List of COVID-19 In Vitro Diagnostic Devices for Export Only Approved by MFDS(`23.5.19)

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
1	KogeneBiotech Co., Ltd.	PowerCheck™2019-nCoV RT PCR kit	Molecular	IVD-20-109	2020. 2. 12.	+82-2-2026-2150
2	Seegene Inc.	Allplex™2019-nCoV Assay	Molecular	IVD-20-119	2020. 2. 17.	+82-2-2240-4166
3	SolGent Co., Ltd	DiaPlexQ™Novel Coronavirus (2019-nCoV) Detection Kit	Molecular	IVD-20-149	2020. 3. 2.	+82-70-7893-7831 +82-70-7006-5962
4	PCL, Inc.	PCLMD nCoV one stop RT-PCR Kit	Molecular	IVD-20-151	2020. 3. 3.	+82-2-2144-3901
5	LabGenomics, Co., Ltd	LabGun™COVID-19 assay	Molecular	IVD-20-152	2020. 3. 3.	+82-31-628-0783
6	SD Biosensor, Inc.	STANDARD™Q COVID-19 IgM/IgG Duo Test	Antibody	IVD-20-177	2020. 3. 11.	+82-31-300-0400
7	OSANG Healthcare Co., Ltd.	GeneFinder COVID-19 Plus RealAmp kit	Molecular	IVD-20-196	2020. 3. 18.	+82-31-460-9921

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
8	WELLS BIO, INC.	careGENE™ N-CoV RT-PCR kit	Molecular	IVD-20-197	2020. 3. 18.	+82-2-3660-6900
9	Genematrix Inc.	NeoPlex™COVID-19 Detection Kit	Molecular	IVD-20-199	2020. 3. 20.	+82-31-628-2020
10	Sugentech, Inc.	SGTi-flex COVID-19 IgM	Antibody	IVD-20-214	2020. 3. 24.	+82-43-710-2822
11	Sugentech, Inc.	SGTi-flex COVID-19 IgG	Antibody	IVD-20-215	2020. 3. 24.	+82-43-710-2822
12	MiCoBioMed, Co., Ltd	Veri-Q PCR 316, nCoV-QS	Molecular	IVD-20-221	2020. 3. 26.	+82-70-5227-6065
13	Gencurix Inc.	GenePro COVID-19 Detection Test	Molecular	IVD-20-222	2020. 3. 26.	+82-2-2621-7038
14	DowGene Co., Ltd	Dow QuickFinder™2019-nCoV Real time PCR	Molecular	IVD-20-225	2020. 3. 27.	+82-2-1566-3313
15	Humasis Co., Ltd.	Humasis COVID-19 IgG/IgM Test	Antibody	IVD-20-226	2020. 3. 27.	+82-31-478-8585 +82-31-478-8546
16	GenBody Inc.	GenBody COVID-19 IgM/IgG	Antibody	IVD-20-227	2020. 3. 27.	+82-41-523-8990

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
17	PCL, Inc.	PCL COVID19 Ag Rapid FIA	Antigen	IVD-20-228	2020. 3. 30.	+82-2-2144-3901
18	PCL, Inc.	PCL COVID19 IgG/IgM Rapid Gold	Antibody	IVD-20-229	2020. 3. 30.	+82-2-2144-3901
19	BIONEER Corporation	AccuPower COVID-19 Real-Time RT-PCR Kit (NCV-1111)	Molecular	IVD-20-231	2020. 3. 31.	+82-42-930-8508
20	BIONEER Corporation	AccuPower SARS-CoV-2 Real-Time RT-PCR Kit(SCV-2122)	Molecular	IVD-20-232	2020. 3. 31.	+82-42-930-8508
21	PaxGenBio Co., Ltd.	PaxView COVID-19 real-time RT-PCR Kit	Molecular	IVD-20-235	2020. 3. 31.	+82-31-244-5036
22	Boditech Med Inc.	AFIAS COVID-19 Ab	Antibody	IVD-20-240	2020. 4. 1.	+82-33-243-1400
23	YD Diagnostics CORP.	MolecuTech® Real-Time COVID-19	Molecular	IVD-20-252	2020. 4. 3.	+82-31-329-2011
24	iNtRON Biotechnology, Inc.	LiliF™COVID-19 Real-time RT-PCR Kit	Molecular	IVD-20-256	2020. 4. 6.	+82-31-739-5678
25	1drop Inc.	1copy™COVID-19 qPCR Multi Kit	Molecular	IVD-20-259	2020. 4. 7.	+82-31-747-0109

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
26	DowGene Co., Ltd	Dow QuickFinder™-G 2019-nCoV Real time PCR	Molecular	IVD-20-260	2020. 4. 8.	+82-2-1566-3313
27	WELLS BIO, INC.	careGENE™COVID-19 RT-PCR kit	Molecular	IVD-20-261	2020. 4. 8.	+82-2-3660-6900
28	M monitor Inc.	Isopolla®COVID-19 detection kit(premix)	Molecular	IVD-20-262	2020. 4. 8.	+82-53-254-2505
29	M monitor Inc.	Isopolla®COVID-19 detection kit(real-time)	Molecular	IVD-20-263	2020. 4. 8.	+82-53-254-2505
30	TCM Biosciences Inc.	TCM-Q Corona Ⅲ kit	Molecular	IVD-20-268	2020. 4. 9.	+82-31-698-3041
31	iONEBIO inc.	iLAMP Novel-CoV19 Detection Kit	Molecular	IVD-20-271	2020. 4. 9.	+82-31-360-1210
32	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit	Molecular	IVD-20-270	2020. 4. 9.	+82-2-2027-6320
33	OPTOLANE Technologies Inc.	Kaira 2019-nCoV Detection Kit	Molecular	IVD-20-279	2020. 4. 10.	+82-31-737-7835
34	KH Medical Co., Ltd.	RADI COVID-19 detection kit	Molecular	IVD-20-280	2020. 4. 10.	+82-31-5180-3018

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
35	Genomictree, Inc.	AccuraDTect™SARS-CoV-2 RT-qPCR kit	Molecular	IVD-20-288	2020. 4. 14.	+82-42-861-4551
36	Boditech Med Inc.	ichroma™COVID-19 Ab	Antibody	IVD-20-289	2020. 4. 14.	+82-33-243-1400
37	Genesystem Co., Ltd.	SMARTCHEKⓡ Novel Coronavirus (SARS-CoV-2)Detection Kit	Molecular	IVD-20-291	2020. 4. 16.	+82-42-863-8551
38	Joonghun Pharmaceutical Co., Ltd.	JD COVID-19 qRT-PCR kit	Molecular	IVD-20-292	2020. 4. 20.	+82-2-2138-8114
39	NanoEntek, Inc.	FREND COVID-19 IgG/IgM Duo	Antibody	IVD-20-296	2020. 4. 20.	+82-2-6220-7940
40	BioZentech, Co., Ltd	BZ QPCR COVID-19 Kit	Molecular	IVD-20-300	2020. 4. 21.	+82-2-855-5194
41	Wizbiosolutions Inc.	WizDx™COVID-19 CrystalMix PCR Kit	Molecular	IVD-20-301	2020. 4. 21.	+82-70-7605-5066
42	RapiGEN, INC	BIOCREDIT COVID-19 Ag	Antigen	IVD-20-305	2020. 4. 21.	+82-31-427-4677
43	RapiGEN, INC	BIOCREDIT COVID-19 IgG+IgM Duo	Antibody	IVD-20-306	2020. 4. 21.	+82-31-427-4677

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
44	Boditech Med Inc.	ExAmplar COVID-19 real time PCR	Molecular	IVD-20-307	2020. 4. 22.	+82-33-243-1400
45	iNtRON Biotechnology, Inc.	LiliF™COVID-19 Multi Real-time RT-PCR Kit	Molecular	IVD-20-327	2020. 4. 28.	+82-31-739-5678
46	Gencurix Inc.	GenePro SARS-CoV-2 Test	Molecular	IVD-20-328	2020. 4. 28.	+82-2-2621-7038
47	Wizbiosolutions Inc.	WizDx™COVID-19 Real-time PCR Kit	Molecular	IVD-20-330	2020. 4. 28.	+82-70-7605-5066
48	Seegene Inc.	Allplex™SARS-CoV-2 Assay	Molecular	IVD-20-335	2020. 4. 28.	+82-2-2240-4166
49	SeaSun Biomaterials	U-TOP COVID-19 Detection Kit	Molecular	IVD-20-343	2020. 5. 4.	+82-42-716-0301
50	Philosys Co.,Ltd.	Gmate® COVID-19	Antigen	IVD-20-348	2020. 5. 7.	+82-31-778-0602
51	Asan pharmaceutical Co., LTD.	Asan Easy Test COVID-19 IgG/IgM	Antibody	IVD-20-349	2020. 5. 8.	+82-31-376-5990 (506)
52	MiCoBioMed, Co., Ltd	Veri-Q, nCoV-OM	Molecular	IVD-20-352	2020. 5. 11.	+82-70-5227-6065

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
53	LabGenomics, Co., Ltd	LabGun™COVID-19 RT-PCR Kit	Molecular	IVD-20-355	2020. 5. 12.	+82-31-628-0783
54	Eudipia	EU™COVID-19 Detection Kit	Molecular	IVD-20-356	2020. 5. 12.	+82-70-8890-2101
55	DIOGENE Co., Ltd	DLP™Q COVID 19 Real Detection Kit	Molecular	IVD-20-361	2020. 5. 14.	+82-31-701-6488
56	WELLS BIO, INC.	careUS™COVID-19 IgM/IgG	Antibody	IVD-20-363	2020. 5. 14.	+82-2-3660-6900
57	HUMEDIX Co,. Ltd.	Accurate Rapid COVID-19 IgM/IgG Combo Test	Antibody	IVD-20-368	2020. 5. 18.	+82-70-7492-5600
58	Macrogen, Inc.	Axen™COVID-19 RT	Molecular	IVD-20-369	2020. 5. 18.	+82-2-2180-7222
59	OPTOLANE Technologies Inc.	Dr. PCR 20K COVID-19 Detection Kit	Molecular	IVD-20-370	2020. 5. 18.	+82-31-737-7835
60	PRIME4DIA Co., Ltd.	P4DETECT COVID-19 IgM/IgG	Antibody	IVD-20-371	2020. 5. 18.	+82-31-478-3105
61	Biometrix Technology, Inc.	COVID19+9G test™	Molecular	IVD-20-374	2020. 5. 19.	+82-33-258-6097

