List of COVID-19 In Vitro Diagnostic Devices Officially Approved by MFDS(`23.2.3)

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
1	SD Biosensor, Inc.	STANDARD™ M nCoV Real-Time Detection kit	Molecular	IVD-20-767	2020. 8. 31.	+82-31-300-0400
2	BioSewoom, Inc.	Real-Q 2019-nCoV Detection kit	Molecular	IVD-20-860	2020. 10. 6.	+82-2-498-2340 (500)
3	SeaSun Biomaterials	U-TOP™ COVID-19 Detection Kit Plus	Molecular	IVD-20-871	2020. 10. 8.	+82-42-716-0301
4	KogeneBiotech Co., Ltd.	PowerChek™ SARS-CoV-2, Influenza A&B Multiplex Real-time PCR Kit	Molecular	IVD-20-923	2020. 11. 3.	+82-2-2026-2150
5	SD Biosensor, Inc.	STANDARD™ Q COVID-19 IgM/IgG Plus Test	Antibody	IVD-20-941	2020. 11. 6.	+82-31-300-0400
6	SD Biosensor, Inc.	STANDARD™ Q COVID-19 Ag Test	Antigen	IVD-20-955	2020. 11. 11.	+82-31-300-0400
7	SeaSun Biomaterials	AQ-TOP™ COVID-19 Rapid Detection Kit Plus	Molecular	IVD-20-990	2020. 11. 23.	+82-42-716-0301
8	KogeneBiotech Co., Ltd.	PowerChek™ SARS-CoV-2 Real-time PCR Kit	Molecular	IVD-20-1000	2020. 11. 26.	+82-2-2026-2150

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
9	Seegene Inc.	Allplex SARS-CoV-2 Assay	Molecular	IVD-20-1049	2020. 12. 7.	+82-2-2026-2150
10	Cancer Rop Co., Ltd.	Q-Sens® COVID-19 Detection Kit V2	Molecular	IVD-20-1088	2020. 12. 14.	+82-2-6964-8773
11	Sugentech, Inc.	SGTi-flex COVID-19 IgM/IgG	Antibody	IVD-20-1112	2020. 12. 18.	+82-43-710-2822
12	GenBody Inc.	GenBody COVID-19 Ag	Antigen	IVD-20-1150	2020. 12. 24.	+82-41-523-8990
13	SD Biosensor, Inc.	STANDARD™ F COVID-19 Ag FIA	Antigen	IVD-21-3	2021. 1. 5.	+82-31-300-0400
14	BioSewoom, Inc.	Real-Q Direct SARS-CoV-2 Detection Kit	Molecular	IVD-21-50	2021. 1. 20.	+82-2-498-2340 (500)
15	Seegene Inc.	Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay	Molecular	IVD-21-65	2021. 1. 26.	+82-2-2026-2150
16	SD Biosensor, Inc.	STANDARD™ F COVID-19 IgM/IgG Combo FIA	Antibody	IVD-21-66	2021. 1. 26.	+82-31-300-0400
17	SML GENETREE CO., LTD.	Ezplex® SARS-CoV-2 Kit	Molecular	IVD-21-75	2021. 1. 29.	+82-2-2057-7900
18	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit	Molecular	IVD-21-187	2021. 3. 12.	+82-2-2027-6320

