

The list of Covid-19 Antibody, Antigen and Nucleic Acid Amplification Test (NAAT) that is recommended for use based on the decision on the consensus of the Covid-19 Test Kit Expert committee is as follows.

All test submissions are scored according to: -

- the manufacturer reported clinical and analytical performance evidence.
- the evaluation test results from IMR and MKAK according to the committee evaluation criteria set by Clinical expert panels.
- Supporting Documents for COVID-19 IVD Test Kits Special Access Notification.

Below is the list of all tests that have been selected to date and the status is Recommended for Use (please note: list is updated on a routine basis).

NO	PRODUCT NAME	MANUFACTURER	DETECTION
1	STANDARD™ Q COVID-19 Ag Test	SD Biosensor, Inc. Republic of Korea	RTK Antigen
2	NowCheck Covid-19 Ag Test	BioNote, Inc. Republic of Korea	RTK Antigen
3	Quidel SOFIA 2 SARS Antigen FIA	Quidel Corporation CA, USA	RTK Antigen
4	STANDARD F COVID-19 Ag FIA	SD Biosensor, Inc. Republic of Korea	RTK Antigen
5	ecotest COVID-19 Antigen Rapid Test Device (Respiratory Specimens)	Assure Tech. (Hangzhou) Co., Ltd. P.R. China	RTK Antigen
6	Panbio™ COVID-19 Ag Rapid Test Device	Abbott Rapid Diagnostics Jena GmbH Germany	RTK Antigen
7	Gmate® COVID-19 Ag	Philosys Co., Ltd Republic of Korea	RTK Antigen
8	SARS-CoV-2 Rapid Antigen Test	SD Biosensor Republic of Korea	RTK Antigen
9	ProDetect® COVID-19 Antigen Rapid Test	Medical Innovation Ventures Sdn. Bhd. Penang, Malaysia	RTK Antigen
10	BIOCREDIT COVID-19 Ag One Step SARS-CoV-2 Antigen Rapid Test	RapiGEN Inc. Republic of Korea.	RTK Antigen
11	VivaDiag™ SARS-CoV-2 Ag Rapid Test	VivaChek Biotech (Hangzhou) Co., Ltd. P.R. China	RTK Antigen
12	SGTi-flex COVID-19 Ag	Sugentech, Inc. Republic of Korea	RTK Antigen
13	Humasis COVID-19 Ag Test	Humasis Co., Ltd., Republic of Korea.	RTK Antigen
14	Healgen® Coronavirus Ag Rapid Test Cassette (Swab)	Healgen Scientific Limited Liability Company, USA	RTK Antigen
15	DIAKEY COVID-19 Ag Rapid Test	Shinjin Medics Inc. Republic of Korea	RTK Antigen
16	UNICELL-2019-nCoV Ag	Shenzhen YHLO Biotech Co., LTD, P.R. China	RTK Antigen
17	Jinwofu Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit Lot # : 20201102	Beijing Jinwofu Bioengineering Technology Co.,Ltd. P.R China.	RTK Antigen

