

Applications that were assessed and failed to meet the required documentary evidence for safety, performance and/ or QMS.
SARS-CoV-2 Antibody Tests

Manufacturer	Product name	Product code(s)	EUL application number
Bioscience(Tianjin) Diagnostic Technology Co.,Ltd	Diagnostic Kit for Novel Coronavirus (2019-nCoV) IgG Antibody (Magnetic particle CLIA)	GAM20200828	EUL 0565-219-00
Bioscience(Tianjin) Diagnostic Technology Co.,Ltd	Novel Coronavirus (2019-nCoV) Antibody Rapid Test (RDT)	ART20200630	EUL 0552-219-00
Bioscience(Tianjin) Diagnostic Technology Co.,Ltd	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Rapid Test	MGRT20200630	EUL 0553-219-00
Genrui Biotech Inc.	Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal gold)	52026069	EUL 0540-216-00
Nanjing Vazyme Medical Technology Co., Ltd.	2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)	C6601C; C6602C; C6604C; C6605C; C6606C; and C6603C	EUL 0576-221-00
Xiamen AmonMed Biotechnology Co., Ltd.	COVID-19 IgM/IgG test kit (Rare Earth Nano Fluorescence Immunochromatography)	RF01Ab-25	EUL 0574-231-00
Shenzhen Microprofit Biotech Co., Ltd.)	SARS-CoV-2 IgG and IgM Antibody Combined Test Kit (Colloidal Gold Chromatographic Immunoassay)	MF-61	EUL 0624-251-00
Xiamen AmonMed Biotechnology Co., Ltd.	COVID-19 IgM/IgG Test Kit (Colloidal Gold)	CG01Ab-25	EUL 0573-231-00

Applications that were assessed and failed to meet the required documentary evidence for safety, performance and/ or QMS.
SARS-CoV-2 Rapid Antigen Tests for Professional Use

Manufacturer	Product name	Product code(s)	EUL application number
Wizchem Co., Ltd	COVICHEK COVID-19 Ag Kit	CAG301-5, CAG301-10, and CAG301-25	EUL 0675-273-00
JOYSBIO (Tianjin) Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	G10313	EUL 0582-223-00
Shenzhen Watmind Medical Co., Ltd	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	LFA0401-25N	EUL 0612-246-00
Shenzhen Kisshealth Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Test Kit (GICA)	K602	EUL 0621-250-00

SARS-CoV-2 Rapid Antigen Tests for Professional Use

Manufacturer	Product name	Product code(s)	EUL application number
Hangzhou Realy Tech Co. Ltd	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	K511416D	EUL 0588-238-00
TaiDoc Technology Corp.	FORA/VTRUST COVID-19 Antigen Rapid Test, TD-4531B	TD-4531B	EUL 0718-272-00
Guangzhou Wondfo Biotech Co., Ltd	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	W196P0003 W196P0004	EUL 0593-004-00
Shenzhen Ultra-diagnostics Biotec	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	SC0201, SC0202, SC0203, and SC0204	EUL 0605-245-00
VivaChek Biotech (Hangzhou) Co., Ltd	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	VCD16-01-011	EUL 0592-222-00
Humasis Co., Ltd.	Humasis COVID-19 Ag Test	ACOVA-7025	EUL 0613-247-00
BGI Europe A/S	SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)	MFG030026	EUL 0630-191-00
Innovita (Tangshan) Biological Technology Co., Ltd	2019-nCoV Ag Test (Latex Chromatography Assay)	YF320C	EUL 0637-249-00
Beijing Hotgen Biotech Co., Ltd	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	HGCG134A0101 HGCG134A0105 HGCG134A0120 HGCG134A0125 HGCG134A0140 HGCG134A0150 HGCG134B0101 HGCG134B0105 HGCG134B0120 HGCG134B0125 HGCG134B0140 HGCG134B0150	EUL 0591-239-00
Core Technology Co., Ltd.	Coretests COVID-19 Ag Test	B291-22	EUL 0607-065-00

