List of COVID-19 In Vitro Diagnostic Devices Officially Approved by MFDS(~22.1.14)

No.	Manufacturer	Device name	Technology	Date of approval	Contact Number
1	SD Biosensor, Inc.	STANDARD™ M nCoV Real-Time Detection kit	Molecular	2020. 8. 31.	+82-31-300-0400
2	BioSewoom, Inc.	Real-Q 2019-nCoV Detection kit	Molecular	2020. 10. 6.	+82-2-498-2340 (500)
3	Cancer Rop Co., Ltd.	Q-Sens® COVID-19 Detection kit	Molecular	2020. 10. 8.	+82-2-6964-8773
4	SeaSun Biomaterials	U-TOP™ COVID-19 Detection Kit Plus	Molecular	2020. 10. 8.	+82-42-716-0301
5	KogeneBiotech Co., Ltd.	PowerChek™ SARS-CoV-2, Influenza A&B Multiplex Real-time PCR Kit	Molecular	2020. 11. 3.	+82-2-2026-2150
6	SD Biosensor, Inc.	STANDARD™ Q COVID-19 IgM/IgG Plus Test	Antibody	2020. 11. 6.	+82-31-300-0400
7	SD Biosensor, Inc.	STANDARD™ Q COVID-19 Ag Test	Antigen	2020. 11. 11.	+82-31-300-0400
8	SeaSun Biomaterials	AQ-TOP™ COVID-19 Rapid Detection Kit Plus	Molecular	2020. 11. 23.	+82-42-716-0301

9	KogeneBiotech Co., Ltd.	PowerChek™ SARS-CoV-2 Real-time PCR Kit	Molecular	2020. 11. 26.	+82-2-2026-2150
10	Seegene Inc.	Allplex SARS-CoV-2 Assay	Molecular	2020. 12. 7.	+82-2-2026-2150
11	Cancer Rop Co., Ltd.	Q-Sens® COVID-19 Detection Kit V2	Molecular	2020. 12. 14.	+82-2-6964-8773
12	Sugentech, Inc.	SGTi-flex COVID-19 IgM/IgG	Antibody	2020. 12. 18.	+82-43-710-2822
13	GenBody Inc.	GenBody COVID-19 Ag	Antigen	2020. 12. 24.	+82-41-523-8990
14	SD Biosensor, Inc.	STANDARD™ F COVID-19 Ag FIA	Antigen	2021. 1. 5.	+82-31-300-0400
15	BioSewoom, Inc.	Real-Q Direct SARS-CoV-2 Detection Kit	Molecular	2021. 1. 20.	+82-2-498-2340 (500)
16	Seegene Inc.	Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay	Molecular	2021. 1. 26.	+82-2-2026-2150
17	SD Biosensor, Inc.	STANDARD™ F COVID-19 IgM/IgG Combo FIA	Antibody	2021. 1. 26.	+82-31-300-0400
18	SML GENETREE CO., LTD.	Ezplex® SARS-CoV-2 Kit	Molecular	2021. 1. 29.	+82-2-2057-7900
19	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit	Molecular	2021. 3. 12.	+82-2-2027-6320

20	RapiGEN, INC	BIOCREDIT COVID-19 Ag	Antigen	2021. 3. 18.	+82-31-427-4677
21	Humasis Co., Ltd.	Humasis COVID-19 Ag Test	Antigen	2021. 3. 18.	+82-31-478-8585 +82-31-478-8546
22	LabGenomics, Co., Ltd	LabGun™ COVID-19 ExoFast RT-PCR Kit	Molecular	2021. 3. 18.	+82-31-628-0783
23	OPTOLANE Technologies Inc.	Dr. PCR™ Di20K COVID-19 Detection kit	Molecular	2021. 3. 23.	+82-31-737-7835
24	SeaSun Biomaterials	U-TOP™ SARS-CoV-2 & Flu A/B	Molecular	2021. 4. 1.	+82-42-716-0301
25	Roche Diagnostics Korea Co., Ltd.	Elecsys Anti-SARS-CoV-2	Antibody	2021. 4. 16.	+82-2-550-0759
26	Siemens Healthineers Ltd.	ADVIA Centaur SARS-CoV-2 Total (COV2T)	Antibody	2021. 4. 16.	+82-2-3450-1073
27	GenBody Inc.	GenBody COVID-19 IgM/IgG	Antibody	2021. 4. 20.	+82-41-523-8990
28	Humasis Co., Ltd.	Humasis COVID-19 Ag Home Test	Antigen	2021. 4. 23.	+82-31-478-8585 +82-31-478-8546
29	SD Biosensor, Inc.	STANDARD™ Q COVID-19 Ag Home Test	Antigen	2021. 4. 23.	+82-31-300-0400
30	OSANG Healthcare Co., Ltd.	GeneFiner COVID-19 Fast RealAmp Kit	Molecular	2021. 4. 26.	+82-31-460-9921