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
19	RapiGEN, INC	BIOCREDIT COVID-19 Ag	Antigen	IVD-21-200	2021. 3. 18.	+82-31-427-4677
20	Humasis Co., Ltd.	Humasis COVID-19 Ag Test	Antigen	IVD-21-201	2021. 3. 18.	+82-31-478-8585 +82-31-478-8546
21	LabGenomics, Co., Ltd	LabGun™ COVID-19 ExoFast RT-PCR Kit	Molecular	IVD-21-202	2021. 3. 18.	+82-31-628-0783
22	OPTOLANE Technologies Inc.	Dr. PCR™ Di20K COVID-19 Detection kit	Molecular	IVD-21-209	2021. 3. 23.	+82-31-737-7835
23	SeaSun Biomaterials	U-TOP™ SARS-CoV-2 & Flu A/B	Molecular	IVD-21-244	2021. 4. 1.	+82-42-716-0301
24	Roche Diagnostics Korea Co., Ltd.	Elecsys Anti-SARS-CoV-2	Antibody	IVD-21-100	2021. 4. 16.	+82-2-550-0759
25	Siemens Healthineers Ltd.	ADVIA Centaur SARS-CoV-2 Total (COV2T)	Antibody	IVD-21-101	2021. 4. 16.	+82-2-3450-1073
26	GenBody Inc.	GenBody COVID-19 IgM/IgG	Antibody	IVD-21-308	2021. 4. 20.	+82-41-523-8990
27	Humasis Co., Ltd.	Humasis COVID-19 Ag Home Test	Antigen (Home test)	IVD-21-321	2021. 4. 23.	+82-31-478-8585 +82-31-478-8546
28	SD Biosensor, Inc.	STANDARD™ Q COVID-19 Ag Home Test	Antigen (Home test)	IVD-21-322	2021. 4. 23.	+82-31-300-0400

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
29	OSANG Healthcare Co., Ltd.	GeneFiner COVID-19 Fast RealAmp Kit	Molecular	IVD-21-329	2021. 4. 26.	+82-31-460-9921
30	BioSewoom, Inc.	Real-Q SARS-CoV-2/FluA/FluB Detection Kit	Molecular	IVD-21-330	2021. 4. 26.	+82-2-498-2340 (500)
31	BIONEER Corporation	AccuPower® RV1 Real-Time RT-PCR Kit (RV1-1111)	Molecular	IVD-21-339	2021. 4. 30.	+82-42-930-8508
32	Roche Diagnostics Korea Co., Ltd.	cobas SARS-CoV-2 & Influenza A/B	Molecular	IVD-21-115	2021. 5. 4.	+82-2-550-0759
33	Humasis Co., Ltd.	Humasis COVID-19 IgG/IgM Test	Antibody	IVD-21-352	2021. 5. 6.	+82-31-478-8585 +82-31-478-8546
34	SG Medical, Inc.	R-FIND COVID-19 IgM ELISA	Antibody	IVD-21-357	2021. 5. 6.	+82-2-2240-7062
35	SG Medical, Inc.	R-FIND COVID-19 IgG ELISA	Antibody	IVD-21-359	2021. 5. 6.	+82-2-2240-7062
36	SG Medical, Inc.	R-FIND COVID-19 IgG/M/A ELISA	Antibody	IVD-21-360	2021. 5. 6.	+82-2-2240-7062
37	PaxGenBio Co., Ltd.	PaxView® SARS-CoV-2 real-time RT-PCR Kit	Molecular	IVD-21-371	2021. 5. 12.	+82-31-244-5036
38	Sugentech, Inc.	SGTi-flex COVID-19 Ag	Antigen	IVD-21-407	2021. 5. 25.	+82-43-710-2822

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
39	BIONEER Corporation	AccuPower® RV1 Multiplex Kit (RV1-2112)	Molecular	IVD-21-413	2021. 5. 26.	+82-42-930-8508
40	WELLS BIO, INC.	careUS™ COVID-19 IgM/IgG Ab	Antibody	IVD-21-419	2021. 5. 27.	+82-2-3660-6900
41	LG Chem, Ltd.	AdvanSure™ SARS-CoV-2 IgG (S1) ELISA	Antibody	IVD-21-424	2021. 5. 27.	+82-2-6987-4432
42	Genomictree, Inc.	AccuraDTect™ COVID-19 RT-qPCR Kit	Molecular	IVD-21-487	2021. 6. 17.	+82-42-861-4551
43	SML GENETREE CO., LTD.	Ezplex® SARS-CoV2/RV Fast Kit	Molecular	IVD-21-494	2021. 6. 21.	+82-2-2057-7900
44	GenBody Inc.	GenBody FIA COVID-19 Ag	Antigen	IVD-21-499	2021. 6. 21.	+82-41-523-8990
45	AMSBIO	A+CheQ COVID-19 RT-qPCR Detection kit	Molecular	IVD-21-506	2021. 6. 22.	+82-2-2086-1621
46	PCL, Inc.	PCL COVID 19 Ag Gold	Antigen	IVD-21-514	2021. 6. 23.	+82-2-2144-3901
47	Genematrix Inc.	NeoPlex™ FluCOVID Kit	Molecular	IVD-21-543	2021. 7. 1.	+82-31-628-2020
48	RapiGEN, INC	BIOCREDIT COVID-19 Ag Home Test Nasal	Antigen (Home test)	IVD-21-595	2021. 7. 13.	+82-31-427-4677

