

## List of SFDA Emergency Use Authorization (EUA) and Medical Devices Marketing Authorization for COVID-19 IVD test Kits

#	Manufacturer	Kit	Approval	Type	AR
1	Roche Molecular Systems	cobas SARS-CoV-2 test	SFDA Emergency Use Authorization (EUA)  SFDA IVD (MDMA 33156)  FDA EUA  CE	RT-PCR	Farouk Mamoun Tamer and Co
2	Genekam	Novel Coronavirus 2020 (Wuhan Strain specific) Realtime PCR	SFDA (EUA)	RT-PCR	Medical Supplies and Services Co Ltd
3	Primerdesign Ltd.	genesig Real-Time PCR COVID-19	SFDA (EUA)  CE	RT-PCR	Cigalah group warehouse for Drug
4	BGI	Real-Time Fluorescent RT- PCR kit for detecting SARS-CoV-2	SFDA (EUA)  FDA EUA  CE	RT-PCR	BGI HEALTH (HK) CO. LTD/ Fetal Care Medical expired AR
5	altona-diagnostic	RealStar® SARS-CoV-2 RT-PCR Kit RUO	SFDA (EUA)  FDA (EUA)	RT-PCR	Abdulla Fouad Company
6	Inzek International Trading BV	COVID-19 IgM/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	SFDA IVD (MDMA 26502)	Rapid	First Technology Trading Est
7	Prima Lab SA	Prima COVID-19 IgG/IgM RAPID TEST	SFDA IVD (MDMA 25555)	Rapid	Tanami Global for Business Services
8	Kogene Biotech	2019 Novel Coronavirus Real-time PCR Kit	SFDA (EUA)  Korea  CE	RT-PCR	HIGH STANDARD MEDICAL INC
9	TIB Molbiol Syntheselabor	Sarbecovirus E-gene	SFDA (EUA) CE	RT-PCR	Farouk Mamoun Tamer and Co
10	Becton Dickinson and Company	BD Universal Viral Transport	SFDA IVD (MDMA 23702)	Transport media	Becton Dickinson BV Saudi

					Limited Company
11	Becton Dickinson and Company	SARS-COV-2 s Gen realtime	SFDA IVD (MDMA 33909)	RT-PCR	Becton Dickinson BV Saudi Limited Company
12	CTK Biotech Inc	OnSite COVID-19 IgG/IgM Rapid Test	SFDA IVD (MDMA 31496) TGA	Rapid	WAREED ALHAYAT Est
13	Abbott Molecular Division Inc.	Abbott RealTime SARS-CoV-2 Amplification Reagent Kit Abbott RealTime SARS-CoV-2 Control Kit	SFDA IVD (MDMA 33883)	RT-PCR	Medical Supplies and Services Co Ltd
14	VIVACHEK BIOTECH (HANGZHOU) CO., LTD	VivaDiag™ COVID-19 IgM/IgG Rapid Test	SFDA IVD (MDMA 30335) TGA Singapore	Rapid	ALJEEL MEDICAL COMPANY
15	KogeneBiotech Co., Ltd.	PowerChek 2019-nCoV Real-time PCR Kit Real-time PCR System	SFDA IVD (MDMA 27154)	RT-PCR	HIGH STANDARD MEDICAL INC
16	1drop Inc.	1copy™ COVID-19 qPCR Kit	SFDA IVD MDMA CE FDA EUA	RT-PCR	Sciences and Supply limited co
17	Wuhan MGI Tech Co, Ltd	High-throughput Automated Sample Preparation System Nucleic Acid Extraction Kit Genetic Sequencer	SFDA IVD (MDMA 2020-36265)	RT-PCR	Farabi Trading Establishment
18	Lingen Precision Medical Products (Shanghai) Co., Ltd	Disposable Virus Sampling kit	SFDA IVD (MDMA 2020-37939)	Transport media	Alsana Mdeical company
19	Snibe Diagnostics	Maglumi 2019-nCoV (SARS-CoV-2) IgM/IgG kits	SFDA MDMA (2020-28765) CE	Immunoassay	United Diagnostics Industry
20	QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel Single-plex real-time PCR tests for SARS-CoV-2	SFDA MDMA (2020-39975)	RT-PCR	Abdulla Fouad Company

