

WHO DOES NOT RECOMMEND USE OF SEROLOGY ASSAYS FOR DIAGNOSIS OF COVID-19

List of Immunoassays which have been authorized for Emergency Use during the

Jurisdiction/Cou	Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)
USFDA	9/9/20	BioCheck, Inc.	BioCheck SARS-CoV-2 IgM Antibody Test Kit
USFDA	9/9/20	BioCheck, Inc.	BioCheck SARS-CoV-2 IgG Antibody Test Kit
USFDA	3/9/20	Sugentech, Inc.	SGTi-flex COVID-19 IgG
USFDA	08/31/2020	TBG Biotechnology Corp.	TBG SARS-CoV-2 IgG / IgM Rapid Test Kit
USFDA	08/31/2020	University of Arizona Genetics Core for Clinical Services	COVID-19 ELISA pan-Ig Antibody Test
USFDA	08/31/2020	TBG Biotechnology Corp.	TBG SARS-CoV-2 IgG / IgM Rapid Test Kit
USFDA	08/25/2020	Biocan Diagnostics Inc.	Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test - Letter of Authorization
USFDA	08/17/2020	BioCheck, Inc.	BioCheck SARS-CoV-2 IgG and IgM Combo Test
USFDA	08/17/2020	Diazyme Laboratories, Inc.	Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit
USFDA	6/8/20	bioMérieux SA	VIDAS SARS-CoV-2 IgM
USFDA	6/8/20	bioMérieux SA	VIDAS SARS-CoV-2 IgG
USFDA	5/8/20	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab ELISA
USFDA	07/31/2020	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 IgG (COV2G)
USFDA	07/31/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur SARS-CoV-2 IgG (COV2G)
USFDA	07/24/2020	Xiamen Biotime Biotechnology Co., Ltd.	BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test
USFDA	07/24/2020	Access Bio, Inc.	CareStart COVID-19 IgM/IgG
USFDA	07/17/2020	Megna Health, Inc.	Rapid COVID-19 IgM/IgG Combo Test Kit
USFDA	07/16/2020	Luminex Corporation	xMAP SARS-CoV-2 Multi-Antigen IgG Assay
USFDA	07/13/2020	Salofa Oy	IgG/IgM Rapid Test Cassette
USFDA	10/7/20	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab Rapid Test
USFDA	8/7/20	Diazyme Laboratories, Inc.	Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit
USFDA	6/7/20	Assure Tech. (Hangzhou Co., Ltd)	Assure COVID-19 IgG/IgM Rapid Test Device
USFDA	06/30/2020	InBios International, Inc.	SCoV-2 Detect IgM ELISA
USFDA	06/26/2020	Beckman Coulter, Inc.	Access SARS-CoV-2 IgG
USFDA	06/23/2020	Babson Diagnostics, Inc.	Babson Diagnostics aC19G1
USFDA	06/19/2020	Hangzhou Laihe Biotech Co., Ltd.	LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)

