



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: 07 April 2022

Rapid Antigen Detection Tests

Date Listed	Manufacturer	Product name	Product code(s)	Regulatory version	EUL application number	Packaging
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, 25 T/kit, 25 T/kit, 25 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	Bioeksens 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
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