



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health  
**Health Security**

## **- ADDENDUM -**

*To the EU Common list of COVID-19 antigen tests*

***This document provides further background information to the decisions taken by the HSC Technical Working Group in the context of the updates to the EU Common list of COVID-19 antigen tests, as agreed on 26 July 2023.***

*In addition to information put forward by EU Member States, the HSC technical working group reviewed proposals submitted by manufacturers until*  
***31 March 2023, 23:59 CET.***

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

**IMPORTANT:** Please note that following a decision of the Health Security Committee, the work of the technical working group on COVID-19 diagnostic tests has formally ended.

Manufacturers were able to submit applications for antigen devices to be included in the EU common list until **31 March 2023, 23:59 CET**. After this date, no new applications have been considered or assessed. The technical working group and its activities formally stopped on 30 June 2023, with the end of validity of the EU Digital COVID Certificate Regulation.

## **PART I: Devices removed from the EU Common list of COVID-19 antigen tests**

### ***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:

**Note: As of 2023, a grace period of 7 weeks applies whenever updates are made to the EU common list of COVID-19 rapid antigen tests.**

<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
Azure Biotech, Inc.	COVID-19 Antigen Rapid Test Device	1906	21 Dec 2021	15 Feb 2022, 23:59 CET
Core Technology Co., Ltd	Coretests COVID-19 Ag Test	1919	10 June 2022	8 July 2022, 23:59 CET
Hangzhou Immuno Biotech Co., Ltd	Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)	1844	10 June 2022	8 July 2022, 23:59 CET
Humasis	Humasis COVID-19 Ag Test	1263	10 June 2022	8 July 2022, 23:59 CET
JINAN BABIO BIOTECHNOLOGY CO., LTD., China	SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method)	2151	10 June 2022	8 July 2022, 23:59 CET
Nal von minden GmbH	NADAL COVID -19 Ag +Influenza A/B Test	2104	10 June 2022	8 July 2022, 23:59 CET
PCL Inc.	PCL COVID19 Ag Gold	2243	10 June 2022	8 July 2022, 23:59 CET
PCL Inc.	PCL COVID19 Ag Rapid FIA	308	10 June 2022	8 July 2022, 23:59 CET
Shenzhen Zhenrui Biotech Co., Ltd	Zhenrui @COVID-19 Antigen Test Cassette	1574	10 June 2022	8 July 2022, 23:59 CET
Beijing Hotgen Biotech Co., Ltd.	Coronavirus (2019-nCoV)-Antigentest	2807	14 October 2022	9 November 2022, 23:59 CET
Assure Tech. (Hangzhou) Co., Ltd.	COVID-19 & Influenza A/B Antigen Combo Test Device	1371	15 March 2023	3 May 2023, 23:59 CET
Assure Tech. (Hangzhou) Co., Ltd.	COVID-19 & Influenza A/B & RSV Antigen Nasal Test Kit	5803	15 March 2023	3 May 2023, 23:59 CET
Hangzhou AllTest Biotech Co., Ltd	SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test (Nasopharyngeal Swab)	2390	15 March 2023	3 May 2023, 23:59 CET
Hangzhou AllTest Biotech Co., Ltd	SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen	2392	15 March 2023	3 May 2023, 23:59 CET

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE OF REMOVAL	END OF GRACE PERIOD
	Combo Rapid Test (Nasopharyngeal Swab)			
Vitrosens Biotechnology Co., Ltd	RapidFor™ SARS-CoV-2 + FLU A/B + RSV Combo Test Kit	5804	15 March 2023	3 May 2023, 23:59 CET
Vitrosens Biotechnology Co., Ltd	RapidFor™ SARS-CoV-2 & FLU A/B Antigen Combo Test	4065	15 March 2023	3 May 2023, 23:59 CET