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USFDA	06/18/2020	Biohit Healthcare (Hefei) Co. Ltd.	Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit
USFDA	06/15/2020	Emory Medical Laboratories	SARS-CoV-2 RBD IgG test
USFDA	10/6/20	InBios International, Inc.	S-CoV-2 Detect IgG ELISA
USFDA	8/6/20	Siemens Healthcare Diagnostics Inc.	Dimension Vista SARS-CoV-2 Total antibody assay (COV2T)
USFDA	8/6/20	Siemens Healthcare Diagnostics Inc.	Dimension EXL SARS-CoV-2 Total antibody assay (CV2T)
USFDA	4/6/20	Vibrant America Clinical Labs	Vibrant COVID-19 Ab Assay
USFDA	4/6/20	Hangzhou Biotest Biotech Co., Ltd.	RightSign COVID-19 IgG/IgM Rapid Test Cassette
USFDA	05/29/2020	Healgen Scientific LLC	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)
USFDA	05/29/2020	Siemens Healthcare Diagnostics Inc.	Atellica IM SARS-CoV-2 Total (COV2T)
USFDA	05/29/2020	Siemens Healthcare Diagnostics Inc.	ADVIA Centaur SARS-CoV-2 Total (COV2T)
USFDA	4/5/20	EUROIMMUN US Inc.	Anti-SARS-CoV-2 ELISA (IgG)
USFDA	2/5/20	Roche Diagnostics	Elecsys Anti-SARS-CoV-2
USFDA	04/30/2020	Wadsworth Center, New York State Department of Health	New York SARS-CoV Microsphere Immunoassay for Antibody Detection
USFDA	04/29/2020	Bio-Rad Laboratories, Inc.	Platelia SARS-CoV-2 Total Ab assay
USFDA	04/26/2020	Abbott Laboratories Inc.	SARS-CoV-2 IgG assay
USFDA	04/24/2020	DiaSorin Inc.	LIAISON SARS-CoV-2 S1/S2 IgG
USFDA	04/24/2020	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack
USFDA	04/15/2020	Mount Sinai Laboratory	COVID-19 ELISA IgG Antibody Test
USFDA	04/14/2020	Ortho Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack
USFDA	1/4/20	Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test
USFDA	08/26/2020	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card
USFDA	08/18/2020	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test
USFDA	2/7/20	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2
USFDA	8/5/20	Quidel Corporation	Sofia SARS Antigen FIA
Authorized settings include the following:			
H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 162.101			
M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 162.101			
W - Patient care settings operating under a CLIA Certificate of Waiver.			
https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-a			
Jurisdiction/Country	Name of the assay	Manufacturer	Device type
Canada	Liaison SARS-Cov-2 S1/S2 IgG	Diasorin Inc. (United States)	Serological technology

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Canada	SARS-CoV-2 IgG Assay	Abbott Laboratories, Diagnostics Division (United States)	Serological technology
Canada	Elecsys Anti-SARS-CoV-2	Roche Diagnostics GmbH (Germany)	Serological technology
Canada	Vitros Immunodiagnostic Products Anti-Sars-Cov-2 Total Reagent Pack, Vitros Immunodiagnostic Products Anti-Sars-Cov-2 Total Calibrator	Ortho-Clinical Diagnostics Inc. (United States)	Serological Technology
Canada	SARS-CoV-2 IgG Assay (Alinity I)	Abbott Laboratories Diagnostics Division (United States)	Serological technology
Canada	Atellica Im Sars-Cov-2 Total (Cov2t) / Atellica	Siemens Healthcare Diagnostics Inc.	Serological Technology
Canada	Advia Centaur Sars-Cov-2 Total (Cov2t) / Advia	Siemens Healthcare Diagnostics Inc. (United States)	Serological technology
Canada	Dimension Exl Sars-Cov-2 Total Antibody (Cv2t)	Siemens Healthcare Diagnostics Inc. (United States)	Serological Technology
https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html#wb-auto-5			
Jurisdiction/Country	Applicant	Name of test	Date approved
Singapore	Everest Links Pte Ltd	VivaDiag™ COVID-19 IgM/IgG Rapid Test	20-Mar-20
Singapore	Biolidics Limited	Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit. also marketed as Biolidics 2019-nCoV IgG/IgM Detection Kit	20-Mar-20
Singapore	SkyQuest Pte Ltd	Wondfo SARS-CoV-2 Antibody Test	9-Apr-20
Singapore	Camtech Diagnostics Pte Ltd	Camtech COVID-19 IgM/IgG	9-Apr-20
Singapore	Grit Overseas Pte Ltd	DiagnoSure COVID-19 IgG/ IgM Rapid Test Cassette	24-Apr-20

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Singapore	Shanghai LiangRun	LionRun Diagnostic Kit for Antibody IgM-IgG of Novel	27-Apr-20
Singapore	Bioforge Solutions Pte Ltd	INNOVITA 2019-nCoV Ab Test (Colloidal Gold)	27-Apr-20
Singapore	Abbott Laboratories (S) Pte Ltd	Abbott SARS-CoV-2 IgG – ARCHITECT assay	30-Apr-20
Singapore	Ortho Clinical Diagnostics	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	8-May-20
Singapore	MP Biomedicals Asia Pacific Pte Ltd	MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test	8-May-20
Singapore	Biomed Diagnostics Pte Ltd	INNOVITA 2019-nCoV Ab Test (Colloidal Gold)	8-May-20
Singapore	Genscript Biotech (Singapore) Pte Ltd	SARS-CoV-2 Neutralization Antibody Detection Kit	8-May-20
Singapore	All Eights (Singapore) Pte Ltd	EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit	15-May-20
Singapore	All Eights (Singapore) Pte Ltd	EDI™ Novel Coronavirus COVID-19 IgM ELISA Kit	15-May-20
Singapore	Healthgroup Medical Pte Ltd	HealthGroup Medical V-CODE Sars-CoV-2 (COVID-19) IgG/IgM Rapid Test	18-May-20
Singapore	I-Test Pte Ltd	i-Test COVID -19 IgM/IgG Antibody Rapid Test (Colloidal Gold)	20-May-20
Singapore	Ying Assets Management Pte Ltd	INNOVITA 2019-nCoV Ab Test (Colloidal Gold)	20-May-20
Singapore	Abbott Laboratories (S) Pte Ltd	ABBOTT Alinity i SARS-CoV-2 IgG	22-May-20

