



## - 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 second update to the common list of COVID-19 rapid antigen tests, as agreed by the HSC on 7 July 2021***

*In addition to information put forward by EU Member States, the HSC technical working group also reviewed information submitted by manufacturers until 21 June 2021.*

*Information submitted after this date will be reviewed by the HSC technical working group 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	unknown
RapigGEN Inc.	BIOCREDIT COVID-19 Ag - SARS-CoV 2 Antigen test	1606

## **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 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
Assure Tech. (Hangzhou) Co., Ltd.	COVID-19 Antigen Rapid Test Device	770
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 Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) - Saliva	1798
Beijing Tigsun Diagnostics Co.;Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	1290
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	Wantai SARS-CoV-2 Ag Rapid Test (Colloidal Gold)	1485
BioMaxima SA	SARS-CoV-2 Ag Rapid Test	2035
BioMaxima SA	COVID-19 Antigen Rapid Test	2036
BIOTEKE CORPORATION (WUXI) CO., LTD	SARS-CoV-2 Antigen Test Kit (colloidal gold method)	2067
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

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID
Chongqing Novegent Biotech Company Limited, China	Novegent COVID-19 Antigen Rapid Test Kit	1189
Diasia Biomedical Technology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	1986
DIASORIN	LIAISON SARS-CoV-2 Ag assay	1960
DIAsource	COVID-19 Antigen Rapid Test	1792
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
Guangdong Longsee Biomedical Co., Ltd.	2019-nCoV Ag Rapid Detection Kit(Immuno-Chromatography)	1216
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 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
InTec PRODUCTS, INC.	Rapid SARS-CoV-2 Antigen Test	1783
Jiangsu Bioperfectus Technologies Co., Ltd.	Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit	2107
Jiangsu Diagnostics Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	1920
Jiangsu Well Biotech Co., Ltd.	COVID-19 Ag Rapid Test Device	2144
Koch Biotechnology (Beijing) Co., Ltd	COVID-19 Antigen Rapid Test Kit	2038
Monocent, Inc.	Monocent SARS-CoV2 Antigen Rapid Test	1320
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
OSANG Healthcare Co., Ltd	GeneFinder COVID-19 Ag Rapid Test	1593
PZ CORMAY S.A.	Cormay Rapid SARS-CoV-2 ANTIGEN Test Kit	1810
R-Biopharm AG	RIDA@QUICK SARS-CoV-2 Antigen	1846
Salofa OY	Salocor SARS-CoV-2 Antigen Rapid Test Cassette	2129
SG Diagnostics	SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based)	2003
Shenzhen Micropoint	SARS-CoV-2 Antigen Test Kit (Fluorescence)	1968

MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID
Biotech Co., Ltd	Immunoassay)	
Shenzhen Micropofit Biotech Co., Ltd.	SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	1178
Shenzhen YHLO Biotech Co., Ltd.	GLINE-2019-nCoV Ag	1347
ulti med Products (Deutschland) GmbH	COVID-19 Antigen Speicheltest (Immunochromatographie)	1641
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, China	Verino Pro SARS CoV 2 Ag Rapid Test	2100
Wenzhou OJA Biotechnology Co.,Ltd	SARS CoV-2 Antigen Detection Kit (Colloidal Gold Method)	1575
Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	1600
Zhuhai Lituo Biotechnology Co., Ltd.	COVID-19 Antigen Detection Kit (Colloidal Gold)	1957

### **Rapid antigen tests under discussion**

The following rapid antigen tests 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
ACON Biotech(Hangzhou) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test	1457
ArcDia International Oy Ltd	mariPOC Respi+	2078
ArcDia International Oy Ltd	mariPOC Quick Flu+	2079
Artron Laboratories Inc.	Artron COVID-19 Antigen Test	1618
Assure Tech. (Hangzhou) Co., Ltd.	COVID-19 Antigen Rapid Test Device	770
Beijing Diagreat Biotechnologies Co., Ltd	2019-nCoV Antigen Rapid Test Kit (colloidal gold assay)	1283
Beijing Jinwofu Bioengineering Technology Co.,Ltd.	Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit	2072
DNA Diagnostic	COVID-19 Antigen Detection Kit	2242
Edinburgh Genetics Limited	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	1243
Getein Biotech, Inc	SARS-CoV-2 Antigen (Colloidal Gold)	1820
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
Jiangsu Konsung Bio-Medical Science and Technology Co.	H+W_COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	1899

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Jiangsu Mole Bioscience CO., LTD	SARS-CoV-2 Antigen Test Cassette (Nasal Swab Specimen)	1644
MED TRUST Handelsges.m.b.H.	Wellion SARS-CoV-2 PLUS ANTIGEN Rapid Test	2162
Monlab	Sars- cov2 Monlabtest	1961
NanoRepro AG	NanoRepro SARS-CoV-2 Antigen Rapid Test	2200
Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Test Kit (Colloidal Gold)	1353
NESAPOR EUROPA	MARESKIT COVID-19 ANTIGEN RAPID TEST KIT	2241
NOVATECH TİBBİ CİHAZ URUNLERİ SANAYİ VE TİCARET A.Ş.	Novacheck SARS-CoV-2 Antigen Rapid Test	1762
PRIMA Lab SA	COVID-19 Antigen Rapid Test	1797
Procomcure	SARS-CoV-2 Antigen Test Kit	2080
Salofa OY	SIENNA Covid-19 Antigen Rapid Test	2127