List of COVID-19 in-vitro diagnostic devices approved by MFDS(7.9)

No.	Manufacturer	Device name	Technology	Date of approval	Contact Number	Remarks
1	KogeneBiotech Co., Ltd.	PowerCheck™2019-nCoV RT PCR kit	Molecular	2020. 2. 12.	+82-2-2026-2150	Approval for Exports only
2	Seegene Inc.	Allplex™2019-nCoV Assay	Molecular	2020. 2. 17.	+82-2-2240-4166	Approval for Exports only
3	SD Biosensor, Inc.	STANDARD M nCoV Real-Time Detection kit	Molecular	2020. 2. 28.	+82-31-300-0400	Approval for Exports only
4	SolGent Co., Ltd	DiaPlexQ™Novel Coronavirus (2019-nCoV) Detection Kit	Molecular	2020. 3. 2.	+82-70-7893-7831 +82-70-7006-5962	Approval for Exports only
5	PCL, Inc.	PCLMD nCoV one stop RT-PCR Kit	Molecular	2020. 3. 3.	+82-2-2144-3901	Approval for Exports only
6	LabGenomics, Co., Ltd	LabGun™COVID-19 assay	Molecular	2020. 3. 3.	+82-31-628-0783	Approval for Exports only
7	Cancer Rop Co., Ltd.	Q-Sens 2019-nCoV detection Kit	Molecular	2020. 3. 11.	+82-2-6964-8773	Approval for Exports only
8	SD Biosensor, Inc.	STANDARD™Q COVID-19 IgM/IgG Duo Test	Antibody	2020. 3. 11.	+82-31-300-0400	Approval for Exports only
9	OSANG Healthcare Co., Ltd.	GeneFinder COVID-19 Plus RealAmp kit	Molecular	2020. 3. 18.	+82-31-460-9921	Approval for Exports only

10	WELLS BIO, INC.	careGENE™ N-CoV RT-PCR kit	Molecular	2020. 3. 18.	+82-2-3660-6900	Approval for Exports only
11	Genematrix Inc.	NeoPlex™COVID-19 Detection Kit	Molecular	2020. 3. 20.	+82-31-628-2020	Approval for Exports only
12	BioSewoom, Inc.	Real-Q 2019-nCoV Detection kit	Molecular	2020. 3. 20.	+82-2-498-2340 (500)	Approval for Exports only
13	SML GENETREE CO., LTD.	Ezplex®2019-nCoV RTPCR Kit	Molecular	2020. 3. 24.	+82-2-2057-7900	Approval for Exports only
14	Sugentech, Inc.	SGTi-flex COVID-19 IgM/IgG	Antibody	2020. 3. 24.	+82-43-710-2822	Approval for Exports only
15	Sugentech, Inc.	SGTi-flex COVID-19 IgM	Antibody	2020. 3. 24.	+82-43-710-2822	Approval for Exports only
16	Sugentech, Inc.	SGTi-flex COVID-19 IgG	Antibody	2020. 3. 24.	+82-43-710-2822	Approval for Exports only
17	SD Biosensor, Inc.	STANDARD™Q COVID-19 Ag Test	Antigen	2020. 3. 25.	+82-31-300-0400	Approval for Exports only
18	SD Biosensor, Inc.	STANDARD™F COVID-19 Ag FIA	Antigen	2020. 3. 25.	+82-31-300-0400	Approval for Exports only
19	MiCoBioMed, Co., Ltd	Veri-Q PCR 316, nCoV-QS	Molecular	2020. 3. 26.	+82-70-5227-6065	Approval for Exports only
20	Gencurix Inc.	GenePro COVID-19 Detection Test	Molecular	2020. 3. 26.	+82-2-2621-7038	Approval for Exports only
21	GenBody Inc.	GenBody COVID-19 IgM/IgG	Antibody	2020. 3. 27.	+82-41-523-8990	Approval for Exports only
22	Humasis Co., Ltd.	Humasis COVID-19 IgG/IgM Test	Antibody	2020. 3. 27.	+82-31-478-8585 +82-31-478-8546	Approval for Exports only
23	DowGene Co., Ltd	Dow QuickFinder™2019-nCoV Real time PCR	Molecular	2020. 3. 27.	+82-2-1566-3313	Approval for Exports only

