



# World Health Organization

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

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Last updated: 07 June 2022

### Rapid Antigen Detection Tests

Date Listed	Manufacturer	Product name	Product code(s)	Regulatory version	EUL application number	Packaging
06 June 2022	Shanghai Kehua Bioengineering Co. Ltd.	Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold)	R-425-25-T	RoW	EUL 0658-037-00	25 T/kit
13 May 2022	LumiraDx UK Ltd	LumiraDx SARS-CoV-2 Ag Test	L016000110012, L016000110024 and L016000110048	CE mark	EUL 0578-234-00	12 T/kit, 24 T/kit, 48 T/kit
04 April 2022	Acon Biotech (Hangzhou) Co. Ltd	SARS-CoV-2 Antigen Rapid Test ( <i>Flowflex</i> )	L031-129R5, L031-129T5, L031-129U5, L031-129V5, L031-129W5 L031-129Y5	CE mark	EUL 0597-021-00	25 T/kit, 25 T/kit, 5 T/kit, 25 T/kit, 25 T/kit, 5 T/kit
01 February 2022	CTK Biotech, Inc.	OnSite COVID-19 Ag Rapid Test	R0182C	CE mark	EUL 0653-143-00	20 T/kit
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
28 September 2021	KH Medical Co., Ltd.	RADI COVID-19 Detection Kit	RV008	CE mark	EUL 0538-214-00	100 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
02 September 2020	Fosun Diagnostics (Shanghai) 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



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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
23 June 2020	Cepheid AB	Xpert Xpress SARS-CoV-2	XPRSARS-COV2-10	CE mark	EUL 0511-070-00	10 T/kit
15 June 2020	Chaozhaou Hyribio 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	MFG030010	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



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### 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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