



World Health Organization

WHO Emergency Use Listing for In vitro diagnostics (IVDs) Detecting SARS-CoV-2

RoW: Rest of the world. Regulatory version applied to products not approved by stringent/mature NRAs or not regulated
Last updated: 30 April 2021

Rapid Antigen Detection Tests

| Date Listed | Manufacturer | Product name | Product code(s) | Regulatory version | EUL application number | Packaging |
|-------------------|---|---|-----------------|--------------------|------------------------|-----------|
| 17 March 2021 | Premier Medical Corporation Private Limited | Sure Status COVID-19 Antigen Card Test | SS03P25 | RoW | EUL-0590-010-00 | 25 T/kit |
| 19 November 2020 | Abbott Rapid Diagnostics Jena GmbH | Panbio COVID-19 Ag Rapid Test Device (NASAL) | 41FK11, 41FK21 | CE-mark | EUL-0587-032-00 | 25 T/kit |
| 02 October 2020 | Abbott Rapid Diagnostics Jena GmbH | Panbio COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL) | 41FK10, 41FK20 | CE-mark | EUL-0564-032-00 | 25 T/kit |
| 22 September 2020 | SD Biosensor, Inc | STANDARD Q COVID-19 Ag Test | 09COV30D | CE-mark | EUL-0563-117-00 | 25 T/kit |

Nucleic Acid Detection Tests

| Date Listed | Manufacturer | Product name | Product code(s) | Regulatory version | EUL application number | Packaging |
|-------------------|--|--|---|--------------------|------------------------|----------------------------------|
| 10 December 2020 | MiCo BioMed Co Ltd | Veri-Q PCR 316 Coronavirus disease 2019 (COVID-19) Detection System | 7K105 | RoW | EUL-0495-188-00 | 50 T/kit |
| 30 November 2020 | Bioeksen R&D Technologies Ltd | Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit | BS-SY-WCOR-304-100 | CE-mark | EUL-0497-190-00 | 100 T/kit |
| 23 November 2020 | 3D Biomedicine Science & Technology Co., Ltd. | 3DMed 2019-nCoV RT-qPCR Detection Kit | 3103010011 | RoW | EUL-0488-184-00 | 100 T/kit |
| 15 September 2020 | Tellgen Corporation | SARS-CoV-2 Nucleic acid detection kit based on Real-Time PCR platform | PGA4102P1 (liquid) PGA4102P2 (lyophilized) | CE-mark | EUL-0517-204-00 | 48 T/kit 48 T/kit |
| 02 September 2020 | Shanghai Fosun Long March Medical Science Co., Ltd. | Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit (commercial name: Fosun 2019-nCoV qPCR) | PCSYHF-32 PCSYHF-48 PCSYHF-96 | CE-mark | EUL-0516-203-00 | 32 T/kit 48 T/kit 96 T/kit |
| 28 August 2020 | Ningbo Health Gene Technologies Co., Ltd. | SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method) | XC25073 XC25087 | CE-mark | EUL-0494-189-00 | 50 T/kit 200 T/kit |
| 14 August 2020 | Thermo Fisher Scientific | TaqPath COVID-19 CE-IVD RT-PCR Kit | A48067 | CE-mark | EUL-0525-156-00 | 1000 T/kit |
| 14 August 2020 | Beijing Wantai Biological Pharmacy Enterprise Co., Ltd | Wantai SARS-CoV-2 RT-PCR | WS-1248 | CE-mark | EUL-0500-005-00 | 48 T/kit |
| 09 July 2020 | Jiangsu Biopertectus Technologies Co.,Ltd | COVID-19 Coronavirus Real Time PCR Kit | JC10223-1NW-50T | CE-mark | EUL-0515-202-00 | 50 T/kit |
| 06 July 2020 | DiaSorin | Simplexa COVID-19 Direct and Simplexa COVID-19 Positive control Pack | MOL4150 MOL4160 | CE-mark | EUL-0526-212-00 | 50 T/kit 10 T/kit |
| 23 June 2020 | Cepheid AB | Xpert Xpress SARS-CoV-2 | XPRSARS-COV2-10 | CE-mark | EUL-0511-070-00 | 10 T/kit |



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|---------------|--|--|----------------------------|--------------------|------------------------|----------------------------------|
| 15 June 2020 | Chaozhaou Hybrilio Biochemistry Ltd. | COVID-19 Real-Time PCR Kit | HBRT-COVID-19 | CE-mark | EUL-0535-196-00 | 24 T/kit |
| 11 June 2020 | Shanghai GeneDx Biotechnology Co., Ltd | Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR) | GZ-D2RM25 | CE-mark | EUL-0513-200-00 | 50 T/kit |
| 08 June 2020 | Shanghai Kehua Bio-engineering Co., Ltd. | Diagnostic kit for SARS-CoV-2 Nucleic acid (Real-time PCR) | KH-G-M-574-48 | RoW | EUL-0492-037-00 | 48 T/kit |
| 22 May 2020 | Shanghai ZJ Bio-Tech Co., Ltd | Novel Coronavirus (SARS-CoV-2) Real Time Multiplex RT-PCR Kit | RR-0485-02 | RoW | EUL-0486-139-00 | 50 T/kit |
| 21 May 2020 | Fast Track Diagnostics Luxembourg S.à r.l. | FTD SARS-CoV-2 | 11416300 11416284 | CE-mark | EUL-0502-193-00 | 32 T/kit 96 T/kit |
| 19 May 2020 | Beijing Applied Biological Technologies Co. Ltd., (XABT) | Multiple Real-Time PCR Kit for Detection of 2019-nCoV | CT8233-48T | RoW | EUL-0491-187-00 | 48 T/kit |
| 14 May 2020 | Da An Gene Co., Ltd. Of Sun Yat-sen University | Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR- Fluorescence Probing) | DA0930 DA0931 DA0932 | RoW | EUL-0493-141-00 | 24 T/kit 48 T/kit 96 T/kit |
| 07 May 2020 | BGI Europe A/S | Real-time fluorescent RT-PCR kit for detecting 2019-nCoV | MFG030011 | CE-mark | EUL-0498-191-00 | 50 T/kit |
| 24 April 2020 | PerkinElmer Inc. | PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay | SY580 | CE-mark | EUL-0501-192-00 | 48 T/kit |
| 09 April 2020 | Abbott Molecular Inc. | Abbott Realtime SARS-CoV-2 | 09N77-090 09N77-080 | CE-mark | EUL-0503-027-00 | 96 T/kit controls |
| 07 April 2020 | Primerdesign Ltd. | Primerdesign Ltd COVID-19 genesig Real-Time PCR assay | Z-Path-COVID-19-CE | CE-mark | EUL-0489-185-00 | 96 T/kit |
| 03 April 2020 | Roche Molecular Systems, Inc. | cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems | 09175431190 09175440190 | CE-mark | EUL 0504-046-00 | 192 T/kit controls |

Antibody Detection Tests

| Date Listed | Manufacturer | Product name | Product code(s) | Regulatory version | EUL application Number | Packaging |
|------------------|------------------------|--|---|--------------------|------------------------|------------------------------------|
| 07 December 2020 | Roche Diagnostics GmbH | Elecsys Anti-SARS-CoV-2 Qualitative assay for use on the cobas e 411/601/602/801 immunoanalyzers | 09203095190 09203079190 09216928190 | CE-mark | EUL 0542-118-00 | 200 T/kit 300 T/kit controls |

Final Public Reports to be posted on the website once completed

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