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
62	B-bio, Co., Ltd	ChekR™COVID-19 IgM/IgG Rapid test	Antibody	IVD-20-375	2020. 5. 20.	+82-70-4163-6894
63	CALTH Inc.	AllCheck COVID-19 IgG/IgM	Antibody	IVD-20-380	2020. 5. 21.	+82-70-4238-5244
64	SLSBio Co., Ltd	SsmarTest COVID-19 IgM/IgG Detection Kit	Antibody	IVD-20-381	2020. 5. 21.	+82-70-8857-2657
65	ADTceh Co., LTD	ADTech COVID-19 IgM/IgG	Antibody	IVD-20-382	2020. 5. 21.	+82-70-4659-1811
66	ShinJin Medics Inc.	DIAKEY COVID-19 IgM/IgG Rapid Test	Antibody	IVD-20-383	2020. 5. 21.	+82-70-8277-6929
67	CTCBIO INC.	CTC™Q COVID-19 IgM/IgG Combo Test	Antibody	IVD-20-384	2020. 5. 21.	+82-70-4033-0233
68	BIONOTE, INC.	NowCheck COVID-19 Ag Test	Antigen	IVD-20-385	2020. 5. 21.	+82-70-4066-1412
69	BIONOTE, INC.	NowCheck COVID-19 IgM/IgG Test	Antibody	IVD-20-386	2020. 5. 21.	+82-70-4066-1412
70	GOODGENE Inc.	GG COVID-19 Quadplex Reverse Transcription Real Time Polymerase Chain Reaction Kit	Molecular	IVD-20-387	2020. 5. 26.	+82-2-2088-0055

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
71	GREENCROSS MEDICAL SCIENCE	GENEDIA W ONE COVID-19 IgM/IgG	Antibody	IVD-20-404	2020. 5. 28.	+82-31-260-1926
72	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 IgM/IgG	Antibody	IVD-20-405	2020. 5. 28.	+82-31-260-1926
73	ShinJin Medics Inc.	DIAKEY REALcheck COVID-19(nCOV) Detection kit	Molecular	IVD-20-406	2020. 5. 28.	+82-70-8277-6929
74	GENECAST Co., Ltd.	SMARTROL™ 2019-nCoV Detection Kit v1	Molecular	IVD-20-422	2020. 5. 29.	+82-2-2157-3151
75	NDFOS Co., Ltd.	ND COVID-19 Detection Kit	Molecular	IVD-20-426	2020. 6. 1.	+82-2-6203-0733
76	DxGen Corp.	Epithod®616 COVID-19 IgM/IgG Test kit	Antibody	IVD-20-440	2020. 6. 3.	+82-31-427-8450
77	Precision Biosensor Inc.	PBCheck COVID-19 IgG/IgM	Antibody	IVD-20-446	2020. 6. 5.	+82-70-7167-0331
78	ProteomeTech Inc.	KOVIcheck COVID-19 IgG/IgM	Antibody	IVD-20-448	2020. 6. 5.	+82-2-6968-5277
79	TNS Co., Ltd	COVID-19 RT-qPCR PNA kit	Molecular	IVD-20-452	2020. 6. 5.	+82-42-861-2223

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
80	BIONEER Corporation	AccuPower SARS-CoV-2 Multiplex Real-Time RT-PCR Kit	Molecular	IVD-20-453	2020. 6. 5.	+82-42-930-8508
81	Heimbiotek Inc.	HB BestPlex™ COVID-19 RT-PCR	Molecular	IVD-20-457	2020. 6. 9.	+82-31-548-2130
82	Precision Biosensor Inc.	Exdia COVID-19 IgG/IgM	Antibody	IVD-20-458	2020. 6. 9.	+82-70-7167-0331
83	Genes Laboratories	NEXDia™ 2019-nCoV Detection Kit	Molecular	IVD-20-459	2020. 6. 9.	+82-31-756-5656
84	NanoEntek, Inc.	En-swer COVID-19 RT-PCR	Molecular	IVD-20-461	2020. 6. 10.	+82-2-6220-7940
85	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 Real-Time RT-PCR kit	Molecular	IVD-20-462	2020. 6. 10.	+82-31-260-1926
86	Boditech Med Inc.	ichroma™ COVID-19 Ag	Antigen	IVD-20-470	2020. 6. 11.	+82-33-243-1400
87	Sanigen Co., Ltd.	Genelix™ COVID-19 Real-Time PCR Kit	Molecular	IVD-20-476	2020. 6. 15.	+82-1833-8010
88	LabGenomics, Co., Ltd	LabGun™ COVID-19 Assay plus	Molecular	IVD-20-477	2020. 6. 15.	+82-31-628-0783

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
89	Plexense, Inc.	ACCEL ELISA COVID-19 Kit	Antibody	IVD-20-486	2020. 6. 17.	+82-70-4725-4683
90	Cancer Rop Co., Ltd.	Q-Sens COVID 19 IgG/IgM Rapid Kit	Antibody	IVD-20-490	2020. 6. 18.	+82-2-6964-8773
91	CALTH Inc.	DxReal COVID-19 Detection Kit	Molecular	IVD-20-491	2020. 6. 18.	+82-70-4238-5244
92	LabGenomics, Co., Ltd	LabGun™ COVID-19 Fast RT-PCR Kit	Molecular	IVD-20-497	2020. 6. 22.	+82-31-628-0783
93	Boditech Med Inc.	AFIAS COVID-19 Ag	Antigen	IVD-20-496	2020. 6. 22.	+82-33-243-1400
94	Absology Co., Ltd.	Absoludy COVID-19 IgM/IgG Rapid	Antibody	IVD-20-504	2020. 6. 24.	+82-31-348-8637
95	NanoBioLife Inc.	Nano-KGIC COVID-19 IgM/IgG Kit	Antibody	IVD-20-514	2020. 6. 25.	+82-2-858-3635
96	BioSewoom, Inc.	Real-Q Direct SARS-CoV-2 Detection Kit	Molecular	IVD-20-513	2020. 6. 25.	+82-2-498-2340 (500)
97	PROTANBIO Inc.	PROTAN COVID-19 IgM/IgG	Antibody	IVD-20-512	2020. 6. 25.	+82-2-3285-1413

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
98	MicroDigital Co., Ltd.	MDGen-AB96 COVID-19 IgG	Antibody	IVD-20-511	2020. 6. 25.	+82-31-701-2225
99	SeaSun Biomaterials	AQ-TOP™ COVID-19 Rapid Detection Kit	Molecular	IVD-20-526	2020. 6. 30.	+82-42-716-0301
100	SML GENETREE CO., LTD.	Ezplex® SARS-CoV-2 FAST G Kit	Molecular	IVD-20-529	2020. 7. 2.	+82-2-2057-7900
101	AccessBioKorea	CareStart™ COVID-19 IgM/IgG	Antibody	IVD-20-536	2020. 7. 3.	+82-54-906-9800
102	iNtRON Biotechnology, Inc.	LiliF™ GBN COVID-19 IgG Rapid Kit	Antibody	IVD-20-538	2020. 7. 3.	+82-31-739-5678
103	COSMAX PHARMA Co., Ltd.	iDetect™ SARS-CoV-2 Detection Kit	Molecular	IVD-20-549	2020. 7. 7.	+82-70-5101-1139
104	CellSafe Co., Ltd.	LAMPlex RT-qLAMP COVID-19 Detection Assay	Molecular	IVD-20-554	2020. 7. 9.	+82-31-285-9958
105	Z Biotech Inc.	AnyLab COVID-19 IgM/IgG Test Kit	Antibody	IVD-20-557	2020. 7. 10.	+82-43-278-0075
106	Eudipia	EuDX™ COVID-19 Multiplex Detection Kit	Molecular	IVD-20-560	2020. 7. 13.	+82-70-8890-2101

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
107	GenBody Inc.	GenBody COVID-19 Ag	Antigen	IVD-20-558	2020. 7. 13.	+82-41-523-8990
108	SD Biosensor, Inc.	STANDARD™ Q COVID-19 IgM/IgG Combo Test(Q-NCOV-01C)	Antibody	IVD-20-568	2020. 7. 14.	+82-31-300-0400
109	ACEBiomed, Inc.	Palm PCR™ COVID-19 Fast Real-time RT-PCR Kit	Molecular	IVD-20-569	2020. 7. 14.	+82-2-783-0803
110	ProteomeTech Inc.	GENEdania COVID-19 qRT-PCR	Molecular	IVD-20-570	2020. 7. 15.	+82-2-6968-5277
111	MEDIAN DIAGNOSTICS INC.	MDxⓡ COVID-19 Ab Rapid Test	Antibody	IVD-20-580	2020. 7. 16.	+82-33-244-0100
112	MediHelpLine Co., Ltd.	KORA COVID19 IgM/IgG	Antibody	IVD-20-579	2020. 7. 16.	+82-2-6960-4100
113	PCL, Inc.	PCL COVID19 Speedy RT-PCR	Molecular	IVD-20-582	2020. 7. 17.	+82-2-2144-3901
114	WOORIDUL PHARMACEUTICAL LTD.	findGENE™ COVID-19 RT-PCR kit	Molecular	IVD-20-583	2020. 7. 20.	+82-2-582-4211
115	WOORIDUL PHARMACEUTICAL LTD.	findGENE™ N-CoV RT-PCR kit	Molecular	IVD-20-584	2020. 7. 20.	+82-2-582-4211

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
116	NDFOS Co., Ltd.	ND COVID-19 IgG/IgM Rapid Test	Antibody	IVD-20-585	2020. 7. 20.	+82-2-6203-0733
117	GenBody Inc.	GenBody Influenza/COVID-19 Ag Multi	Antigen	IVD-20-591	2020. 7. 21.	+82-41-523-8990
118	AMSBIO	A+CheQ COVID-19 High-Speed RT-qPCR Detection Kit	Molecular	IVD-20-595	2020. 7. 22.	+82-2-2086-1621
119	MiCoBioMed, Co., Ltd	VERI-Q COVID-19 IgG/IgM Rapid Test	Antibody	IVD-20-600	2020. 7. 23.	+82-70-5227-6065
120	BioZentech, Co., Ltd	BZ COVID-19 IgM/IgG	Antibody	IVD-20-610	2020. 7. 29.	+82-2-855-5194
121	BioZentech, Co., Ltd	BZ IsoMDx COVID-19 kit	Molecular	IVD-20-615	2020. 8. 3.	+82-2-855-5194
122	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 Colorimetric LAMP premix kit	Molecular	IVD-20-616	2020. 8. 3.	+82-31-260-1926
123	SeaSun Biomaterials	AQ-TOP™ COVID-19 Rapid Detection Kit Plus	Molecular	IVD-20-617	2020. 8. 3.	+82-42-716-0301
124	RapiGEN, INC	BIOCREDIT COVID-19 IgG/IgM Combo	Antibody	IVD-20-629	2020. 8. 10.	+82-31-427-4677

