

## List of COVID-19 IVD test

#	Manufacturer	Kit	Approval	Type	AR
1.	Roche Molecular Systems	-cobas SARS-CoV-2 test  -cobas SARS-CoV-2 Control Kit	SFDA MDMA (2020-33156)	PCR	Roche Diagnostics Saudi Arabia Limited
2.	Genekam	Novel Coronavirus 2020 (Wuhan Strain specific) Realtime PCR	SFDA (EUA) اعتماد استخدام طوارئ	PCR	Medical Supplies and Services Co Ltd
3.	Primerdesign Ltd.	genesig Real-Time PCR COVID-19	SFDA (EUA) اعتماد استخدام طوارئ	PCR	مخازن سقاه للأدوية
4.	BGI Europe A/S	-Real-Time Fluorescent RT- PCR kit for detecting 2019- nCoV	SFDA MDMA (2020-69591)	PCR	Bio Standards LLC
5.	altona Diagnostics GmbH	-RealStar® SARS-CoV-2 RT- PCR Kit 1.0	SFDA MDMA (2020-53451)	PCR	Abdulla Fouad For Medical Supplies and Services Company
6.	Inzek International Trading BV	-COVID-19 IgM/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	SFDA MDMA (2020-26502)	Rapid	First Technology Trading Est
7.	Prima Lab SA	-Prima COVID-19 IgG/IgM RAPID TEST	SFDA MDMA (2019-25555)	Rapid	Tanami Global for Business Services
8.	KogeneBiotech Co., Ltd.	-PowerChek 2019-nCOV Real- time PCR Kit  -PowerCheck SARS-COV-2 Real-time PCR Kit	SFDA MDMA (2021-5418)	PCR	HIGH STANDARD MEDICAL INC
9.	TIB Molbiol Syntheselabor	Sarbecovirus E-gene	SFDA (EUA) اعتماد استخدام طوارئ	PCR	Farouk Mamoun Tamer and Co
10.	CerTest Biotec S.L	-SARS-CoV-2 S gene Real Time PCR Detection kit	SFDA MDMA (2020-33909)	PCR	Becton Dickinson BV Saudi Limited Company
		-VIASURE SARS-CoV-2 Real Time PCR Detection Kit	SFDA MDMA	PCR	Tehama Medical Est

			(2020-38668)		
11.	Becton Dickinson and Company	-BD SARS-CoV-2 Reagents for BD MAX System	SFDA MDMA (2020-40517)	PCR	Becton Dickinson BV Saudi Limited Company
		-BD Veritor™ System For Rapid Detection of SARS-CoV-2	SFDA MDMA (2020-97490)	Immunoassay	
12.	CTK Biotech Inc	-OnSite COVID-19 IgG/IgM Rapid Test	SFDA MDMA (2020-31496)	Rapid	WAREED ALHAYAT Est
13.	Abbott Molecular Inc.	-Abbott RealTime SARS-CoV-2 Amplification Reagent Kit	SFDA MDMA (2020-33883)	PCR	Medical Supplies and Services Co Ltd
		-Abbott RealTime SARS-CoV-2 Control Kit			
		-Alinity m SARS-CoV-2 AMP Kit	SFDA MDMA (2020-86129)	PCR	
14.	VIVACHEK BIOTECH (HANGZHOU) CO., LTD	-VivaDiag™ COVID-19 IgM/IgG Rapid Test	SFDA MDMA (2020-30335)	Rapid	ALJEEL MEDICAL COMPANY
15.	1DROP INC	-1copy™ COVID-19 qPCR Multi Kit	SFDA MDMA (2020-37189)	PCR	Sciences and Supply limited co
16.	Shenzhen New Industries Biomedical Engineering Co., Ltd ( SNIBE )	- MAGLUMI 2019-nCoV IgM (CLIA)	SFDA MDMA (2020-28765)	Immunoassay	United Diagnostics Industry
		- MAGLUMI 2019-nCoV IgG (CLIA)			
17.	Qiagen GmbH	-QIAstat-Dx® Respiratory SARS-CoV-2 Panel	SFDA MDMA (2020-39975)	PCR	Abdulla Fouad For Medical Supplies and Services Company
18.	Quidel Corporation	-Lyra SARS-CoV-2 Assay	SFDA MDMA (2020-47739)	PCR	Abdulla Fouad for Medical Supplies and Services Company
		-Sofia SARS Antigen FIA	SFDA MDMA (2020-67397)	Immunoassay	