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
49	Boditech Med Inc.	ichroma™ COVID-19 Ag	Antigen	IVD-21-596	2021. 7. 13.	+82-33-243-1400
50	Boditech Med Inc.	AFIAS COVID-19 Ag	Antigen	IVD-21-608	2021. 7. 15.	+82-33-243-1400
51	SolGent Co., Ltd	DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit	Molecular	IVD-21-626	2021. 7. 22.	+82-70-7893-7831 +82-70-7006-5962
52	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 Ag	Antigen	IVD-21-649	2021. 7. 30.	+82-31-260-1926
53	Precision Biosensor Inc.	PBCheck COVID-19 Ag	Antigen	IVD-21-658	2021. 8. 3.	+82-70-7167-0331
54	BBB Inc	MARK-B™ COVID-19 Ag	Antigen	IVD-21-673	2021. 8. 9.	+82-2-565-9653
55	Precision Biosensor Inc.	Exdia COVID-19 Ag	Antigen	IVD-21-674	2021. 8. 10.	+82-70-7167-0331
56	PCL, Inc.	PCL SARS-CoV-2 IgG EIA	Antibody	IVD-21-688	2021. 8. 12.	+82-2-2144-3901
57	MiCoBioMed, Co., Ltd	COVID-19 Biokit IgG/IgM	Antibody	IVD-21-692	2021. 8. 13.	+82-70-5227-6065
58	MiCoBioMed, Co., Ltd	VERI-Q COVID-19 Ag Rapid Test	Antigen	IVD-21-702	2021. 8. 20.	+82-70-5227-6065

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
59	WELLS BIO, INC.	careUS™ COVID-19 antigen	Antigen	IVD-21-718	2021. 8. 25.	+82-2-3660-6900
60	Genematrix Inc.	NeoPlex™ COVID-19 Detection	Molecular	IVD-21-729	2021. 8. 27.	+82-31-628-2020
61	Asan pharmaceutical Co., LTD.	Asan Easy Test COVID-19 Ag	Antigen	IVD-21-754	2021. 9. 9.	+82-31-376-5990 (506)
62	BIONEER Corporation	AccuPower® COVID-19 Multiplex Real-Time RT-PCR Kit (NCVM-1211)	Molecular	IVD-21-765	2021. 9. 13.	+82-42-930-8508
63	Abbott Diagnostics Korea Inc.	Panbio™ COVID-19 Ag Rapid Test Device(Nasopharyngeal)	Antigen	IVD-21-799	2021. 9. 28.	+82-31-899-2837
64	MiCoBioMed, Co., Ltd	Veri-Q COVID-19 Multiplex Detection Kit	Molecular	IVD-21-851	2021. 10. 20.	+82-70-5227-6065
65	KH Medical Co., Ltd.	RADI COVID-19 Detection Kit	Molecular	IVD-21-890	2021. 11. 8.	+82-31-5180-3018
66	WON Medical Co., Ltd.	WonMed Covid-19 Ag(WM COVAG-25T)	Antigen	IVD-21-895	2021. 11. 10.	+82-32-219-0077 +82-32-219-0079
67	Abbott Korea Ltd.	SARS-CoV-2 IgG II Quant Reagent Kit	Antibody	IVD-21-304	2021. 12. 10.	+82-2-3429-3528
68	iNtRON Biotechnology, Inc.	LiliF™ COVID-19 Multi Real-time RT-PCR Kit	Molecular	IVD-21-998	2021. 12. 10.	+82-31-739-5678