SARS-CoV-2 Rapid Antigen Tests for Professional Use

Manufacturer	Product name	Product code(s)	EUL application number
Sorrento Therapeutics, Inc.	COVISTIX COVID-19 VIRUS Rapid Antigen Detection Test	COV-ST02	EUL 0656-262-00
Mylab Discovery Solutions Pvt Ltd	PathoCatch COVID-19 Antigen Lateral Flow Test Device	AG00001	EUL 0602-236-00
GenSure Biotech Inc.	GenSure COVID-19 Antigen Rapid Test Kit	P2004 and P2004s	EUL 0654-261-00

SARS-CoV-2 Rapid Antigen Tests for Self-Testing

Manufacturer	Product name	Product code(s)	EUL application number
Phase Scientific International Ltd	INDICAID COVID-19 Rapid antigen Self-Test	P0079, P0080, P0081, P0082	EUL 0700-282-00
OSANG Healthcare Co., Ltd	OHC COVID-19 Antigen Self Test	OI-01SA-SH	EUL 0698-281-00

SARS-CoV-2 Nucleic Acid Tests

Manufacturer	Product name	Product code(s)	EUL application number
Trentron Biomedical Ltd.	VitaPCR SARS-CoV-2 Gen 2 assay	PCRAE0120	EUL 0629-252-00
Wuhan EasyDiagnosis Biomedicine Co., Ltd	COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit	NCOV-PCR-02-100B	EUL 0523-209-00
Molbio Diagnostics Private Limited	Truenat COVID-19	601430005, 601430020, 601430025, 601430050, 601430100, 601430200	EUL 0713-240-00
Beijing Kinghawk Pharmaceutical Co. Ltd.	Novel Coronavirus (2019-nCoV) Nucleic Acid Detection Kit (fluorescence PCR)	081	EUL 0510-198-00
HaploX Biotechnology Co., LTD	RT- PCR kit for Detecting SARS - CoV-2 (Real-time fluorescent PCR)	Not specified	EUL 0507-195-00
Jiangsu Mole Bioscience Co.,Ltd.	2019-Novel Coronavirus (ORF1ab, E & N genes) nucleic acid test kit (Fluorescent Probe-based real-time PCR assay)	R205T050B0C0	EUL 0509-197-00
Jiangsu Qitian Gene Biotechnology Co., Ltd.	SARS-CoV-2 Nucleic Acid Detection Kit (Fluorescent RT-RAA)	F02R13A-48	EUL 0512-199-00
Nanjing Vazyme Medical Technology Co., Ltd.	2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit	CD302-02	EUL 0555-221-00
QuantuMDx Group Ltd	QuantuMDx SARS-CoV-2 RT-PCR Detection Assay	Q22003	EUL 0570-229-00
RTA Laboratuvarları Biyolojik Ueruenler İlac ve Makine San. Tic. A. S.	Diagnovital SARS-CoV-2 Real Time PCR Kit	09065025, 09065050, 09065100	EUL 0531-129-00

SARS-CoV-2 Nucleic Acid Tests

Manufacturer	Product name	Product code(s)	EUL application number
Shenrui Biopharmaceuticals Co., Ltd.	CoVTest-SR	Not specified	EUL 0506-194-00
UStar Biotechnologies (Hangzhou) Ltd.	Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification- Real Time Fluorescence Assay)	U20223	EUL 0522-208-00
Viet A Technology corporation	LightPower iVASARS-CoV-2 1stRT-rPCR Kit	VA.A02-055H	EUL 0524-210-00
#Beijing Applied Biological Technologies Co. Ltd., (XABT)	#Multiple Real-Time PCR Kit for Detection of 2019-nCoV	CT8233-48T	EUL 0491-187-00
Molbio Diagnostics Private Limited	Truenat COVID-19	601430005,601430020, 601430025, 601430050, 601430100 and 601430200 .	EUL 0647-240-00
Zybio Inc.	SARS-CoV-2 Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method)	1.10.11.09.nc.02	EUL 0490-186-00
#Tellgen Corporation, Shanghai	#SARS-CoV-2 Nucleic acid detection kit based on Real-Time PCR platform	PGA4102P1 (liquid) PGA4102P2 (lyophilized)	EUL 0517-204-00
Wuhan EasyDiagnosis Biomedicine Co., Ltd.	COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit	nCOV-PCR-02-100B	EUL 0523-209-00

The product was initially listed but then failed QMS assessment during EUL renewal assessment.