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Singapore	Euroimmun (South East Asia) Pte. Ltd.	EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG)	28-May-20
Singapore	SPD Scientific Pte Ltd	2019-nCoV IgG/IgM Rapid Test	28-May-20
Singapore	Trident Pharm Pte Ltd	SARS-CoV-2 Antibody Test Strip	28-May-20
Singapore	Sinch Medical Pte Ltd	2019-nCoV/COVID-19 IgG/IgM Rapid Test Device	28-May-20
Singapore	Euroimmun (South East Asia) Pte. Ltd.	EUROIMMUN Anti-SARS-CoV-2 ELISA (IgA)	28-May-20
Singapore	Transmedic Pte Ltd	Genrui Novel Coronavirus (2019- nCoV) IgG/IgM Test Kit (Colloidal Gold)	29-May-20
Singapore	Siemens Healthcare Pte Ltd	Siemens Atellica® IM SARS-CoV- 2 Total (COV2T)	29-May-20
Singapore	Siemens Healthcare Pte Ltd	Siemens ADVIA Centaur® SARS- CoV-2 Total (COV2T)	29-May-20
Singapore	Xentific Labs Pte Ltd	Standard Q COVID-19 Ag Test	3-Jun-20
Singapore	Ortho Clinical Diagnostics	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack	3-Jun-20
Singapore	Alcotech Pte Ltd	2019-nCoV IgG/IgM Rapid Test Cassette	5-Jun-20
Singapore	Unison Collaborative Pte Ltd	RightSign COVID-19 IgG/IgM Rapid Test Cassette	11-Jun-20

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Singapore	Bio-Rad Laboratories (Singapore) Pte Ltd	Biorad Platelia SARS-CoV-2 Total Ab	22-Jun-20
Singapore	Beckman Coulter Singapore Pte Ltd	ACCESS SARS-CoV-2 IgG	22-Jun-20
Singapore	ZMC Technologies (Singapore) Pte Ltd	Novel Coronavirus (2019-nCoV) IgG/IgM Antibody Test Kit (Colloidal Gold)	23-Jun-20
Singapore	Unison	Panbio™ COVID-19 IgG/IgM	23-Jun-20
Singapore	RAS Pharma and Biochem Pte Ltd	RAS Rapid Test - 2019-nCoV IgG/IgM Rapid Test	24-Jun-20
Singapore	Cell ID Pte Ltd	Smart COVID-19 IgM-IgG Rapid Diagnostic Test	25-Jun-20
Singapore	Restalyst Pte Ltd	RAPIT COVID-19 IgM/IgG Test Kit	1-Jul-20
Singapore	Genomax Technologies Pte Ltd	Hangzhou Lysun 2019-nCoV IgG/IgM Rapid Test Device	7-Jul-20
Singapore	Alcotech Pte Ltd	FaStep COVID-19 Antigen Rapid Test Device (Nasopharyngeal/ Oropharyngeal Swab)	7-Jul-20
Singapore	Siemens Healthcare Pte Ltd	Siemens Atellica® IM SARS-CoV-2 IgG (COV2G)	13-Jul-20
Singapore	Siemens Healthcare Pte Ltd	Siemens ADVIA Centaur® SARS-CoV-2 IgG (COV2G)	13-Jul-20
Singapore	Hi-Beau Group	SAVANT™ New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography)	13-Jul-20