24	PCL, Inc.	PCL COVID19 IgG/IgM Rapid Gold	Antibody	2020. 3. 30.	+82-2-2144-3901	Approval for Exports only
25	PCL, Inc.	PCL COVID19 Ag Rapid FIA	Antigen	2020. 3. 30.	+82-2-2144-3901	Approval for Exports only
26	BIONEER Corporation	AccuPower COVID-19 Real-Time RT-PCR Kit (NCV-1111)	Molecular	2020. 3. 31.	+82-42-930-8508	Approval for Exports only
27	BIONEER Corporation	AccuPower SARS-CoV-2 Real-Time RT-PCR Kit(SCV-2122)	Molecular	2020. 3. 31.	+82-42-930-8508	Approval for Exports only
28	PaxGenBio Co., Ltd.	PaxView COVID-19 real-time RT-PCR Kit	Molecular	2020. 3. 31.	+82-31-244-5036	Approval for Exports only
29	Boditech Med Inc.	AFIAS COVID-19 Ab	Antibody	2020. 4. 1.	+82-33-243-1400	Approval for Exports only
30	YD Diagnostics CORP.	MolecuTech® Real-Time COVID-19	Molecular	2020. 4. 3.	+82-31-329-2011	Approval for Exports only
31	iNtRON Biotechnology, Inc.	LiliF™COVID-19 Real-time RT-PCR Kit	Molecular	2020. 4. 6.	+82-31-739-5678	Approval for Exports only
32	1drop Inc.	1copy™COVID-19 qPCR Multi Kit	Molecular	2020. 4. 7.	+82-31-747-0109	Approval for Exports only
33	DowGene Co., Ltd	Dow QuickFinder™-G 2019-nCoV Real time PCR	Molecular	2020. 4. 8.	+82-2-1566-3313	Approval for Exports only
34	WELLS BIO, INC.	careGENE™COVID-19 RT-PCR kit	Molecular	2020. 4. 8.	+82-2-3660-6900	Approval for Exports only
35	M monitor Inc.	Isopolla®COVID-19 detection kit(real-time)	Molecular	2020. 4. 8.	+82-53-254-2505	Approval for Exports only
36	M monitor Inc.	Isopolla®COVID-19 detection kit(premix)	Molecular	2020. 4. 8.	+82-53-254-2505	Approval for Exports only

37	iONEBIO inc.	iLAMP Novel-CoV19 Detection Kit	Molecular	2020. 4. 9.	+82-31-360-1210	Approval for Exports only
38	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit	Molecular	2020. 4. 9.	+82-2-2027-6320	Approval for Exports only
39	TCM Biosciences Inc.	TCM-Q Corona Ⅲ kit	Molecular	2020. 4. 9.	+82-31-698-3041	Approval for Exports only
40	OPTOLANE Technologies Inc.	Kaira 2019-nCoV Detection Kit	Molecular	2020. 4. 10.	+82-31-737-7835	Approval for Exports only
41	KH Medical Co., Ltd.	RADI COVID-19 detection kit	Molecular	2020. 4. 10.	+82-31-5180-3018	Approval for Exports only
42	Boditech Med Inc.	ichroma™COVID-19 Ab	Antibody	2020. 4. 14.	+82-33-243-1400	Approval for Exports only
43	Genomictree, Inc.	AccuraDTect™SARS-CoV-2 RT-qPCR kit	Molecular	2020. 4. 14.	+82-42-861-4551	Approval for Exports only
44	Genesystem Co., Ltd.	SMARTCHEKⓡ Novel Coronavirus (SARS-CoV-2)Detection Kit	Molecular	2020. 4. 16.	+82-42-863-8551	Approval for Exports only
45	Joonghun Pharmaceutical Co., Ltd.	JD COVID-19 qRT-PCR kit	Molecular	2020. 4. 20.	+82-2-2138-8114	Approval for Exports only
46	NanoEntek, Inc.	FREND COVID-19 IgG/IgM Duo	Antibody	2020. 4. 20.	+82-2-6220-7940	Approval for Exports only
47	Wizbiosolutions Inc.	WizDx™COVID-19 CrystalMix PCR Kit	Molecular	2020. 4. 21.	+82-70-7605-5066	Approval for Exports only
48	BioZentech, Co., Ltd	BZ QPCR COVID-19 Kit	Molecular	2020. 4. 21.	+82-2-855-5194	Approval for Exports only
49	RapiGEN, INC	BIOCREDIT COVID-19 Ag	Antigen	2020. 4. 21.	+82-31-427-4677	Approval for Exports only