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
125	WON Medical Co., Ltd.	Wonmed Covid-19 IgM/IgG	Antibody	IVD-20-634	2020. 8. 10.	+82-32-219-0077 +82-32-219-0079
126	SML GENETREE CO., LTD.	Ezplex® SARS-CoV-2 G Kit	Molecular	IVD-20-635	2020. 8. 10.	+82-2-2057-7900
127	MiCoBioMed, Co., Ltd	Veri-Q nCoV-QM-N	Molecular	IVD-20-637	2020. 8. 10.	+82-70-5227-6065
128	NGeneBio Co., Ltd	NGenePlex™ nCoV qRT-PCR kit	Molecular	IVD-20-662	2020. 8. 14.	+82-2-867-9798
129	WOORIDUL PHARMACEUTICAL LTD.	findUS™ COVID-19 IgM/IgG	Antibody	IVD-20-663	2020. 8. 14.	+82-2-582-4211
130	Sugentech, Inc.	SGT Anti-SARS-CoV-2 Total Ab ELISA	Antibody	IVD-20-664	2020. 8. 14.	+82-43-710-2822
131	SD Biosensor, Inc.	STANDARD™ E COVID-19 Total Ab ELISA	Antibody	IVD-20-665	2020. 8. 14.	+82-31-300-0400
132	1drop Inc.	1copy™ COVID-19 qPCR Triplex Kit	Molecular	IVD-20-666	2020. 8. 14.	+82-31-747-0109
133	Gencurix Inc.	GenePro COVID-19 IgG/IgM Test	Antibody	IVD-20-667	2020. 8. 14.	+82-2-2621-7038

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
134	BIOPOA Co., Ltd.	Rapid COVID-19 PoaCheck	Molecular	IVD-20-668	2020. 8. 14.	+82-31-375-8304
135	Sugentech, Inc.	SGTi-flex COVID-19 Ag	Antigen	IVD-20-675	2020. 8. 18.	+82-43-710-2822
136	MicroDigital Co., Ltd.	MDGen CL96-COVID-19 IgG	Antibody	IVD-20-678	2020. 8. 19.	+82-31-701-2225
137	NB POSTECH, Inc.	CHEXEL COVID-19 IgM/IgG	Antibody	IVD-20-680	2020. 8. 20.	+82-70-8255-8100
138	CALTH Inc.	AccuFind COVID19 IgG	Antibody	IVD-20-727	2020. 8. 26.	+82-70-4238-5244
139	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 AG	Antigen	IVD-20-756	2020. 8. 28.	+82-31-260-1926
140	ACEBiomed, Inc.	ACEBiomed COVID-19 IgM/IgG	Antibody	IVD-20-755	2020. 8. 28.	+82-2-783-0803
141	CHUNGDO PHARM. CO., LTD.	CD COVID-19 assay Kit	Antibody	IVD-20-764	2020. 8. 31.	+82-33-258-6114
142	BBB Inc	Sampinute™ COVID-19 Antigen MIA	Antigen	IVD-20-766	2020. 8. 31.	+82-2-565-9653

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
143	BBB Inc	MARK-B^{TM} COVID-19 Ag S	Antigen	IVD-20-761	2020. 8. 31.	+82-2-565-9653
144	MicroDigital Co., Ltd.	MDGen AB96-COVID-19 IgM	Antibody	IVD-20-773	2020. 9. 2.	+82-31-701-2225
145	OSANG Healthcare Co., Ltd.	GeneFinder COVID-19 Fast RealAmp kit	Molecular	IVD-20-788	2020. 9. 8.	+82-31-460-9921
146	Humasis Co., Ltd.	Humasis COVID-19 Ag Test	Antigen	IVD-20-789	2020. 9. 8.	+82-31-478-8585 +82-31-478-8546
147	NanoEntek, Inc.	FREND COVID-19 SP	Antibody	IVD-20-791	2020. 9. 9.	+82-2-6220-7940
148	GloryBiotech corp.	GBT COVID-19 RAPID KIT	Antibody	IVD-20-797	2020. 9. 10.	+82-2-6095-7858
149	ImmuneMed Inc.	IMMUNEMED COVID-19 IgM/IgG RAPID	Antibody	IVD-20-796	2020. 9. 10.	+82-33-258-6554
150	Precision Biosensor Inc.	Exdia COVID-19 Ag	Antigen	IVD-20-795	2020. 9. 10.	+82-70-7167-0331
151	NDFOS Co., Ltd.	ND COVID-19 & Flu Combo Kit	Molecular	IVD-20-799	2020. 9. 10.	+82-2-6203-0733

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
152	Asan pharmaceutical Co., LTD.	Asan qPCR Test COVID-19	Molecular	IVD-20-808	2020. 9. 15.	+82-31-376-5990 (506)
153	TCM Biosciences Inc.	TCM-Q SARS-CoV-2 Real-time PCR Kit	Molecular	IVD-20-810	2020. 9. 15.	+82-31-698-3041
154	SG Medical, Inc.	InstaView COVID-19 IgG/IgM	Antibody	IVD-20-809	2020. 9. 15.	+82-2-2240-7062
155	Humasis Co., Ltd.	Humasis COVID-19/Flu Ag Combo Test	Antigen	IVD-20-827	2020. 9. 22.	+82-31-478-8585 +82-31-478-8546
156	DIOGENE Co., Ltd	DLPTMQ COVID19 RT-LAMP Kit	Molecular	IVD-20-833	2020. 9. 23.	+82-31-701-6488
157	LG Chem, Ltd.	AdvanSure™ SARS-CoV-2 IgG(S1) ELISA	Antibody	IVD-20-832	2020. 9. 23.	+82-2-6987-4432
158	Abbott Diagnostics Korea Inc.	Panbio™ COVID-19 Ag Rapid Test Device	Antigen	IVD-20-835	2020. 9. 23.	+82-31-899-2837
159	Absology Co., Ltd.	Absolusy COVID19 IgM/IgG Combo	Antibody	IVD-20-837	2020. 9. 24.	+82-31-348-8637
160	KogeneBiotech Co., Ltd.	PowerChek™ SARS-CoV-2 Influenza A&B RSV Multiplex Real-time PCR kit	Molecular	IVD-20-839	2020. 9. 24.	+82-2-2026-2150

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
161	Seegene Inc.	Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay	Molecular	IVD-20-845	2020. 9. 28.	+82-2-2240-4166
162	Genematrix Inc.	NeoPlexTM FluCOVID Detection Kit	Molecular	IVD-20-849	2020. 9. 29.	+82-31-628-2020
163	RapiGEN, INC	BIOCREDIT CoviFlu Ag Duo	Antigen	IVD-20-853	2020. 10. 5.	+82-31-427-4677
164	NanoEntek, Inc.	FREND COVID-19 Ag	Antigen	IVD-20-855	2020. 10. 5.	+82-2-6220-7940
165	COSMAX PHARMA Co., Ltd.	NOW Detect COVID-19 IgM/IgG Rapid Test	Antibody	IVD-20-863	2020. 10. 6.	+82-70-5101-1139
166	CALTH Inc.	AllCheck COVID19 Ag	Antigen	IVD-20-875	2020. 10. 12.	+82-70-4238-5244
167	Rmedica Co., Ltd.	BUZZARTM SARS-CoV-2 IgG/IgM	Antibody	IVD-20-877	2020. 10. 13.	+82-70-5138-3096
168	PRIME4DIA Co., Ltd.	P4DETECT COVID-19/Flu	Antigen	IVD-20-883	2020. 10. 14.	+82-31-478-3105
169	PRIME4DIA Co., Ltd.	P4DETECT COVID-19 Ag	Antigen	IVD-20-884	2020. 10. 14.	+82-31-478-3105

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
170	ACEBiomed, Inc.	Palm PCR™ Fast COVID-19 Assay	Molecular	IVD-20-881	2020. 10. 14.	+82-2-783-0803
171	NDFOS Co., Ltd.	ND COVID-19 Ag Test	Antigen	IVD-20-892	2020. 10. 15.	+82-2-6203-0733
172	M monitor Inc.	Mmax™ SARS-CoV-2 Detection Kit	Molecular	IVD-20-904	2020. 10. 26.	+82-53-254-2505
173	Asan pharmaceutical Co., LTD.	Asan Easy Test COVID-19 Ag	Antigen	IVD-20-912	2020. 10. 28.	+82-31-376-5990 (506)
174	GREENCROSS MEDICAL SCIENCE	GENEDIA Quantum COVID-19 Ag	Antigen	IVD-20-916	2020. 10. 28.	+82-31-260-1926
175	BIONEER Corporation	AccuPower® RV1 Multiplex Kit	Molecular	IVD-20-913	2020. 10. 28.	+82-42-930-8508
176	BIONEER Corporation	AccuPower® RV1 Real-Time RT-PCR Kit	Molecular	IVD-20-915	2020. 10. 28.	+82-42-930-8508
177	BIONEER Corporation	AccuPower® COVID-19 Multiplex Real-Time RT-PCR Kit	Molecular	IVD-20-917	2020. 10. 28.	+82-42-930-8508
178	Boditech Med Inc.	ExAmplex Influenza A/B SARS-CoV-2 PCR Kit	Molecular	IVD-20-919	2020. 10. 28.	+82-33-243-1400

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
179	Sugentech, Inc.	SGTi-flex COVID-19 & Flu A/B Ag DUO	Antigen	IVD-20-920	2020. 10. 29.	+82-43-710-2822
180	SD Biosensor, Inc.	STANDARD M Flu/SARS-CoV-2 Real-time Detection kit	Molecular	IVD-20-924	2020. 11. 3.	+82-31-300-0400
181	SeaSun Biomaterials	U-TOP™ SARS-CoV-2 & Flu A/B	Molecular	IVD-20-925	2020. 11. 3.	+82-42-716-0301
182	IVDLab Co., Ltd	IVDLAB COVID-19 Ag Test	Antigen	IVD-20-931	2020. 11. 4.	+82-31-452-6912
183	NDFOS Co., Ltd.	ND COVID-19 & Flu Duo Test	Antigen	IVD-20-929	2020. 11. 4.	+82-2-6203-0733
184	WELLS BIO, INC.	careUSTM COVID-19 antigen	Antigen	IVD-20-934	2020. 11. 5.	+82-2-3660-6900
185	ShinJin Medics Inc.	DIAKEY COVID-19 Ag Rapid Test	Antigen	IVD-20-942	2020. 11. 6.	+82-70-8277-6929
186	SD Biosensor, Inc.	SARS-CoV-2 & Flu A/B Rapid Antigen Test	Antigen	IVD-20-944	2020. 11. 6.	+82-31-300-0400
187	SD Biosensor, Inc.	STANDARD™ F COVID/Flu Ag Combo FIA	Antigen	IVD-20-947	2020. 11. 11.	+82-31-300-0400

