List of COVID-19 In Vitro Diagnostic Devices Officially Approved by MFDS(~21.3.18)

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