**PART II: Devices (or studies) rejected for inclusion in the EU common list of COVID-19 antigen tests**

**II.1) Rapid antigen tests not included in the EU common list**

The following rapid antigen tests – **applications submitted until 31 March 2023, 23:59 CET** - 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:

MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
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 20 July 2021
ACRO Biotech Inc.	SARS-CoV-2 Antigen Rapid Test (Swab)	1948	6 July 2021
Alphagen Bio-technology Co.,Ltd	SARS-CoV-2 Antigen Test Kit	3965	5 October 2022
Anbio (Xiamen) Biotechnology Co. Ltd.,	BOIRON TEST&CARE COVID-19 TEST RAPIDE ANTIGÉNIQUE	2239	31 Jan 2023
Anhui Bessie Biological Technology Co. , Ltd.	COVID- 19 Antigen Rapid Test Kit	4142	11 Nov 2022
Anhui Formaster Biosci Co., Ltd.	New Coronavirus (COVID-19) Antigen Rapid Test (saliva)	2480	20 Oct 2021
Aripa Biotec GmbH	Aripa® COVID-19-N-Antigen Rapid Test SARS-CoV-2 (anterior nasal swab)	2169	5 October 2022
Assure Tech (Hangzhou) Co. Ltd.	COVID-19& Influenza A/B& RSV Antigen Combo Rapid Test	5824	15 March 2023
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.	COVID-19 Antigen Rapid Test Device	24760	17 May 2023
ASSUT EUROPE SPA	SARS-CoV-2 Antigen Rapid Swab	2248	20 July 2021
Asterion Otel İnşaat Bilişim	As-check	2454	10 Feb 2022

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<b>MANUFACTURER</b>	<b>COMMERCIAL NAME RAPID ANTIGEN TEST</b>	<b>DEVICE ID</b>	<b>DATE(S) OF REJECTION</b>
Medikal Maden Tic.Ltd.Şti.			
Atlas Medical GmbH	Atlas COVID-19 Antigen (Nasal Swab) Test Cassette	2959	11 Nov 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 22 July 2022
Avacta Life Sciences Ltd	AffIDx SARS-CoV-2 Antigen Lateral Flow Test	2426	10 Feb 2022
Avioq Bio-tech Co., Ltd.	Novel Coronavirus (SARS-CoV-2) Antigen Detection Kit(Colloidal Gold)	1972	10 June 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 6 May 2022
Beijing Beier Bioengineering Co., Ltd.	Covid-19 Antigen Rapid Test Kit	2769	21 Jan 2022 10 June 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 Antigen Rapid Test	3009	10 June 2022
BEIJING NORTH INSTITUTE OF BIOTECHNOLOGY CO.LTD	COVID-19 TEST RAPIDO ANTIGENE RICOV4	2733	21 Dec 2021 6 May 2022
Beijing Strong Biotechnologies Inc.	SARS-CoV-2 Antigen Test	3083	5 October 2022
Beijing Strong Biotechnologies Inc.	SARS-CoV-2 Antigen Test	3722	11 Nov 2022
Beijing Tigsun Diagnostics Co.;Ltd.	Tigsun Covid-19 Antigen Rapid Test	1292	21 Jan 2022 5 October 2022
Beijing Tigsun Diagnostics Co.;Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	1290	6 July 2021
Beijing Unidiag Technology Inc	Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit(Colloidal Gold)	3033	10 June 2022 22 July 2022
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	3079	10 June 2022
Bioantibody Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Detection Kit (Latex Chromatography)	2704	8 April 2022
Biobase Diagnostic Technology (Shandong) Co., Ltd.	BIOBASE COVID-19 Antigen Rapid Test	3071	10 June 2022