18	LEPU SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatography)	Beijing Lepu Medical Technology Co., Ltd. P.R. China	RTK Antigen
19	Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co., Ltd. P.R. China	RTK Antigen
20	FASTEP Covid-19 Antigen Rapid Test Device	Assure Tech (Hangzhou) Co. Ltd Zhejiang, P.R. China	RTK Antigen
21	Helix i-SARS-CoV-2 Ag Rapid Test	Cellex, Inc. 76 TQ Alexander Dr Research Triangle Park, Durham NC 27709-0002 USA	RTK Antigen
22	TOP RAPID COVID-19 Rapid Antigen Test Kit	Top Biotech Sdn Bhd 12A, Jalan TP 5, Taman Perindustrian UEP, 47600 Subang Jaya, Selangor,	RTK Antigen
23	RightSign SARS-CoV-2 Antigen Rapid Test Cassette	Hangzhou Biotest Biotech Co. Ltd 17# Futai Road, Zhongtai Street Yuhang District 311121 Hangzhou, China	RTK Antigen
24	PerkinElmer® 96 SARS-CoV-2 kit	Suzhou SYM-BIO LifeScience Co.,Ltd. 215400 Jiangsu Province, China	RTK Antigen
25	Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co., Ltd ,Zhejiang,China	RTK Antigen
26	SARS-CoV-2 Antigen Test kit	Shenzhen Ultra-Diagnostics Biotec. Co., Ltd. P.R.China	RTK Antigen
27	NATEJAH COVID-19 Antigen Rapid Test (Swab)	Lana Al Khaleej Al Awal Factory for Medical Supplies Second Industrial City, Kingdom of Saudi Arabia	RTK Antigen
28	NADAL® COVID-19 Ag Test (test cassette)	nal von minden GmbH Carl- Zeiss-Strasse 12 • 47445 Moers • Germany	RTK Antigen
29	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method)	Wenzhou OJA Biotechnology Co., Ltd. China	RTK Antigen
30	Getein Biotech GP One Step Test For Sars-Cov-2 Antigen (Colloidal Gold)	Getein Biotech, Inc No.9 Bofu Road, Luhe District, Nanjing, 211505, China	RTK Antigen
31	Longsee 2019-nCoV Ag & Influenza A/B Ag Rapid Co-Detection Kit	Guangdong Longsee Biomedical Co.,Ltd A501, Building A, No 83, Ruihe Road, Huangpu District Guangzhou, China	RTK Antigen
32	Hotgen Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Beijing Hotgen Biotech Co., Ltd. 9th Building, No. 9 Tianfu Street, Biomedical Base,Daxing District, Beijing, 102600, P.R. China.	RTK Antigen
33	StrongStep SARS-CoV-2 Antigen Rapid Test	Nanjing Liming Bio-products Co. Ltd. Jiangsu China	RTK Antigen
34	LabGun™ COVID-19 Rapid Antigen Kit	CALTH Inc. Republic of Korea	RTK Antigen
35	Lifotronic SARS-CoV-2 Antigen (GICA)	Shenzhen Lifotronic Technology Co., Ltd.,P.R. China	RTK Antigen

36	Innova SARS-CoV-2 Antigen Rapid Qualitative Test	Innova Medical Group, Inc., USA	RTK Antigen
37	TOP RAPID COVID-19 Rapid Antigen Test Kit	Top Biotech Sdn Bhd, Selangor	RTK Antigen

NO	PRODUCT NAME	MANUFACTURER	GENE	DETECTION
1	QIAstat-Dx Respiratory SARS-CoV-2 Panel	Qiagen N.V Netherlands	ORF1ab and E gene	RT-PCR (POCT)
2	EasyNAT COVID-19 Nucleic Acid Detection Kit	Ustar Biotechnologies (Hangzhou) Co., Ltd., P.R. China	ORF1ab, N and E gene	RT-LAMP (POCT)
3	Xpert Xpress SARS-CoV-2	Cepheid, 904 Caribbean Drive, Sunnyvale, CA, USA	N and E gene	RT-PCR (POCT)
4	ID NOW Covid-19 Assay	Abbott Diagnostics Scarborough, Inc., USA	RdRp gene	RAPID ISOTHERMAL NEAR (Rapid Molecular)
5	Sansure Biotech Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Sansure Biotech Inc. P.R. China	ORF1ab and N gene	RT-PCR (POCT)
6	AQ-TOP COVID-19 Rapid Detection Kit PLUS	Seasun Biomaterials Inc. Republic of Korea.	ORF1ab and, RNase P gene	RT-LAMP (POCT)
7	Isopollo® COVID-19 Detection Kit (real-time)	M monitor Inc. Republic of Korea	RdRp and N gene	RT-LAMP (POCT)
8	CELLSAFE LAMPlex™ RT-qLAMP COVID-19 Detection Assay	CellSafe Co., Ltd. Republic of Korea	N gene	RT-qLAMP (Rapid Molecular)
9	VERI-Q PCR 316 Coronavirus Disease 2019 (COVID-19) Detection Kit nCoV-QS	MiCo BioMed Co., Ltd., Republic of Korea.	N and ORF3a gene	RT-PCR (POCT)
10	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	BGI Europe A/S Denmark	ORF1ab gene	RT-PCR
11	3DMed 2019-nCoV RT-qPCR Detection Kit	3D Biomedicine Science & Technology Co., Ltd. P.R. China.	ORF1ab, E and N gene	RT-PCR
12	STANDARD M nCoV Real-Time Detection Kit	SD Biosensor Republic Of Korea	ORF1ab (RdRp) and E gene	RT-PCR
13	cobas® SARS-CoV-2 cobas® SARS-CoV-2 Control Kit	Roche Diagnostics GmbH Mannheim, Germany	ORF1ab and E gene	RT-PCR
14	Real-Q 2019-nCoV Detection Kit	BioSewoom Inc. Republic of Korea	RdRp and E gene	RT-PCR
15	Toneker Novel coronavirus (SARS-CoV-2) nucleic acid detection kit (PCR fluorescence method)	Anhui Toneker Biotechnology Co., Ltd. P.R. China.	ORF1ab and N gene	RT-PCR