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
69	SD Biosensor, Inc.	STANDARD™ M10 SARS-CoV-2	Molecular	IVD-21-1030	2021. 12. 21.	+82-31-300-0400
70	Z Biotech Inc.	AnyLab COVID-19 Ag Test Kit	Antigen	IVD-22-14	2022. 1. 11.	+82-43-278-0075
71	AccessBioKorea	CareStart COVID-19 Ag Plus	Antigen	IVD-22-15	2022. 1. 11.	+82-54-906-9800
72	CALTH Inc.	AllCheck COVID19 Ag	Antigen	IVD-22-19	2022. 1. 13.	+82-70-4238-5244
73	NanoEntek, Inc.	FREND COVID-19 SP	Antibody	IVD-22-48	2022. 1. 24.	+82-2-6220-7940
74	GenBody Inc.	GenBody COVID-19 Ag Home Test	Antigen (Home test)	IVD-22-72	2022. 2. 4.	+82-41-523-8990
75	Sugentech, Inc.	SGTi-flex COVID-19 Ag Self	Antigen (Home test)	IVD-22-73	2022. 2. 4.	+82-43-710-2822
76	SD Biosensor, Inc.	STANDARD™ i-Q COVID-19 Ag Home Test	Antigen (Home test)	IVD-22-90	2022. 2. 11.	+82-31-300-0400
77	Biomerieux Korea	BioFire Respiratory Panel 2.1plus (RP2.1plus)	Molecular	IVD-20-44	2022. 2. 14.	+82-2-2188-4781
78	PCL, Inc.	PCLOK II SARS-CoV-2 Dual IgG	Antibody	IVD-22-101	2022. 2. 15.	+82-2-2144-3901

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
79	PCL, Inc.	PCLOK II ABC	Antigen	IVD-22-103	2022. 2. 15.	+82-2-2144-3901
80	MEDIAN DIAGNOSTICS INC.	MDx COVID-19 Ag Home Test	Antigen (Home test)	IVD-22-105	2022. 2. 15.	+82-33-244-0100
81	OSANG Healthcare Co., Ltd.	GeneFinder™ COVID-19 Ag Self Test	Antigen (Home test)	IVD-22-106	2022. 2. 15.	+82-31-460-9921
82	WELLS BIO, INC.	careUS™ COVID-19 Antigen Home Test	Antigen (Home test)	IVD-22-113	2022. 2. 17.	+82-2-3660-6900
83	MEDISENSOR, Inc.	CareU™ COVID-19 SARS-COV-2 Antigen Rapid Test Kit	Antigen	IVD-22-126	2022. 2. 24.	+82-54-906-9810
84	Siemens Healthineers Ltd.	ADVIA Centaur SARS-CoV-2 IgG (sCOVG)	Antibody	IVD-22-48	2022. 3. 11.	+82-2-3450-1073
85	Asan pharmaceutical Co., LTD.	Asan Easy Test COVID-19 IgG/IgM (N)	Antibody	IVD-22-171	2022. 3. 14.	+82-31-376-5990 (506)
86	Genes Laboratories	GCdia™ COVID-19 Fast Detection Kit	Molecular	IVD-22-172	2022. 3. 14.	+82-31-756-5656
87	LG Chem, Ltd.	AdvanSure™ SARS-CoV-2 IgG (RBD) ELISA	Antibody	IVD-22-184	2022. 3. 17.	+82-2-6987-4432
88	YD Diagnostics CORP.	Real Time COVID-19	Molecular	IVD-22-223	2022. 4. 4.	+82-31-329-2011

