



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management  
**Health Security**

## **- ADDENDUM -**

*To the common list of COVID-19 rapid antigen tests (part I)  
and  
To the list of mutually recognised COVID-19 lab-based antigenic assays  
(part II)*

***This document provides further background information to the decisions taken by the HSC Technical Working Group in the context of the tenth update to the common list of COVID-19 rapid antigen tests as well as the common list of COVID-19 lab-based antigenic assays, as agreed on ~~8 April 2022~~[TBC]***

*In addition to information put forward by EU Member States, the HSC technical working group reviewed proposals submitted by manufacturers until ~~25 February~~1 April 2022.*

*All the proposals were assessed against the criteria agreed by the HSC technical working group on 21 September 2021.*

**IMPORTANT: As of 2022, a grace period of 4 weeks applies whenever updates are made to the common list of COVID-19 rapid antigen tests.**

## **PART I: RAPID ANTIGEN TESTS**

### **Rapid antigen tests removed from the HSC agreed common list of COVID-19 rapid antigen tests**

The following rapid antigen tests were removed from the EU common list as the available information was incomplete or new validation studies showed that the test(s) no longer met the required criteria established by Council Recommendation 2021/C 24/01 and/or the further criteria agreed by the experts participating in the technical working group on COVID-19 diagnostic tests on 21 September 2021:

<b>MANUFACTURER</b>	<b>COMMERCIAL NAME RAPID ANTIGEN TEST</b>	<b>DEVICE ID</b>	<b>DATE OF REMOVAL</b>	<b>END OF GRACE PERIOD</b>
Core Technology Co., Ltd	Canea Covid-19 Antigen Rapid Test	<i>unknown</i>	7 July 2021	1 Sept 2021, 23:59 CET
RapigGEN Inc.	BIOCREDIT COVID-19 Ag - SARS-CoV 2 Antigen test	1606	7 July 2021	1 Sept 2021, 23:59 CET
Tody Laboratories Int.	Coronavirus (SARS-CoV 2) Antigen - Oral Fluid	1934	14 July 2021	8 Sept 2021, 23:59 CET
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd	Wantai SARS-CoV-2 Ag Rapid Test (FIA)	1484	20 Oct 2021	15 Dec 2021, 23:59 CET
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	2103	10 Nov 2021	5 Jan 2022, 23:59 CET
Atlas Link Technology Co. Ltd.	NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	2010	8 Dec 2021	2 Feb 2022, 23:59 CET
DIALAB GmbH	DIAQUICK COVID -19 Ag Cassette	1375	8 Dec 2021	2 Feb 2022, 23:59 CET
Azure Biotech, Inc.	COVID-19 Antigen Rapid Test Device	1906	21 Dec 2021	15 Feb 2022, 23:59 CET

### **Rapid antigen tests rejected for inclusion**

The following rapid antigen tests – **applications submitted until ~~25 February~~ 1 April 2022** - were rejected for inclusion in the EU common list as the information and data provided submitted by manufacturers was incomplete, could not be confirmed by the experts of the HSC technical working group on COVID-19 diagnostic tests, was not in line with practical use of the tests in EU Member States, and/or did not meet the criteria as established by Council Recommendation 2021/C 24/01 and/or the further criteria agreed by the experts participating in the technical working group on COVID-19 diagnostic tests on 21 September 2021:

<b>MANUFACTURER</b>	<b>COMMERCIAL NAME RAPID ANTIGEN TEST</b>	<b>DEVICE ID</b>	<b>DATE(S) OF REJECTION</b>
<u>AAZ-LMB</u>	<u>COVID-VIRO ALL IN</u>	<u>3037</u>	<u>[TBC]</u>
Absology Co., Ltd.	Absoludy COVID-19 Ag	1982	10 Nov 2021
AccuBioTech Co.,Ltd	Accu-Tell COVID-19 Antigen Cassette (Nasal Swab)	2578	20 Oct 2021
ACON Biotech (Hangzhou) Co., Ltd.	FIAflex SARS-CoV-2 Antigen FIA	1669	4 March 2022
ACRO Biotech Inc.	COVID-19 Antigen Rapid Test	1688	6 July 2021