16	Real time RT PCR Detection Kit For 2019 nCoV	Hangzhou DIAN Biotechnology Co Ltd. P.R. China	ORF1ab and E gene	RT-PCR
17	Liferiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	Shanghai ZJ Bio-tech Co., Ltd. P.R. China.	ORF1ab, N and E gene	RT-PCR
18	XABT Multiple Real-Time PCR Kit for Detection of 2019-nCoV	Beijing Applied Biological Technologies Co., Ltd. P.R.China	ORF1ab, N and E gene	RT-PCR
19	AccuraDTect™ SARS-CoV-2 RT-qPCR Kit	Genomictree Inc. Republic of Korea	N and RNase P gene	RT-PCR
20	eDiagnosis COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit	Wuhan EasyDiagnosis Biomedicine Co.,Ltd. P.R. China	ORF1ab and N gene	RT-PCR
21	BioFire RP 2.1 plus	Biofire Defence, Utah, USA	S and M gene	RT-PCR
22	Allplex™ SARS-CoV-2	Seegene Inc, Republic of Korea	E, RdRP, S and N gene	RT-PCR
23	Allplex™ 2019-nCoV Assay	Seegene Inc, Republic of Korea	E, RdRP and N gene	RT-PCR
24	TaqPath™ COVID-19 CE-IVD RT-PCR Kit (Cat.No: A48067)	Life Technologies Corporation CA, USA	ORF1ab, S and N gene	RT-PCR
25	FTD SARS-CoV-2	Fast Track Diagnostics Luxembourg S.a.r.l Germany	ORF1ab and N gene	RT-PCR
26	GeneFirst COVID-19 Nucleic Acid Diagnostic Kit	GeneFirst Limited, United Kingdom	ORF1ab and N gene	RT-PCR
27	TaqPath™ COVID-19 Combo Kit (Cat No.: A47814)	Life Technologies Corporation, USA.	ORF1ab, N and S gene	RT-PCR
28	Viasure Sars-CoV-2 Real Time PCR Detection kit	CerTest Biotec SL. Spain	ORF1ab and N gene	RT-PCR
29	Fosun 2019-nCoV qPCR	Shanghai Fosun Long March Medical Science Co., Ltd. P.R. China	ORF1ab, N and E gene	RT-PCR
30	LabGun COVID-19 RT-PCR Kit	LabGenomics Co.,Ltd. Republic of Korea	RdRp and E gene	RT-PCR
31	GenoAmp® Real-Time RT-PCR SARS-CoV-2	Medical Innovation Ventures Sdn. Bhd. Penang, Malaysia.	RdRp, S and N gene	RT-PCR
32	MolecuTech® Real-Time COVID-19	YD Diagnostics Corp. Republic of Korea	RdRp and E gene	RT-PCR
33	WellsBio CareGENE N- CoV RT-PCR kit	Wells Bio, Inc Republic of Korea	RdRp and E gene	RT-PCR
34	Maccura SARS-CoV-2 Fluorescent PCR	Maccura Biotechnology Co. Ltd. P.R. China	ORF1ab, E and N gene	RT-PCR
35	Genefinder Covid-19 Plus RealAmp Kit	Osang Healthcare Co. Ltd. Republic of Korea	RdRP, E and N gene	RT-PCR

