# List of COVID-19 In Vitro Diagnostic Devices Officially Approved by MFDS(~22.9.16)

| 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 |

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| 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 |

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| 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<br>+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<br>+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 |

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| 31 | BioSewoom, Inc. | Real-Q SARS-CoV-2/FluA/FluB Detection Kit | Molecular | 2021. 4. 26. | +82-2-498-2340<br>(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<br>+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 |

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| 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<br>+82-70-7006-5962 |

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| 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 |

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| 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<br>+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 |
| 74 | NanoEntek, Inc. | FREND COVID-19 SP | Antibody | 2022. 1. 24. | +82-2-6220-7940 |

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| 75 | GenBody Inc. | GenBody COVID-19 Ag Home Test | Antigen | 2022. 2. 4. | +82-41-523-8990 |
| 76 | Sugentech, Inc. | SGTi-flex COVID-19 Ag Self | Antigen | 2022. 2. 4. | +82-43-710-2822 |
| 77 | SD Biosensor, Inc. | STANDARD™ i-Q COVID-19 Ag Home Test | Antigen | 2022. 2. 11. | +82-31-300-0400 |
| 78 | Biomerieux Korea | BioFire Respiratory Panel 2.1plus (RP2.1plus) | Molecular | 2022. 2. 14. | +82-2-2188-4781 |
| 79 | PCL, Inc. | PCLOK II SARS-CoV-2 Dual IgG | Antibody | 2022. 2. 15. | +82-2-2144-3901 |
| 80 | PCL, Inc. | PCLOK II ABC | Antigen | 2022. 2. 15. | +82-2-2144-3901 |
| 81 | MEDIAN DIAGNOSTICS INC. | MDx COVID-19 Ag Home Test | Antigen | 2022. 2. 15. | +82-33-244-0100 |
| 82 | OSANG Healthcare Co., Ltd. | GeneFinder™ COVID-19 Ag Self Test | Antigen | 2022. 2. 15. | +82-31-460-9921 |
| 83 | WELLS BIO, INC. | careUS™ COVID-19 Antigen Home Test | Antigen | 2022. 2. 17. | +82-2-3660-6900 |
| 84 | MEDISENSOR, Inc. | CareU™ COVID-19 SARS-COV-2 Antigen Rapid Test Kit | Antigen | 2022. 2. 24. | +82-54-906-9810 |
| 85 | Siemens Healthineers Ltd. | ADVIA Centaur SARS-CoV-2 IgG (sCOVG) | Antibody | 2022. 3. 11. | +82-2-3450-1073 |

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| 86 | Asan pharmaceutical Co., LTD. | Asan Easy Test COVID-19 IgG/IgM (N) | Antibody | 2022. 3. 14. | +82-31-376-5990 (506) |
| 87 | Genes Laboratories | GCdia™ COVID-19 Fast Detection Kit | Molecular | 2022. 3. 14. | +82-31-756-5656 |
| 88 | LG Chem, Ltd. | AdvanSure™ SARS-CoV-2 IgG (RBD) ELISA | Antibody | 2022. 3. 17. | +82-2-6987-4432 |
| 89 | YD Diagnostics CORP. | Real Time COVID-19 | Molecular | 2022. 4. 4. | +82-31-329-2011 |
| 90 | GenBody Inc. | GenBody Influenza/COVID-19 Ag Triple | Antigen | 2022. 4. 11. | +82-41-523-8990 |
| 91 | MEDIAN DIAGNOSTICS INC. | MDx COVID-19 Ag Rapid Kit | Antigen | 2022. 4. 12. | +82-33-244-0100 |
| 92 | Philosys Co.,Ltd. | Gmate® COVID-19 Ag | Antigen | 2022. 4. 12. | +82-31-778-0602 |
| 93 | MiCoBioMed, Co., Ltd | Veri-Q COVID-19 & Flu A/B Multiplex Detection Kit | Molecular | 2022. 4. 13. | +82-70-5227-6065 |
| 94 | Abbott Korea Ltd. | Alinity m SARS-CoV-2 AMP Kit | Molecular | 2022. 4. 14. | +82-2-3429-3528 |
| 95 | AccessBioKorea | CareStart™ COVID-19 IgM/IgG Ab | Antibody | 2022. 4. 18. | +82-54-906-9800 |
| 96 | ImmuneMed Inc. | IMMUNEMED COVID-19 Ag RAPID | Antigen | 2022. 4. 21. | +82-33-258-6554 |