50	RapiGEN, INC	BIOCREDIT COVID-19 IgG+IgM Duo	Antibody	2020. 4. 21.	+82-31-427-4677	Approval for Exports only
51	Boditech Med Inc.	ExAmplar COVID-19 real time PCR	Molecular	2020. 4. 22.	+82-33-243-1400	Approval for Exports only
52	KogeneBiotech Co., Ltd.	PowerChcek™SARS-CoV-2 Real-time PCR Kit	Molecular	2020. 4. 22.	+82-2-2026-2150	Approval for Exports only
53	SD Biosensor, Inc.	STANDARD™Q COVID-19 IgM/IgG Combo Test	Antibody	2020. 4. 23.	+82-31-300-0400	Approval for Exports only
54	Seegene Inc.	Allplex™SARS-CoV-2 Assay	Molecular	2020. 4. 28.	+82-2-2240-4166	Approval for Exports only
55	iNtRON Biotechnology, Inc.	LiliF™COVID-19 Multi Real-time RT-PCR Kit	Molecular	2020. 4. 28.	+82-31-739-5678	Approval for Exports only
56	Wizbiosolutions Inc.	WizDx™COVID-19 Real-time PCR Kit	Molecular	2020. 4. 28.	+82-70-7605-5066	Approval for Exports only
57	Gencurix Inc.	GenePro SARS-CoV-2 Test	Molecular	2020. 4. 28.	+82-2-2621-7038	Approval for Exports only
58	SD Biosensor, Inc.	STANDARD™F COVID-19 IgM/IgG Combo Test	Antibody	2020. 4. 28.	+82-31-300-0400	Approval for Exports only
59	SeaSun Biomaterials	U-TOP COVID-19 Detection Kit	Molecular	2020. 5. 4.	+82-42-716-0301	Approval for Exports only
60	Philosys Co.,Ltd.	Gmate® COVID-19	Antigen	2020. 5. 7.	+82-31-778-0602	Approval for Exports only
61	Asan pharmaceutical Co., LTD.	Asan Easy Test COVID-19 IgG/IgM	Antibody	2020. 5. 8.	+82-31-376-5990 (506)	Approval for Exports only
62	MiCoBioMed, Co., Ltd	Veri-Q, nCoV-OM	Molecular	2020. 5. 11.	+82-70-5227-6065	Approval for Exports only

63	Eudipia	EU™COVID-19 Detection Kit	Molecular	2020. 5. 12.	+82-70-8890-2101	Approval for Exports only
64	LabGenomics, Co., Ltd	LabGun™COVID-19 RT-PCR Kit	Molecular	2020. 5. 12.	+82-31-628-0783	Approval for Exports only
65	DIOGENE Co., Ltd	DLP™Q COVID 19 Real Detection Kit	Molecular	2020. 5. 14.	+82-31-701-6488	Approval for Exports only
66	WELLS BIO, INC.	careUS™COVID-19 IgM/IgG	Antibody	2020. 5. 14.	+82-2-3660-6900	Approval for Exports only
67	PRIME4DIA Co., Ltd.	P4DETECT COVID-19 IgM/IgG	Antibody	2020. 5. 18.	+82-31-478-3105	Approval for Exports only
68	OPTOLANE Technologies Inc.	Dr. PCR 20K COVID-19 Detection Kit	Molecular	2020. 5. 18.	+82-31-737-7835	Approval for Exports only
69	Macrogen, Inc.	Axen™COVID-19 RT	Molecular	2020. 5. 18.	+82-2-2180-7222	Approval for Exports only
70	HUMEDIX Co,. Ltd.	Accurate Rapid COVID-19 IgM/IgG Combo Test	Antibody	2020. 5. 18.	+82-70-7492-5600	Approval for Exports only
71	Biometrix Technology, Inc.	COVID19+9G test™	Molecular	2020. 5. 19.	+82-33-258-6097	Approval for Exports only
72	B-bio, Co., Ltd	ChekR™COVID-19 IgM/IgG Rapid test	Antibody	2020. 5. 20.	+82-70-4163-6894	Approval for Exports only
73	ShinJin Medics Inc.	DIAKEY COVID-19 IgM/IgG Rapid Test	Antibody	2020. 5. 21.	+82-70-8277-6929	Approval for Exports only
74	ADTceh Co., LTD	ADTech COVID-19 IgM/IgG	Antibody	2020. 5. 21.	+82-70-4659-1811	Approval for Exports only
75	CTCBIO INC.	CTC™Q COVID-19 IgM/IgG Combo Test	Antibody	2020. 5. 21.	+82-70-4033-0233	Approval for Exports only
76	SLSBio Co., Ltd	SsmarTest COVID-19 IgM/IgG Detection Kit	Antibody	2020. 5. 21.	+82-70-8857-2657	Approval for Exports only