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
89	GenBody Inc.	GenBody Influenza/COVID-19 Ag Triple	Antigen	IVD-22-239	2022. 4. 11.	+82-41-523-8990
90	MEDIAN DIAGNOSTICS INC.	MDx COVID-19 Ag Rapid Kit	Antigen	IVD-22-240	2022. 4. 12.	+82-33-244-0100
91	Philosys Co.,Ltd.	Gmate® COVID-19 Ag	Antigen	IVD-22-241	2022. 4. 12.	+82-31-778-0602
92	MiCoBioMed, Co., Ltd	Veri-Q COVID-19 & Flu A/B Multiplex Detection Kit	Molecular	IVD-22-247	2022. 4. 13.	+82-70-5227-6065
93	Abbott Korea Ltd.	Alinity m SARS-CoV-2 AMP Kit	Molecular	IVD-22-82	2022. 4. 14.	+82-2-3429-3528
94	AccessBioKorea	CareStart™ COVID-19 IgM/IgG Ab	Antibody	IVD-22-252	2022. 4. 18.	+82-54-906-9800
95	ImmuneMed Inc.	IMMUNEMED COVID-19 Ag RAPID	Antigen	IVD-22-260	2022. 4. 21.	+82-33-258-6554
96	PCL, Inc.	PCL SELF TEST - COVID19 Ag	Antigen (Home test)	IVD-22-275	2022. 4. 29.	+82-2-2144-3901
97	Genes Laboratories	GCdia™ SARS-CoV-2 Detection Kit	Molecular	IVD-22-282	2022. 5. 3.	+82-31-756-5656
98	AccessBioKorea	CareStart™ COVID-19 Antigen Home Test	Antigen (Home test)	IVD-22-303	2022. 5. 16.	+82-54-906-9800

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
99	OSANG Healthcare Co., Ltd.	GeneFinder™ COVID-19 Ag Plus Rapid Test	Antigen	IVD-22-322	2022. 5. 19.	+82-31-460-9921
100	Genesystem Co., Ltd.	SMARTCHEK® SARS-CoV-2 Detection Kit	Molecular	IVD-22-342	2022. 5. 26.	+82-42-863-8551
101	Anse Co., Ltd	Aptima SARS-CoV-2 Assay	Molecular	IVD-22-115	2022. 5. 26.	+82-31-777-9181
102	OPTOLANE Technologies Inc.	Genoplexor™ COVID-19 Detection Kit (COR104-Z)	Molecular	IVD-22-350	2022. 5. 30.	+82-31-737-7835
103	SG Medical, Inc.	InstaView COVID-19 Antigen	Antigen	IVD-22-351	2022. 5. 30.	+82-2-2240-7062
104	Roche Diagnostics Korea Co., Ltd.	Elecsys Anti-SARS-CoV-2 S	Antibody	IVD-22-117	2022. 5. 31.	+82-2-550-0759
105	Sugentech, Inc.	INCLIX TRF COVID-19 Ag	Antigen	IVD-22-377	2022. 6. 10.	+82-43-710-2822
106	SeaSun Biomaterials	U-TOP FAST COVID19	Molecular	IVD-22-418	2022. 6. 29.	+82-42-716-0301
107	WELLS BIO, INC.	careGENE™ COVID-19 detection kit	Molecular	IVD-22-419	2022. 6. 30.	+82-2-3660-6900
108	InSol Co., Ltd	INSOL COVID-19 Real Time PCR Kit	Molecular	IVD-22-421	2022. 6. 30.	+82-2-404-7990