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<b>MANUFACTURER</b>	<b>COMMERCIAL NAME RAPID ANTIGEN TEST</b>	<b>DEVICE ID</b>	<b>DATE(S) OF REJECTION</b>
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 5 October 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	AFIAS COVID-19/Flu Ag Combo	1449	21 Jan 2022 10 June 2022
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
Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sist. İnş.Müh.Dan.San.Tic.Ltd.Şti.	CheckUp COVID-INF A/B-RSV COMBO RAPID NASAL TEST KITv	5820	15 March 2023
Changzhou Biowin Pharmaceutical Co., Ltd.	Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	2871	10 Feb 2022
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 and Influenza A+B Antigen Combo Rapid Test (Nasopharyngeal Swab)	2437	17 May 2023
Citest Diagnostics Inc.	COVID-19 Antigen Rapid Test	2300	13 July 2021
Core Technology Co., Ltd.	Coretests® COVID-19 Ag Test	3025	10 June 2022
Core Technology Co., Ltd	Coretests COVID-19 Ag Test	1919	10 June 2022 9 Dec 2022 31 Jan 2023 17 May 2023
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 9 Dec 2022
Devidia GmbH	Dediatest 2019-nCoV Antigen Rapid Test	2190	14 Oct 2022
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
Diasia Biomedical	SARS-CoV-2 Antigen Rapid Test Kit	1986	15 June 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>
Technology Co., Ltd.			
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
Fosun Diagnostics (Shanghai) Co., Ltd.	Covid-19 Antigen CARD Kit	4055	11 Nov 2022
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 22 July 2022
Genesprint Group Limited	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	1595	6 May 2022
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 6 May 2022
GPPS Europe GmbH (authorised representative) Genius Pharmaceutical AG (manufacturer)	GENnow SARS-CoV-2 Antigen Rapid Test Cassette	3127	22 July 2022
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
HA TECH PTY LTD	SARS-CoV-2 Rapid Antigen Test Kit RAT-01	4160	11 Nov 2022
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
Hangzhou AllTest Biotech Co., Ltd	SARS-COV-2 rapid antigen test (Swab)	1946	15 June 2021
Hangzhou AllTest Biotech Co., Ltd	SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test (Nasopharyngeal Swab)	2396	15 March 2023
Hangzhou Biotest Biotech Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)	1868	13 July 2021 10 Feb 2022

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<b>MANUFACTURER</b>	<b>COMMERCIAL NAME RAPID ANTIGEN TEST</b>	<b>DEVICE ID</b>	<b>DATE(S) OF REJECTION</b>
Hangzhou Biotest Biotech Co., Ltd	COVID-19 + Flu A&B Antigen Combo Rapid Test Cassette(Nasal Swab)	4119	15 March 2023
Hangzhou Biotest Biotech Co., Ltd.	COVID-19 + Flu A&B + RSV Antigen Combo Rapid Test Cassette(Nasal Swab)	4120	15 March 2023
Hangzhou Biotest Biotech Co., Ltd.	COVID-19 + Flu A&B +RSV Antigen Combo Rapid Test Cassette(Nasal Swab/Nasopharyngeal Swab)	24752	17 May 2023
Hangzhou Biotest Biotech Co., Ltd.	COVID-19 + Flu A&B Antigen Combo Rapid Test Cassette(Nasal Swab/Nasopharyngeal Swab)	24751	17 May 2023
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 Device (nasal swab)	2018	6 July 2021 10 June 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
Hangzhou Tongzhou Biotechnology Co., Ltd	SARS-CoV-2 Antigen Test (Nasal swab)	4108	9 Dec 2022 17 May 2023
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
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)	2585	21 Dec 2021 10 Feb 2022 4 March 2022 5 October 2022
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.	SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)-Nasal	2658	8 Dec 2021
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.	SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)-Nasopharyngeal	2887	8 April 2022
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.	SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)-nasal	2907	4 March 2022 10 June 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
JSC " LT Biotech"	COVID19AgLTFLOW	2094	6 May 2022