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
			20 July 2021
ACRO Biotech Inc.	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	2267	20 Oct 2021 21 Jan 2022
ACRO Biotech Inc.	SARS-CoV-2 Antigen Rapid Test (Swab)	1948	6 July 2021
Amazing Biotech (Shanghai) Co.,LTD.	COVID-19 Antigen Sealing tube test strip(Colloidal Gold)	2075	15 June 2021 13 July 2021 20 Oct 2021 10 Nov 2021 [TBC]
AMPER INC	AMPER COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)	2936	4 March 2022
Anhui Formaster Biosci Co., Ltd.	New Coronavirus (COVID-19) Antigen Rapid Test (saliva)	2480	20 Oct 2021
Assure Tech. (Hangzhou) Co., Ltd	COVID-19 Antigen Saliva Test Kit	2037	20 July 2021
Assure Tech. (Hangzhou) Co., Ltd.	COVID-19 Antigen Rapid Test Device	2270	10 Nov 2021 4 March 2022
Assure Tech. (Hangzhou) Co., Ltd.	ECOTEST COVID-19 Antigen Nasal Test Kit	2277	20 July 2021 20 Oct 2021 21 Dec 2021 21 Jan 2022 8 April 2022 [TBC]
ASSUT EUROPE SPA	SARS-CoV-2 Antigen Rapid Swab	2248	20 July 2021
Asterion Otel İnşaat Bilişim Medikal Maden Tic.Ltd.Şti.	As-check	2454	10 Feb 2022
Atlas Link Technology Co. Ltd.	NOVA Test @ SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gld Immunochromatography)	2010	8 Dec 2021 4 March 2022
<u>AUTOBIO DIAGNOSTICS., LTD.</u>	<u>SARS-CoV-2 Ag Rapid Test</u>	<u>2538</u>	[TBC]
Avacta Life Sciences Ltd	AffIDX SARS-CoV-2 Antigen Lateral Flow Test	2426	10 Feb 2022
Azure Biotech Inc.	Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	2060	6 July 2021
Baicare (Tianjin) Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test	2602	8 Dec 2021
Bakter Medical s.r.o.	Saligen – Rapid Antigen Saliva Test	1782	6 July 2021
Beijing Applied Biological Technologies Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	2839	8 April 2022 [TBC]
Beijing Beier Bioengineering Co., Ltd.	Covid-19 Antigen Rapid Test Kit	2769	21 Jan 2022
Beijing Beier Bioengineering Co., Ltd.	Covid-19 Antigen Schnelltest	1310	6 July 2021 13 July 2021
Beijing Diagreat Biotechnologies Co., Ltd	2019-nCoV Antigen Rapid Test Kit (colloidal gold assay)	1283	20 July 2021 20 Oct 2021 21 Dec 2021
Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) - Saliva	1798	6 July 2021
Beijing Hotgen Biotech Co., Ltd.	SARS-CoV-2 and Flu A/B Antigen Combo Rapid Test (Colloidal Gold)	2810	21 Jan 2022
BEIJING NORTH INSTITUTE OF BIOTECHNOLOGY CO.LTD	COVID-19 TEST RAPIDO ANTIGENE RICOV4	2733	21 Dec 2021 [TBC]
Beijing Tigsun Diagnostics	Tigsun Covid-19 Antigen Rapid Test	1292	21 Jan 2022

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Co.;Ltd.			
Beijing Tigsun Diagnostics Co.;Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	1290	6 July 2021
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd	Wantai SARS-CoV-2 Ag Rapid Test (FIA)	1484	20 Oct 2021 21 Jan 2022
Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	2841	8 April 2022
Bioantibody Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Detection Kit (Latex Chromatography)	2704	8 April 2022
BioDetect (Xiamen) Biotechnology Co., Ltd	RAPID SARS-COV-2 ANTIGEN TEST CARD	2902	8 April 2022
BioMaxima SA	COVID-19 Antigen Rapid Test	2036	15 June 2021
Biopanda Reagents Ltd	COVID-19 Rapid Antigen Test	2034	10 Nov 2021
BioSpeedia International	BioSpeedia COVID19 Nasal Antigen Test BSD_0506	2381	10 Nov 2021
BioSpeedia International	BioSpeedia COVID19 Non-Invasive Antigen Test BSD_0504	2379	10 Nov 2021
BIOSYNEX S.A.	BIOSYNEX COVITOP	2947	8 April 2022
Blue Cross Bio-Medical (Beijing) Co., Ltd	COVID-19 Antigen Test	2627	8 April 2022
BN SANTE	Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	1828	20 July 2021
Boditech Med Inc	Ichroma COVID-19 Ag	1990	13 July 2021 20 July 2021
Camp Medica Distribution	See Now Coronavirus nCoV Antigen test	1999	13 July 2021
Canary Global Inc	Pelican COVID-19 Ultra-Rapid Mobile Test	2283	20 July 2021
Changzhou Biowin Pharmaceutical Co., Ltd.	Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	2871	10 Feb 2022
<del>Changzhou Biowin Pharmaceutical Co.,Ltd.</del>	<del>Novel Coronavirus(COVID-19) Antigen Test Kit (Colloidal Gold)</del>	<del>2588</del>	<del>20-Oct-2021 10-Feb-2022</del>
Changzhou Biowin Pharmaceutical Co.,Ltd.	Novel Coronavirus(COVID-19) Antigen Test Kit (Colloidal Gold)	2641	10 Nov 2021
Chongqing iSIA Biotechnology Co. Ltd	Covid-19 Antigen Rapid Test Kit (Swab)	1937	15 June 2021
Chongqing Novegent Biotech Company Limited, China	Novegent COVID-19 Antigen Rapid Test Kit	1189	6 July 2021 20 July 2021
Citest Diagnostics Inc.	COVID-19 Antigen Rapid Test	2300	13 July 2021
CITEST Diagnostics Inc.	COVID-19 Antigen Rapid Test (Nasal Swab)	2449	20 Oct 2021 8 Dec 2021
Coris BioConcept	Covdi-19 Ag K-Set	2648	10 Nov 2021 21 Jan 2022
Cypress Diagnostics	COVID-19 Ag Rapid Test	2499	20 Oct 2021 21 Dec 2021
DDS DIAGNOSTIC	Test Rapid Combo Covid-19/Influenza A+B Antigen (tampon nazofaringian))	1226	10 Nov 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	SARS-CoV-2 Antigen	2457	10 Nov 2021
Diacarta Inc	QuantiVirus SARS-CoV-2 Antigen Rapid Test	3001	8 April 2022
<del>DIALAB GmbH</del>	<del>DIAQUICK COVID-19 Ag Cassette</del>	<del>1375</del>	<del>8-Dec-2021 4-March-2022 8-April-2022</del>
Diasia Biomedical Technology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	1986	15 June 2021