36	GB SARS-CoV-2 Real-Time RT-PCR	General Biologicals Corporation, Taiwan	ORF1ab and E gene	RT-PCR
37	1copy™ COVID-19 qPCR Multi Kit	1drop Inc. Republic of Korea	E and RdRp gene	RT-PCR
38	Labsystems Diagnostics Covid-19 Real-Time PCR Kit	Labsystems Diagnostics Oy Vantaa, Finland	ORF1ab, E and N gene	RT-PCR
39	GenoAmp® Real-Time RT-PCR Flu A/ Flu B/SARS-CoV-2/MERS-CoV	Medical Innovation Ventures Sdn. Bhd. Penang, Malaysia.	RdRp, S and N gene	RT-PCR
40	iAMP® COVID-19 Detection Kit	Atila BioSystems, Inc. CA, USA	ORF1ab and N gene	RT-PCR
41	Alinity m SARS-CoV-2 AMP kit Alinity m SARS-CoV-2 CTRL kit Alinity m SARS-CoV-2 application Specification File Ver 2.00	Abbott Molecular Inc. USA	RdRp and N gene	RT-PCR
42	RESOLUTE 2.0 SARS-CoV-2 Direct Detection Kit	AMT Pte. Ltd. Singapore	E, N and RNase P gene	RT-PCR
43	AccuPower SARS-CoV-2 Multiplex Real-Time RT-PCR Kit	Bioneer Corporation Republic of Korea	E, RdRp and N gene	RT-PCR
44	Biofire Defence, USA	BioFire® Respiratory Panel 2.1 (RP2.1)	S gene and M gene	RT-PCR
45	ADT Biotech Sdn Bhd, Malaysia	LyteStar™ 2019-nCoV PCR Kit 2.0	E gene and RdRP gene	RT-PCR
46	Vazyme 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit	Nanjing Vazyme Medical Technology Co., Ltd. Nanjing, P.R. China	ORF1ab, N and RNase P gene	RT-PCR
47	Real-time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2	BGI Europe A/S Denmark	ORF1ab, and N gene	RT-PCR
48	Genedrive® 96 SARS-CoV-2 Kit	Genedrive Diagnostics Ltd., Manchester United Kingdom	E and N gene	RT-PCR

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1	Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19	Shanghai Liangrun Biomedicine Technology Co., Ltd. P.R. China	RTK Antibody
2	STANDARD Q COVID-19 IgM/IgG Combo	SD Biosensor, Inc. Republic of Korea	RTK Antibody
3	Standard Q SARS-CoV-2 Rapid Antibody Test	SD Biosensor, Inc. Republic of Korea	RTK Antibody
4	Asan Easy Test COVID-19 IgG/IgM	Asan Pharmaceutical Co., Ltd. Republic of Korea	RTK Antibody