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
188	Biowithus, Inc.	INFINA™ 2019_nCoV Real-time RT-PCR kit	Molecular	IVD-20-958	2020. 11. 11.	+82-2-2223-2121
189	DxGen Corp.	Epithod®616 COVID-19 IgG Test Kit	Antibody	IVD-20-956	2020. 11. 11.	+82-31-427-8450
190	MEDIAN DIAGNOSTICS INC.	MDx® COVID-19 Ag Rapid Test	Antigen	IVD-20-960	2020. 11. 12.	+82-33-244-0100
191	NanoEntek, Inc.	FREND™ COVID-19+FLU A&B	Antigen	IVD-20-966	2020. 11. 16.	+82-2-6220-7940
192	Z Biotech Inc.	AnyLab COVID-19 Ag Test Kit	Antigen	IVD-20-965	2020. 11. 16.	+82-43-278-0075
193	1drop Inc.	1copy™ COVID-19 qPCR 4plex Kit	Molecular	IVD-20-971	2020. 11. 17.	+82-31-747-0109
194	KH Medical Co., Ltd.	RADI COVID-19 Ag Rapid Test	Antigen	IVD-20-983	2020. 11. 19.	+82-31-5180-3018
195	OSANG Healthcare Co., Ltd.	GeneFinder COVID-19 Ag Rapid Test	Antigen	IVD-20-987	2020. 11. 23.	+82-31-460-9921
196	OSANG Healthcare Co., Ltd.	GeneFinder COVID-19/Flu A&B RealAmp Kit	Molecular	IVD-20-986	2020. 11. 23.	+82-31-460-9921

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
197	BioCore Co., Ltd.	BioCore COVID-19 Fast Real Time PCR Kit	Molecular	IVD-20-988	2020. 11. 23.	+82-2-2027-6320
198	Asan pharmaceutical Co., LTD.	Asan Easy Test Flu/COVID-19 Ag Combo	Antigen	IVD-20-996	2020. 11. 25.	+82-31-376-5990 (506)
199	AccessBioKorea	CareStart™ COVID-19 Antigen	Antigen	IVD-20-999	2020. 11. 26.	+82-54-906-9800
200	BioZentech, Co., Ltd	BZ COVID-19 Ag Test	Antigen	IVD-20-998	2020. 11. 26.	+82-2-855-5194
201	MiCoBioMed, Co., Ltd	VERI-Q COVID-19 Ag Rapid Test	Antigen	IVD-20-1019	2020. 12. 1.	+82-70-5227-6065
202	Boditech Med Inc.	AFIAS COVID-19/Flu Ag Combo	Antigen	IVD-20-1025	2020. 12. 4.	+82-33-243-1400
203	Boditech Med Inc.	ichroma™ COVID-19/Flu Ag Combo	Antigen	IVD-20-1028	2020. 12. 4.	+82-33-243-1400
204	OPTOLANE Technologies Inc.	Direct Dr. PCRTM SARS-CoV-2 Detection Kit	Molecular	IVD-20-1053	2020. 12. 8.	+82-31-737-7835
205	Absology Co., Ltd.	Absoludy COVID-19 Ag Rapid	Antigen	IVD-20-1057	2020. 12. 9.	+82-31-348-8637

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
206	GenBody Inc.	GenBody Influenza/COVID-19 Ag Triple	Antigen	IVD-20-1058	2020. 12. 9.	+82-41-523-8990
207	PCL, Inc.	PCLMA ABC multi RT-PCR Kit	Molecular	IVD-20-1059	2020. 12. 9.	+82-2-2144-3901
208	Cancer Rop Co., Ltd.	Q-Sens® COVID-19 Detection kit v2	Molecular	IVD-20-1063	2020. 12. 10.	+82-2-6964-8773
209	WOORIDUL PHARMACEUTICAL LTD.	findUS™ COVID-19 Antigen	Antigen	IVD-20-1087	2020. 12. 14.	+82-2-582-4211
210	ACEBiomed, Inc.	AMB COVID-19 Ag	Antigen	IVD-20-1094	2020. 12. 16.	+82-2-783-0803
211	GenBody Inc.	GenBody FIA COVID-19 Ag	Antigen	IVD-20-1097	2020. 12. 17.	+82-41-523-8990
212	Precision Biosensor Inc.	Exdia Multiplex COVID-19 & flu	Antigen	IVD-20-1104	2020. 12. 18.	+82-70-7167-0331
213	PCL, Inc.	PCL COVID 19 Ag Gold	Antigen	IVD-20-1102	2020. 12. 18.	+82-2-2144-3901
214	AccessBioKorea	CareStart™ COVID-19 Antigen	Antigen	IVD-20-1114	2020. 12. 21.	+82-54-906-9800

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
215	CHUNGDO PHARM. CO., LTD.	CD COVID-19 Ag assay Ki	Antigen	IVD-20-1119	2020. 12. 21.	+82-33-258-6114
216	DiNonA, Inc.	DiNonA COVID-19 Ab IgM/IgG	Antibody	IVD-20-1142	2020. 12. 23.	+82-63-838-1701
217	SolGent Co., Ltd	DiaPlexQ™ COVID-19 (N, ORF1a) Detection Kit	Molecular	IVD-20-1143	2020. 12. 23.	+82-70-7893-7831 +82-70-7006-5962
218	NB POSTECH, Inc.	CHEXEL™ COVID-19 Ag	Antigen	IVD-20-1140	2020. 12. 23.	+82-70-8255-8100
219	NDFOS Co., Ltd.	ND COVID-19 & Flu Duo Plus	Antigen	IVD-20-1152	2020. 12. 28.	+82-2-6203-0733
220	KH Medical Co., Ltd.	RADI COVID-19 IgG/IgM Rapid Test	Antibody	IVD-20-1151	2020. 12. 28.	+82-31-5180-3018
221	KH Medical Co., Ltd.	RADI Flu-SC2 Ag Rapid Test	Antigen	IVD-20-1155	2020. 12. 29.	+82-31-5180-3018
222	Abbott Diagnostics Korea Inc.	Panbio™ COVID-19 Ag Rapid Device (41FK11)	Antigen	IVD-20-1161	2020. 12. 30.	+82-31-899-2837
223	DowGene Co., Ltd	Dow NETPlex™ SARS-CoV-2 RT-PCR Kit	Molecular	IVD-20-1163	2020. 12. 31.	+82-2-1566-3313

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
224	SML GENETREE CO., LTD.	Ezplex® SARS-CoV-2/RV G Kit	Molecular	IVD-21-1	2021. 1. 4.	+82-2-2057-7900
225	Korea Genome Information Institute	KGIC™ COVID-19 Antigen (Ag) Kit	Antigen	IVD-21-14	2021. 1. 11.	+82-2-1800-7882
226	ProteomeTech Inc.	GENEdania SARS-CoV-2/Flu A/Flu B Fast qRT-PCR	Molecular	IVD-21-22	2021. 1. 12.	+82-2-6968-5277
227	BBB Inc	MARK-B™ COVID-19 Ag	Antigen	IVD-21-23	2021. 1. 12.	+82-2-565-9653
228	RapiGEN, INC	BIOCREDIT COVID-19 IgG	Antibody	IVD-21-32	2021. 1. 14.	+82-31-427-4677
229	InTelos Inc.	MAUVE™ COVID-19 Ag, SARS-CoV-2 Ag Test	Antigen	IVD-21-35	2021. 1. 15.	+82-53-243-1325
230	YOUNG WOO SCIENCE	WEMED™ COVID-19 Antigen (Ag) Test	Antigen	IVD-21-42	2021. 1. 18.	+82-70-7825-3636
231	Inogenix Inc.	INO SARS-CoV-2 Detection Kit	Molecular	IVD-21-38	2021. 1. 18.	+82-33-258-6375
232	Boditech Med Inc.	AFIAS COVID-19 nAb	Antibody	IVD-21-43	2021. 1. 19.	+82-243-1400

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
233	KNAX Ltd.	KNAX-SMART SARS-CoV-2 IgM/IgG	Antibody	IVD-21-54	2021. 1. 21.	+82-31-5180-3184
234	Philosys Co.,Ltd.	Gmate® COVID-19 Ag	Antigen	IVD-21-55	2021. 1. 21.	+82-31-778-0602
235	SLSBio Co., Ltd	SsmarTest COVID-19 Ag Detection Kit	Antigen	IVD-21-56	2021. 1. 21.	+82-70-8857-2657
236	EzDiaTech, Inc.	EDT™ COVID-19 Ag Rapid Card	Antigen	IVD-21-59	2021. 1. 25.	+82-70-4910-8480
237	Korea Genome Information Institute	KGIC™ COVID-19 RT-LAMP Pro kit	Molecular	IVD-21-68	2021. 1. 27.	+82-2-1800-7882
238	NDFOS Co., Ltd.	ND COVID-19 Multi Kit	Molecular	IVD-21-76	2021. 1. 29.	+82-2-6203-0733
239	KNAX Ltd.	KNAX-SMART SARS-CoV-2 Ag	Antigen	IVD-21-82	2021. 2. 2.	+82-31-5180-3184
240	KNAX Ltd.	KNAX-SMART SARS-CoV-2, Influenza A&B Ag Combo	Antigen	IVD-21-88	2021. 2. 3.	+82-31-5180-3184
241	KH Medical Co., Ltd.	RADI Flu-SC2 Detection Kit	Molecular	IVD-21-87	2021. 2. 3.	+82-31-5180-3018

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
242	PaxGenBio Co., Ltd.	PaxView® SARS-CoV-2 MPCR-ULFA Kit	Molecular	IVD-21-93	2021. 2. 4.	+82-31-244-5036
243	K-BioCELF Inc.	KDx-SARS-CoV-2 (SM) LAMP RT-PCR Kit	Molecular	IVD-21-101	2021. 2. 9.	+82-31-4639-0347
244	MiCoBioMed, Co., Ltd	Veri-Q COVID-19 ELISA Kit	Antibody	IVD-21-107	2021. 2. 10.	+82-70-5227-6065
245	GenBody Inc.	iFinDx COVID-19 IgM/IgG	Antibody	IVD-21-113	2021. 2. 16.	+82-41-523-8990
246	SD Biosensor, Inc.	STANDARD™ easy Q COVID-19 Ag Test	Antigen	IVD-21-128	2021. 2. 22.	+82-31-300-0400
247	I-SENS, Inc.	COVID-19 IgG Cartridge	Antibody	IVD-21-140	2021. 2. 23.	+82-2-910-0623
248	1drop Inc.	1copy™ COVID-19/FluA/FluB/RSV qPCR Kit	Molecular	IVD-21-148	2021. 2. 24.	+82-31-747-0109
249	Asan pharmaceutical Co., LTD.	Asan Easy Test COVID-19 IgG/IgM (N)	Antibody	IVD-21-158	2021. 3. 2.	+82-31-376-5990 (506)
250	Absology Co., Ltd.	Absoludy COVID-19 Ag	Antigen	IVD-21-159	2021. 3. 2.	+82-31-348-8637