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
109	ProteomeTech Inc.	KOVIcheck COVID-19 IgG/IgM	Antibody	IVD-22-440	2022. 7. 8.	+82-2-6968-5277
110	NDFOS Co., Ltd.	ND COVID-19 Ag Test	Antigen	IVD-22-450	2022. 7. 12.	+82-2-6203-0733
111	1drop Inc.	1copy™ COVID-19 4plex RT-PCR Kit	Molecular	IVD-22-471	2022. 7. 20.	+82-31-747-0109
112	GenBody Inc.	iFinDx COVID-19 IgM/IgG	Antibody	IVD-22-486	2022. 7. 27.	+82-41-523-8990
113	SML GENETREE CO., LTD.	Ezplex™ SARS-CoV-2 Variants Kit	Molecular	IVD-22-498	2022. 7. 29.	+82-2-2057-7900
114	LG Chem, Ltd.	AdvanSure™ One-Stop COVID-19 Plus Kit	Molecular	IVD-22-499	2022. 7. 29.	+82-2-6987-4432
115	Abbott Diagnostics Korea Inc.	Panbio™ COVID-19 Ag Self-Test	Antigen (Home test)	IVD-22-507	2022. 7. 29.	+82-31-899-2837
116	RapiGEN, INC	BIOCREDIT CoviFlu Ag Duo	Antigen	IVD-22-528	2022. 8. 5.	+82-31-427-4677
117	SD Biosensor, Inc.	STANDARD M SARS-CoV-2 Real-Time Detection Kit	Molecular	IVD-22-575	2022. 8. 25.	+82-31-300-0400
118	BIONEER Corporation	AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit (SCVM-2212)	Molecular	IVD-22-597	2022. 9. 6.	+82-42-930-8508

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
119	CALTH Inc.	AllCheck Flu/COVID-19 Ag Duo	Antigen	IVD-22-612	2022. 9. 14.	+82-70-4238-5244
120	U2Bio co., Ltd.	U2PlexTMQ COVID-19 Fast Real-time PCR Kit	Molecular	IVD-22-641	2022. 9. 26.	+82-2-910-2137
121	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 & Flu A/B Ag	Antigen	IVD-22-643	2022. 9. 26.	+82-31-260-1926
122	ProteomeTech Inc.	KOVIcheck COVID-19 Ag	Antigen	IVD-22-651	2022. 9. 29.	+82-2-6968-5277
123	Sugentech, Inc.	SGTi-flex COVID-19 & Flu A/B Ag DUO	Antigen	IVD-22-652	2022. 9. 29.	+82-43-710-2822
124	WELLS BIO, INC.	careUS™ COVID/Flu A&B Antigen Duo	Antigen	IVD-22-689	2022. 10. 17.	+82-2-3660-6900
125	Boditech Med Inc.	ichroma™ COVID-19 Ag/Flu A+B	Antigen	IVD-22-728	2022. 11. 1.	+82-33-243-1400
126	Boditech Med Inc.	Boditech Quick™ COVID-19 Ag Saliva	Antigen (Home test)	IVD-22-736	2022. 11. 3.	+82-33-243-1400
127	AccessBioKorea	CareStart™ COVID/Flu A&B Antigen Duo Plus	Antigen	IVD-22-742	2022. 11. 7.	+82-54-906-9800
128	iNtRON Biotechnology, Inc.	LiliF™ GBN COVID-19 Ag Rapid kit	Antigen	IVD-22-771	2022. 11. 17.	+82-31-739-5678

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
129	Precision Biosensor Inc.	Exdia COVID Flu Ag Duo	Antigen	IVD-22-779	2022. 11. 21.	+82-70-7167-0331
130	SG Medical, Inc.	InstaView COVID-19 Antigen Home Test	Antigen (Home test)	IVD-22-787	2022. 11. 22.	+82-2-2240-7062
131	Humasis Co., Ltd.	Humasis COVID-19 RT-PCR Kit	Molecular	IVD-22-882	2022. 12. 21.	+82-31-478-8585 +82-31-478-8546
132	Abbott Diagnostics Korea Inc.	Panbio™ COVID-19 Ag Self-Test	Antigen	IVD-23-39	2023. 1. 18.	+82-31-899-2837
133	BioSquare Inc.	NanoPACK™ COVID-19 Ag	Antigen	IVD-23-43	2023. 1. 18.	+82-31-8050-1119
134	SML GENETREE CO., LTD.	Ezplexⓡ SARS-CoV-2 V2 Kit	Molecular	IVD-23-52	2023. 1. 20.	+82-2-2057-7900
135	Precision Biosensor Inc.	PBCheck COVID-19 Ag Home Test	Antigen (Home test)	IVD-23-67	2023. 1. 30.	+82-70-7167-0331