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
LABORATOIRE SALEM	Précisio TEST COVID-19 ANTIGENE	3967	31 Jan 2023
Laipac Technology Inc.	Look SPOT	1667	13 July 2021 10 Feb 2022
Lansion Biotechnology Co., Ltd.	COVID-19 Antigen Test Kit(Dry Color Latex Immunoassay)	2818	6 May 2022
LumiraDx UK Ltd	LumiraDx SARS-COV-2 Antigen Pool Test	2342	20 Oct 2021
Maccura Biotechnology Co., Ltd.	Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2) Antigen Assay Kit by Colloidal Gold Method	1917	22 July 2022
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
MEDsan GmbH	MEDsan® SARS-CoV-2 Ag Duo	3111	11 Nov 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
Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Saliva Test Kit (Colloidal Gold)	1617	6 July 2021 20 Oct 2021
NINGBO LVTANG BIOTECHNOLOGY CO., LTD.	SARS-CoV-2 Antigen Detection Kit ( Colloidal Gold Method)	3137	22 July 2022
NOVATECH TİBBİ CİHAZ URUNLERİ SANAYİ VE TİCARET A.Ş.	SARS CoV-2 Antigen Rapid Test	2157	20 July 2021 8 April 2022
PHASE Scientific International Limited	China INDICAID COVID-19 Rapid Antigen Test Kit	3014	10 June 2022
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



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<b>MANUFACTURER</b>	<b>COMMERCIAL NAME RAPID ANTIGEN TEST</b>	<b>DEVICE ID</b>	<b>DATE(S) OF REJECTION</b>
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 ANTIGEN Test Kit	1810	6 July 2021
Quidel	QuickVue SARS Antigen Test	2269	20 Oct 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
Reach Diagnostic (Wuhan) Biotech Co., Ltd.	SARS-COV-2 Ag Rapid Test Cassette	3154	5 Oct 2022 11 Nov 2022 31 Jan 2023
Response Biomedical Corp.	RAMP COVID-19 Antigen Test	2095	6 May 2022
Roche (SD BIOSENSOR)	SARS-CoV-2 Rapid Antigen Test 2.0 Nasal	5839	17 May 2023
Roche (SD BIOSENSOR)	SARS-CoV-2 & Flu A/B Rapid Antigen Test	25547	17 May 2023
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
Savyon Diagnostics Ltd.	Savvycheck SARS-CoV-2 Ag	2683	8 Dec 2021 6 May 2022
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 Chemtron Biotech Co.,Ltd.	Chemtrue® COVID-19 (SARS-CoV-2) Antigen Rapid Test Kit (Nasal Swab)	2512	10 June 2022
Shanghai Liangrun Biomedicine Technology Co.,Ltd.	LionRun TM SARS-CoV-2 Antigen Rapid Test (Lateral Flow Immunoassay)	2155	20 Oct 2021
Shenzhen AIVD Biotech Inc.	COVID-19/ FluA/ FluB Antigen Combo Rapid Test Kit (Colloidal Gold Method)	3087	10 June 2022
Shenzhen Aivd Biotechnology Co.,LTD	SARS-CoV-2 Antigen Detection Kit (Latex Lateral Flow Assay)	2834	10 Feb 2022 8 April 2022 6 May 2022
Shenzhen Everbest Machinery Industry Co., Ltd.	COVID-19 Antigen Rapid Test	3125	5 Oct 2022 9 Dec 2022
Shenzhen Kang Sheng Bao	SARS-CoV-2 Antigen Rapid Test	2166	20 July 2021