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Singapore	Becton Dickinson Holding Ptd. Ltd	BD Veritor™ System for Rapid Detection of SARS-CoV-2	22-Jul-20
Singapore	SPD Scientific Pte Ltd	Standard Q COVID-19 Ag Test	24-Jul-20
Singapore	Thermo Scientific Microbiology Pte Ltd	Standard Q COVID-19 Ag Test	4-Aug-20
Singapore	EUROIMMUN (SOUTH EAST ASIA) PTE. LTD.	EUROIMMUN Anti-SARS-CoV-2 NCP ELISA (IgG)	5-Aug-20
Singapore	Quantum Technologies Global Pte Ltd	Sofia SARS Antigen FIA	5-Aug-20
Singapore	Restalyst Pte Ltd	Restalyst COVID19N-REAAD™ Anti-SARS-CoV-2 Nucleocapsid Protein IgG ELISA	7-Aug-20
Singapore	Nova Diagnostics Pte Ltd	MAGLUMI 2019-nCoV IgG (CLIA)	19-Aug-20
Singapore	Nova Diagnostics Pte Ltd	MAGLUMI 2019-nCoV IgM (CLIA)	19-Aug-20
Singapore	Alcotech Pte Ltd	FaStep COVID-19 IgG/IgM Rapid Test Device	28-Aug-20
Singapore	Jian Yuan Holdings Pte Ltd	COVID-19 Antigen Rapid Test Kit	28-Aug-20
Singapore	Camtech Diagnostics Pte Ltd	Camtech COVID-19 Antigen Rapid Test	28-Aug-20

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Singapore	Abbott Laboratories (S) Pte Ltd	Abbott ARCHITECT SARS-CoV-2 IgM	3-Sep-20
Singapore	Unison Collaborative Pte Ltd	GenBody COVID-19 Ag	7-Sep-20
Singapore	Abbott Laboratories (S) Pte Ltd	ABBOTT Alinity i SARS-CoV-2 IgM	7-Sep-20
https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-co			
Jurisdiction/Country	Name of test	Type of test	Australian sponsor**
Australia	NowCheck COVID-19 Antigen Test	Point-of-care test* Antigen Test	Life Bioscience Pty Ltd
Australia	COVID-19 IgG/IgM Rapid Test Kit	Point-of-care test* Lateral Flow IgG/IgM	LJCJ Pty Ltd
Australia	Sofia® SARS Antigen FIA	Point-of-care test* Antigen Test	Point Of Care Diagnostics Australia Pty Ltd
Australia	AtomoRapid™ COVID-19 IgM/IgG Antibody Test	Point-of-care test* Lateral Flow IgG/IgM	Atomo Diagnostics Limited
Australia	Anti-SARS-CoV-2 NCP ELISA (IgG)	Immunoassay	ESL Biosciences Australia 2012 Pty Ltd
Australia	Anti-SARS-CoV-2 NCP ELISA (IgM)	Immunoassay	ESL Biosciences Australia 2012 Pty Ltd
Australia	VIDAS® SARS-COV-2 IgM	Immunoassay	Biomerieux Australia Pty Ltd
Australia	VIDAS® SARS-COV-2 IgG	Immunoassay	Biomerieux Australia Pty Ltd
Australia	iFlash-SARS-CoV-2 IgG	Immunoassay	H3 Diagnostics Pty Ltd
Australia	iFlash-SARS-CoV-2 IgM	Immunoassay	H3 Diagnostics Pty Ltd
Australia	LIAISON® SARS-CoV-2 S1/S2 IgG	Immunoassay	DiaSorin Australia Pty Ltd
Australia	Dimension EXL SARS-CoV-2 Total antibody assay (CV2T)	Immunoassay	Siemens Healthcare Pty Ltd
Australia	Dimension Vista® SARS-CoV-2 Total antibody assay (COV2T)	Immunoassay	Siemens Healthcare Pty Ltd

