



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 common list of 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 sixth update to the common list of COVID-19 rapid antigen tests as well as the common list of COVID-19 rapid antigen assays, both as agreed by the HSC on 20 October 2021

*In addition to information put forward by EU Member States, the HSC technical working group reviewed proposals submitted by manufacturers between **13 July 2021** and **10 September 2021**.*

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

IMPORTANT: Until the end of 2021, a grace period of 8 weeks applies whenever updates are made to the common list of COVID-19 rapid antigen tests. As of 2022, a grace period of 4 weeks will apply.

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:

MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE OF REMOVAL	END OF GRACE PERIOD
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
GenBody Inc	Genbody COVID-19 Ag Test	1244	20 Oct 2021	15 Dec 2021, 23:59 CET

Rapid antigen tests rejected for inclusion

The following rapid antigen tests – applications submitted until 10 September 2021 - 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
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
ACRO Biotech Inc.	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	2267	20 Oct 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
Anhui Formaster Biosci Co., Ltd.	New Coronavirus (COVID-19) Antigen Rapid Test (saliva)	2480	20 Oct 2021
Assure Tech. (Hangzhou)	COVID-19 Antigen Saliva Test Kit	2037	20 July 2021

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

MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Co., Ltd			
Assure Tech. (Hangzhou) Co., Ltd.	COVID-19 Antigen Nasal Test Kit	2277	20 July 2021 20 Oct 2021
ASSUT EUROPE SPA	SARS-CoV-2 Antigen Rapid Swab	2248	20 July 2021
Azure Biotech Inc.	Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	2060	6 July 2021
Bakter Medical s.r.o.	Saligen – Rapid Antigen Saliva Test	1782	6 July 2021
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
Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) - Saliva	1798	6 July 2021
Beijing Tigsun Diagnostics Co.,Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	1290	6 July 2021
BioMaxima SA	COVID-19 Antigen Rapid Test	2036	15 June 2021
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)	2588	20 Oct 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 (Nasal Swab)	2449	20 Oct 2021
Citest Diagnostics Inc.	COVID-19 Antigen Rapid Test	2300	13 July 2021
Cypress Diagnostics	COVID-19 Ag Rapid Test	2499	20 Oct 2021
Diasia Biomedical Technology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	1986	15 June 2021
DIAsource	COVID-19 Antigen Rapid Test	1792	6 July 2021
EON Biotechnology Limited	EONBT COVID-19 Antigen	2032	6 July 2021
EON Biotechnology Limited	EONBT COVID-19 Antigen-Saliva	2161	6 July 2021
fameditec GmbH	CORA CHECK-19	1744	20 Oct 2021
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
Genomica Sau	qCOVID-19	185	23 June 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 Kit (Fluorescence Immunochromatographic Assay)	1326	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	2019-nCoV Rapid Antigen Test	2468	20 Oct 2021

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Guangzhou Wondfo Biotech Co. Ltd	Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	1312	6 July 2021
Hangzhou AllTest Biotech Co., Ltd	SARS-COV-2 rapid antigen test (Swab)	1946	15 June 2021
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 Antigen Rapid Test (Nasal Swab)	2257	20 July 2021 20 Oct 2021
Hangzhou AllTest Biotech Co., Ltd	GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP Swab)	2319	20 Oct 2021
Hangzhou Biotest Biotech Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)	1868	13 July 2021
Hangzhou Clongene Biotech Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Saliva)	1746	13 July 2021
Hangzhou Realy Tech Co., Ltd	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	1220	6 July 2021 20 July 2021
Hangzhou Realy Tech Co., Ltd	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)	2018	6 July 2021
Hangzhou Sejoy Electronics & Instruments Co.Ltd	SARS-CoV-2 Antigen Rapid Test Cassette	1945	15 June 2021
Hangzhou Singclean Medical Products Co., Ltd.	COVID-19 Test Kit (Colloidal Gold Method)	2210	20 Oct 2021
ImmunoDiagnostics Limited	COVID-19 Ag Detection Kit (Colloidal Gold Immunochromatography)	2265	20 Oct 2021
Immunospark s.r.l.	Rapid SARS-Cov2 Antigen Test	1791	20 Oct 2021
INNOVITA (Tangshan) Biological Technology Co., Ltd.	2019-nCoV Ag Test (Latex Chromatography Assay)	1994	20 Oct 2021
InTec PRODUCTtS, INC.	Rapid SARS-CoV-2 Antigen Test	1783	6 July 2021
iXensor Co., Ltd.	PixoTest® POCT COVID-19 Antigen Test	2217	20 July 2021
Jiangsu Mole Bioscience CO., LTD	SARS-CoV-2 Antigen Test Cassette (Nasal Swab Specimen)	1644	20 July 2021
JINAN BABIO BIOTECHNOLOGY CO., LTD	SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method)	2151	13 July 2021
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
Lansion Biotechnology Co., Ltd.	COVID-19 Antigen Test Kit (Dry Fluorescence Immunoassay)	1648	20 July 2021
LumiraDx UK Ltd	LumiraDx SARS-COV-2 Antigen Pool Test	2342	20 Oct 2021
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	20 Oct 2021
Medice Arzneimittel Pütter GmbH & Co. KG	Medicovid-AG SARS-CoV-2 Antigen Selbsttest-Nase	2318	20 Oct 2021
MEDICE Arzneimittel Pütter GmbH & Co. KG	Medicovid-AG SARS-CoV-2 Antigen Schnelltest-Nase	2526	20 Oct 2021
Meril Diagnostics Pvt Ltd	MERISCREEN COVID-19 Antigen Detection Test	2582	20 Oct 2021
Merlin Biomedical (Xiamen)	SARS-CoV-2 Antigen Rapid Test	2030	20 Oct 2021