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Bio-Technology Co.,Ltd.	(Lateral Flow Assay)		
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 & 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 New Industries Biomedical Engineering Co., Ltd.	RapiSafe SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	2978	22 July 2022
Shenzhen Superbio Technology Co.,Ltd.	2019-nCoV Antigen Rapid Test (Immunochromatography Assay)	3086	22 July 2022 9 Dec 2022
Shenzhen Uni-medica Technology Co. Ltd	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	2999	10 June 2022
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
SHENZHEN YHLO BIOTECH Co. Ltd.	GLINE-2019-nCoV Ag & Influenza A/B Ag Combo Rapid Test (Colloidal Gold Assay)	24753	17 May 2023
Shenzhen Zijian Biotechnology Co., Ltd.	SARS-CoV-2 (COVID-19) Antigen Rapid Detection Kit (Lateral Flow Method)	3104	22 July 2022
Shijiazhuang Hipro Biotechnology Co., Ltd	SARS-COV-2 ANTIGEN TEST KIT (COLLOIDAL GOLD)	2546	20 Oct 2021
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
TaiDoc Technology Corporation	VTRUST COVID-19 Antigen Rapid Test TD-4531	1096	8 April 2022 10 June 2022
TargetingOne Technology (Beijing) Corporation	TARGETINGONE® SARS-CoV-2 Antigen Test	3066	10 June 2022
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 and Influenza A+B Antigen Combo Rapid Test (Nasopharyngeal Swab)	1391	10 June 2022
ulti med Products (Deutschland) GmbH	COVID-19 Antigen Speicheltest (Immunochromatographie)	1641	13 July 2021
ulti med Products (Deutschland) GmbH	COVID-19 Antigen Test (Nasopharyngeal Swab)	1455	10 June 2022
Unioninvest Ltd	COVID-19 ANTIGEN RAPID TEST NASAL	2249	20 July 2021
VEDALAB	COVID-19-CHECK-1 Antigen	1956	20 Oct 2021 8 April 2022

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
			10 June 2022
Vision Biyoteknoloji Ar-Ge Lab Sist. San. Ve Tic. LTD. Şti	VISION® SARS-COV-2 AG RAPID NASOPHARYNGEAL TEST KIT	2835	21 Dec 2021 10 Feb 2022
Vision Biyoteknoloji Araştırma Geliştirme Laboratuvar Sistemleri Sanayi ve Ticaret Limited Şirketi	VISION COVID-19 RAPID ANTIGEN TEST KIT	2776	15 March 2023
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.Şti	RapidFor™ SARS-CoV-2+RSV Combo Test Kit	5810	15 March 2023
Vitrosens Biyoteknoloji Ltd. Sti	RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	2180	20 July 2021
Vitrosens Biyoteknoloji Ltd. Şti.	RapidFor™ SARS-CoV-2 & FLU A/B Antigen Combo Test	4063	11 Nov 2022 9 Dec 2022
Vitrosens Biyoteknoloji Ltd. Şti.	RapidFor™ SARS-CoV-2 + FLU A/B + RSV+ADV Combo Test Kit	5816	15 March 2023
Vitrosens Biyoteknoloji Ltd. Şti.	RapidFor™ SARS-CoV-2 +FLUA/B + RSV + ADV + M. Pneumoniae Combo Test Kit	5834	15 March 2023
Vitrosens Biotechnology Ltd. Sti.	RAPIDNEXT SARS-CoV-2 Rapid Antigen Test	3118	14 Oct 2022
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	2768	6 May 2022
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	2103	10 Nov 2021 21 Dec 2021 10 Feb 2022
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag Wellion SARS-CoV-2 Antigen Rapid Test	2163	20 July 2021 20 Oct 2021
Weihai Dishang Medical Technology Co., Ltd	SARS-CoV-2 Antigen Test Kit (LFIA)	2804	6 May 2022
WEIHAI KANGZHOU BIOTECHNOLOGY ENGINEERING CO., LTD.	COVID-19 Antigen Rapid Test	2688	21 Dec 2021
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	SARS-CoV-2 Antigen Rapid Test Kit	1655	20 Oct 2021