			CE US FDA EUA		
21	Quidel	Lyra SARS-CoV-2 Assay	SFDA MDMA (2020-47739)  CE FDA EUA  Health Canada	RT-PCR	Abdulla Fouad for Medical Supplies and Services Company
22	Cepheid	Xpert Xpress SARS-CoV-2 test	SFDA EUA  FDA EUA	RT-PCR (Laboratory/POCT)	Abdulla Fouad for Medical Supplies and Services Company
23	Bioeksan, Buyukdere Turkey	Bio-Speedy Covid-19 QPCR detection kit / Bio- Speedy Viral Nucleic Acid Isolation kit	SFDA EUA	RT-PCR	Abdulla Fouad for Medical Supplies and Services Company
24	GUANGZHOU IMPROVE MEDICAL INSTRUMENTS CO., LTD.	Viral Preservative Medium	SFDA EUA	Transport media	Abdulla Fouad for Medical Supplies and Services Company
25	Boditech Med Inc.	AFIAS COVID-19 Ab ichroma COVID-19 Ab	SFDA MDMA (2020-39987)	Immunoassay	Abdulla Fouad for Medical Supplies and Services Company
26	Bioneer	AccuPower SARS-CoV-2 Real-Time RT-PCR Kit; ExiPrep 96 Viral DNA/RNA Kit; ExiPrep 96 Lite Automated NA Purification System	SFDA MDMA (2020-45979)  CE	RT-PCR	HIGH STANDARD MEDICAL INC
27	CerTest	VIASURE SARS-CoV-2 Real Time PCR Detection Kit	SFDA MDMA (2020-38668)  CE  TGA  Korea	RT-PCR	Tehama Medical Est
28	Jiangsu Rongye Technology Co., Ltd.	Viral Transport media with Swab	SFDA MDMA (2020-46115)	Transport media	FUAD ABDUL JALIL AL FADHLI AND SONS TRADING CO

29	Wells Bio, Inc	careGENE™ N-CoV RT-PCR Kit; careGENE COVID-19 RT-PCR kit	SFDA MDMA (2020-36627)	RT-PCR	Dar Al Farabi Corporation for Medical DAFCO
30	SD Biosensor, Inc.	STANDARD M nCoV Real-Time Detection Kit	SFDA MDMA (2020-32762) FDA EUA	RT-PCR	AlKamal Import Office
31	Abbott Ireland Diagnostics Division	-SARS-CoV-2 IgG Reagent Kit -SARS-CoV-2 IgG Calibrator Kit -SARS-CoV-2 IgG Control Kit	SFDA MDMA (2020-46442)	Rapid	Medical Supplies and Services Co Ltd
32	King Faisal Specialist Hospital & Research Centre	SARS-CoV-2 SYBER® Green rtPCR SARS-CoV-2 Nested PCR	SFDA EUA	RT-PCR	King Faisal Specialist Hospital & Research Centre
33	Roche Diagnostics	Elecsys Anti-SARS-CoV-2	SFDA MDMA (2020-48744) FDA EUA	Immunoassay	Roche Diagnostics Saudi Arabia Limited
34	BIOMERIEUX S.A.	ARGENE® SARS-COV-2 R-GENE®	SFDA MDMA (2020-37990)	RT-PCR	ALJEEL MEDICAL COMPANY
35	Shenzhen Lifotronic Technology Co., Ltd.	SARS-CoV-2 IgM (Electrochemiluminescence Immunoassay) SARS-CoV-2 IgG (Electrochemiluminescence Immunoassay)	SFDA MDMA (2020-43328)	ECLIA	Yood Company
36	Shenzhen Mindray Bio-Medical Electronics Co.,Ltd.	SARS-CoV-2 IgG (CLIA) SARS-CoV-2 IgM (CLIA)	SFDA MDMA (2020-47379)	CLIA	Abdulla Fouad For Medical Supplies and Services Company
37	Becton Dickinson and Company	BD SARS-CoV-2 Reagents for BD MAX System	SFDA MDMA (2020-40517)  CE  FDA EUA	RT-PCR	Becton Dickinson B.V Saudi Limited Company
38	VIRCELL, S.L	-COVID-19 ELISA IgG -COVID-19 ELISA IgM+IgA -COVID-19 VIRCLIA IgG MONOTEST -COVID-19 VIRCLIA IgM+IgA MONOTEST	SFDA MDMA (2020-45823)	ELISA	Abdulla Fouad For Medical Supplies and Services Company

39	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	SFDA MDMA (2020-44842)  FDA EUA	ELISA	Samir Trading and Marketing CJSC
40	Guangzhou Deaou Biotechnology co.,Ltd	Virus Sampling Tube	SFDA MDMA (2020-38297)	Transport medium	ALOSOOL MEDICAL TRADING COMPANY
41	Bosch Healthcare Solutions GmbH	Vivalytic one	SFDA MDMA (2020-41155)	Nucleic Acid extraction	Binary System Medical Co
42	Lana Al Khaleej Al Awal for medical supplies	NATEJAH New Coronavirus (COVID-19) IgG/IgM Rapid Test	SFDA MDMA (2020-32275)	Rapid	Lana Al Khaleej Al Awal for medical supplies
43	King Abdulaziz Medical City (NGHA)	SARS-CoV-2 Multiplex One Step RT-PCR	SFDA EUA	RT-PCR	King Abdulaziz Medical City (NGHA)
44	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	SFDA MDMA (2020-46522)	RT-PCR	Intgerated Gulfbiosystems