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Australia	SARS-CoV-2 IgG Kit	Immunoassay	Abbott Australasia Pty Ltd Diagnostic Division
Australia	Access SARS-CoV-2 IgG Antibody Test	Immunoassay	Beckman Coulter Australia Pty Ltd
Australia	COVID-19 IgG/IgM Rapid Test Cassette	Lateral Flow IgG/IgM	Kissun Pharmaceuticals Pty Ltd
Australia	Platelia SARS-CoV-2 Total Ab	Immunoassay	Bio-Rad Laboratories Pty Ltd
Australia	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total	Immunoassay	Ortho-Clinical Diagnostics Australia Pty Ltd
Australia	ADVIA Centaur® SARS-CoV-2 Total (COV2T) assay	Immunoassay	Siemens Healthcare Pty Ltd
Australia	Atellica® IM SARS-CoV-2 Total (COV2T) assay	Immunoassay	Siemens Healthcare Pty Ltd
Australia	COVID-19 IgG/IgM Rapid Test Kit	Lateral Flow IgG/IgM	Lavinia Medical Pty Ltd
Australia	Lateral Flow IgG/IgM Manufacturer: NTBIO Diagnostics Inc (Canada) Name of test:	Lateral Flow IgG/IgM	Healtheguru Pty Ltd
Australia	Elecsys Anti-SARS-CoV-2	Immunoassay	Roche Diagnostics Australia Pty Limited
Australia	SARS-CoV-2 IgM/IgG Antibody Test Kit	Lateral Flow IgG/IgM	Australian Trefoil Health Technologies Pty Ltd
Australia	NOVA Test® COVID-19 IgG/IgM Antibody Test (Colloidal Gold)	Lateral Flow IgG/IgM	Pharmaceuticals (Australia) Pty Ltd
Australia	Anti-SARS-CoV-2 ELISA (IgA)	Immunoassay	ESL Biosciences Australia 2012 Pty Ltd
Australia	Anti-SARS-CoV-2 ELISA (IgG)	Immunoassay	ESL Biosciences Australia 2012 Pty Ltd
Australia	InnoScreen™ COVID-19 IgG/IgM Rapid Test	Lateral Flow IgG/IgM	Innovation Scientific Pty Ltd

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Australia	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)	Lateral Flow IgG/IgM	Emergence Technology Pty Ltd
Australia	VivaDiag™ COVID-19 IgM/IgG Rapid Test	Lateral Flow IgG/IgM	Endo X Pty Ltd
Australia	SARS-CoV-2 IgM/IgG Antibody Rapid Test	Lateral Flow IgG/IgM	CK Surgitech Pty Ltd
Australia	PCL COVID19 IgG/IgM Rapid Gold	Lateral Flow IgG/IgM	Haemokinesis Pty Ltd
Australia	InnoScreen™ COVID-19 IgG/IgM Rapid Test	Lateral Flow IgG/IgM	Innovation Scientific Pty Ltd (Australia)
Australia	COVID-19 IgG/IgM Rapid Test Cassette	Lateral Flow IgG/IgM	Southwind International Pty Ltd
Australia	GenBody COVID-19 IgM/IgG	Lateral Flow IgG/IgM	Biovent Consulting Pty Ltd
Australia	2019-nCoV IgG/IgM Rapid Test Cassette	Lateral Flow IgG/IgM	AM Diagnostics - DC
Australia	2019-nCoV Ab Test (Colloidal Gold)	Lateral Flow IgG/IgM	AM Diagnostics
Australia	2019-nCoV/COVID-19 IgG/IgM Rapid Test Device	Lateral Flow IgG/IgM	Solasta Life Pty Ltd
Australia	Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test kit	Lateral Flow IgG/IgM	Medicision Pty Ltd
Australia	COVID-19 IgG/IgM Rapid Test Cassette	Lateral Flow IgG/IgM	Amandla China Pty Limited
Australia	OnSite COVID-19 IgG/IgM Rapid Test	Lateral Flow IgG/IgM	MD Solutions Australasia Pty Ltd