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Biotechnology Co., Ltd.	(Colloidal gold Immunoassay)		
Xenta Biomedical Science Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	3115	5 October 2022
Z Biotech Inc.	AnyLab COVID-19 Ag Test Kit	2599	15 March 2023
ZEKMED Ltd.	ZEKMED LUNA Ag Antigen Rapid Test Kit	2842	10 Feb 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 11 Nov 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 Greyllynx Biotech Co., Ltd	NADAL GX COVID-19 Ag Test	3097	14 Oct 2022
Zhejiang Hongyu Medical Commodity Co.,Ltd	SARS-CoV-2 Ag Rapid Test Kit	2309	20 Oct 2021 21 Jan 2022
Zhuhai Lituo Biotechnology Co. Ltd.	COVID-19/FluA/FluB Antigen Detection Kit (Colloidal Gold)	5792	31 Jan 2023

**II.2) Lab-based antigenic assays not included in the EU common list**

The following lab-based antigenic assays – **applications submitted until 31 March 2023, 23:59 CET** - 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:

MANUFACTURER	COMMERCIAL NAME LAB-BASED ANTIGENIC ASSAY	DEVICE ID	DATE(S) OF REJECTION
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	COVID-19 Spike 1&2 IgG	2456	20 Oct 2021

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MANUFACTURER	COMMERCIAL NAME LAB-BASED ANTIGENIC ASSAY	DEVICE ID	DATE(S) OF REJECTION
Bioprobes S.r.l.			
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 Antigen Kit	2378	20 Oct 2021
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 10 June 2022
Siemens Healthineers	Atellica IM Sars-cov-2 Antigen (Cov2Ag)	2015	22 July 2022

**II.3) Rejection of new evaluation studies of rapid antigen tests already included in the EU common list**

The following **applications putting forward new studies evaluating devices already included in the EU common list submitted until 31 March 2023, 23:59 CET** 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:

MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Abbott Rapid Diagnostics Jena GmbH	Panbio™ COVID-19 Ag Rapid Test Device	1232	5 Oct 2022
Anbio (Xiamen) Biotechnology Co., Ltd.	Rapid COVID-19 Antigen-Test (Colloidal Gold)	1822	15 March 2023
Beijing Jinwofu Bioengineering Technology Co.,Ltd.	Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit	2072	5 Oct 2022
Beijing Lepu Medical	SARS-CoV-2 Antigen Rapid Test Kit	1331	31 Jan 2023

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<b>MANUFACTURER</b>	<b>COMMERCIAL NAME RAPID ANTIGEN TEST</b>	<b>DEVICE ID</b>	<b>DATE(S) OF REJECTION</b>
Technology	(Colloidal Gold immuno-chromatography)		
Chil Tibbi Malzeme Sanayi ve Ticaret Limited Şirketi	CHIL COVID-19 Antigen Rapid Test (Nasal / Nasopharyngeal / Oropharyngeal Swab-Casette)	1691	14 Oct 2022
CTK Biotech, Inc	OnSite COVID-19 Ag Rapid Test	1581	31 Jan 2023
Hangzhou Funworld Biotech Co., Ltd	SARS-CoV-2 Antigen Rapid Test Device	2862	11 Nov 2022
Hangzhou Jucheng Medical Products Co., Ltd	SARS-CoV-2 Ag Rapid Test Kit	2979	17 May 2023
Hangzhou Laihe Biotech Co., Ltd.	LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	1215	31 Jan 2023
Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette	2063	17 May 2023
Jiangsu Medomics medical technology Co.,Ltd.	SARS-CoV-2 antigen Test Kit (LFIA)	2006	9 Dec 2022 31 Jan 2023
Jiangxi Province JinHuan Medical Instrument Co., LTD.	DREHA Novel Coronavirus (SARS-CoV-2) Antigen Rapid Detection Kit	2963	9 Dec 2022
Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	2029	11 Nov 2022
Nanjing Synthgene Medical Technology Co., Ltd.	SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method)	2164	5 Oct 2022 17 May 2023
VivaChek Biotech (Hangzhou) Co., Ltd, China	Verino Pro SARS CoV 2 Ag Rapid Test	2100	11 Nov 2022