



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

This document provides further background information to the decisions taken by the HSC Technical Working Group in the context of the fifth update to the common list of COVID-19 rapid antigen tests, as agreed by the HSC on 23 July 2021

*In addition to information put forward by EU Member States, the HSC technical working group also reviewed information submitted by manufacturers until **12 July 2021**.*

Information submitted after this date will be reviewed by the HSC technical working group as of September 2021, in the context of the next update of the common list of COVID-19 rapid antigen tests.

IMPORTANT: A (interim) grace period of 8 weeks applies whenever updates are made to the common list of COVID-19 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 additional criteria agreed by the experts participating in the technical working group on COVID-19 diagnostic tests on 29 June 2021:

MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID
Core Technology Co., Ltd	Canea Covid-19 Antigen Rapid Test	<i>unknown</i>
RapigGEN Inc.	BIOCREDIT COVID-19 Ag - SARS-CoV 2 Antigen test	1606
Tody Laboratories Int.	Coronavirus (SARS-CoV 2) Antigen - Oral Fluid	1934

Note: The two first tests were taken out as of 7 July 2021, which means that a grace period applies until 1 September 2021. The third test was taken out as of 14 July 2021, which means that a grace period applies until 8 September 2021.

Rapid antigen tests rejected for inclusion

The following rapid antigen tests 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 additional criteria agreed by the experts participating in the technical working group on COVID-19 diagnostic tests on 29 June 2021:

MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID
ACRO Biotech Inc.	COVID-19 Antigen Rapid Test	1688
ACRO Biotech Inc.	SARS-CoV-2 Antigen Rapid Test (Swab)	1948
Amazing Biotech (Shanghai) Co.,LTD.	COVID-19 Antigen Sealing tube test strip(Colloidal Gold)	2075
Anhui Formaster Biosci Co., Ltd.	New Coronavirus (COVID-19) Antigen Rapid Test	2089
Assure Tech. (Hangzhou) Co., Ltd	COVID-19 Antigen Saliva Test Kit	2037
Assure Tech. (Hangzhou) Co., Ltd.	COVID-19 Antigen Nasal Test Kit	2277
ASSUT EUROPE SPA	SARS-CoV-2 Antigen Rapid Swab	2248
Azure Biotech Inc.	Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	2060
Bakter Medical s.r.o.	Saligen – Rapid Antigen Saliva Test	1782
Beijing Beier Bioengineering Co., Ltd.	Covid-19 Antigen Schnelltest	1310
Beijing Diagreat Biotechnologies Co., Ltd	2019-nCoV Antigen Rapid Test Kit (colloidal gold assay)	1283
Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) - Saliva	1798