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
DIASource	COVID-19 Antigen Rapid Test	1792	6 July 2021
DS Bio and Nano Technology Product Tracking Verification Corp.	DS AntijenX	2551	21 Jan 2022
EMBIO Diagnostics LTD	CovBELD	1313	21 Jan 2022
EON Biotechnology Limited	EONBT COVID-19 Antigen	2032	6 July 2021
EON Biotechnology Limited	EONBT COVID-19 Antigen-Saliva	2161	6 July 2021
fago medikal san. tic. ltd. ti.	FAMEX SARS-CoV-2 AG KIT RAPIDO NASOPHARTNGEAL TEST	2173	8 Dec 2021
fameditec GmbH	CORA CHECK-19	1744	20 Oct 2021 21 Jan 2022
fameditec GmbH	CORA-CHECK-19-comfort	1781	6 July 2021 20 Oct 2021
FUJIFILM Corporation, Japan	FUJIFILM COVID-19 Ag Test	2428	20 Oct 2021
Gaobeidian PRISES Biotechnology Co., Ltd.	SAR-COV-2 Antigen Tes	2781	21 Jan 2022
GenBody Inc	Genbody COVID-19 Ag Test	1244	20 Oct 2021 21 Jan 2022
<a href="#">Genesprint Group Limited</a>	<a href="#">SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)</a>	<a href="#">1595</a>	<a href="#">[TBC]</a>
Genomica Sau	qCOVID-19	185	23 June 2021
Glallergen Co. LTD	Novel Coronavirus (2019-nCov) Antigen Test Kit (Colloidal gold immunochromatography) Nasal	2800	21 Jan 2022 8 April 2022 <a href="#">[TBC]</a>
Guangzhou Decheng Biotechnology Co., Ltd	2019-nCoV Rapid Antigen Test	2468	20 Oct 2021
Guangzhou Decheng Biotechnology Co., Ltd	V-CHEK 2019-nCoV Ag Rapid Test Kit	1316	6 July 2021
Guangzhou Decheng Biotechnology Co., Ltd	V-CHEK, 2019-nCoV Ag Rapid Test Card (Immunochromatography)	1883	6 July 2021 20 Oct 2021
Guangzhou Decheng Biotechnology Co., Ltd	V-CHEK, 2019-nCoV Ag Rapid Test Kit (Fluorescence Immunochromatographic Assay)	1326	6 July 2021
Guangzhou Wondfo Biotech Co. Ltd	Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	1312	6 July 2021 8 April 2022
<a href="#">Hangzhou Aichek Medical Technology Co., Ltd.</a>	<a href="#">COVID-19 Antigen Rapid Test Device</a>	<a href="#">3005</a>	<a href="#">[TBC]</a>
Hangzhou AllTest Biotech Co., Ltd	COVID-19 Antigen Rapid Test (Oral Fluid)	1947	15 June 2021
Hangzhou AllTest Biotech Co., Ltd	COVID-19 Antigen Rapid Test (Oral Fluid) SELFTESTING	2159	15 June 2021 23 June 2021
<a href="#">Hangzhou AllTest Biotech Co., Ltd</a>	<a href="#">GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP Swab)</a>	<a href="#">2319</a>	<a href="#">20 Oct 2021</a> <a href="#">8 April 2022</a>
Hangzhou AllTest Biotech Co., Ltd	SARS-COV-2 rapid antigen test (Swab)	1946	15 June 2021
Hangzhou Biotest Biotech Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)	1868	13 July 2021 10 Feb 2022
Hangzhou Clongene Biotech Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Saliva)	1746	13 July 2021
Hangzhou GENESIS Biodetection and Biocontrol CO.,LTD	KaiBiLi COVID-19 Antigen	2085	15 June 2021 20 July 2021 8 Dec 2021
Hangzhou Realy Tech Co., Ltd	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	1220	6 July 2021 20 July 2021
<a href="#">Hangzhou Realy Tech Co., Ltd</a>	<a href="#">Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)</a>	<a href="#">2018</a>	<a href="#">6 July 2021</a>