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
251	Seegene Inc.	Allplex™ SARS-CoV-2/Flu/RSV Assay	Molecular	IVD-21-164	2021. 3. 4.	+82-2-2240-4166
252	ADTceh Co., LTD	ADTech COVID-19 Ag RAPID KIT	Antigen	IVD-21-169	2021. 3. 4.	+82-70-4659-1811
253	Korea Genome Information Institute	KGIC™COVID-19 IgM/IgG Kit	Antibody	IVD-21-171	2021. 3. 4.	+82-2-1800-7882
254	AddBioMeditek Co.	AddMedi SARS-CoV-2 RT-qPCR Kit	Molecular	IVD-21-173	2021. 3. 8.	+82-43-719-2037
255	SeaSun Biomaterials	SSa-19/A&B	Molecular	IVD-21-174	2021. 3. 8.	+82-42-716-0301
256	Boditech Med Inc.	REF:CFPC-120, ichroma™ COVID-19 nAb	Antibody	IVD-21-176	2021. 3. 9.	+82-33-243-1400
257	Macrogen, Inc.	Axen™ COVID-19 IgM/IgG RAPID	Antibody	IVD-21-180	2021. 3. 10.	+82-2-2180-7222
258	GloryBiotech corp.	GBT COVID-19 Ag RAPID KIT	Antigen	IVD-21-185	2021. 3. 12.	+82-2-6095-7858
259	EzDiaTech, Inc.	EDT™ COVID-19 IgG/IgM Rapid Card	Antibody	IVD-21-186	2021. 3. 12.	+82-70-4910-8480

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
260	I-SENS, Inc.	COVID-19 IgM/IgG Cartridge	Antibody	IVD-21-198	2021. 3. 17.	+82-2-910-0623
261	SD Biosensor, Inc.	SARS-CoV-2 Rapid Antigen Test Nasal	Antigen	IVD-21-199	2021. 3. 18.	+82-31-300-0400
262	OPTOLANE Technologies Inc.	Kaira™ COVID-19/Flu Detection Kit	Molecular	IVD-21-214	2021. 3. 25.	+82-31-737-7835
263	KogeneBiotech Co., Ltd.	PowerChek™ SARS-CoV-2 Advanced Real-time PCR Kit	Molecular	IVD-21-216	2021. 3. 25.	+82-2-2026-2150
264	DxGen Corp.	Epithod®616 COVID-19 Ag Test Kit	Antigen	IVD-21-215	2021. 3. 25.	+82-31-427-8450
265	KH Medical Co., Ltd.	CHAMP COVID-19 Multiplex Kit	Molecular	IVD-21-233	2021. 3. 30.	+82-31-5180-3018
266	COSMAX PHARMA Co., Ltd.	NOW Detect COVID-19 Antigen Rapid Test	Antigen	IVD-21-251	2021. 4. 5.	+82-70-5101-1139
267	iNtRON Biotechnology, Inc.	LiliF™ GBN COVID-19 Ag Rapid Kit	Antigen	IVD-21-252	2021. 4. 5.	+82-31-739-5678
268	SML GENETREE CO., LTD.	Ezplex® SARS-CoV2/RV Fast G Kit	Molecular	IVD-21-259	2021. 4. 6.	+82-2-2057-7900

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
269	SG Medical, Inc.	R-FIND SARS-CoV-2 Neutralizing Antibody ELISA	Antibody	IVD-21-271	2021. 4. 7.	+82-2-2240-7062
270	ImmuneMed Inc.	IMMUNEMED COVID-19 Ag RAPID	Antigen	IVD-21-274	2021. 4. 8.	+82-33-258-6554
271	RapiGEN, INC	BIOCREDIT COVID-19 Ag Test Nasal	Antigen	IVD-21-275	2021. 4. 8.	+82-31-427-4677
272	SolGent Co., Ltd	DiaPlexQ™ Flu A/B & SARS-CoV-2 Detection Kit	Molecular	IVD-21-273	2021. 4. 8.	+82-70-7893-7831 +82-70-7006-5962
273	Heimbiotek Inc.	HB BestPlex™ 3C COVID-19 RT-PCR Kit	Molecular	IVD-21-282	2021. 4. 12.	+82-31-548-2130
274	Seegene Inc.	Allplex™ SARS-CoV-2 Variants I Assay	Molecular	IVD-21-283	2021. 4. 12.	+82-2-2240-4166
275	Seegene Inc.	Allplex™ SARS-CoV-2 Master Assay	Molecular	IVD-21-284	2021. 4. 12.	+82-2-2240-4166
276	Genes Laboratories	NEXdia™ COVID-19 & Influenza A/B Detection kit	Molecular	IVD-21-296	2021. 4. 14.	+82-31-756-5656
277	HB Healthcare Corp.	HBelisa™ SARS-CoV-2 Neutralizing Antibody Detection Kit	Antibody	IVD-21-297	2021. 4. 14.	+82-2-897-0209

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
278	Macrogen, Inc.	Axen™ COVID-19 Ag RAPID	Antigen	IVD-21-302	2021. 4. 16.	+82-2-2180-7222
279	Sugentech, Inc.	SGT SARS-CoV-2 In Vitro Neutralizing Antibody Test(IVnAT)	Antibody	IVD-21-303	2021. 4. 16.	+82-43-710-2822
280	MicroDigital Co., Ltd.	MDGen AB96-COVID-19 dual IgG	Antibody	IVD-21-307	2021. 4. 20.	+82-31-701-2225
281	Humasis Co., Ltd.	Humasis COVID-19 Ag Home Test	Antigen (Home test)	IVD-21-314	2021. 4. 21.	+82-31-478-8585 +82-31-478-8546
282	WON Medical Co., Ltd.	WonMed Covid-19 Ag	Antigen	IVD-21-316	2021. 4. 22.	+82-32-219-0077 +82-32-219-0079
283	SGENEBIO	SARS-CoV-2 Easy Kit (Real-time PCR)	Molecular	IVD-21-323	2021. 4. 23.	+82-70-4010-8722
284	THERAGEN GENOMECARE CO., LTD	THERAGEN COVID-19 ASSAY	Molecular	IVD-21-324	2021. 4. 23.	+82-70-4680-2317
285	Genes Laboratories	NEXdia™COVID-19 & Influenza A/B Detection kit(For ABI 7500)	Molecular	IVD-21-326	2021. 4. 26.	+82-31-756-5656
286	Abbott Diagnostics Korea Inc.	Panbio™ COVID-19 Antigen Self-Test	Antigen (Home test)	IVD-21-328	2021. 4. 26.	+82-31-899-2837

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
287	OSANG Healthcare Co., Ltd.	GeneFinder COVID-19 Ag Plus Rapid Test	Antigen	IVD-21-341	2021. 5. 3.	+82-31-460-9921
288	Genoplan Korea, Inc.	Genoplan SARS-CoV-2 Assay	Molecular	IVD-21-344	2021. 5. 4.	+82-70-8671-6658
289	QUANTAMATRIX Inc.	QPLEX™ COVID-19 Test	Molecular	IVD-21-353	2021. 5. 6.	+82-2-6947-7600
290	Wizbiosolutions Inc.	WizDx™ COVID-19 CrystalMix® Multi PCR Kit	Molecular	IVD-21-369	2021. 5. 11.	+82-70-7605-5066
291	Korea Heavy Industry and Development Co., Ltd.	Grace Tree COVID-19 IgM/IgG	Antibody	IVD-21-377	2021. 5. 13.	+82-2-785-1003
292	Korea Heavy Industry and Development Co., Ltd.	Grace Tree COVID-19 Ag	Antigen	IVD-21-378	2021. 5. 14.	+82-2-785-1003
293	Boditech Med Inc.	Boditech Quick™ COVID-19 Ag	Antigen	IVD-21-385	2021. 5. 17.	+82-243-1400
294	Heimbiotek Inc.	HB BestPlex™ 3C Flu/COVID-19 RT-PCR Kit	Molecular	IVD-21-394	2021. 5. 20.	+82-31-548-2130
295	SD Biosensor, Inc.	STANDARD™ Q COVID-19 Ag Saliva Test	Antigen	IVD-21-405	2021. 5. 24.	+82-31-300-0400

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
296	KNAX Ltd.	KNAX-SMART SARS-CoV-2 IgM/IgG (N)	Antibody	IVD-21-423	2021. 5. 27.	+82-31-5180-3184
297	OSANG Healthcare Co., Ltd.	GeneFinder™ COVID-19 & Flu Duo Rapid Test	Antigen	IVD-21-418	2021. 5. 27.	+82-31-460-9921
298	SeaSun Biomaterials	SSf-COVID19	Molecular	IVD-21-440	2021. 6. 1.	+82-42-716-0301
299	CALTH Inc.	AllCheck COVID19 Ag Nasal	Antigen	IVD-21-442	2021. 6. 2.	+82-70-4238-5244
300	Sugentech, Inc.	SGTi-flex COVID-19 Ag Self	Antigen (Home test)	IVD-21-452	2021. 6. 8.	+82-43-710-2822
301	GenBody Inc.	GenBody FIA COVID-19 NAb	Antibody	IVD-21-456	2021. 6. 8.	+82-41-523-8990
302	GenBody Inc.	GenBody COVID-19 Ag Nasal Test	Antigen	IVD-21-459	2021. 6. 9.	+82-41-523-8990
303	Sugentech, Inc.	SGTi-Self COVID-19 IgM/IgG	Antibody (Home test)	IVD-21-465	2021. 6. 9.	+82-43-710-2822
304	1drop Inc.	1copy™ COVID-19 MDx Kit Professional	Molecular	IVD-21-474	2021. 6. 14.	+82-31-747-0109

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
305	SolGent Co., Ltd	DiaPlexQ™ SARS-CoV-2 Detection Kit	Molecular	IVD-21-485	2021. 6. 17.	+82-70-7893-7831 +82-70-7006-5962
306	Boditech Med Inc.	ExAmplex COVID-19 PCR 3-gene kit	Molecular	IVD-21-500	2021. 6. 22.	+82-33-243-1400
307	Boditech Med Inc.	ExAmplex COVID-19 PCR 3-gene Lyo kit	Molecular	IVD-21-502	2021. 6. 22.	+82-33-243-1400
308	SD Biosensor, Inc.	STANDARD™ F SARS-CoV-2 nAb FIA	Antibody	IVD-21-515	2021. 6. 24.	+82-31-300-0400
309	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 Ag(643K)	Antigen	IVD-21-526	2021. 6. 25.	+82-31-260-1926
310	NanoEntek, Inc.	FREND COVID-19 Neutralization Ab	Antibody	IVD-21-527	2021. 6. 25.	+82-2-6220-7940
311	Philosys Co.,Ltd.	Gmate® COVID-19 Total antibody/Neutralizing antibody	Antibody	IVD-21-525	2021. 6. 25.	+82-31-778-0602
312	SolGent Co., Ltd	DiaRapid™ COVID-19 Ag Test Kit	Antigen	IVD-21-531	2021. 6. 28.	+82-70-7893-7831 +82-70-7006-5962
313	RapiGEN, INC	BIOCREDIT COVID-19 Ag Home Test Saliva	Antigen (Home test)	IVD-21-532	2021. 6. 29.	+82-31-427-4677

