowerChek 2019-nCoV Real-time PCR Kit Real-time PCR System	RT-PCR	HIGH STANDARD MEDICAL INC	
Saudi FDA	1drop Inc.	1copy™ COVID-19 qPCR Kit	RT-PCR	Sciences and Supply limited co	
Saudi FDA	QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel Single-plex real-time P	RT-PCR	Abdulla Fouad Company	
Saudi FDA	Quidel	Lyra SARS-CoV-2 Assay	RT-PCR	Abdulla Fouad for Medical Supplies and Services Company	
Saudi FDA	Cepheid	Xpert Xpress SARS-CoV-2 test	RT-PCR	Abdulla Fouad for Medical Supplies and Services Company	
			RT-PCR		
Saudi FDA	Bioeksan, Buyukdere Turke	Bio-Speedy Covid-19 QPCR detection kit / Bio- Speedy Viral Nucleic Acid Isolation kit	RT-PCR	Abdulla Fouad for Medical Supplies and Services Company	
Saudi FDA	Bioneer	AccuPower SARS-CoV-2 Real-Time RT-PCR Kit; ExiPrep 96 Viral DNA/RNA Kit; ExiPrep 96 Lite Automated NA Purification System	RT-PCR	HIGH STANDARD MEDICAL INC	
Saudi FDA	CerTest	VIASURE SARS-CoV-2 Real Time PCR Detection Kit	RT-PCR	Tehama Medical Est	
Saudi FDA	Wells Bio, Inc	careGENETM N-CoV RT- PCR Kit; careGENE COVID-19 RT- PCR kit	RT-PCR	Dar Al Farabi Corporation for Medical DAFCO	
Saudi FDA	SD Biosensor, Inc.	STANDARD M nCoV Real-Time Detection Kit	RT-PCR	AlKamal Import Office	
Saudi FDA	King Faisal Specialist Hospi	SARS-CoV-2 SYBER® Green rtPCR SARS-CoV-2 Nested PCR	RT-PCR	King Faisal Specialist Hospital & Research Centre	
Saudi FDA	BIOMERIEUX S.A.	ARGENE® SARS-COV-2 SFDA R-GENE® MDMA	RT-PCR	ALJEEL MEDICAL COMPANY	
Saudi FDA	Becton Dickinson and Comp	BD SARS-CoV-2 Reagents for BD MAX System	RT-PCR	Becton Dickinson B.V Saudi Limited Company	
Saudi FDA	King Abdulaziz Medical City	SARS-CoV-2 Multiplex One Step RT-PCR	RT-PCR	King Abdulaziz Medical City (NGHA)	

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Saudi FDA	Life Technologies Corporation	TaqPath COVID-19 Control Dilution Buffer, TaqPath COVID-19 RT- PCR Kit TaqPath COVID-19 Control TaqPath 1-Step Multiplex Master Mix	RT-PCR	Intgerated Gulfbiosystems	
https://www.sfda.gov.sa/en/medicaldevices/Authorized/Documents/EAUdevices.pdf					
Jurisdiction/ Country	Product name	Manufacturer's name	Gene target	Recommended Ct cut-off	Date approved for emergency use
Nigeria	Cobas SARS-CoV2 Test	Roche Molecular Systems, Inc	ORF-1a/b and E-gene	Automated Ct analysis	3/13/20
Nigeria	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2	BGI Genomics Co. Ltd	ORF1	< 37	3/26/20
Nigeria	Liferiver Novel Coronavirus (SARS-CoV-2) Real Time Multiplex RT-PCR	Biovendor Research and Diagnostics	E-gene, N-gene and ORF 1a/b	≤ 40	
Nigeria	COVID-19 genesig® R Real-Time PCR assay	Primerdesign Ltd	RdRp	≤ 35	4/7/20
Nigeria	Dectetion kit for 2019 novel Coronavirus (2019-nCov) RNA (PCR - Fluorescence Probing)	Da An Gene Co. Ltd	ORF 1a/b	≤ 40	
Nigeria	Lightmix Modular SARS and WuHan CoV E-gene, N-gene and RdRp gene	TibMolbiol/Roche Diagnostics	E-gene, N-gene and RdRp	Depends on instrument setting	

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2020

Foundation for Innovative New Diagnostics (FIND) has conducted independent evaluations at the Hôpitaux Universitaires de Genève, to verify the limit of "detection (LOD) and the

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clinical performance (as reported by the manufacturers) of the SEVERAL molecular test kits. The most recent performance can be found in the links below"

<https://www.finddx.org/covid-19/sarscov2-eval-molecular/>

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KEY

Recently added tests are indicated by Green fonts

The list is for information only.