Applications that were not assessed, withdrawn or did not meet the eligibility criteria for EUL assessment.

SARS-CoV-2 Antibody Tests

Manufacturer	Product name	Product code(s)	EUL Application number
Chembio Diagnostic Systems, Inc.	DPP® COVID-19 IgM/IgG System	65-9572-0	EUL 0527-006-00
InTec Products, Inc.	Rapid SARS-CoV-2 Antibody (IgM/IgG) Test	ITP16001-TC25 and ITP16002-TC25	EUL 0547-017-00
Roche Diagnostics GmbH	*Elecsys Anti-SARS-CoV-2 Qualitative assay for use on the cobas e 411/601/602/801 immunoanalyzers	09203095190 09203079190 09216928190	EUL 0542-118-00

*Withdrawn from listed products. Manufacturer did not express interest to extend the EUL for another period.

SARS-CoV-2 Rapid Antigen Tests

Manufacturer	Product name	Product code(s)	EUL Application number
Mologic Ltd	COVID 19 Rapid Antigen Test	11811125	EUL 0644-220-00
Roche Diagnostics GmbH	SARS-CoV-2 Rapid Antigen Test	9327592190	EUL 0579-118-00
Dynamiker Biotechnology (Tianjin) Co., Ltd.	Dynamiker SARS SARS-CoVCoV-2 Ag Rapid Test	DNK-1425-1	EUL 0619-233-00
Fujirebio Inc.	ESPLINE SARS-CoV-2	231906	EUL 0670-022-00
Immunodiagnosics Limited	COVID-19 Ag Detection Kit (Immunofluorescence-Based)	41A254	EUL 0649-260-00
Vitrosens Biyoteknoloji Ltd. Şti	RapidFor SARS-CoV-2 Rapid Antigen Test	VSCD02	EUL 0663-266-00

SARS-CoV-2 Rapid Antigen Tests

Manufacturer	Product name	Product code(s)	EUL Application number
Shenzhen Bioeasy Biotechnology Co., Ltd	2019-nCoV Ag Rapid Test Kit (Fluorescence)	YRLF04401025, YRLF04401050 YRLF04401100	EUL 0572-230-00
Multibrands International Ltd	Panodyne Covid-19 SARS-Cov-2 Antigen Test kit	PDRTKTA-U	EUL 0635-254-00
Beijing Jinwofu Bioengineering Technology Co., Ltd.	Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit	C3042	EUL 0671-270-00
GenBody Inc.	GenBody COVID-19 Ag	COVAG025	EUL 0645-259-00
Genobio Pharmaceutical Co., Ltd	COVID-19 Antigen Lateral Flow Assay	CoVAgLFA-01	EUL 0664-267-00
Hangzhou Singclean Medical Products Co., Ltd.	COVID-19 Test kit (Colloidal Gold Method)	6936020111690, 6936020111706	EUL 0622-232-00
Beijing Diagreat Biotechnologies Co., Ltd	2019-nCoV Antigen Rapid Test Kit (Colloidal gold Assay)	G11801	EUL 0639-257-00
Guangdong Longsee Biomedical Co. Ltd.	2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	LS-C-T-008, LS-C-T-009	EUL 0660-264-00
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd	SARS-CoV-2 Virus Antigen Detection Kit (Immunofluorescence Chromatography)	HWTS-RT054A	EUL 0615-248-00
TaiDoc Technology Corp.	URIGHT COVID-19 Antigen Rapid Test	TD-4531	EUL 0674-272-00
Zephyr Biomedicals, A Division of Tulip Diagnostics (P) Ltd	CoviRAT	502100025	EUL 0665-025-00
GenesPrint Group Ltd	GenesPrint Colloidal Gold Rapid Antigen Test for SARS CoV-2	COV-AG-CT	EUL 0636-255-00
Jiangsu Diagnostics Biotechnology Co	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	DGNS102103	EUL 0684-277-00