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
314	BioZentech, Co., Ltd	BZ COVID-19 Neutralizing Ab Test	Antibody	IVD-21-538	2021. 6. 30.	+82-2-855-5194
315	Seegene Inc.	Allplex™ SARS-CoV-2 Variants II Assay	Molecular	IVD-21-537	2021. 6. 30.	+82-2-2240-4166
316	Boditech Med Inc.	ichroma™ COVID-19 Neutralizing Ab	Antibody	IVD-21-536	2021. 6. 30.	+82-33-243-1400
317	UNIANCE GENE	UGDx COVID-19 Ag Rapid Test	Antigen	IVD-21-548	2021. 7. 2.	+82-2-6953-7741
318	OPTOLANE Technologies Inc.	Dr. PCR™ DiS 20K SARS-CoV-2 Detection Kit	Molecular	IVD-21-560	2021. 7. 5.	+82-31-737-7835
319	OSANG Healthcare Co., Ltd.	GeneFinder COVID-19 IgG Rapid Test	Antibody	IVD-21-558	2021. 7. 5.	+82-31-460-9921
320	OSANG Healthcare Co., Ltd.	GeneFinder COVID-19 IgG/IgM Rapid Test	Antibody	IVD-21-559	2021. 7. 5.	+82-31-460-9921
321	K-BioCELF Inc.	KDx-SIplex Fast One Step RT-PCR Kit	Molecular	IVD-21-557	2021. 7. 5.	+82-31-4639-0347
322	Plexense, Inc.	ACCEL ELISA COVID-19 Saliva Antigen Kit	Antigen	IVD-21-571	2021. 7. 7.	+82-70-4725-4683

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
323	Genesystem Co., Ltd.	SMARTCHEK® SARS-CoV-2/Flu/RSV Simultaneous Detection Kit	Molecular	IVD-21-575	2021. 7. 8.	+82-42-863-8551
324	Korea Genome Information Institute	KGIC™ COVID-19 RT-LAMP Pro Kit PLUS	Molecular	IVD-21-581	2021. 7. 9.	+82-2-1800-7882
325	GenBody Inc.	GenBody COVID-19 Ag Saliva Test	Antigen	IVD-21-583	2021. 7. 9.	+82-41-523-8990
326	LUCA AICELL, INC.	LUCA NK COVID-19 IgG/IgM	Antibody	IVD-21-580	2021. 7. 9.	+82-31-8091-1000
327	Genematrix Inc.	NeoPlex™ COVID-19 FAST	Molecular	IVD-21-586	2021. 7. 12.	+82-31-628-2020
328	SLSBio Co., Ltd	SsmarTest COVID 19 Neutralizing Ab Test	Antibody	IVD-21-603	2021. 7. 14.	+82-70-8857-2657
329	Absology Co., Ltd.	Absoludy COVID-19 Nab	Antibody	IVD-21-602	2021. 7. 14.	+82-31-348-8637
330	PROTANBIO Inc.	PROTAN COVID-19 IgG Type2	Antibody	IVD-21-607	2021. 7. 15.	+82-2-3285-1413
331	Philosys Co.,Ltd.	Gmate® COVID-19 Neutralizing antibody	Antibody	IVD-21-609	2021.7.16.	+82-31-778-0602

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
332	LUCA AICELL, INC.	LUCA NK COVID-19 Ag	Antigen	IVD-21-622	2021. 7. 21.	+82-31-8091-1000
333	NanoBioLife Inc.	NanoCare™ COVID-19 Antigen (Ag) Kit	Antigen	IVD-21-648	2021. 7. 29.	+82-2-858-3635
334	COSMAX PHARMA Co., Ltd.	iDetect-2 SARS-CoV-2 Real-time PCR Kit	Molecular	IVD-21-656	2021. 8. 3.	+82-70-5101-1139
335	Humasis Co., Ltd.	Humasis COVID-19 RBD/IgG Antibody Test	Antibody	IVD-21-683	2021. 8. 12.	+82-31-478-8585 +82-31-478-8546
336	NDFOS Co., Ltd.	ND COVID-19 Easy Kit(Saliva)	Antigen	IVD-21-695	2021. 8. 12.	+82-2-6203-0733
337	Genes Laboratories	GCdia™ COVID-19 Fast Detection Kit	Molecular	IVD-21-696	2021. 8. 17.	+82-31-756-5656
338	SD Biosensor, Inc.	STANDARD™ Q SARS-CoV-2 Spike IgG Test	Antibody	IVD-21-703	2021. 8. 20.	+82-31-300-0400
339	M.I.Tech Co., Ltd	RAPICHECK COVID-19 Ag	Antigen	IVD-21-705	2021. 8. 23.	+82-70-4304-7400
340	BIONOTE, INC.	NowCheck COVID-19 Spike IgG Test	Antibody	IVD-21-721	2021. 8. 26.	+82-70-4066-1412

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
341	MiCoBioMed, Co., Ltd	VERI-Q COVID-19 IgG/IgM Home Test	Antibody (Home test)	IVD-21-723	2021. 8. 26.	+82-70-5227-6065
342	OSANG Healthcare Co., Ltd.	GeneFinder COVID-19 Ag Dipstick	Antigen	IVD-21-724	2021. 8. 26.	+82-31-460-9921
343	M monitor Inc.	MmaxSure™ EZ SARS-CoV-2 Detection Kit	Molecular	IVD-21-737	2021. 9. 1.	+82-53-254-2505
344	WIZCHEM Co., Ltd.	COVICHEK COVID-19 Ag Saliva HT	Antigen (Home test)	IVD-21-738	2021. 9. 2.	+82-70-7802-2420
345	SD Biosensor, Inc.	STANDARD™ Q COVID-19 Ag Test 2.0	Antigen	IVD-21-767	2021. 9. 15.	+82-31-300-0400
346	OptiBio Co., Ltd.	Optical Q CoV-19 RBD IgG	Antibody	IVD-21-770	2021. 9. 16.	+82-43-217-7030
347	Bore Da BioTech. Co., Ltd.	BOREDA COVID-19 Ag test KIT	Antigen	IVD-21-771	2021. 9. 16.	+82-31-8018-2880
348	LG Chem, Ltd.	AdvanSure™ One-Stop COVID-19 Kit	Molecular	IVD-21-779	2021. 9. 17.	+82-2-6987-4432
349	BIONEER Corporation	AccuPower® SARS-CoV-2 Variants ID2 Kit-A (SMVR2-2112)	Molecular	IVD-21-791	2021. 9. 24.	+82-42-930-8508

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
350	BIONEER Corporation	AccuPower® SARS-CoV-2 Variants ID2 Kit-B (SMVR2-2113)	Molecular	IVD-21-792	2021. 9. 24.	+82-42-930-8508
351	BIONEER Corporation	AccuPower® SARS-CoV-2 Variants ID2 Real-Time RT-PCR Kit (SMVR2-1111)	Molecular	IVD-21-793	2021. 9. 24.	+82-42-930-8508
352	SD Biosensor, Inc.	STANDARD™ M SARS-CoV-2 Real-Time Detection Kit	Molecular	IVD-21-789	2021. 9. 24.	+82-31-300-0400
353	WIZCHEM Co., Ltd.	COVICHEK™ COVID-19 Fast Detection Kit	Molecular	IVD-21-790	2021. 9. 24.	+82-70-7802-2420
354	SolGent Co., Ltd	DiaPlexQ™ SARS-CoV-2 (N, ORF1a, RdRp) Fast Detection Kit	Molecular	IVD-21-795	2021. 9. 27.	+82-70-7893-7831 +82-70-7006-5962
355	MiCoBioMed, Co., Ltd	Veri-Q SARS-CoV-2 Neutralizing antibody detection ELISA kit	Antibody	IVD-21-804	2021. 9. 29.	+82-70-5227-6065
356	BIONEER Corporation	AccuPower® SARS-CoV-2 Variants ID Kit-A (SMVR-2112)	Molecular	IVD-21-808	2021. 9. 29.	+82-42-930-8508
357	BIONEER Corporation	AccuPower® SARS-CoV-2 Variants ID Kit-B (SMVR-2113)	Molecular	IVD-21-809	2021. 9. 29.	+82-42-930-8508
358	BIONEER Corporation	AccuPower® SARS-CoV-2 Variants ID Real-Time RT-PCR Kit (SMVR-1111)	Molecular	IVD-21-812	2021. 9. 29.	+82-42-930-8508

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
359	AMSBIO	A+CheQ COVID-19 RT-qPCR Kit for Swab/Sputum/Saliva	Molecular	IVD-21-816	2021. 9. 30.	+82-2-2086-1621
360	LUCA AICELL, INC.	LUCA NK COVID-19 Ag NP LLB	Antigen	IVD-21-820	2021. 10. 1.	+82-31-8091-1000
361	LUCA AICELL, INC.	LUCA NK COVID-19 Ag Saliva LLB	Antigen	IVD-21-821	2021. 10. 1.	+82-31-8091-1000
362	LUCA AICELL, INC.	LUCA NK COVID-19 Ag Nasal LLB	Antigen	IVD-21-822	2021. 10. 1.	+82-31-8091-1000
363	AccessBioKorea	CareStart COVID-19 Antigen Home Test	Antigen (Home test)	IVD-21-830	2021. 10. 6.	+82-54-906-9800
364	Z Biotech Inc.	AnyLab COVID-19 Ag Nasal Test Kit	Antigen	IVD-21-844	2021. 10. 15.	+82-43-278-0075
365	EONE BIOTECH Co., Ltd.	ElsiQ™ 2019-nCoV Detection Kit	Molecular	IVD-21-845	2021. 10. 15.	+82-32-210-2391
366	Biometro Co., Ltd.	COVID-19 Antigen Test Kit (Colloidal Gold)	Antigen	IVD-21-856	2021. 10. 25.	+82-2-839-8236
367	RapiGEN, INC	BIOCREDIT COVID-19 Ag Test Saliva	Antigen	IVD-21-871	2021. 11. 1.	+82-31-427-4677

