



SARS-CoV-2 IVDs: Products not accepted for EUL: Last update: 04 August 2021

Applications that were assessed and failed to meet the required documentary evidence of 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 of safety, performance and/ or QMS.

SARS-CoV-2 Rapid Antigen Tests

Manufacturer	Product name	Product code(s)	EUL application number
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
Hangzhou Realy Tech Co. Ltd	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	K511416D	EUL 0588-238-00
Humasis Co., Ltd.	Humasis COVID-19 Ag Test	ACOVA-7025	EUL 0613-247-00
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

Applications that were assessed and failed to meet the required documentary evidence of safety, performance and/ or QMS.

SARS-CoV-2 Nucleic Acid Tests

Manufacturer	Product name	Product code(s)	EUL application number
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
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
Zybio Inc.	SARS-CoV-2 Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method)	1.10.11.09.nc.02	EUL 0490-186-00

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

SARS-CoV-2 Rapid Antigen Tests

Manufacturer	Product name	Product code(s)	EUL Application number
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

SARS-CoV-2 Nucleic Acid Tests

Manufacturer	Product name	Product code(s)	EUL Application number
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
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

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