

SARS-CoV-2 Nucleic Acid Tests: progress of the active applications in the emergency use listing assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	QMS Desk Assessment
3DMed 2019-nCoV qRT-PCR Detection Kit	3103010011	3D Biomedicine Science & Technology Co., Ltd.		◆
VERI-Q PCR 316 COVID-19 Detection System	7K105	MiCo BioMed Co., Ltd.		◆
Bio-Speedy SARS-COV2 (2019-nCoV) qPCR Detection Kit	BS-SY-WCOR-303-100	Bioeksen R&D Technologies Ltd.	R	◆
SARS-CoV-2 (ORF1ab/N) Nucleic Acid Detection Kit (PCR-Fluorescent Probe)	SUPI-2501	Guangzhou Supbio Bio-technology and Science Co., Ltd		◆
COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit	nCOV-PCR-02-100B	Wuhan EasyDiagnosis Biomedicine Co., Ltd.		R
SAMBA II SARS-CoV-2 Test	8500-12	Diagnostics for the Real World Ltd	awaiting submission	awaiting submission
Diagnovital SARS-CoV-2 Real Time PCR Kit	09065025, 09065050, 09065100	RTA Laboratories		R
Wondfo SARS-CoV-2 Real-Time RT PCR assay	W275P0009, W275P0010, W275P0011 and W275P0012.	Guangzhou Wondfo Biotech Co., Ltd		R
RADI COVID-19 Detection Kit	RV008	KH Medical Co., Ltd		◆
SarbecoV E-gene EAV	40-0776-96	TIB MOLBIOL Syntheselabor GmbH	R	awaiting submission
Genedrive 96 SARS-CoV2 kit	ID-CoV2-01-LPC	Genedrive Diagnostics Ltd		◆
2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit	CD302-02	Nanjing Vazyme Medical Technology Co., Ltd.		
Allplex SARS-CoV-2 Assay	RV10248X and RV10247Y	Seegene Inc.	awaiting submission	awaiting submission
PowerCheck SARS-CoV-2 Real-time PCR kit	IR6902	Kogene Biotech Co.,Ltd	awaiting submission	awaiting submission
QuantuMDx SARS-CoV-2 RT-PCR Detection Assay	Q22003	QuantuMDx Group Ltd	awaiting submission	awaiting submission

SARS-CoV-2 Rapid Antigen Tests: progress of the active applications in the emergency use listing assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	QMS Desk Assessment
Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal)	41FK10	Abbott Rapid Diagnostics Jena GmbH		◆
STANDARD Q COVID-19 Ag Test	09COV30D	SD Biosensor Inc.	◆	◆
ESPLINE SARS-CoV-2	231906	Fujirebio, Inc		
BIOEASY Diagnostic kit for SARS-CoV-2 Ag (Fluorescence Immunochromatographic Assay)	YRLF04401025, YRLF04401050 and YRLF04401100	Shenzhen Bioeasy Biotechnology Co., Ltd	awaiting submission	awaiting submission
LumiraDx SARS-CoV-2 Ag Test	L0160001nnxxx	LumiraDx UK Ltd	awaiting submission	awaiting submission
SARS-CoV-2 Rapid Antigen Test	9327592190	Roche Diagnostics GmbH	awaiting submission	awaiting submission

SARS-CoV-2 Antibody Tests: progress of the active applications in the emergency use listing assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	QMS Desk Assessment
DPP COVID-19 IgM/IgG System	65-9572-0	Chembio Diagnostic Systems Inc	awaiting submission	awaiting submission
2019-nCoV IgG/IgM Rapid Test Cassette (Whole BloodSerumPlasma)	INCP-402B	Hangzhou AllTest Biotech Co. Ltd.	awaiting submission	awaiting submission
Diagnostic Kit for SARS-CoV-2 IgG/IgM Antibody (Colloidal Gold)	R-423-20-C, R-423-25-C	Shanghai Kehua Bioengineering Co., Ltd.		◆
One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)	CG2057	Getein Biotech Inc.		◆
SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method)	109.01.96.02	Biohit Healthcare (Hefei) Co., Ltd.	R	◆
Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal gold)	52026069	Genrui Biotech Inc.	awaiting submission	awaiting submission
Bel test it ! COV-2 -SARS CoV- 2 specific IgM / IgG Test Kit	CV 10.01	Pharmact GmbH		
Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)	W195	Guangzhou Wondfo Biotech Co., Ltd		R
Rapid SARS-CoV-2 Antibody (IgM/IgG) Test	ITP16001-TC25 and ITP16002-TC25	InTec PRODUCTS, INC		◆