19.	Cepheid	-Xpert Xpress SARS-CoV-2	SFDA MDMA (2020-41726)	PCR	Abdulla Fouad for Medical Supplies and Services Company
20.	Bioeksan, Buyukdere Turkey	-Bio-Speedy Covid-19 QPCR detection kit / Bio-Speedy Viral Nucleic Acid Isolation kit	SFDA EUA	PCR	Abdulla Fouad for Medical Supplies and Services Company
21.	Boditech Med Inc.	-AFIAS COVID-19 Ab	SFDA MDMA (2020-39987)	Immunoassay	Abdulla Fouad for Medical Supplies and Services Company
		-ichroma COVID-19 Ab		Immunoassay	
21.	Boditech Med Inc.	-ichroma COVID-19 Ag	SFDA MDMA (2020-75722)	Immunoassay	Abdulla Fouad for Medical Supplies and Services Company
		-AFIAS COVID-19 Ag			
21.	Boditech Med Inc.	-Boditech COVID-19 Ab Control	SFDA MDMA (2020-75722)	Immunoassay	Abdulla Fouad for Medical Supplies and Services Company
		-Boditech COVID-19 Ag Control			
22.	Bioneer Corporation	-AccuPower SARS-CoV-2 Real-Time RT-PCR Kit	SFDA MDMA (2020-45979)	PCR	HIGH STANDARD MEDICAL INC
23.	Wells Bio, Inc	-careGENE™ N-CoV RT-PCR Kit	SFDA MDMA (2020-36627)	PCR	Dar Al Farabi Corporation for Medical DAFCO
		-careGENE COVID-19 RT- PCR kit			
24.	SD Biosensor, Inc.	-STANDARD M nCoV Real- Time Detection Kit	SFDA MDMA (2020-32762)	PCR	AlKamal Import Office
		-STANDARD Q COVID-19 IgM/IgG Duo		Rapid	Branch of Khusheim Company for industrial equipment
24.	SD Biosensor, Inc.	-STANDARD Q COVID-19 Ag	SFDA MDMA (2020-52281)	Rapid	Branch of Khusheim Company for industrial equipment
		-STANDARD Q COVID-19 Ag			
25.	Abbott Ireland Diagnostics Division	-SARS-CoV-2 IgG Reagent Kit	SFDA MDMA (2020-80622)	Immunoassay	Medical Supplies and Services Co Ltd
		-SARS-CoV-2 IgG Calibrator Kit			
		-SARS-CoV-2 IgG Control Kit			
		-SARS-CoV-2 IgM Reagent Kit			
		-SARS-CoV-2 IgM Calibrator Kit			

		-SARS-CoV-2 IgM Control Kit			
26.	King Faisal Specialist Hospital & Research Centre	-SARS-CoV-2 SYBER ® Green rtPCR	SFDA EUA	PCR	King Faisal Specialist Hospital & Research Centre
27.	Roche Diagnostics GmbH	-SARS-CoV-2 Nested PCR			
		-Elecsys Anti-SARS-CoV-2	SFDA MDMA (2020-97895)	Immunoassay	Roche Diagnostics Saudi Arabia Limited
		-PeciControl Anti-SARS-CoV-2			
		-Elecsys Anti-SARS-CoV-2			
		-CalSet Anti-SARS-CoV-2 S			
		-PeciControl Anti-SARS-CoV-2 S			
		-Elecsys SARS-CoV-2 Antigen	SFDA MDMA (2021-2505)	Immunoassay	
		-Elecsys SARS-CoV-2 Antigen	SFDA MDMA (2021-6334)	Immunoassay	
		-PeciControl SARS-CoV-2 Antigen			
		-SARS-CoV-2 Extraction Solution C			
		-SARS-CoV-2 Extraction Solution			
28.	BIOMERIEUX S.A.	-ARGENE® SARS-COV-2 R-GENE®	SFDA MDMA (2020-37990)	PCR	ALJEEL MEDICAL COMPANY
		-VIDAS® SARS-COV-2 IgM	SFDA MDMA (2020-56148)	Immunoassay	
		-VIDAS® SARS-COV-2 IgG			
29.	Shenzhen Lifotronic Technology Co., Ltd.	-SARS-CoV-2 IgM (Electrochemiluminescence Immunoassay)	SFDA MDMA (2020-43328)	Immunoassay	Yood Company
		-SARS-CoV-2 IgG (Electrochemiluminescence Immunoassay)			
30.	Shenzhen Mindray Bio-Medical Electronics Co.,Ltd.	-SARS-CoV-2 IgG (CLIA)	SFDA MDMA (2020-47379)	Immunoassay	Abdulla Fouad For Medical Supplies and Services Company
		-SARS-CoV-2 IgM (CLIA)			
31.	VIRCELL, S.L	-COVID-19 ELISA IgG	SFDA MDMA (2020-45823)	Immunoassay	Abdulla Fouad For Medical Supplies and Services Company
		-COVID-19 ELISA IgM+IgA			
		-COVID-19 VIRCLIA IgG MONOTEST			
		-COVID-19 VIRCLIA IgM+IgA MONOTEST			