5	Maccura SARS-CoV-2 Antibody Assay Kit	Maccura Biotechnology Co., Ltd. P.R. China.	RTK Antibody
6	SARS-CoV-2 IgM/IgG Antibody Test Kit (Colloidal Gold Method)	ZYbio Inc. P.R. China	RTK Antibody
7	careUS™ COVID-19 IgM IgG	Wells Bio Inc. Republic of Korea	RTK Antibody
8	Covid-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)	Zhejiang Orient Gene Biotech Co Ltd. P.R. China	RTK Antibody
9	2019-nCoV IgG/IgM Rapid Test Cassette	Hangzhou AllTest Biotech Co. Ltd. P.R. China	RTK Antibody
10	Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	Cellex Inc. USA	RTK Antibody
11	Covid-19 Rapid IgG/IgM Combined Antibody Pre-Screening Kit	Spring Healthcare Services AG Switzerland	RTK Antibody
12	Rightsign Covid-19 IgG/IgM Rapid Test Cassette	Hangzhooou Biotest Biotech Co., Ltd P.R.China	RTK Antibody
13	Biolidics 2019-nCoV IgG/IgM Antibody Detection Kit	Biolidics Ltd, Singapore	RTK Antibody
14	Covid-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	HEALGEN Scientific Limited Liability Company, USA.	RTK Antibody
15	ProDetect® COVID-19 IgG/IgM Rapid Test (Dipstick)	Medical Innovation Ventures Sdn. Bhd. Penang, Malaysia	RTK Antibody
16	ProDetect® COVID-19 IgG/IgM Rapid Test (cassette)	Medical Innovation Ventures Sdn. Bhd. Penang, Malaysia	RTK Antibody
17	NADAL® COVID-19 IgG/IgM Test (test cassette)	nal von minden GmbH Carl-Zeiss-Strasse 12 • 47445 Moers • Germany	RTK Antibody
18	Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test	Qingdao Hightop Biotech Co., Ltd, China	RTK Antibody
19	Reszon COVID 19 Rapid IgG/IgM Test	Reszon Diagnostics International Sdn. Bhd. Selangor, Malaysia	RTK Antibody
20	ADVIA Centaur® SARS-CoV-2 Total (COV2T) ADVIA Centaur® SARS-CoV-2 Total Quality Control (COV2T QC)	Siemens Healthcare Diagnostics Inc. USA	Antibody Assay
21	Atellica® IM SARS-CoV-2 Total (COV2T) Atellica® IM SARS-CoV-2 Total Quality Control (COV2T QC)	Siemens Healthcare Diagnostics Inc. USA	Antibody Assay
22	Elecsys® Anti-SARS-CoV-2 CalSet Anti-SARS-CoV-2 S PreciControl Anti-SARS-CoV-2 S	Roche Diagnostics GmbH, Mannheim, Germany	Antibody Assay
23	SARS-CoV-2 IgG Reagent Kit SARS-CoV-2 IgG Calibrator Kit SARS-CoV-2 IgG Control Kit	Abbott Ireland, Diagnostics Division, Sligo, Ireland.	Antibody Assay
24	Access SARS-CoV-2 IgG Access SARS-CoV-2 IgG Calibrator Access SARS-CoV-2 IgG QC:QC (Quality Control) materials	Beckman Coulter, Inc. CA U.S.A.	Antibody Assay
25	ImmuSAFE™ COVID+ Biochip Test	Applied Microarrays, Inc. USA	Antibody MicroArray

26	VITROS Immunodiagnostic Products Anti-SARS-2 Total Reagent Pack VITROS Immunodiagnostic Products Anti-SARS-2 Total Control VITROS Immunodiagnostic Products Anti-SARS-2 Total Calibrator	Ortho-Clinical Diagnostics, Inc. New York	Antibody Assay
27	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG	Ortho-Clinical Diagnostics United Kingdom	Antibody Assay
28	Elecsys Anti-SARS-CoV-2	Roche Diagnostics GmbH, Sandhofer Strasse 116, Mannheim, Germany 68305.	Antibody Assay
29	ADVIA Centaur® SARS-CoV-2 IgG (sCOVG)	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue, Tarrytown, NY 10591, USA	Antibody Assay
30	Atellica® IM SARS-CoV-2 IgG (sCOV2G)	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue, Tarrytown, NY 10591, USA	Antibody Assay
31	SARS-CoV-2 Rapid Antibody Test	SD Biosensor., Republic Of Korea	RTK Antibody
32	WANTAI SARS-COV-2 Ab ELISA (Total)	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, No.31 Kexueyuan Road, Changping District, Beijing 102206, China	Antibody Assay
33	COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma)	Assure Tech. (Hangzhou) Co., Ltd, China	RTK Antibody
34	Anti-SARS-CoV-2 ELISA (IgG)	Euroimmun Medizinische Labordiagnostika AG, Deutschland	Antibody Assay
35	Neutralizing Antibody of SARS-CoV-2 Test	Anbio (Xiamen) Biotechnology Co., Ltd	Neutralizing Antibody Assay
36	SARS-CoV-2 IgM	Abott Ireland, Ireland	Antibody Assay
37	E Diagnosis COVID-19(SARS-CoV-2) IgM/IgG Antibody Test Kit	Wuhan EasyDiagnosis Biomedicine Co., Ltd. P.R. China	RTK Antibody
38	Bel TEST-It! SARS-CoV-2 IgM/IgG rapid test	PharmACT GmbH, Berlin, Deutschland	RTK Antibody