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Australia	SARS-CoV-2 Antibody Test (Lateral Flow Method)	Lateral Flow IgG/IgM	Allsafe Medical Pty Ltd
Australia	Wantai SARS-CoV-2 Ab Rapid Test kit	Lateral Flow IgG/IgM	Life Clinic Australia Pty Ltd
Australia	NOVA Test® COVID-19 IgG/IgM Antibody Test (Colloidal Gold)	Lateral Flow IgG/IgM	Adelco Pharmaceuticals (Australia) Pty Ltd
Australia	OnSite COVID-19 IgG/IgM Rapid Test	Lateral Flow IgG/IgM	MD Solutions Australasia Pty Ltd
Australia	COVID-19 IgG/IgM Rapid Test Cassette	Lateral Flow IgG/IgM	Medsupply Australia Pty Ltd
Australia	COVID-19 IgG/IgM Rapid Test Cassett	Lateral Flow IgG/IgM	Zenpharm Pty Ltd
https://www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia?order=title&sort=desc			
Jurisdiction/Country	Name of the kit	Name of the Manufacturer	Type of the Test
S Arabia	Inzek International Trading BV	COVID-19 IgM/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	Rapid
S Arabia	Prima Lab SA	Prima COVID-19 IgG/IgM RAPID TEST	Rapid
S Arabia	CTK Biotech Inc	OnSite COVID-19 IgG/IgM Rapid Test	Rapid
S Arabia	VIVACHEK BIOTECH (HANGZHOU) CO., LTD	VivaDiag™ COVID-19 IgM/IgG Rapid Test	Rapid
S Arabia	Snibe Diagnostics	Maglumi 2019-nCoV (SARS-CoV-2) IgM/IgG kits	Immunoassay
S Arabia	Boditech Med Inc.	AFIAS COVID-19 Ab ichroma COVID-19 Ab	Immunoassay
S Arabia	Abbott Ireland Diagnostics Division	SARS-CoV-2 IgG Reagent Kit SARS-CoV-2 IgG Calibrator Kit, SARS-CoV-2 IgG Control Kit	Rapid
S Arabia	Roche Diagnostics	Elecsys Anti-SARS-CoV-2	Immunoassay

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S Arabia	Ortho Clinical Diagnostics, Inc.	VITROS® Immunodiagnostic Products Anti-SARS-CoV- 2 total reagent pack, VITROS® Immunodiagnostic Products Anti-SARS-CoV- 2 total Calibrator, VITROS® Immunodiagnostic Products Anti-SARS-CoV- 2 Total Controls	ELISA
S Arabia	Lana Al Khaleej Al Awal for medical supplies	NATEJAH New Coronavirus (COVID-19) IgG/IgM Rapid Test	Rapid
	https://old.sfda.gov.sa/en/medicaldevices/Authorized/Documents/EAUdevices.pdf		
	SAHPRA Licence Holder	Product Name	Product Description
S Africa	Tiptoptrade (Pty) Ltd	SARS CoV-2 IgG/IgM test	Serological Corona virus IgG/ IgM Rapid Test Kit
S Africa	Link Medical Solutions (Pty) Ltd	SARS CoV-2 IgG/IgM test	Serological Corona virus IgG/ IgM Rapid Test Kit
S Africa	Direct Retail Goods	SARS CoV-2 IgG/IgM test	Serological Corona virus IgG/ IgM Rapid Test Kit
S Africa	Nu-world Industries	SARS CoV-2 IgG/IgM test	Serological Corona virus IgG/ IgM Rapid Test Kit
S Africa	Inqaba Health Solutions	SARS CoV-2 IgG/IgM test Rapid	Serological Corona virus IgG/ IgM Rapid Test Kit
S Africa	Sinosa Trading (Pty) Ltd	SARS CoV-2 IgG/IgM test Rapid	Serological Corona virus IgG/ IgM Rapid Test Kit
S Africa	Doctor Four You Practice	SARS CoV-2 IgG/IgM test Rapid	Serological Corona virus IgG/ IgM Rapid Test Kit
S Africa	Roche Diagnostics (Pty) Ltd	Elecsys Anti-SARS-COV-2 (E1G)	SARS CoV-2 ELISA IgG
S Africa	Abbott Laboratories South Africa (Pty) Ltd	Architect SARS-CoV-2 IgG Control / Assay / Calibrator	SARS CoV-2 ELISA IgG
S Africa	Euroimmun Medical Laboratory Diagnostics South Africa (Pty) Ltd	Anti SARS-CoV-2 ELISA IgA	SARS CoV-2 ELISA IgA
S Africa	Abbott Laboratories South Africa (Pty) Ltd	Alinity SARS-CoV-2 IgG Control / Assay / Calibrator	SARS CoV-2 ELISA IgG
S Africa	Euroimmun Medical Laboratory Diagnostics South Africa (Pty) Ltd	Anti SARS-CoV-2 ELISA IgG	SARS CoV-2 ELISA IgG
	http://www.sahpra.org.za/be-prepared-for-covid-19/		