32.	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)	Immunoassay	Samir Trading and Marketing CJSC
		-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 (2020-109601)	Immunoassay	
33.	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
34.	King Abdulaziz Medical City (NGHA)	SARS-CoV-2 Multiplex One Step RT-PCR	SFDA EUA	PCR	King Abdulaziz Medical City (NGHA)
35.	Life Technologies Corporation	- TaqPath COVID-19 Control Dilution Buffer - TaqPath COVID-19 RT-PCR Kit - TaqPath COVID-19 Control	SFDA MDMA (2020-46522)	PCR	Intgerated Gulfbiosystems
36.	Goldsite Diagnostics Inc	-SARS-CoV-2 IgG/IgM Kit	SFDA MDMA (2020-36732)	Rapid	Taaml Trading Company
37.	BIOSYNEX SWISS SA	-BIOSYNEX COVID-19 BSS	SFDA MDMA (2020-35184)	Rapid	Abdulrehman Algoaibi GTC
38.	Beijing Applied Biological Technologies Co. Ltd.	-Multiple Real-Time PCR Kit for Detection of 2019-nCoV	SFDA MDMA (2020-45701)	PCR	Bayouni Trading Company
39.	AniCon Labor GmbH	-Kylt® SARS-CoV-2 Screening RTU -Kylt® SARS-CoV-2 Confirmation RTU	SFDA MDMA (2020-51928)	PCR	Artat Enterprise for Medical Device
40.	EUROIMMUN Medizinische Labordiagnostika AG	-EURORealTime SARS-CoV-2	SFDA MDMA (2020-39782)	PCR	Medical Regulations Gate

		-Anti-SARS-CoV-2 ELISA (IgA) -Anti-SARS-CoV-2 ELISA (IgG) -Anti-SARS-CoV-2 NCP ELISA (IgG)	SFDA MDMA (2020-52536)	Immunoassay	
41.	Seegene Inc	-Allplex 2019-nCoV Assay	SFDA MDMA (2020-34703)	PCR	Bayouni Trading Company
42.	Bio-Rad	-Platelia SARS-CoV-2 Total Ab assay	SFDA MDMA (2020-41806)	Immunoassay	ALJEEL MEDICAL COMPANY
43.	Biopanda Reagents LTD	-COVID-19 Rapid Test Kit	SFDA MDMA (2020-37212)	Rapid	Ashnan Medical Est
44.	Cellex Inc.	-qSARS-CoV-2 IgG/IgM Rapid Test	SFDA MDMA (2020-41106)	Rapid	Awad Medical Company
45.	Fast Track Diagnostics Luxembourg S.á.r.l.	-FTD SARS-CoV-2	SFDA MDMA (2020-52521)	PCR	Intgerated Gulfbiosystems
46.	Diapro Diagnostic Bioprobes srl	-COVID-19 IgG	SFDA MDMA (2020-52438)	Immunoassay	NAIZAK GLOBAL ENGINEERING LAB SYSTEMS
		-COVID-19 IgM			
		-COVID-19 IgA			
		-COVID-19 IgG Confirmation			
		-WUHAN COVID-19	SFDA MDMA (2021-6341)	PCR	
		-COVID-19 RNA			
		-COVID-19 RNA Vs 2			
47.	PCL, Inc.	-PCL COVID IgG/IgM Rapid Gold	SFDA MDMA (2020-34137)	Rapid	NAIZAK GLOBAL ENGINEERING LAB SYSTEMS
48.	GA Generic Assays GmbH	-GA CoV-2 IgM	SFDA MDMA (2020-54173)	Immunoassay	Raez Environmental Systems Advanced Technologies Est
		-GA CoV-2 IgG			
		-GA CoV-2 IgG +			