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Hangzhou Sejoy Electronics & Instruments Co.Ltd	SARS-CoV-2 Antigen Rapid Test Cassette	2671	21 Dec 2021
Hangzhou Singclean Medical Products Co., Ltd.	COVID-19 Test Kit (Colloidal Gold Method)	2210	20 Oct 2021 8 April 2022
Hangzhou Singclean Medical Products Co., Ltd.	COVID-19 Test Kit (Colloidal Gold Method) (Nasal Swab)	2609	10 Nov 2021 10 Feb 2022 8 April 2022
Hoyotek Biomedical Co.,Ltd	Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)	1931	10 Nov 2021
ImmunoDiagnostics Limited	COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography)	2265	20 Oct 2021
<del>Immunospark s.r.l.</del>	<del>Rapid SARS-Cov2 Antigen Test</del>	<del>1794</del>	<del>20 Oct 2021 10 Feb 2022 8 April 2022</del>
innovative diagnostics	iD Rapid® COVID-19 Antigen	1728	10 Nov 2021
INNOVITA (Tangshan) Biological Technology Co., Ltd.	2019-nCoV Ag Test (Latex Chromatography Assay)	1994	20 Oct 2021 10 Feb 2022
INNOVITA (Tangshan) Biological Technology Co., Ltd.	2019-nCoV Ag Test (Latex Chromatography Assay) (Anterior Nasal Swab)	2910	8 April 2022
iXensor Co., Ltd.	PixoTest® POCT COVID-19 Antigen Test	2217	20 July 2021
Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	2066	8 Dec 2021
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.	SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)-Nasal	2658	8 Dec 2021
<del>Jiangsu Macro &amp; Micro-Test Med-Tech Co., Ltd.</del>	<del>SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)-nasal</del>	<del>2907</del>	<del>4 March 2022</del>
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.	SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)-Nasopharyngeal	2887	8 April 2022
Jiangsu Mole Bioscience CO., LTD	SARS-CoV-2 Antigen Test Cassette (Nasal Swab Specimen)	1644	20 July 2021
Joinstar Biomedical Technology Co., Ltd	COVID-19 Antigen Rapid Test (Latex)	1205	10 Nov 2021
<del>JSC " LT Biotech"</del>	<del>COVID19AgLTFLOW</del>	<del>2094</del>	<del>[TBC]</del>
Koch Biotechnology (Beijing) Co., Ltd	COVID-19 Antigen Rapid Test Kit	2038	15 June 2021 20 July 2021
Laipac Technology Inc.	Look SPOT	1667	13 July 2021 10 Feb 2022
<del>Lansion Biotechnology Co., Ltd.</del>	<del>COVID-19 Antigen Test Kit(Dry Color Latex Immunoassay)</del>	<del>2818</del>	<del>[TBC]</del>
Lomina Superbio, a.s.	Lomina SARS-CoV-2 Antigen LTX test	2560	21 Dec 2021 8 April 2022
LumiraDx UK Ltd	LumiraDx SARS-COV-2 Antigen Pool Test	2342	20 Oct 2021
Macrogen, Inc.	Axen™ COVID-19 Ag RAPID	2125	4 March 2022
MED TRUST Handelsges.m.b.H.	Wellion SARS-CoV-2 PLUS ANTIGEN Rapid Test	2162	20 July 2021 20 Oct 2021
MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD	SARS-CoV-2 Antigen (GICA)	1711	8 Dec 2021
MEDICE Arzneimittel Pütter GmbH & Co. KG	Medicovid-AG SARS-CoV-2 Antigen Schnelltest-Nase	2526	20 Oct 2021
Medice Arzneimittel Pütter GmbH & Co. KG	Medicovid-AG SARS-CoV-2 Antigen Selbsttest-Nase	2318	20 Oct 2021

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<b>MANUFACTURER</b>	<b>COMMERCIAL NAME RAPID ANTIGEN TEST</b>	<b>DEVICE ID</b>	<b>DATE(S) OF REJECTION</b>
Medifood Hungary Innovation Kft.	MediDia COVID-19 Ag	2973	8 April 2022
Meril Diagnostics Pvt Ltd	MERISCREEN COVID-19 Antigen Detection Test	2582	20 Oct 2021 8 April 2022
Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette (saliva)	2030	20 Oct 2021
MiCo Biomed Co., Ltd.	VERI-Q COVID-19 Ag Rapid Test	2792	10 Feb 2022 4 March 2022
Monlab	Sars- cov2 Monlabtest	1961	20 July 2021
Monocent, Inc.	Monocent SARS-CoV2 Antigen Rapid Test	1320	15 June 2021
Multi-G	Covid19Check-GEN	2258	10 Nov 2021
Mylab Discovery Solutions Pvt. Ltd.	PathoCatch	2320	20 July 2021
nal von minden GmbH	dedicio® COVID-19 Ag pro Test	2373	20 Oct 2021 21 Dec 2021 21 Jan 2022
Nanjing Liming Bio-Products Co., Ltd	COVID-19 Antigen Rapid Test Device	263	20 July 2021
Nanjing Vazyme Medical Technology Co., Ltd.	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	1849	15 June 2021 6 July 2021 20 Oct 2021 21 Jan 2022 4 March 2022 8 April 2022
Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Saliva Test Kit (Colloidal Gold)	1617	6 July 2021 20 Oct 2021
NDFOS Co., Ltd.	ND COVID-19 Ag Test	2678	21 Dec 2021
NG Biotech	NG Test SARS CoV 2 Ag	1646	20 July 2021 20 Oct 2021 21 Jan 2022 8 April 2022
NOVATECH TIBBİ CİHAZ URUNLERİ SANAYİ VE TİCARET A.Ş.	SARS CoV-2 Antigen Rapid Test	2157	20 July 2021 8 April 2022
OSANG Healthcare Co., Ltd	GeneFinder COVID-19 Ag Rapid Test	1593	6 July 2021 20 July 2021
Philosys ., Co Ltd	SoluM COVID-19 Ag	2830	10 Feb 2022
Pierenkemper GmbH	(SARS-CoV-2) Antigen Rapid Test COVIDENT COVID-19	2197	20 Oct 2021 21 Dec 2021
Polonord Adeste Srl	POLOFLUOR 2	2583	10 Nov 2021
Precision Biosensor	PBCheck COVID-19 Ag	2467	20 Oct 2021
PREMIER MEDICAL CORPORATION PRIVATE LIMITED	SURE STATUS COVID-19 ANTIGEN CARD TEST	2299	20 July 2021
Prestige Diagnostics UK Ltd	2019-nCoV Antigen Device (Anterior Nasal Swab)	2570	20 Oct 2021
PRIMA Lab SA	COVID-19 Antigen Rapid Test	1797	20 July 2021
Procomcure	SARS-CoV-2 Antigen Test Kit	2080	20 July 2021
Pro-med (Beijing) Technology Co., Ltd.	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold)	2636	8 Dec 2021 4 March 2022
Pro-med (Beijing) Technology Co., Ltd.	COVID-19 Antigen Rapid Detection Kit (Colloidal Gold)	2482	20 Oct 2021
Pro-med (Beijing) Technology Co., Ltd.	COVID-19 IgM/IgG Antibody Rapid Detection Kit (Colloidal Gold)	2486	20 Oct 2021
Pro-med (Beijing) Technology Co., Ltd.	COVID-19 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold)	2485	20 Oct 2021
PZ CORMAY S.A.	Cormay Rapid SARS-CoV-2	1810	6 July 2021