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
368	LH KOREA	AccuFind COVID19 Ab Rapid Kit	Antibody	IVD-21-874	2021. 11. 2.	+82-31-603-3611
369	Absology Co., Ltd.	Absoludy COVID-19 NAb Rapid	Antibody	IVD-21-881	2021. 11. 3.	+82-31-348-8637
370	M.I.Tech Co., Ltd	RAPICHECK COVID-19 Ag Home Test	Antigen (Home test)	IVD-21-882	2021. 11. 4.	+82-70-4304-7400
371	EzDiaTech, Inc.	EDT™ COVID-19 Neutralizing Antibody Rapid Card	Antibody	IVD-21-885	2021. 11. 4.	+82-70-4910-8480
372	WIZCHEM Co., Ltd.	COVICHEK COVID-19 Ag Saliva Test At-Home	Antigen (Home test)	IVD-21-909	2021. 11. 15.	+82-70-7802-2420
373	MICROUNI Co., Ltd.	MU COVID-19 Rapid & Simple Detection kit	Molecular	IVD-21-910	2021. 11. 15.	+82-43-261-3778
374	ImmuneMed Inc.	ImmuneMed COVID-19 Ag NPS, Nasal, Saliva Rapid	Antigen	IVD-21-912	2021. 11. 16.	+82-33-258-6554
375	Biometro Co., Ltd.	Novel Coronavirus (SARS-CoV-2) S Protein Antibody Test (Colloidal Gold)	Antibody	IVD-21-915	2021. 11. 16.	+82-2-839-8236
376	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 Ag (SALIVA)	Antigen	IVD-21-924	2021. 11. 18.	+82-31-260-1926

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
377	COSMAX PHARMA Co., Ltd.	NOW Detect SARS-CoV-2 Antigen Saliva Test Kit	Antigen	IVD-21-953	2021. 11. 25.	+82-70-5101-1139
378	Seegene Inc.	Allplex™ RV Master Assay	Molecular	IVD-21-958	2021. 11. 29.	+82-2-2240-4166
379	ImmuneMed Inc.	ImmuneMed COVID-19 Ag Saliva Rapid	Antigen	IVD-21-967	2021. 11. 30.	+82-33-258-6554
380	Sugentech, Inc.	INCLIX COVID-19 nAb	Antibody	IVD-21-978	2021. 12. 6.	+82-43-710-2822
381	iONEBIO inc.	iONE Neutralized Antibody Detection kit	Antibody	IVD-21-979	2021. 12. 6.	+82-31-360-1210
382	Cancer Rop Co., Ltd.	Q-Sens® COVID-19 Detection Kit V3	Molecular	IVD-21-984	2021. 12. 7.	+82-2-6964-8773
383	CALTH Inc.	AllCheck COVID-19 Antigen Self-Test	Antigen (Home test)	IVD-21-985	2021. 12. 7.	+82-70-4238-5244
384	EzDiaTech, Inc.	EDGC™ RapidCare COVID-19 Ag kit	Antigen	IVD-21-996	2021. 12. 9.	+82-70-4910-8480
385	Boditech Med Inc.	Boditech COVID-19 Ag Rapid Test	Antigen	IVD-21-1001	2021. 12 13.	+82-243-1400

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
386	Absology Co., Ltd.	Absoludy Flu A/B & COVID-19 Ag	Antigen	IVD-21-1014	2021. 12. 16.	+82-31-348-8637
387	MARA NANOTECH KOREA Inc.	MARA ESEN COVID-19 Ag Test device	Antigen	IVD-21-1015	2021. 12. 16.	+82-51-242-0126
388	Boditech Med Inc.	REF: CFPC-124. ichroma™ COVID-19 SP/NP IgG	Antibody	IVD-21-1016	2021. 12 16.	+82-243-1400
389	Boditech Med Inc.	REF: SMFP-103. AFIAS COVID-19 SP/NP IgG	Antibody	IVD-21-1023	2021. 12 20.	+82-243-1400
390	Seegene Inc.	Allplex™ SARS-CoV-2 fast PCR Assay	Molecular	IVD-21-1024	2021. 12. 20.	+82-2-2240-4166
391	Biometro Co., Ltd.	BM Fast COVID-19 RT-PCR	Molecular	IVD-21-1034	2021. 12. 22.	+82-2-839-8236
392	Genes Laboratories	GCdia™ COVID-19 & Flu A/B Detection Kit	Molecular	IVD-21-1035	2021. 12. 23.	+82-31-756-5656
393	BIONOTE, INC.	NowCheck Baronasal COVID-19 Ag Test	Antigen (Home test)	IVD-21-1036	2021. 12. 23.	+82-70-4066-1412
394	Macrogen, Inc.	Axen™ COVID-19 Ag NPS, Nasal, Saliva RAPID	Antigen	IVD-21-1043	2021. 12. 28.	+82-2-2180-7222

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
395	MicroDigital Co., Ltd.	MDGen AB96-COVID-19 SP RBD IgG(E)	Antibody	IVD-21-1045	2021. 12. 28.	+82-31-701-2225
396	Macrogen, Inc.	Axen™ COVID-19 Ag Saliva RAPID	Antigen	IVD-21-1051	2021. 12. 29.	+82-2-2180-7222
397	Boditech Med Inc.	REF: CFPT-09. Boditech Quick™ COVID-19 Neutralizing Ab	Antibody	IVD-21-1052	2021. 12. 29.	+82-243-1400
398	Plexense, Inc.	ACCEL ELISA COVID-19 Neutralizing Ab kit	Antibody	IVD-21-1058	2021. 12. 30.	+82-70-4725-4683
399	Genes Laboratories	GCdia™ SARS-CoV-2 Detection Kit	Molecular	IVD-22-3	2022. 1. 5.	+82-31-756-5656
400	OSANG Healthcare Co., Ltd.	Immuno-on™ COVID-19 IgG Test	Antibody	IVD-22-18	2022. 1. 13.	+82-31-460-9921
401	SD Biosensor, Inc.	COVID-19 At-Home Test	Antigen (Home test)	IVD-22-20	2022. 1. 13.	+82-31-300-0400
402	Gencurix Inc.	GenePro LAMP SARS-CoV-2	Molecular	IVD-22-23	2022. 1. 14.	+82-2-2621-7038
403	BIONEER Corporation	AccuPower® SARS-CoV-2 Variants ID3 Kit-B(SMVR3-2113)	Molecular	IVD-22-65	2022. 1. 27.	+82-42-930-8508

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
404	BIONEER Corporation	AccuPower® SARS-CoV-2 Variants ID3 Kit-A(SMVR3-2112)	Molecular	IVD-22-66	2022. 1. 27.	+82-42-930-8508
405	BioSewoom, Inc.	Real-Q SARS-CoV-2 Detection Kit	Molecular	IVD-22-82	2022. 2. 9.	+82-2-498-2340 (500)
406	Humasis Co., Ltd.	Humasis COVID-19 RT-qPCR Kit	Molecular	IVD-22-83	2022. 2. 9.	+82-31-478-8585 +82-31-478-8546
407	ProteomeTech Inc.	KOVIcheck COVID-19 Ag	Antigen	IVD-22-84	2022. 2. 9.	+82-2-6968-5277
408	Abbott Diagnostics Korea Inc.	Panbio™ COVID-19/Flu A&B Rapid Panel	Antigen	IVD-22-114	2022. 2. 18.	+82-31-899-2837
409	WIZCHEM Co., Ltd.	COVICHEK COVID-19 Ag Kit	Antigen	IVD-22-133	2022. 2. 25.	+82-70-7802-2420
410	SG Medical, Inc.	InstaView COVID-19 Antigen Home Test	Antigen (Home test)	IVD-22-137	2022. 2. 28.	+82-2-2240-7062
411	Seegene Inc.	Allplex™ SARS-CoV-2 fast MDx Assay	Molecular	IVD-22-138	2022. 2. 28.	+82-2-2240-4166
412	MiCoBioMed, Co., Ltd	Veri-Q COVID-19 Variant Detection Kit I	Molecular	IVD-22-142	2022. 3. 3.	+82-70-5227-6065

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
413	MiCoBioMed, Co., Ltd	Veri-Q COVID-19 Variant Detection Kit II	Molecular	IVD-22-141	2022. 3. 3.	+82-70-5227-6065
414	Humasis Co., Ltd.	Humasis COVID-19 Variant RT-qPCR Kit	Molecular	IVD-22-155	2022. 3. 8.	+82-31-478-8585 +82-31-478-8546
415	SD Biosensor, Inc.	STANDARD™ M SARS-CoV-2/Variant I Real-Time Detection Kit	Molecular	IVD-22-167	2022. 3. 14.	+82-31-300-0400
416	SG Medical, Inc.	ACROSIS COVID-19 Ag (NPS)	Antigen	IVD-22-168	2022. 3. 14.	+82-2-2240-7062
417	BIONOTE, INC.	NowCheck COVID-19 Ag Home Test	Antigen (Home test)	IVD-22-176	2022. 3. 15.	+82-70-4066-1412
418	Attoplex Inc.	Attoplex ® SARS-CoV-2 Real-time PCR Kit	Molecular	IVD-22-177	2022. 3. 15.	+82-31-793-5490
419	1drop Inc.	1copy™ COVID-19 Variants Kit	Molecular	IVD-22-182	2022. 3. 16.	+82-31-747-0109
420	SolGent Co., Ltd	DiaRapid™ COVID-19 Ag RDT Kit	Antigen	IVD-22-201	2022. 3. 22.	+82-70-7893-7831 +82-70-7006-5962
421	MiCoBioMed, Co., Ltd	Veri-Q SARS-CoV-2 Neutralizing Antibody Rapid Test Kit	Antibody	IVD-22-206	2022. 3. 24.	+82-70-5227-6065

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
422	Gencurix Inc.	GenePro LAMP SARS-CoV-2 V1	Molecular	IVD-22-207	2022. 3. 24.	+82-2-2621-7038
423	EONE-DIAGNOMICS Genome Center, Co., Ltd.	EDGC™ COVID-19 S1 RBD IgG/Neutralizing Ab Test	Antibody	IVD-22-209	2022. 3. 28.	+82-2-785-2389
424	SG Medical, Inc.	ACROSIS COVID-19 Ag (NS and OS)	Antigen	IVD-22-218	2022. 3. 30.	+82-2-2240-7062
425	SML GENETREE CO., LTD.	Ezplex™ SARS-CoV-2 Variants kit	Molecular	IVD-22-230	2022. 4. 6.	+82-2-2057-7900
426	Attoplex Inc.	Attoplex® SARS-CoV-2 Real-time PCR Kit V2	Molecular	IVD-22-231	2022. 4. 6.	+82-31-793-5490
427	MiCoBioMed, Co., Ltd	VERI-Q COVID-19 Ag Home Test	Antigen (Home test)	IVD-22-237	2022. 4. 8.	+82-70-5227-6065
428	WIZCHEM Co., Ltd.	COVICHEK COVID-19 Antigen Self-Test, COVICHEK COVID-19 Ag Kit Home Test	Antigen (Home test)	IVD-22-249	2022. 4. 14.	+82-70-7802-2420
429	INFUSION TECH	Primera™ COVID-19 RT-PCR Power Detection Kit	Molecular	IVD-22-256	2022. 4. 19.	+82-31-687-3459
430	BioFront, Inc.	RapiSure™ COVID-19 Ag Kit, Vcapture™ COVID-19 Ag Kit	Antigen	IVD-22-274	2022. 4. 29.	+82-2-2638-5380