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Country	Product name	Marketing Authorization Holder	Type
Japan	ESPLINE SARS-CoV-2	Fujirebio Inc.	Antigen (simple kit)
Japan	Lumipulse G SARS-CoV-2 Ag	Fujirebio Inc.	Antigen (quantitative test)
Japan	QuickNavi-COVID19 Ag	Denka Co., Ltd.	Antigen (simple kit)
https://www.mhlw.go.jp/stf/newpage_11332.html			
Foundation for Innovative New Diagnostics (FIND) has conducted independent evaluations at the Hôpitaux Ur			
https://www.finddx.org/covid-19/sarscov2-eval-immuno/			

Key

Recently added tests are indicated by Green fonts

The list is for information only. AMDF does not endorse use of any of the assay

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COVID-19 pandemic by different Jurisdictions	
Type of the assay	Authorized settings
IgM, CLIA	H, M
IgG, CLIA	H, M
IgG, Lateral Flow	H, M
IgM and IgG, Lateral Flow	H, M
Total Antibody, ELISA	H
IgM and IgG, Lateral Flow	H, M
IgM and IgG, Lateral Flow	H, M
IgM and IgG, CLIA	H, M
IgM, CLIA	H, M
IgM, ELFA	H, M
IgG, ELFA	H, M
Total Antibody, ELISA	H
IgG, Semi-quantitative	H, M
IgG, Semi-quantitative	H, M
IgM and IgG, Lateral Flow	H, M
IgM and IgG, Lateral Flow	H, M
IgM and IgG, Lateral Flow	H, M
IgG, FMIA	H
IgM and IgG, Lateral Flow	H, M
Total Antibody, Lateral Flow	H, M
IgG, CLIA	H, M
IgM and IgG, Lateral Flow	H, M
IgM, ELISA	H
IgG, CLIA	H, M
IgG, CLIA	H
IgM and IgG Lateral Flow	H, M

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IgM and IgG Lateral Flow	H, M
IgG, ELISA	H
IgG, ELISA	H
Total Antibody, CLIA	H, M
Total Antibody, CLIA	H, M
IgM and IgG, CLIA	H
IgM and IgG Lateral Flow	H, M
IgM and IgG Lateral Flow	H, M
Total Antibody, CLIA	H, M
Total Antibody, CLIA	H, M
IgG, ELISA	H
Total Antibody, ECLIA	H, M
Total Antibody, FMIA	H
Total Antibody, ELISA	H
IgG, CMIA	H, M
IgG, CLIA	H, M
IgG, CLIA	H, M
IgG, ELISA	H
Total Antibody, CLIA	H, M
IgM and IgG, Lateral Flow	H, M
Antigen	H, M, W
Antigen	H, M, W
Antigen	H, M, W
Antigen	H, M, W
§263a, that meet requirements to perform high complexity tests.	
63a, that meet requirements to perform moderate complexity tests	
authorizations-medical-devices/vitro-diagnostics-euas#individual-	
Laboratory of point of Care test	Date authorized
Lab-based test	5/12/20

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Lab-based test	5/14/20
Lab-based test	6/5/20
Lab-based test	6/8/20
Lab-based test	6/11/20
Lab-based test	8/14/20
Lab-based test	8/14/20
Lab-based test	9/8/20
	Updated 22 September 2020
More information	
https://www.hsa.gov.sg/docs/default-source/hprg-mdb/everest-links_provisional-authorisation-for-covid-19-testing.pdf	
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vid-19-diagnostic-tests-in-singapore-via-provisional-authorisation	
Manufacturer	Date approved for supply
BioNote Inc (Korea - Republic of)	11-Sep-20
Zhongshan Chuangyi Biochemical Engineering Co Ltd (China)	7-Sep-20
Quidel Corporation (United States Of America)	26-Aug-20
Atomo Diagnostics Limited (Australia)	12-Aug-20
EUROIMMUN Medizinische Labordiagnostika AG (Germany)	5-Aug-20
EUROIMMUN Medizinische Labordiagnostika AG (Germany)	5-Aug-20
Biomerieux SA (France)	3 Aug 2020
Biomerieux SA (France)	3 Aug 2020
Shenzhen YHLO Biotech Co Ltd (China)	31 Jul 2020
Shenzhen YHLO Biotech Co Ltd (China)	31 Jul 2020
DiaSorin SpA (Italy)	31 Jul 2020
Siemens Healthcare Diagnostics Inc (United States Of America)	30-Jul-20
Siemens Healthcare Diagnostics Inc (United States Of America)	30-Jul-20