THIS DOCUMENT IS NOT THE HSC AGREED COMMON LIST OF COVID-19 RAPID ANTIGEN TESTS

MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID
Beijing Tigsun Diagnostics Co.,Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	1290
Boditech Med Inc	Ichroma COVID-19 Ag	1990
BioMaxima SA	COVID-19 Antigen Rapid Test	2036
BN SANTE	Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	1828
Camp Medica Distribution	See Now Coronavirus nCoV Antigen test	1999
Canary Global Inc	Pelican COVID-19 Ultra-Rapid Mobile Test	2283
CHIL Medical Supplies Ltd	CHIL COVID-19 Antigen Rapid Test (Nasopharyngeal / Oropharyngeal Swab-Casette)	1691
Chongqing iSIA Biotechnology Co. Ltd	Covid-19 Antigen Rapid Test Kit (Swab)	1937
Chongqing Novegent Biotech Company Limited, China	Novegent COVID-19 Antigen Rapid Test Kit	1189
Citest Diagnostics Inc.	COVID-19 Antigen Rapid Test	2300
Diasia Biomedical Technology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	1986
DIAsource	COVID-19 Antigen Rapid Test	1792
Dräger Safety AG & Co. KGaA	Dräger Antigen Test SARS-CoV-2	2273
EON Biotechnology Limited	EONBT COVID-19 Antigen	2032
EON Biotechnology Limited	EONBT COVID-19 Antigen-Saliva	2161
fameditec GmbH	CORA-CHECK-19-comfort	1781
Genomica Sau	qCOVID-19	185
Guangzhou Decheng Biotechnology Co., Ltd	V-CHEK 2019-nCoV Ag Rapid Test Kit	1316
Guangzhou Decheng Biotechnology Co., Ltd	V-CHEK, 2019-nCoV Ag Rapid Test Kit (Fluorescence Immunochromatographic Assay)	1326
Guangzhou Decheng Biotechnology Co., Ltd	V-CHEK, 2019-nCoV Ag Rapid Test Card (Immunochromatography)	1883
Guangzhou Wondfo Biotech Co. Ltd	Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	1312
Hangzhou AllTest Biotech Co., Ltd	SARS-COV-2 rapid antigen test (Swab)	1946
Hangzhou AllTest Biotech Co., Ltd	COVID-19 Antigen Rapid Test (Oral Fluid)	1947
Hangzhou AllTest Biotech Co., Ltd	COVID-19 Antigen Rapid Test (Oral Fluid) SELFTESTING	2159
Hangzhou AllTest Biotech Co., Ltd	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	2257
Hangzhou Biotest Biotech Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)	1868
Hangzhou Clongene Biotech Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Saliva)	1746
Hangzhou GENESIS Biodetection and Biocontrol CO.,LTD	KaiBiLi COVID-19 Antigen	2085
Hangzhou Realy Tech Co., Ltd	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	1220
Hangzhou Realy Tech Co., Ltd	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)	2018
Hangzhou Sejoy Electronics & Instruments Co.Ltd	SARS-CoV-2 Antigen Rapid Test Cassette	1945
innovative diagnostics	iD Rapid® COVID-19 Antigen	1728
InTec PRODUCTS, INC.	Rapid SARS-CoV-2 Antigen Test	1783
iXensor Co., Ltd.	PixoTest® POCT COVID-19 Antigen Test	2217
Jiangsu Konsung Bio-	H+W_COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	1899

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID
Medical Science and Technology Co.		
Jiangsu Mole Bioscience CO., LTD	SARS-CoV-2 Antigen Test Cassette (Nasal Swab Specimen)	1644
Jiangsu Well Biotech Co., Ltd.	COVID-19 Ag Rapid Test Device	2144
JINAN BABIO BIOTECHNOLOGY CO., LTD	SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method)	2151
Laipac Technology Inc.	Look SPOT	1667
Lansion Biotechnology Co., Ltd.	COVID-19 Antigen Test Kit (Dry Fluorescence Immunoassay)	1648
MED TRUST Handelsges.m.b.H.	Wellion SARS-CoV-2 PLUS ANTIGEN Rapid Test	2162
Monlab	Sars- cov2 Monlabtest	1961
Monocent, Inc.	Monocent SARS-CoV2 Antigen Rapid Test	1320
Mylab Discovery Solutions Pvt. Ltd.	PathoCatch	2320
Nanjing Liming Bio-Products Co., Ltd	COVID-19 Antigen Rapid Test Device	263
Nanjing Vazyme Medical Technology Co., Ltd.	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	1849
Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Saliva Test Kit (Colloidal Gold)	1617
Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Test Kit (Colloidal Gold)	1353
NG Biotech	NG Test SARS CoV 2 Ag	1646
NG Biotech	Ninonasal	1880
NOVATECH TIBBİ CİHAZ URUNLERİ SANAYİ VE TİCARET A.Ş.	SARS CoV-2 Antigen Rapid Test	2157
OSANG Healthcare Co., Ltd	GeneFinder COVID-19 Ag Rapid Test	1593
PREMIER MEDICAL CORPORATION PRIVATE LIMITED	SURE STATUS COVID-19 ANTIGEN CARD TEST	2299
PRIMA Lab SA	COVID-19 Antigen Rapid Test	1797
Procomcure	SARS-CoV-2 Antigen Test Kit	2080
PZ CORMAY S.A.	Cormay Rapid SARS-CoV-2 ANTIGEN Test Kit	1810
R-Biopharm AG	RIDA@QUICK SARS-CoV-2 Antigen	1846
Safecare Biotech (Hangzhou) Co. Ltd	COVID-19 Antigen Rapid Test Kit (Saliva)	1819
Salofa OY	Salocor SARS-CoV-2 Antigen Rapid Test Cassette	2129
Salofa OY	SIENNA Covid-19 Antigen Rapid Test	2127
Sansure Biotech Inc.	SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)	2097
SCREEN ITALIA S.R.L.	SCREEN TEST COVID-19 AG - COVID-19 ANTIGEN RAPID TEST	1681
SG Diagnostics	SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based)	2003
Shandong ThinkLab Biotechnology Co.,Ltd., China	Coronavirus Ag Rapid Test Cassette (Swab)	2154
Shenzhen CAS - Envision Medical Technology Co., Ltd.	SARS-CoV-2-Antigen Rapid Detection Kit	2152
Shenzhen Kang Sheng Bao Bio-Technology Co.,Ltd.	SARS-CoV-2 Antigen Rapid Test (Lateral Flow Assay)	2166