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
	ANTIGEN Test Kit		
Quidel	QuickVue SARS Antigen Test	2269	20 Oct 2021
RapiGEN Inc	BIOCREDIT COVID-19 Ag Test Nasal	1963	10 Nov 2021
Rapigen Inc.	BIOCREDIT COVID-19 Ag - SARS-CoV 2 Antigen test	1606	10 Nov 2021
R-Biopharm AG	RIDA@QUICK SARS-CoV-2 Antigen	1846	6 July 2021
<a href="#">Response Biomedical Corp.</a>	<a href="#">RAMP COVID-19 Antigen Test</a>	<a href="#">2095</a>	<a href="#">[TBC]</a>
Safecare Biotech (Hangzhou) Co. Ltd	COVID-19 Antigen Rapid Test Kit (Saliva)	1819	20 July 2021
Salofa OY	Salocor SARS-CoV-2 Antigen Rapid Test Cassette	2129	6 July 2021 10 Feb 2022
Salofa OY	SIENNA Covid-19 Antigen Rapid Test	2127	8 Dec 2021
Sansure Biotech Inc.	SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay)	2366	20 Oct 2021 4 March 2022
SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)	SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)	2585	21 Dec 2021 10 Feb 2022 4 March 2022
Savyon Diagnostics Ltd.	Savvycheck SARS-CoV-2 Ag	2683	8 Dec 2021 <a href="#">[TBC]</a>
SCREEN ITALIA S.R.L.	SCREEN TEST COVID-19 AG - COVID-19 ANTIGEN RAPID TEST	1681	20 July 2021
Senova Gesellschaft für Biowissenschaft und Technik mbH	Senova Greenlight	1818	8 Dec 2021
SG Diagnostics	SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based)	2003	6 July 2021 20 July 2021 20 Oct 2021
SG Diagnostics Pte Ltd	SG Diagnostics COVID-19 and Influenza A/B Rapid Test Kit	2564	10 Nov 2021
Shandong ThinkLab Biotechnology Co.,Ltd., China	Coronavirus Ag Rapid Test Cassette (Swab)	2154	20 July 2021
Shanghai Liangrun Biomedicine Technology Co.,Ltd.	LionRun TM SARS-CoV-2 Antigen Rapid Test (Lateral Flow Immunoassay)	2155	20 Oct 2021
Shen Zhen Zi Jian Biotechnology Co., Ltd.	SARS-CoV-2 (COVID-19) Antigen Rapid Detection Kit (Lateral Flow Method)	2491	20 Oct 2021 10 Nov 2021 21 Dec 2021
Shenzhen Aivd Biotechnology Co.,LTD	SARS-CoV-2 Antigen Detection Kit (Latex Lateral Flow Assay)	2834	10 Feb 2022 8 April 2022 <a href="#">[TBC]</a>
Shenzhen Kang Sheng Bao Bio-Technology Co.,Ltd.	SARS-CoV-2 Antigen Rapid Test (Lateral Flow Assay)	2166	20 July 2021
Shenzhen Lvshiyuan Biotechnology Co.,Ltd	SARS-CoV-2 Antigen Rapid Test Kit (Immunofluorescence Assay)	2989	8 April 2022
Shenzhen Microprofit Biotech Co., Ltd	SARS-CoV-2 Antigen Test Kit (Fluorescence Immunoassay)	1968	15 June 2021 21 Dec 2021
Shenzhen Microprofit Biotech Co., Ltd.	SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)	2231	10 Nov 2021
Shenzhen Microprofit Biotech Co., Ltd.	SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	2501	8 Dec 2021
Shenzhen YHLO Biotech Co., Ltd.	GLINE-2019-nCoV Ag Saliva	1893	20 July 2021
Shenzhen YHLO Biotech Co., Ltd.	UNICELL-2019-nCoV Ag	1170	20 July 2021
Shijiazhuang Hipro	SARS-COV-2 ANTIGEN TEST KIT	2546	20 Oct 2021



