

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

Last update: 22 September 2020

Date Listed	Product name	Product code(s)	Manufacturer
03 April 2020	cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems	09175431190 and 09175440190	Roche Molecular Systems, Inc.
07 April 2020	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Z-Path-COVID-19-CE	Primerdesign Ltd.
09 April 2020	Abbott Realtime SARS-CoV-2	09N77-090 and 09N77-080	Abbott Molecular Inc.
24 April 2020	PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay	SY580	PerkinElmer Inc.
07 May 2020	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	MFG030011	BGI Europe A/S
14 May 2020	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing)	DA0930, DA0931 and DA0932	Da An Gene Co., Ltd. Of Sun Yat-sen University
19 May 2020	Multiple Real-Time PCR Kit for Detection of 2019-nCoV	CT8233-48T	Beijing Applied Biological Technologies Co. Ltd., (XABT)
21 May 2020	FTD SARS-CoV-2 (FTD-114-32)□	11416300	Fast Track Diagnostics Luxembourg S.à r.l.
22 May 2020	Novel Coronavirus (SARS-CoV-2) Real Time Multiplex RT-PCR Kit	RR-0485-02	Shanghai ZJ Bio-Tech Co., Ltd
08 June 2020	Diagnostic kit for SARS-CoV-2 Nucleic acid (Real-time PCR)	KH-G-M-574-48	Shanghai Kehua Bio-engineering Co., Ltd.
11 June 2020	Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR)	GZ-D2RM25	Shanghai GeneoDx Biotechnology Co., Ltd
15 June 2020	COVID-19 Real-Time PCR Kit	HBRT-COVID-19	Chaozhaou Hyribio Biochemistry Ltd.
23 June 2020	Xpert Xpress SARS-CoV-2	XPRSARS-COV2-10	Cepheid AB
06 July 2020	Simplexa COVID-19 Direct and Simplexa COVID-19 Positive control Pack	MOL4150, MOL4160	DiaSorin
09 July 2020	COVID-19 Coronavirus Real Time PCR Kit	JC10223-1NW-50T	Jiangsu Bioperfectus Technologies Co.,Ltd

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14 August 2020	Wantai SARS-CoV-2 RT-PCR	WS-1248	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd
14 August 2020	TaqPath COVID-19 CE-IVD RT-PCR Kit	A48067	Thermo Fisher Scientific
28 August 2020	SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method)	XC25073	Ningbo Health Gene Technologies Co., Ltd.
02 September 2020	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit (commercial name: Fosun 2019-nCoV qPCR)	PCSYHF	Shanghai Fosun Long March Medical Science Co., Ltd.
15 September 2020	SARS-CoV-2 Nucleic acid detection kit based on Real-Time PCR platform	PGA4102P1 (liquid) / PGA4102P2 (lyophilized form)	Telgen Corporation
22 September 2020	STANDARD Q COVID-19 Ag Test	09COV30D	SD Biosensor, Inc

Final Public Reports to be posted on the website once completed

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