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
431	Boditech Med Inc.	Boditech Quick™ COVID-19 Ag Saliva	Antigen (Home test)	IVD-22-278	2022. 5. 2.	+82-243-1400
432	HANCOM HEALTHCARE INC.	Malang Malang COVID-19 Ag Easy Test Nasal, NOVAREX COVID-19 Ag Easy Test Nasal, AsanCOVID-19 Ag Easy Test Nasal	Antigen	IVD-22-283	2022. 5. 3.	+82-44-864-4285
433	Abbott Diagnostics Korea Inc.	Panbio™ COVID-19/Flu A&B Rapid Panel (Nasopharyngeal)	Antigen	IVD-22-291	2022. 5. 6.	+82-31-899-2837
434	Gencurix Inc.	GenePro LAMP SARS-CoV-2 EF, GenePro LAMP SARS-CoV-2 EF_N	Molecular	IVD-22-315	2022. 5. 18.	+82-2-2621-7038
435	Noble Biosciences, Inc.	VUER™ COVID-19 Ag Kit	Antigen	IVD-22-334	2022. 5. 24.	+82-31-291-0044
436	BioFront, Inc.	RapiSure™ COVID-19 Ag Kit NS	Antigen	IVD-22-337	2022. 5. 25.	+82-2-2638-5380
437	BioFront, Inc.	RapiSure™ COVID-19 Ag Kit NPS	Antigen	IVD-22-338	2022. 5. 25.	+82-2-2638-5380
438	BioFront, Inc.	RapiSure™ COVID-19 Ag Kit SA	Antigen	IVD-22-339	2022. 5. 25.	+82-2-2638-5380
439	GOODGENE Inc.	Good Ag COVID-19 antigen test	Antigen	IVD-22-340	2022. 5. 25.	+82-2-2088-0055

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
440	BioFront, Inc.	RapiSure™ COVID-19 S1 RBD IgG/Neutralizing Ab Test	Antibody	IVD-22-362	2022. 6. 2.	+82-2-2638-5380
441	ACEBiomed, Inc.	Palm PCR™ Fast COVID-19 Kit	Molecular	IVD-22-386	2022. 6. 13.	+82-2-783-0803
442	SG Medical, Inc.	ACROSIS COVID-19 Ag Home Test	Antigen (Home test)	IVD-22-398	2022. 6. 20.	+82-2-2240-7062
443	NGeneBio Co., Ltd	NGenePlex™ nCoV/Flu A.B Detection Kit	Molecular	IVD-22-407	2022. 6. 22.	+82-2-867-9798
444	Noble Biosciences, Inc.	VUER™ COVID-19 Ag Kit Saliva	Antigen	IVD-22-409	2022. 6. 23.	+82-31-291-0044
445	LabGenomics, Co., Ltd	LabGun™ SARS-CoV-2 RT-PCR Kit	Molecular	IVD-22-414	2022. 6. 28.	+82-31-628-0783
446	EzDiaTech, Inc.	EDT™ COVID Flu Ag Combo	Antigen	IVD-22-420	2022. 6. 30.	+82-70-4910-8480
447	PROTANBIO Inc.	PROTAN COVID-19 Ag Nasal	Antigen	IVD-22-426	2022. 7. 4.	+82-2-3285-1413
448	SD Biosensor, Inc.	STANDARD™ F Covi-FERON FIA (IFN-gamma)	Antibody	IVD-22-457	2022. 7. 14.	+82-31-300-0400

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
449	OSANG Healthcare Co., Ltd.	GeneFinder™ COVID-19 Ag Dipstick Self Test	Antigen (Home test)	IVD-22-463	2022. 7. 18.	+82-31-460-9921
450	SD Biosensor, Inc.	STANDARD™ M10 Flu/RSV/SARS-CoV-2	Molecular	IVD-22-475	2022. 7. 21.	+82-31-300-0400
451	Noble Biosciences, Inc.	VUER™ COVID-19 Ag Kit Nasopharyngeal	Antigen	IVD-22-505	2022. 7. 29.	+82-31-291-0044
452	Noble Biosciences, Inc.	VUER™ COVID-19 Ag Kit Nasal	Antigen	IVD-22-506	2022. 7. 29.	+82-31-291-0044
453	BioSquare Inc.	NanoPACK™ COVID-19 Ag Home Test	Antigen (Home test)	IVD-22-529	2022. 8. 5.	+82-31-8050-1119
454	1drop Inc.	1copy™ COVID-19 RT-PCR Dry Kit	Molecular	IVD-22-551	2022. 8. 12.	+82-31-747-0109
455	SolGent Co., Ltd	DiaPlexQ™ RV16 Detection Kit (with SARS-CoV-2)	Molecular	IVD-22-569	2022. 8. 23.	+82-70-7893-7831 +82-70-7006-5962
456	WIZCHEM Co., Ltd.	COVICHEK COVID-19 Ag Kit Home Test (Nasal & Saliva)	Antigen (Home test)	IVD-22-576	2022. 8. 25.	+82-70-7802-2420
457	OSANG Healthcare Co., Ltd.	OHC COVID-19 Antigen Self Test, QuickFinder COVID-19 Antigen Self Test	Antigen (Home test)	IVD-22-588	2022. 9. 1.	+82-31-460-9921

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
458	Noble Biosciences, Inc.	VUER™ COVID-19 Ag Home Test Nasal	Antigen (Home test)	IVD-22-590	2022. 9. 1.	+82-31-291-0044
459	Noble Biosciences, Inc.	VUER™ COVID-19 Ag Home Test Rolli	Antigen (Home test)	IVD-22-592	2022. 9. 2.	+82-31-291-0044
460	Asan pharmaceutical Co., LTD.	Asan Easy Self-Test COVID-19 Ag	Antigen (Home test)	IVD-22-598	2022. 9. 6.	+82-31-376-5990 (506)
461	SD Biosensor, Inc.	STANDARD™ M10 SARS-CoV-2 Turbo	Molecular	IVD-22-642	2022. 9. 26.	+82-31-300-0400
462	Bionics.INC	NICSPRESSⓡ SARS-CoV2 Variants RT-PCR kit	Molecular	IVD-22-650	2022. 9. 26.	+82-2-6925-1625
463	Noble Biosciences, Inc.	VUER™ COVID-19 Ag Kit Nasal or Saliva	Antigen	IVD-22-670	2022. 10. 5.	+82-31-291-0044
464	Noble Biosciences, Inc.	VUER™ COVID-19 Ag Home Test Nasal or Rolli	Antigen (Home test)	IVD-22-672	2022. 10. 5.	+82-31-291-0044
465	CTCVAC Inc.	CTCVAC COVID-19 Ag Test	Antigen	IVD-22-678	2022. 10. 11.	+82-70-5112-2511
466	SD Biosensor, Inc.	STANDARD™ Q COVID/Flu Ag Combo Test	Antigen	IVD-22-687	2022. 10. 14.	+82-31-300-0400

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
467	Genesystem Co., Ltd.	SMARTCHEK® SARS-CoV-2 Fast Detection Kit	Molecular	IVD-22-688	2022. 10. 14.	+82-42-863-8551
468	KNAX Ltd.	KNAX-SMART SARS-CoV-2/Influenza A&B Multiplex Real-time PCR Plus Kit-E	Molecular	IVD-22-691	2022. 10. 18.	+82-31-5180-3184
469	BIONOTE, INC.	NowCheck COVID/Flu Ag Test	Antigen	IVD-22-704	2022. 10. 20.	+82-70-4066-1412
470	SD Biosensor, Inc.	STANDARD™ i-Q COVID/Flu Ag Combo Test	Antigen	IVD-22-738	2022. 11. 4.	+82-31-300-0400
471	KNAX Ltd.	KX-MDV1PAE	Molecular	IVD-22-753	2022. 11. 9.	+82-31-5180-3184
472	SD Biosensor, Inc.	STANDARD™ Q COVID-19 Ag Home Test	Antigen (Home test)	IVD-22-778	2022. 11. 21.	+82-31-300-0400
473	Humasis Co., Ltd.	Humasis COVID-19 AgN Test	Antigen	IVD-22-804	2022. 11. 30.	+82-31-478-8585 +82-31-478-8546
474	Sugentech, Inc.	SGTi-flex COVID-19 & Flu A/B Ag	Antigen	IVD-22-820	2022. 12. 5.	+82-43-710-2822
475	SD Biosensor, Inc.	STANDARD™ Q COVID-19 Ag Test 2.0 (Q-NCOV-07G)	Antigen	IVD-22-851	2022. 12. 13.	+82-31-300-0400

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
476	Wizbiosolutions Inc.	WizDx™ SARS-CoV-2/Flu CrystalMix PCR Kit	Molecular	IVD-22-856	2022. 12. 14.	+82-70-7605-5066
477	OptiBio Co., Ltd.	Optical Q CoV-19 nAb	Antibody	IVD-22-865	2022. 12. 15.	+82-43-217-7030
478	BioZentech, Co., Ltd	BZ COVID-19 Ag Home Test	Antigen (Home test)	IVD-22-880	2022. 12. 20.	+82-2-855-5194
479	LUCA AICELL, INC.	LUCA NK COVID-19 Ag Nasal LLB Self-Test	Antigen (Home test)	IVD-23-21	2023. 1. 11.	+82-31-8091-1000
480	BIONEER Corporation	IRON-qPCR™ COVID-19 Kit (QCOV2-1113)	Molecular	IVD-23-24	2023. 1. 12.	+82-42-930-8508
481	RapiGEN, INC	BIOCREDIT COVID-19 IgG Home Test	Antibody (Home test)	IVD-23-116	2023. 2. 20.	+82-31-427-4677
482	Bore Da BioTech. Co., Ltd.	ASSURE-100 Home test	Antigen (Home test)	IVD-23-303	2023. 3. 10.	+82-31-8018-2880
483	SG Medical, Inc.	ACROSIS COVID-19 Ag Home Test	Antigen	IVD-23-525	2023. 4. 21.	+82-2-2240-7062
484	KH Medical Co., Ltd.	RADI FAST Flu-SC2-RSV Detection Kit	Molecular	IVD-23-575	2023. 5. 11.	+82-31-5180-3018

No.	Manufacturer	Device name	Technology	No. of product license	Date of approval	Contact Number
485	HANCHANG MEDIC Co.,Ltd	HAN.CHANG COVID-19 Ag Test+TM	Antigen	IVD-23-590	2023. 5. 19.	+82-41-547-8805