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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Biotechnology Co., Ltd	(COLLOIDAL GOLD)		
Sichuan Xincheng Biological Co.,LTD	SARS-Cov-2 Antigen Assay kit by Immunofluorescence Chromatography method	1659	8 April 2022
Spartacus-Biomed	COVID-19 Antigen Rapid Test	2185	20 Oct 2021 10 Feb 2022
SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ LTD. ŞTİ.	Covid-19 Antijen Hızlı Test Kaseti	2246	20 Oct 2021
Spring Healthcare Services AG	SARS-Cov-2 Antigen Rapid Test Cassette (swab)	1780	13 July 2021
STARK S.A.R.L	Stark Portable COVID-19 Antigen Lab	2554	20 Oct 2021
<del>TaiDec Technology Corporation</del>	<del>VTRUST COVID-19 Antigen Rapid Test TD-4531</del>	<del>4096</del>	<del>8 April 2022</del>
TBG BIOTECHNOLOGY XIAMEN INC.	SARS-CoV-2 Antigen Rapid Test	1338	21 Jan 2022
Tody Laboratories Int.	Coronavirus (SARS-CoV 2) Antigen - Swab Specimen	1935	20 July 2021
ulti med Products (Deutschland) GmbH	COVID-19 Antigen Speicheltest (Immunochromatographie)	1641	13 July 2021
Unioninvest Ltd	COVID-19 ANTIGEN RAPID TEST NASAL	2249	20 July 2021
<del>VEDALAB</del>	<del>COVID-19-CHECK-1 Antigen</del>	<del>4956</del>	<del>20-Oct-2021</del> <del>8-April-2022</del>
Vision Biyoteknoloji Ar-Ge Lab Sist. San. Ve Tic. LTD. ŞTİ	VISION® SARS-COV-2 AG RAPID NASOPHARYNGEAL TEST KIT	2835	21 Dec 2021 10 Feb 2022
VITASSAY HEALTHCARE SL	Vitassay SARS-CoV-2	2268	8 April 2022
VITASSAY HEALTHCARE SL	Vitassay SARS-CoV-2+Influenza A+B+RSV+Adenovirus Resp.	2272	8 April 2022
Vitrosens Biyoteknoloji Ltd. Sti	RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	2180	20 July 2021
<del>VivaChek Biotech (Hangzhou) Co., Ltd</del>	<del>SARS-CoV-2 Ag Rapid Test</del>	<del>2444</del>	<del>21 Jan 2022</del>
VivaChek Biotech (Hangzhou) Co., Ltd	SARS-CoV-2&Flu A& Flu B Ag Rapid Test	2119	13 July 2021
VivaChek Biotech (Hangzhou) Co., Ltd	Vivadiag SARS CoV 2 Ag Rapid Test	1246	15 June 2021 20 July 2021 21 Dec 2021
VivaChek Biotech (Hangzhou) Co., Ltd	VivaDiag SARS-CoV-2 Ag FIA Test	2105	13 July 2021
VivaChek Biotech (Hangzhou) Co., Ltd	VivaDiag SARS-CoV-2 Ag Saliva Rapid Test	1980	15 June 2021
VivaChek Biotech (Hangzhou) Co., Ltd, China	VivaDiag SARS-CoV-2 Ag Rapid Test	2102	20 Oct 2021
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	2103	10 Nov 2021 21 Dec 2021 10 Feb 2022
<del>VivaChek Biotech (Hangzhou) Co., Ltd.</del>	<del>VivaDiag Pro SARS-CoV-2 Ag</del>	<del>2768</del>	<del>[TBC]</del>
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag Wellion SARS-CoV-2 Antigen Rapid Test	2163	20 July 2021 20 Oct 2021
<del>Weihai Dishang Medical Technology Co., Ltd</del>	<del>SARS-CoV-2 Antigen Test Kit (LFIA)</del>	<del>2804</del>	<del>[TBC]</del>
WEIHAI KANGZHOU BIOTECHNOLOGY ENGINEERING CO., LTD.	COVID-19 Antigen Rapid Test	2688	21 Dec 2021

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Wenzhou OJA Biotechnology Co.,Ltd	SARS CoV-2 Antigen Detection Kit (Colloidal Gold Method)	1575	15 June 2021 13 July 2021
Willi Fox GmbH	Willi Fox COVID-19 Antigen rapid test	1276	20 July 2021
WIZCHEM CO., LTD	COVICHEK COVID-19 Ag KIT	2661	8 Dec 2021
Wuhan Healthcare Biotech CO. LTD	SARS CoV 2 Antigen Test Kit (Colloidal Gold)	2444	20 Oct 2021 10 Nov 2021
Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	1600	6 July 2021
Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal gold Immunoassay)	1655	20 Oct 2021
<del>Xiamen Jiqing Biomedical Technology Co.,Ltd</del>	<del>SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method)</del>	<del>4588</del>	<del>40 Feb 2022</del>
ZEKMED Ltd.	ZEKMED LUNA Ag Antigen Rapid Test Kit	2842	10 Feb 2022
Zephyr Biomedicals - Tulip Diagnostics	PerkinElmer COVID 19 Antigen Test (NS, NP)	2687	8 April 2022
Zet Medikal Tekstil Dis Ticaret Ltd. STI. / SANSURE BIOTECH	softec SARS COV-2 (Covid-19) Antigen Test Kit	2226	13 July 2021 10 Feb 2022
Zhejiang Anji Saianfu Biotech Co.,Ltd.	Seinofy COVID-19 Antigen Rapid Test	2223	20 July 2021
Zhejiang GENE SCIENCE Co., Ltd	Novel Coronavirus (COVID-19) Antigen Detection Kit (Latex Immunochromatography )	2557	20 Oct 2021 4 March 2022
Zhejiang Hongyu Medical Commodity Co.,Ltd	SARS-CoV-2 Ag Rapid Test Kit	2309	20 Oct 2021 21 Jan 2022