Wantai SARS-CoV-2 Antibody Rapid Test	WJ-2710 and WJ-2750	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.		◆
Elecsys Anti-SARS-CoV-2 Qualitative assay for use on the cobas e 411/601/602/801 immunoanalyzers	9203095190; 09203079190; 09216928190	Roche Diagnostics GmbH	R	◆
COVID-19IgM/IgG Antibody Test	A03-51-322	Artron Laboratories Inc.	R	R
Novel Coronavirus (2019-nCoV) Antibody Rapid Test	ART20200630	Bioscience(Tianjin) Diagnostic Technology Co.,Ltd	awaiting submission	awaiting submission
Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Rapid Test	MGRT20200630	Bioscience(Tianjin) Diagnostic Technology Co.,Ltd		awaiting submission
Mologic COVID-19 blood IgA/IgG/IgM rapid diagnostic test	11911125	Mologic		◆
VivaDiag COVID-19 IgM/IgG Rapid Test	VID35-08-011	VivaChek Biotech (Hangzhou) Co. Ltd		
DS-EIA-ANTI-SARS-CoV-2-G	S-2382/1.1	RPC Diagnostic Systems, Ltd.		
DS-EIA-ANTI-SARS-CoV-2	S-2372/1.1	RPC Diagnostic Systems, Ltd.	awaiting submission	awaiting submission
Wantai SARS-CoV-2 Ab ELISA	WS-1096	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	R	◆
ASSURE SARS-CoV-2 IgG/IgM Rapid Test	43140-020	MP Biomedical Asia Pacific Pte Ltd	awaiting submission	awaiting submission
JOYSBIO COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)	G10312	JOYSBIO (Tianjin) Biotechnology Co., Ltd		
iFlash-SARS-CoV-2 IgG (iFlash-2019-nCoV IgG)	C86095G	SHENZHEN YHLO BIOTECH CO., LTD		
Diagnostic Kit for Novel Coronavirus (2019-nCoV) IgG Antibody (Magnetic particle CLIA)	GAM20200828	Bioscience(Tianjin) Diagnostic Technology Co.,Ltd	awaiting submission	awaiting submission
Novel Coronavirus (2019-nCoV) IgM/IgG Antibody ComboTest Kit (Colloidal Gold)	303002	Hangzhou Laihe Biotech Co., Ltd		
2019-nCoV IgG/IgM Rapid Test(Colloidal Gold)	COV-102	Hangzhou Lysun Biotechnology Co., Ltd		
COVID-19 IgM/IgG Test Kit (Colloidal Gold)	CG01Ab-25	Xiamen AmonMed Biotechnology Co., Ltd.	awaiting submission	awaiting submission
COVID-19 IgM/IgG test kit (Rare earth nano fluorescence immunochromatography)	RF01Ab-25	Xiamen AmonMed Biotechnology Co., Ltd.	awaiting submission	awaiting submission
COVID-19 IgG/IgM Test kit (Colloidal Gold Method)	6936020111621 and 6936020111614	Hangzhou Singclean Medical Products Co., Ltd.	awaiting submission	awaiting submission
2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)	C6601C; C6602C; C6604C; C6605C; C6606C; and C6603C	Nanjing Vazyme Medical Technology Co., LTD	awaiting submission	awaiting submission
2019-nCoV IgG/IgM Rapid Test	DNK-1419-1	Dynamiker Biotechnology (Tianjin) Co., Ltd		

Disclaimer: This list does not reflect a decision on EUL assessment and must not be used to inform procurement as it does not constitute an endorsement or WHO listing of the products.

R information requested from manufacturer	 in process	 stage complete	F follow-up amendments
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