49.	nal von minden GmbH	-NADAL® COVID-19 IgG/IgM Test	SFDA MDMA (2020-28470)	Rapid	FUAD ABDUL JALIL AL FADHLI AND SONS TRADING CO
50.	NeuMoDx Molecular, Inc.	-NeuMoDx SARS-CoV-2 Test Strip -NeuMoDx Viral Lysis Buffer -NeuMoDx Lysis Buffer 6	SFDA MDMA (2020-55178)	PCR	Abdulla Fouad For Medical Supplies and Services Company
51.	Artron Laboratories Inc.	-COVID-19 IgM/IgG Ab cassette Test	SFDA MDMA (2020-48153)	Rapid	Sidanah International Co
52.	Abbott Rapid Diagnostics Jena GmbH	-Panbio™ COVID-19 IgG/IgM Rapid Test Device (Fingerstick Whole Blood/ Venous Whole Blood/Serum/Plasma)	SFDA MDMA (2020-32637)	Rapid	Medical Supplies and Services Co Ltd
		-Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal)	SFDA MDMA (2020-83869)	Rapid	
53.	LabGenomics Co., Ltd.	-LabGun™ COVID-19 Assay	SFDA MDMA (2020-60374)	PCR	Diwan AL Rawnaq Co
54.	Sacace Biotechnologies S.r.l.	-SARS-CoV-2 Real-TM	SFDA MDMA (2020-63447)	PCR	Sciences and Supply limited co
55.	Hologic, Inc	-Aptima SARS-CoV-2 Assay -Aptima SARS-CoV-2 Controls Kit	SFDA MDMA (2020-57046)	PCR	ALJEEL MEDICAL COMPANY
56.	REDCELL BIOTECHNOLOGY A.S	-Direct RT-qPCR SARS-CoV-2	SFDA MDMA (2020-53040)	PCR	Rezaik Abdullah Saeed AlGedrawy



					AlThabaiti and Partners
57.	Xiamen Zeesan Biotech Co., Ltd.	-SARS-CoV-2 Test Kit	SFDA MDMA (2020-53977)	PCR	ALJEEL MEDICAL COMPANY
58.	Siemens Healthcare Diagnostics Inc.	-Dimension® EXL™ Integrated Chemistry System CV2T  -Dimension Vista® / Dimension® EXL™ COV2T CAL / CV2T CAL  -Dimension Vista® System COV2  -Dimension Vista® / Dimension® EXL™ COV2T / CV2T POS/NEG CONTROL  -Dimension® EXL™ integrated chemistry system CV2G  -Dimension Vista® System COV2G  -Dimension Vista® / Dimension® EXL™ COV2G CAL / CV2G CAL  -Dimension Vista® / Dimension® EXL™ COV2G QC / CV2G QC	SFDA MDMA (2020-90610)	Immunoassay	Abdulrehman Algozaibi GTC
		-ADVIA Centaur® COV2T - ADVIA Centaur® QC COV2T - Atellica® IM COV2T - Atellica® IM COV2T QC -ADVIA Centaur® COV2G -ADVIA Centaur® QC COV2G -Atellica® IM COV2G -Atellica® IM COV2G QC		SFDA MDMA (2020-90607)	

		-ADVIA Centaur® sCOVG -ADVIA Centaur® sCOVG QC -Atellica® IM sCOVG -Atellica® IM sCOVG QC -Atellica® IM sCOVG MCM	SFDA MDMA (2021-9749)	Immunoassay	
59.	Eurobio Scientific	-EurobioPlex SARS-CoV-2 Multiplex	SFDA MDMA (2020-62393)	PCR	Dar AlZahrawi Medical Co LLC
60.	Beckman Coulter, Inc.	-Access SARS-CoV-2 IgG -Access SARS-CoV-2 IgG Calibrator -Access SARS-CoV-2 IgG QC	SFDA MDMA (2020-60037)	Immunoassay	Beckman Coulter Saudi Arabia Co Ltd
		-ACCESS SARS-CoV-2 IgM -ACCESS SARS-CoV-2 IgM CALIBRATOR -ACCESS SARS-CoV-2 IgM QC	SFDA MDMA (2020-110007)	Immunoassay	
61.	GUANGZHOU Wondfo Biotech Co., Ltd.	-SARS-CoV-2 Antibody Test (Lateral Flow Method)	SFDA MDMA (2020-59762)	Rapid	Regulatory Standards Est
62.	Exact Diagnostics	-SARS-COV-2 Positive Run Control -SARS-CoV-2 Negative Run Control	SFDA MDMA (2020-55263)	PCR	ALJEEL MEDICAL COMPANY
63.	Sugentech, Inc.	-SGTi-flex COVID-19 IgM/IgG	SFDA MDMA (2020-45610)	Rapid	Rokn AlMadaen Trading Establishment
64.	Immundiagnostik AG	-MutaPLEX Coronavirus	SFDA MDMA (2020-66505)	PCR	United Care Medical Company
65.	DiaSorin S.p.A.	-LIAISON SARS-CoV-2 S1/S2 IgG -LIAISON Control SARS-CoV-2 S1/S2 IgG -LIAISON SARS-CoV-2 IgM -LIAISON Control SARS-CoV-2 IgM	SFDA MDMA (2020-69204)	Immunoassay	Abdulla Fouad For Medical Supplies and Services Company