SARS-CoV-2 Rapid Antigen Tests

Manufacturer	Product name	Product code(s)	EUL Application number
Hangzhou AllTest Biotech Co. Ltd	SARS-CoV-2 Antigen Rapid Test	INCP-502-N	EUL 0631-111-00
Immunodiagnosics Limited	COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography)	41A254	EUL 0648-260-00
Mediclone Biotech Pvt. Ltd.	@sight COVID-19 Antigen Test	RP403	EUL 0686-276-00
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd	SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)-Nasal	WTS-RT062BQ , HWTS-RT062BR , HWTS-	EUL 0703-248-00

SARS-CoV-2 Nucleic Acid Tests

Manufacturer	Product name	Product code(s)	EUL Application number
GenesPrint Group Ltd	GenesPrint Colloidal Gold Rapid Antigen Test for SARS CoV-2	COV-AG-CT	EUL 0636-255-00
Jiangsu Diagnostics Biotechnology Co	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	DGNS102103	EUL 0684-277-00
Hangzhou AllTest Biotech Co. Ltd	SARS-CoV-2 Antigen Rapid Test	INCP-502-N	EUL 0631-111-00
Immunodiagnosics Limited	COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography)	41A254	EUL 0648-260-00
Mediclone Biotech Pvt. Ltd.	@sight COVID-19 Antigen Test	RP403	EUL 0686-276-00
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd	SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)-Nasal	WTS-RT062BQ , HWTS-RT062BR , HWTS-RT062BS, HWTS-RT062BT	EUL 0703-248-00
altona Diagnostics GmbH	RealStar SARS-CoV-2 RT-PCR kit 1.0	821015 and 821019	EUL 0532-153-00
Coyote Bioscience Co., Ltd	DirectDetect SARS-COV2 Detection Kit (PCR-Fluorescence Probe)	Not specified	EUL 0496-150-00
InBios International, Inc.	Smart Detect SARS-CoV-2 rRT-PCR Kit	COV2-E	EUL 0505-145-00
Liming Bio-Products Co., Ltd.	StrongStep Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (detection for three genes)	500190	EUL 0519-206-00
M monitor Inc	Isopollo COVID-19 detection kit (real-time)	52227	EUL 0548-218-00
Sansure Biotech Inc.	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	S3103E	EUL 0514-201-00
Sunstar Joint Stock Company	One-Step RT-PCR COVID-19 kit Thai Duong Version 1.0	SK128COV01	EUL 0529-211-00

SARS-CoV-2 Nucleic Acid Tests

Manufacturer	Product name	Product code(s)	EUL Application number
Tianjin GensKey Medical Technology Co., Ltd.	Genskey SARS-CoV-2 RT-PCR Kit	Q102	EUL 0518-205-00
TIB Molbiol Syntheselabor GmbH	SarbecoV E-gene EAV	40-0776-96	EUL 0541-162-00
Wells Bio Inc.	careGENE COVID-19 RT-PCR kit	MCDN05082	EUL 0521-113-00
Molbio Diagnostics Private Limited	Truenat Beta CoV	601410005, 601410020 and 601410050	EUL 0595-240-00
Molbio Diagnostics Private Limited	Truenat SARS CoV-2	60142000, 601420020 and 601420050	EUL 0594-240-00
DiaSorin	*Simplexa COVID-19 Direct and Simplexa COVID-19 Positive control Pack	MOL4150 and MOL4160	EUL 0526-212-00
MiCo BioMed Co Ltd	*Veri-Q PCR 316 Coronavirus disease 2019 (COVID-19) Detection System	7K105	EUL 0495-188-00

*Withdrawn from listed products. Manufacturer did not express interest to extend the EUL for another period.

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