77	CALTH Inc.	AllCheck COVID-19 IgG/IgM	Antibody	2020. 5. 21.	+82-70-4238-5244	Approval for Exports only
78	BIONOTE, INC.	NowCheck COVID-19 IgM/IgG Test	Antibody	2020. 5. 21.	+82-70-4066-1412	Approval for Exports only
79	BIONOTE, INC.	NowCheck COVID-19 Ag Test	Antigen	2020. 5. 21.	+82-70-4066-1412	Approval for Exports only
80	GOODGENE Inc.	GG COVID-19 Quadplex Reverse Transcription Real Time Polymerase Chain Reaction Kit	Molecular	2020. 5. 26.	+82-2-2088-0055	Approval for Exports only
81	ShinJin Medics Inc.	DIAKEY REALcheck COVID-19(nCOV) Detection kit	Molecular	2020. 5. 28.	+82-70-8277-6929	Approval for Exports only
82	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 IgM/IgG	Antibody	2020. 5. 28.	+82-31-260-1926	Approval for Exports only
83	GREENCROSS MEDICAL SCIENCE	GENEDIA W ONE COVID-19 IgM/IgG	Antibody	2020. 5. 28.	+82-31-260-1926	Approval for Exports only
84	GENECAST Co., Ltd.	SMARTROL™ 2019-nCoV Detection Kit v1	Molecular	2020. 5. 29.	+82-2-2157-3151	Approval for Exports only
85	NDFOS Co., Ltd.	ND COVID-19 Detection Kit	Molecular	2020. 6. 1.	-	Approval for Exports only
86	DxGen Corp.	Epithod®616 COVID-19 IgM/IgG Test kit	Antibody	2020. 6. 3.	+82-31-427-8450	Approval for Exports only
87	BIONEER Corporation	AccuPower SARS-CoV-2 Multiplex Real-Time RT-PCR Kit	Molecular	2020. 6. 5.	+82-42-930-8508	Approval for Exports only
88	TNS Co., Ltd	COVID-19 RT-qPCR PNA kit	Molecular	2020. 6. 5.	+82-42-861-2223	Approval for Exports only
89	ProteomeTech Inc.	KOVIcheck COVID-19 IgG/IgM	Antibody	2020. 6. 5.	+82-2-6968-5277	Approval for Exports only