66.	Bosch Healthcare Solutions GmbH	-Vivalytic SARS-CoV-2	SFDA MDMA (2020-77947)	PCR	Binary System Medical Co
67.	AESKU Diagnostic	-AESKULISA SARS-CoV-2 NP IgA -AESKULISA SARS-CoV-2 NP IgG -AESKULISA SARS-CoV-2 NP IgM	SFDA MDMA (2020-82065)	Immunoassay	Branch of Kenaaz United For Trading
68.	BioFire Diagnostic, LLC	-BioFire® Respiratory Panel 2.1 plus (RP2.1plus)	SFDA MDMA (2020-75870)	PCR	ALJEEL MEDICAL COMPANY
69.	NanoEnTek Inc.	-Frend Covid-19 IgG/IgM Duo	SFDA MDMA (2020-74395)	Immunoassay	Taaml Trading Company
70.	Abbott Diagnostics Scarborough, Inc.	-ID Now COVID-19 -ID NOW COVID-19 Control Swab Kit	SFDA MDMA (2020-78150)	PCR	Medical Supplies and Services Co Ltd
71.	SureScreen Diagnostics Ltd.	-COVID-19 IgG/IgM RAPID TEST CASSETTE (WHOLE BLOOD, PLASMA, SERUM)	SFDA MDMA (2020-84253)	Rapid	NAQAYA Medica Co
72.	Coyote Bioscience Co., Ltd	-Direct Detect™ SARS-CoV-2 Detection Kit	SFDA MDMA (2020-77911)	PCR	First Desert Company
73.	GenMark Diagnostics, Inc.	-RP2 Respiratory Pathogen Panel 2	SFDA MDMA (2020-104381)	PCR	Dar AlZahrawi Medical Co LLC
74.	Astra Biotech GmbH	-SARS-CoV-2 Triplex PCR kit	SFDA MDMA (2020-70589)	PCR	Dar AlZahrawi Medical Co LLC
75.	Plexense, Inc.	-ACCEL ELISA® COVID-19 Kit	SFDA MDMA (2020-111411)	Immunoassay	Intelligent Regulations Medical Est
76.	BIOMEDOMICS, INC	-Covid-19 IgM-IgG Rapid Test	SFDA MDMA (2020-108493)	Rapid	Basamaa Al Khaleej Trading Establishment

77.	DowGene Co.,Ltd.	-Dow QuickFinder 2019-nCoV Real-time PCR Kit	SFDA MDMA (2020-74264)	PCR	Al Faisaliah Medical systems
78.	BIO-RAD LABORATORIES	-VIROTROL SARS-CoV-2 -VIROCLEAR SARS-CoV-2	SFDA MDMA (2020-121199)	Immunoassay	ALJEEL MEDICAL COMPANY
79.	Sansure Biotech Inc.	-Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	SFDA MDMA (2020-97501)	PCR	Al Faisaliah Medical systems
80.	Trenton Biomedical Ltd	-VitaPCRTM SARS-CoV-2 Gen 2 Assay -VitaPCRTM Influenza/SARS-CoV-2 (Flu/SC2) Assay -VitaPCRTM SARS-CoV-2 Gen 2 External Control Set	SFDA MDMA (2020-118955)	PCR	Binary System Medical Co
81.	PathoFinder B.V.	-MeningoFinder 2SMART -STD-Finder 2SMART -RespiFinder 2SMART	SFDA MDMA (2021-5978)	PCR	Dar AlZahrawi Medical Co LLC
82.	DiaSorin Molecular LLC	-Simplexa™ COVID-19 Direct -Simplexa™ COVID-19 Positive Control Pack	SFDA MDMA (2021-9617)	PCR	Samir Trading and Marketing CJSC
83.	Solgent Co. Ltd.	-DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit	SFDA MDMA (2020-84662)	PCR	Al Faisaliah Medical systems
84.	BioNote, Inc	-NowCheck COVID-19 Ag Test -NowCheck COVID-19 IgG/IgM Test	SFDA MDMA (2020-70425)	Immunoassay	Artat Enterprise for Medical Device