**Rapid antigen tests under discussion**

The following rapid antigen tests – **applications submitted until 25 February 1 April 2022** - require further discussion by the HSC technical working group on COVID-19 diagnostic tests and will be considered for inclusion during the next update of the EU common list of COVID-19 rapid antigen tests:

MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF EARLIER REJECTIONS
<u>Avioq Bio-tech Co., Ltd.</u>	<u>Novel Coronavirus (SARS-CoV-2) Antigen Detection Kit(Colloidal Gold)</u>	<u>1972</u>	
<u>Beijing North Institute of Biotechnology Co.,Ltd</u>	<u>COVID-19 Antigen Rapid Test</u>	<u>3009</u>	
<u>Beijing Unidiag Technology Inc</u>	<u>Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit(Colloidal Gold)</u>	<u>3033</u>	
<u>Bioantibody Biotechnology Co., Ltd.</u>	<u>SARS-CoV-2 Antigen Rapid Detection Kit</u>	<u>3079</u>	
<u>Biobase Diagnostic Technology (Shandong) Co., Ltd.</u>	<u>BIOBASE COVID-19 Antigen Rapid Test</u>	<u>3071</u>	
<u>Bioscience (Tianjin) Diagnostic Technology Co.,Ltd</u>	<u>Novel Coronavirus (2019-nCoV) Antigen Rapid Detection</u>	<u>2858</u>	
Boditech Med Inc	AFIAS COVID-19/Flu Ag Combo	1449	21 Jan 2022
<u>Changzhou Biowin Pharmaceutical Co.,Ltd.</u>	<u>Novel Coronavirus(COVID-19) Antigen Test Kit (Colloidal Gold)</u>	<u>2588</u>	<u>20 Oct 2021</u> <u>10 Feb 2022</u>
<u>Core Technology Co., Ltd.</u>	<u>Coretests® COVID-19 Ag Test</u>	<u>3025</u>	

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<b>MANUFACTURER</b>	<b>COMMERCIAL NAME RAPID ANTIGEN TEST</b>	<b>DEVICE ID</b>	<b>DATE(S) OF EARLIER REJECTIONS</b>
<a href="#"><u>DIALAB GmbH</u></a>	<a href="#"><u>DIAQUICK COVID -19 Ag Cassette</u></a>	<a href="#"><u>1375</u></a>	<a href="#"><u>8 Dec 2021</u></a> <a href="#"><u>4 March 2022</u></a> <a href="#"><u>8 April 2022</u></a>
<a href="#"><u>Hangzhou AllTest Biotech Co., Ltd</u></a>	<a href="#"><u>GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP Swab)</u></a>	<a href="#"><u>2319</u></a>	<a href="#"><u>20 Oct 2021</u></a> <a href="#"><u>8 April 2022</u></a>
Hangzhou GENESIS Biodetection and Biocontrol CO.,LTD	KaiBiLi COVID-19 Antigen Pro	2885	
<a href="#"><u>Hangzhou Realy Tech Co., Ltd</u></a>	<a href="#"><u>Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)</u></a>	<a href="#"><u>2018</u></a>	<a href="#"><u>6 July 2021</u></a>
<a href="#"><u>Hangzhou Sejoy Electronics &amp; Instruments Co.,Ltd.</u></a>	<a href="#"><u>SARS-CoV-2 Antigen Rapid Test Cassette (nasal, nasopharyngeal, oropharyngeal, saliva)</u></a>	<a href="#"><u>1952</u></a>	
<a href="#"><u>Hangzhou Zheda Dixun Biological Gene Engineering Co., Ltd.</u></a>	<a href="#"><u>SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Test Cassette (Swab)</u></a>	<a href="#"><u>2942</u></a>	
<a href="#"><u>Jiangsu Macro &amp; Micro-Test Med-Tech Co., Ltd.</u></a>	<a href="#"><u>SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)-nasal</u></a>	<a href="#"><u>2907</u></a>	<a href="#"><u>4 March 2022</u></a>
JSC "LT-Biotech"	COVID19AgLTFLOW	2094	
Lifecosm Biotech Limited	Lifecosm™ COVID-19 Antigen Rapid Test Cassette	2866	<a href="#"><u>10 Feb 2022</u></a>
<a href="#"><u>Shanghai Chemtron Biotech Co.,Ltd.</u></a>	<a href="#"><u>Chemtrue® COVID-19 (SARS-CoV-2) Antigen Rapid Test Kit (Nasal Swab)</u></a>	<a href="#"><u>2512</u></a>	
<a href="#"><u>Shenzhen Uni-medica Technology Co. Ltd</u></a>	<a href="#"><u>SARS-CoV-2 Antigen Test Kit (Colloidal Gold)</u></a>	<a href="#"><u>2999</u></a>	
<a href="#"><u>TaiDoc Technology Corporation</u></a>	<a href="#"><u>VTRUST COVID-19 Antigen Rapid Test TD-4531</u></a>	<a href="#"><u>1096</u></a>	<a href="#"><u>8 April 2022</u></a>
<a href="#"><u>TargetingOne Technology (Beijing) Corporation</u></a>	<a href="#"><u>TARGETINGONE® SARS-CoV-2 Antigen Test</u></a>	<a href="#"><u>3066</u></a>	
<a href="#"><u>VEDALAB</u></a>	<a href="#"><u>COVID-19-CHECK-1 Antigen</u></a>	<a href="#"><u>1956</u></a>	<a href="#"><u>20 Oct 2021</u></a> <a href="#"><u>8 April 2022</u></a>
<a href="#"><u>VivaChek Biotech (Hangzhou) Co., Ltd</u></a>	<a href="#"><u>SARS-CoV-2 Ag Rapid Test</u></a>	<a href="#"><u>2111</u></a>	<a href="#"><u>21 Jan 2022</u></a>
<a href="#"><u>Xiamen Jiqing Biomedical Technology Co. Ltd</u></a>	<a href="#"><u>SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method)</u></a>	<a href="#"><u>1588</u></a>	<a href="#"><u>10 Feb 2022</u></a>