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| 97 | PCL, Inc. | PCL SELF TEST - COVID19 Ag | Antigen | 2022. 4. 29. | +82-2-2144-3901 |
| 98 | Genes Laboratories | GCdia™ SARS-CoV-2 Detection Kit | Molecular | 2022. 5. 3. | +82-31-756-5656 |
| 99 | AccessBioKorea | CareStart™ COVID-19 Antigen Home Test | Antigen | 2022. 5. 16. | +82-54-906-9800 |
| 100 | OSANG Healthcare Co., Ltd. | GeneFinder™ COVID-19 Ag Plus Rapid Test | Antigen | 2022. 5. 19. | +82-31-460-9921 |
| 101 | Genesystem Co., Ltd. | SMARTCHEK® SARS-CoV-2 Detection Kit | Molecular | 2022. 5. 26. | +82-42-863-8551 |
| 102 | Anse Co., Ltd | Aptima SARS-CoV-2 Assay | Molecular | 2022. 5. 26. | +82-31-777-9181 |
| 103 | OPTOLANE Technologies Inc. | Genoplexor™ COVID-19 Detection Kit (COR104-Z) | Molecular | 2022. 5. 30. | +82-31-737-7835 |
| 104 | SG Medical, Inc. | InstaView COVID-19 Antigen | Antigen | 2022. 5. 30. | +82-2-2240-7062 |
| 105 | Roche Diagnostics Korea Co., Ltd. | Elecsys Anti-SARS-CoV-2 S | Antibody | 2022. 5. 31. | +82-2-550-0759 |
| 106 | Sugentech, Inc. | INCLIX TRF COVID-19 Ag | Antigen | 2022. 6. 10. | +82-43-710-2822 |
| 107 | SeaSun Biomaterials | U-TOP FAST COVID19 | Molecular | 2022. 6. 29. | +82-42-716-0301 |

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| 108 | WELLS BIO, INC. | careGENE™ COVID-19 detection kit | Molecular | 2022. 6. 30. | +82-2-3660-6900 |
| 109 | InSol Co., Ltd | INSOL COVID-19 Real Time PCR Kit | Molecular | 2022. 6. 30. | +82-2-404-7990 |
| 110 | ProteomeTech Inc. | KOVIcheck COVID-19 IgG/IgM | Antibody | 2022. 7. 8. | +82-2-6968-5277 |
| 111 | NDFOS Co., Ltd. | ND COVID-19 Ag Test | Antigen | 2022. 7. 12. | +82-2-6203-0733 |
| 112 | 1drop Inc. | 1copy™ COVID-19 4plex RT-PCR Kit | Molecular | 2022. 7. 20. | +82-31-747-0109 |
| 113 | GenBody Inc. | iFinDx COVID-19 IgM/IgG | Antibody | 2022. 7. 27. | +82-41-523-8990 |
| 114 | SML GENETREE CO., LTD. | Ezplex™ SARS-CoV-2 Variants Kit | Molecular | 2022. 7. 29. | +82-2-2057-7900 |
| 115 | LG Chem, Ltd. | AdvanSure™ One-Stop COVID-19 Plus Kit | Molecular | 2022. 7. 29. | +82-2-6987-4432 |
| 116 | Abbott Diagnostics Korea Inc. | Panbio™ COVID-19 Ag Self-Test | Antigen | 2022. 7. 29. | +82-31-899-2837 |
| 117 | RapiGEN, INC | BIOCREDIT CoviFlu Ag Duo | Antigen | 2022. 8. 5. | +82-31-427-4677 |
| 118 | SD Biosensor, Inc. | STANDARD M SARS-CoV-2 Real-Time Detection Kit | Molecular | 2022. 8. 25. | +82-31-300-0400 |

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| 119 | BIONEER Corporation | AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit (SCVM-2212) | Molecular | 2022. 9. 6. | +82-42-930-8508 |
| 120 | CALTH Inc. | AllCheck Flu/COVID-19 Ag Duo | Antigen | 2022. 9. 14. | +82-70-4238-5244 |