31	BioSewoom, Inc.	Real-Q SARS-CoV-2/FluA/FluB Detection Kit	Molecular	2021. 4. 26.	+82-2-498-2340 (500)
32	BIONEER Corporation	AccuPower® RV1 Real-Time RT-PCR Kit (RV1-1111)	Molecular	2021. 4. 30.	+82-42-930-8508
33	Roche Diagnostics Korea Co., Ltd.	cobas SARS-CoV-2 & Influenza A/B	Molecular	2021. 5. 4.	+82-2-550-0759
34	Humasis Co., Ltd.	Humasis COVID-19 IgG/IgM Test	Antibody	2021. 5. 6.	+82-31-478-8585 +82-31-478-8546
35	SG Medical, Inc.	R-FIND COVID-19 IgM ELISA	Antibody	2021. 5. 6.	+82-2-2240-7062
36	SG Medical, Inc.	R-FIND COVID-19 IgG ELISA	Antibody	2021. 5. 6.	+82-2-2240-7062
37	SG Medical, Inc.	R-FIND COVID-19 IgG/M/A ELISA	Antibody	2021. 5. 6.	+82-2-2240-7062
38	PaxGenBio Co., Ltd.	PaxView® SARS-CoV-2 real-time RT-PCR Kit	Molecular	2021. 5. 12.	+82-31-244-5036
39	Sugentech, Inc.	SGTi-flex COVID-19 Ag	Antigen	2021. 5. 25.	+82-43-710-2822
40	BIONEER Corporation	AccuPower® RV1 Multiplex Kit (RV1-2112)	Molecular	2021. 5. 26.	+82-42-930-8508
41	WELLS BIO, INC.	careUS™ COVID-19 IgM/IgG Ab	Antibody	2021. 5. 27.	+82-2-3660-6900

42	LG Chem, Ltd.	AdvanSure™ SARS-CoV-2 IgG (S1) ELISA	Antibody	2021. 5. 27.	+82-2-6987-4432
43	Genomictree, Inc.	AccuraDTect™ COVID-19 RT-qPCR Kit	Molecular	2021. 6. 17.	+82-42-861-4551
44	SML GENETREE CO., LTD.	Ezplex® SARS-CoV2/RV Fast Kit	Molecular	2021. 6. 21.	+82-2-2057-7900
45	GenBody Inc.	GenBody FIA COVID-19 Ag	Antigen	2021. 6. 21.	+82-41-523-8990
46	AMSBIO	A+CheQ COVID-19 RT-qPCR Detection kit	Molecular	2021. 6. 22.	+82-2-2086-1621
47	PCL, Inc.	PCL COVID 19 Ag Gold	Antigen	2021. 6. 23.	+82-2-2144-3901
48	Genematrix Inc.	NeoPlex™ FluCOVID Kit	Molecular	2021. 7. 1.	+82-31-628-2020
49	RapiGEN, INC	BIOCREDIT COVID-19 Ag Home Test Nasal	Antigen	2021. 7. 13.	+82-31-427-4677
50	Boditech Med Inc.	ichroma™ COVID-19 Ag	Antigen	2021. 7. 13.	+82-33-243-1400
51	Boditech Med Inc.	AFIAS COVID-19 Ag	Antigen	2021. 7. 15.	+82-33-243-1400
52	SolGent Co., Ltd	DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit	Molecular	2021. 7. 22.	+82-70-7893-7831 +82-70-7006-5962

53	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 Ag	Antigen	2021. 7. 30.	+82-31-260-1926
54	Precision Biosensor Inc.	PBCheck COVID-19 Ag	Antigen	2021. 8. 3.	+82-70-7167-0331
55	BBB Inc	MARK-B™ COVID-19 Ag	Antigen	2021. 8. 9.	+82-2-565-9653
56	Precision Biosensor Inc.	Exdia COVID-19 Ag	Antigen	2021. 8. 10.	+82-70-7167-0331
57	PCL, Inc.	PCL SARS-CoV-2 IgG EIA	Antibody	2021. 8. 12.	+82-2-2144-3901
58	MiCoBioMed, Co., Ltd	COVID-19 Biokit IgG/IgM	Antibody	2021. 8. 13.	+82-70-5227-6065
59	MiCoBioMed, Co., Ltd	VERI-Q COVID-19 Ag Rapid Test	Antigen	2021. 8. 20.	+82-70-5227-6065
60	WELLS BIO, INC.	careUS™ COVID-19 antigen	Antigen	2021. 8. 25.	+82-2-3660-6900
61	Genematrix Inc.	NeoPlex™ COVID-19 Detection	Molecular	2021. 8. 27.	+82-31-628-2020
62	Asan pharmaceutical Co., LTD.	Asan Easy Test COVID-19 Ag	Antigen	2021. 9. 9.	+82-31-376-5990 (506)

63	BIONEER Corporation	AccuPower® COVID-19 Multiplex Real-Time RT-PCR Kit (NCVM-1211)	Molecular	2021. 9. 13.	+82-42-930-8508
64	Abbott Diagnostics Korea Inc.	Panbio™ COVID-19 Ag Rapid Test Device(Nasopharyngeal)	Antigen	2021. 9. 28.	+82-31-899-2837
65	MiCoBioMed, Co., Ltd	Veri-Q COVID-19 Multiplex Detection Kit	Molecular	2021. 10. 20.	+82-70-5227-6065
66	KH Medical Co., Ltd.	RADI COVID-19 Detection Kit	Molecular	2021. 11. 8.	+82-31-5180-3018
67	WON Medical Co., Ltd.	WonMed Covid-19 Ag(WM COVAG-25T)	Antigen	2021. 11. 10.	+82-32-219-0077 +82-32-219-0079
68	Abbott Korea Ltd.	SARS-CoV-2 IgG II Quant Reagent Kit	Antibody	2021. 12. 10.	+82-2-3429-3528
69	iNtRON Biotechnology, Inc.	LiliF™ COVID-19 Multi Real-time RT-PCR Kit	Molecular	2021. 12. 10.	+82-31-739-5678
70	SD Biosensor, Inc.	STANDARD™ M10 SARS-CoV-2	Molecular	2021. 12. 21.	+82-31-300-0400
71	Z Biotech Inc.	AnyLab COVID-19 Ag Test Kit	Antigen	2022. 1. 11.	+82-43-278-0075
72	AccessBioKorea	CareStart COVID-19 Ag Plus	Antigen	2022. 1. 11.	+82-54-906-9800
73	CALTH Inc.	AllCheck COVID19 Ag	Antigen	2022. 1. 13.	+82-70-4238-5244