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID
Shenzhen Microprofit Biotech Co., Ltd	SARS-CoV-2 Antigen Test Kit (Fluorescence Immunoassay)	1968
Shenzhen Microprofit Biotech Co., Ltd.	SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)	2231
Shenzhen Reagent Technology Co.,Ltd.	SARS-CoV-2 antigen IVD kit SWAB	2026
Shenzhen YHLO Biotech Co., Ltd.	GLINE-2019-nCoV Ag	1347
Shenzhen YHLO Biotech Co., Ltd.	GLINE-2019-nCoV Ag Saliva	1893
Shenzhen YHLO Biotech Co., Ltd.	UNICELL-2019-nCoV Ag	1170
Sigmed Sp. z o.o.	Redtest Professional Sars-CoV-2 Antigen Rapid Test (Covid-19 Ag)	2256
Spring Healthcare Services AG	SARS-Cov-2 Antigen Rapid Test Cassette (swab)	1780
SureScreen Diagnostics	SARS-CoV-2 Rapid Antigen Test Cassette	2297
Tody Laboratories Int.	Coronavirus (SARS-CoV 2) Antigen - Swab Specimen	1935
ulti med Products (Deutschland) GmbH	COVID-19 Antigen Speicheltest (Immunochromatographie)	1641
Unioninvest Ltd	COVID-19 ANTIGEN RAPID TEST NASAL	2249
Vitrosens Biyoteknoloji Ltd. Sti	RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	2180
VivaChek Biotech (Hangzhou) Co., Ltd	Vivadiag SARS CoV 2 Ag Rapid Test	1246
VivaChek Biotech (Hangzhou) Co., Ltd	VivaDiag SARS-CoV-2 Ag Saliva Rapid Test	1980
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag Wellion SARS-CoV-2 Antigen Rapid Test	2163
VivaChek Biotech (Hangzhou) Co., Ltd	Verino Pro SARS CoV 2 Ag Rapid Test	2100
VivaChek Biotech (Hangzhou) Co., Ltd	SARS-CoV-2&Flu A& Flu B Ag Rapid Test	2119
VivaChek Biotech (Hangzhou) Co., Ltd	VivaDiag SARS-CoV-2 Ag FIA Test	2105
Wenzhou OJA Biotechnology Co.,Ltd	SARS CoV-2 Antigen Detection Kit (Colloidal Gold Method)	1575
Willi Fox GmbH	Willi Fox COVID-19 Antigen rapid test	1276
Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	1600
Wuxi Biohermes Bio & Medical Technology Co., Ltd	SARS-CoV-2 Antigen Test Kit (Lateral Flow Assay)	2143
Zet Medikal Tekstil Dis Ticaret Ltd. STI.	softec SARS COV-2 (Covid-19) Antigen Test Kit	2226
Zhejiang Anji Saianfu Biotech Co.,Ltd.	Seinofy COVID-19 Antigen Rapid Test	2223
Zybio Inc.	SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)	2201