90	Precision Biosensor Inc.	PBCheck COVID-19 IgG/IgM	Antibody	2020. 6. 5.	+82-70-7167-0331	Approval for Exports only
91	Heimbiotek Inc.	HB BestPlex™ COVID-19 RT-PCR	Molecular	2020. 6. 9.	+82-31-548-2130	Approval for Exports only
92	Genes Laboratories	NEXDia™ 2019-nCoV Detection Kit	Molecular	2020. 6. 9.	+82-31-756-5656	Approval for Exports only
93	Precision Biosensor Inc.	Exdia COVID-19 IgG/IgM	Antibody	2020. 6. 9.	+82-70-7167-0331	Approval for Exports only
94	GREENCROSS MEDICAL SCIENCE	GENEDIA W COVID-19 Real-Time RT-PCR kit	Molecular	2020. 6. 10.	+82-31-260-1926	Approval for Exports only
95	NanoEntek, Inc.	En-swer COVID-19 RT-PCR	Molecular	2020. 6. 10.	+82-2-6220-7940	Approval for Exports only
96	Boditech Med Inc.	ichroma™ COVID-19 Ag	Antigen	2020. 6. 11.	+82-33-243-1400	Approval for Exports only
97	SD Biosensor, Inc.	STANDARD™ Q COVID-19 IgM/IgG Combo Plus Test	Antibody	2020. 6. 15.	+82-31-300-0400	Approval for Exports only
98	LabGenomics, Co., Ltd	LabGun™ COVID-19 Assay plus	Molecular	2020. 6. 15.	+82-31-628-0783	Approval for Exports only
99	Sanigen Co., Ltd.	Genelix™ COVID-19 Real-Time PCR Kit	Molecular	2020. 6. 15.	+82-1833-8010	Approval for Exports only
100	Plexense, Inc.	ACCEL ELISA COVID-19 Kit	Antibody	2020. 6. 17.	+82-70-4725-4683	Approval for Exports only
101	Cancer Rop Co., Ltd.	Q-Sens COVID 19 IgG/IgM Rapid Kit	Antibody	2020. 6. 18.	+82-2-6964-8773	Approval for Exports only
102	CALTH Inc.	DxReal COVID-19 Detection Kit	Molecular	2020. 6. 18.	+82-70-4238-5244	Approval for Exports only

103	LabGenomics, Co., Ltd	LabGun™ COVID-19 Fast RT-PCR Kit	Molecular	2020. 6. 22.	+82-31-628-0783	Approval for Exports only
104	Boditech Med Inc.	AFIAS COVID-19 Ag	Antigen	2020. 6. 22.	+82-33-243-1400	Approval for Exports only
105	Absology Co., Ltd.	Absoludy COVID-19 IgM/IgG Rapid	Antibody	2020. 6. 24.	+82-31-348-8637	Approval for Exports only
106	SML GENETREE CO., LTD.	Ezplex® COVID-19 Real-time PCR Kit	Molecular	2020. 6. 25.	+82-2-2057-7900	Approval for Exports only
107	NanoBioLife Inc.	Nano-KGIC COVID-19 IgM/IgG Kit	Antibody	2020. 6. 25.	+82-2-858-3635	Approval for Exports only
108	BioSewoom, Inc.	Real-Q Direct SARS-CoV-2 Detection Kit	Molecular	2020. 6. 25.	+82-2-498-2340 (500)	Approval for Exports only
109	PROTANBIO Inc.	PROTAN COVID-19 IgM/IgG	Antibody	2020. 6. 25.	+82-2-3285-1413	Approval for Exports only
110	MicroDigital Co., Ltd.	MDGen-AB96 COVID-19 IgG	Antibody	2020. 6. 25.	+82-31-701-2225	Approval for Exports only
111	SG Medical, Inc.	R-FIND COVID-19 IgG ELISA	Antibody	2020. 6. 29.	+82-2-2240-7062	Approval for Exports only
112	SeaSun Biomaterials	AQ-TOP™ COVID-19 Rapid Detection Kit	Molecular	2020. 6. 30.	+82-42-716-0301	Approval for Exports only
113	SML GENETREE CO., LTD.	Ezplex® SARS-CoV-2 FAST G Kit	Molecular	2020. 7. 2.	+82-2-2057-7900	Approval for Exports only
114	AccessBioKorea	CareStart™ COVID-19 IgM/IgG	Antibody	2020. 7. 3.	+82-54-906-9800	Approval for Exports only
115	iNtRON Biotechnology, Inc.	LiliF™ GBN COVID-19 IgG Rapid Kit	Antibody	2020. 7. 3.	+82-31-739-5678	Approval for Exports only

116	COSMAX PHARMA Co., Ltd.	iDetect™ SARS-CoV-2 Detection Kit	Molecular	2020. 7. 7.	+82-70-5101-1139	Approval for Exports only
117	CellSafe Co., Ltd.	LAMPlex RT-qLAMP COVID-19 Detection Assay	Molecular	2020. 7. 9.	+82-31-285-9958	Approval for Exports only