

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 update: 19 January 2021

Rapid Antigen Detection Tests

Date Listed	EUL number	Product name	Regulatory version	Product code(s)	Manufacturer	Packaging
19 November 2020	EUL-0587-032-00	Panbio COVID-19 Ag Rapid Test Device (NASAL)	CE-mark	41FK19	Abbott Rapid Diagnostics Jena GmbH	25 T/kit
02 October 2020	EUL-0564-032-00	Panbio COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	CE-mark	41FK10	Abbott Rapid Diagnostics Jena GmbH	25 T/kit
22 September 2020	EUL-0563-117-00	STANDARD Q COVID-19 Ag Test	CE-mark	09COV30D	SD Biosensor, Inc	25 T/kit

Nucleic Acid Detection Tests

Date Listed	EUL number	Product name	Regulatory version	Product code(s)	Manufacturer	Packaging
10 December 2020	EUL-0495-188-00	Veri-Q PCR 316 Coronavirus disease 2019 (COVID-19) Detection System	RoW	QD-P100, 16TU-CV19, nCoV-QS and G2-16TU	MiCo BioMed Co Ltd	50 T/kit
30 November 2020	EUL-0497-190-00	Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit.	CE-mark	BS-SY-WCOR-304-100	Bioeksen R&D Technologies Ltd	100 T/kit
23 November 2020	EUL-0488-184-00	3DMed 2019-nCoV RT-qPCR Detection Kit	RoW	3103010011	3D Biomedicine Science & Technology Co., Ltd.	100 T/kit
15 September 2020	EUL-0517-204-00	SARS-CoV-2 Nucleic acid detection kit based on Real-Time PCR platform	CE-mark	PGA4102P1 (liquid) PGA4102P2 (lyophilized form)	Teligen Corporation	48 T/kit 48 T/kit
02 September 2020	EUL-0516-203-00	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit (commercial name: Fosun 2019-nCoV qPCR)	CE-mark	PCSYHF-32 PCSYHF-48 PCSYHF-96	Shanghai Fosun Long March Medical Science Co., Ltd.	32 T/kit 48 T/kit 96 T/kit
28 August 2020	EUL-0494-189-00	SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method)	CE-mark	XC25073 XC25087	Ningbo Health Gene Technologies Co., Ltd.	50 T/kit 200 T/kit
14 August 2020	EUL-0525-156-00	TaqPath COVID-19 CE-IVD RT-PCR Kit	CE-mark	A48067	Thermo Fisher Scientific	1000 T/kit
14 August 2020	EUL-0500-005-00	Wantai SARS-CoV-2 RT-PCR	CE-mark	WS-1248	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd	48 T/kit
09 July 2020	EUL-0515-202-00	COVID-19 Coronavirus Real Time PCR Kit	CE-mark	JC10223-1NW-50T	Jiangsu Bioperfectus Technologies Co.,Ltd	50 T/kit
06 July 2020	EUL-0526-212-00	Simplexa COVID-19 Direct and Simplexa COVID-19 Positive control Pack	CE-mark	MOL4150, MOL4160	DiaSorin	50 T/kit 10 T/kit
23 June 2020	EUL-0511-070-00	Xpert Xpress SARS-CoV-2	CE-mark	XPRSARS-COV2-10	Cepheid AB	10 T/kit

Nucleic Acid Detection Tests

Date Listed	EUL number	Product name	Regulatory version	Product code(s)	Manufacturer	Packaging
15 June 2020	EUL-0535-196-00	COVID-19 Real-Time PCR Kit	CE-mark	HBRT-COVID-19	Chaozhaou Hyrbio Biochemistry Ltd.	24 T/kit

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 update: 19 January 2021

11 June 2020	EUL-0513-200-00	Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR)	CE-mark	GZ-D2RM25	Shanghai GeneDx Biotechnology Co., Ltd	50 T/kit
08 June 2020	EUL-0492-037-00	Diagnostic kit for SARS-CoV-2 Nucleic acid (Real-time PCR)	RoW	KH-G-M-574-48	Shanghai Kehua Bio-engineering Co., Ltd.	48 T/kit
22 May 2020	EUL-0486-139-00	Novel Coronavirus (SARS-CoV-2) Real Time Multiplex RT-PCR Kit	RoW	RR-0485-02	Shanghai ZJ Bio-Tech Co., Ltd	50 T/kit
21 May 2020	EUL-0502-193-00	FTD SARS-CoV-2 (FTD-114-32) □	CE-mark	11416300	Fast Track Diagnostics Luxembourg S.à r.l.	32 T/kit
19 May 2020	EUL-0491-187-00	Multiple Real-Time PCR Kit for Detection of 2019-nCoV	RoW	CT8233-48T	Beijing Applied Biological Technologies Co. Ltd., (XABT)	48 T/kit
14 May 2020	EUL-0493-141-00	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing)	RoW	DA0930 DA0931 DA0932	Da An Gene Co., Ltd. Of Sun Yat-sen University	24 T/kit 48 T/kit 96 T/kit
07 May 2020	EUL-0498-191-00	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	CE-mark	MFG030011	BGI Europe A/S	50 T/kit
24 April 2020	EUL-0501-192-00	PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay	CE-mark	SY580	PerkinElmer Inc.	48 T/kit
09 April 2020	EUL-0503-027-00	Abbott Realtime SARS-CoV-2	CE-mark	09N77-090 09N77-080	Abbott Molecular Inc.	96 T/kit controls
07 April 2020	EUL-0489-185-00	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	CE-mark	Z-Path-COVID-19-CE	Primerdesign Ltd.	96 T/kit
03 April 2020	EUL 0504-046-00	cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems	CE-mark	09175431190 09175440190	Roche Molecular Systems, Inc.	192 T/kit controls

Antibody Detection Tests

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

Final Public Reports to be posted on the website once completed

End of document