## **PART II: LAB-BASED ANTIGENIC ASSAYS**

### **Lab-based antigenic assays rejected for inclusion**

The following lab-based antigenic assays – **applications submitted until 25 February 1 April 2022** - were rejected for inclusion in the list of mutually recognised COVID-19 lab-based antigenic assays as the information and data provided submitted by manufacturers was incomplete, could not be confirmed by the experts of the HSC technical working group on COVID-19 diagnostic tests, was not in line with practical use of the tests in EU Member States, and/or did not meet the criteria as established by Council Recommendation 2021/C 24/01 and/or the additional criteria agreed by the experts participating in the technical working group on COVID-19 diagnostic tests on 21 September 2021:

<b>MANUFACTURER</b>	<b>COMMERCIAL NAME LAB-BASED ANTIGENIC ASSAY</b>	<b>DEVICE ID</b>	<b>DATE(S) OF REJECTION</b>
Bioneovan Co., Ltd	COVID-19 Antigen Test Kit (Colloidal Gold)	2077	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	ACE2-RBD Neutralization Assay	2462	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	COVID-19 IgA	2455	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	COVID-19 IgG	537	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	COVID-19 IgG Confirmation	539	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	COVID-19 IgG/IgM Confirmation and Typing	2461	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	COVID-19 IgM	538	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	COVID-19 RNA Vs 2	2460	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	COVID-19 Spike 1&2 IgG	2456	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	DIA.CHEMILUX SARS-CoV-2 ACE2-RBD NEUTRALIZATION	2479	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	DIA.CHEMILUX SARS-CoV-2 NCP IgA	2477	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	DIA.CHEMILUX SARS-CoV-2 NCP IgG	2463	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	DIA.CHEMILUX SARS-CoV-2 NCP IgM	2464	20 Oct 2021
Dia.Pro Diagnostic Bioprobes S.r.l.	DIA.CHEMILUX SARS-CoV-2 Spike/RBD Ab	2478	20 Oct 2021
Diasia Biomedical Technology Co., Ltd.,	Diagnostic Kit for SARS-CoV-2 Ag (Fluorescence Immunochromatographic Assay)	2096	21 Jan 2022
DIESSE Diagnostica Senese S.p.A.	CHORUS SARS-CoV-2 ANTIGEN	2708	10 Feb 2022
Lansion Biotechnology Co., Ltd.	COVID-19 Antigen Test Kit (Dry Fluorescence Immunoassay)	1648	20 July 2021 21 Jan 2022 10 Feb 2022
Multi.G bvba	Covid19Check-GEN	2258	20 Oct 2021
Multi-G bvba	Covid19Check-SAL	2261	20 Oct 2021
Plexense, Inc.	ACCEL ELISA COVID-19 Saliva	2378	20 Oct 2021

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MANUFACTURER	COMMERCIAL NAME LAB-BASED ANTIGENIC ASSAY	DEVICE ID	DATE(S) OF REJECTION
	Antigen Kit		
Shenzhen Huian Biosci Technology Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Colloidal Gold )	2414	20 Oct 2021
Siemens Healthineers	ADVIA Centaur XP/XPT SARS-COV2 Antigen (CoV2Ag)	2016	8 April 2022

**Lab-based antigenic assays under discussion**

The following lab-based antigenic assays – **applications submitted until 25 February 1 April 2022** - require further discussion by the HSC technical working group on COVID-19 diagnostic tests and will be considered for inclusion during the next update of the list of mutually recognised COVID-19 lab-based antigenic assays:

MANUFACTURER	COMMERCIAL NAME LAB-BASED ANTIGENIC ASSAY	DEVICE ID	DATE(S) OF REJECTION
<u>Absology Co., Ltd.</u>	<u>Absoludy COVID-19 Ag</u>	<u>1982</u>	
Siemens Healthineers	Atellica IM Sars-cov-2 Antigen (Cov2Ag)	2015	