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Abbott Ireland Diagnostic Division (Ireland)	28-Jul-20
Beckman Coulter Inc (United States Of America)	24-Jul-20
Newscen Coast Bio-Pharmaceutical Co Ltd (China)	23-Jun-20
Bio-Rad (France)	23-Jun-20
Ortho-Clinical Diagnostics (United Kingdom)	19-Jun-20
Siemens Healthcare Diagnostics Inc (United States Of America)	5-Jun-20
Siemens Healthcare Diagnostics Inc (United States Of America)	5-Jun-20
Nantong Egens Biotechnology Co Ltd (China)	27-May-20
NTBIO Diagnostics Inc (Canada)	27-May-20
Roche Diagnostics GmbH (Germany)	20-May-20
Wuhan EasyDiagnosis Biomedicine Co Ltd (China)	19-May-20
Atlaslink Beijing Technology Co Ltd (China)	18-May-20
EUROIMMUN Medizinische Labordiagnostika AG (Germany)	18-May-20
EUROIMMUN Medizinische Labordiagnostika AG (Germany)	18-May-20
Innovation Scientific Pty Ltd (Australia)	11-May-20

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Zhuhai Livzon Diagnostics Inc (China)	5-May-20
VivaCheck Biotech (Hangzhou) Co Ltd (China)	20-Mar-20
Qingdao Hightop Biotech Co Ltd (China)	7-Apr-20
PCL Inc (Korea - Republic of)	1-May-20
Innovation Scientific Pty Ltd	11-May-20
Healgen Scientific Limited Liability Company (United States Of America)	29-Apr-20
GenBody Inc (Korea - Republic of)	28-Apr-20
Hangzhou Alltest Biotech Co Ltd (China)	23-Mar-20
Innovita (Tangshan) Biological Technology Co Ltd (China)	20-Apr-20
Hangzhou Realy Tech Co Ltd (China)	16-Apr-20
Cellex Inc (United States Of America)	31-Mar-20
Zhejiang Orient Gene Biotech Co Ltd (China)	1-Apr-20
CTK Biotech Inc (USA)	19-Mar-20

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Guangzhou Wondfo Biotech Co Ltd (China)	17-Apr-20
Beijing Wantai Biologicalpharmacy Enterprise Co Ltd (China)	27-Mar-20
Atlaslink Beijing Technology Co Ltd (China)	18-May-20
CTK Biotech Inc (USA)	19-Mar-20
Hangzhou Biotest Biotech Co Ltd (China)	4-Apr-20
Hangzhou Clongene Biotech Co Ltd (China)	6-Apr-20
	Updated 14
Local Agent	
First Technology Trading Est	
Tanami Global for Business Services	
W AREED ALHAYAT Est	
ALJEEL MEDICAL COMPANY	
United Diagnostics Industry	
Abdulla Fouad for Medical Supplies and Services Company	
Medical Supplies and Services Co Ltd	
Roche Diagnostics Saudi Arabia Limited	

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Samir Trading and Marketing CJSC	
Lana Al Khaleej Al Awal for medical supplies	
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Original Manufacturer	
ZHEJIANG ORIENT GENE BIOTECH	
ZHEJIANG ORIENT GENE BIOTECH	
ZHEJIANG ORIENT GENE BIOTECH	
ZHEJIANG ORIENT GENE BIOTECH	
ZHEJIANG ORIENT GENE BIOTECH	
ZHEJIANG ORIENT GENE BIOTECH	
ZHEJIANG ORIENT GENE BIOTECH	
ZHEJIANG ORIENT GENE BIOTECH	
Roche Diagnostics GmbH	
Abbott Ireland, Diagnostics Division, Finisklin Business Park, Sligo, Ireland	
Medizinische Labordiagnostika AG, Deutschland, Germany	
Abbott Ireland, Diagnostics Division, Finisklin Business Park, Sligo, Ireland	
Medizinische Labordiagnostika AG, Deutschland, Germany	
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Date of Authorization	Review Outline
May 13, 2020	https://www.mhlw.go.jp/content/11124500/000632304.pdf
June 19, 2020	
August 11, 2020	
Updated 22 September 2020	
iversitaires de Genève, to verify the limit of "detection (LOD) and	
Updated 22 September 2020	