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Co., Ltd.	Cassette (saliva)		
Monlab	Sars- cov2 Monlabtest	1961	20 July 2021
Monocent, Inc.	Monocent SARS-CoV2 Antigen Rapid Test	1320	15 June 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
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
Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Saliva Test Kit (Colloidal Gold)	1617	6 July 2021 20 Oct 2021
Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Test Kit (Colloidal Gold)	1353	13 July 2021 20 Oct 2021
NG Biotech	NG Test SARS CoV 2 Ag	1646	20 July 2021 20 Oct 2021
NOVATECH TİBBİ CİHAZ URUNLERİ SANAYİ VE TİCARET A.Ş.	SARS CoV-2 Antigen Rapid Test	2157	20 July 2021
OSANG Healthcare Co., Ltd	GeneFinder COVID-19 Ag Rapid Test	1593	6 July 2021 20 July 2021
Pierenkemper GmbH	(SARS-CoV-2) Antigen Rapid Test COVIDENT COVID-19	2197	20 Oct 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)	2482	20 Oct 2021
Pro-med (Beijing) Technology Co., Ltd.	COVID-19 Neutralizing Antibody Rapid Detection Kit (Colloidal Gold)	2485	20 Oct 2021
Pro-med (Beijing) Technology Co., Ltd.	COVID-19 IgM/IgG Antibody Rapid Detection Kit (Colloidal Gold)	2486	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
R-Biopharm AG	RIDA®QUICK SARS-CoV-2 Antigen	1846	6 July 2021
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
Sansure Biotech Inc.	SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)	2097	20 July 2021 20 Oct 2021
Sansure Biotech Inc.	SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay)	2366	20 Oct 2021
SCREEN ITALIA S.R.L.	SCREEN TEST COVID-19 AG - COVID-19 ANTIGEN RAPID TEST	1681	20 July 2021
SG Diagnostics	SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based)	2003	6 July 2021 20 July 2021 20 Oct 2021
Shandong ThinkLab	Coronavirus Ag Rapid Test Cassette	2154	20 July 2021

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
Biotechnology Co.,Ltd., China	(Swab)		
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
Shenzhen CAS - Envision Medical Technology Co., Ltd.	SARS-CoV-2-Antigen Rapid Detection Kit	2152	20 July 2021
Shenzhen Kang Sheng Bao Bio-Technology Co.,Ltd.	SARS-CoV-2 Antigen Rapid Test (Lateral Flow Assay)	2166	20 July 2021
Shenzhen Microprofit Biotech Co., Ltd	SARS-CoV-2 Antigen Test Kit (Fluorescence Immunoassay)	1968	15 June 2021
Shenzhen YHLO Biotech Co., Ltd.	GLINE-2019-nCoV Ag	1347	15 June 2021 6 July 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 Biotechnology Co., Ltd	SARS-COV-2 ANTIGEN TEST KIT (COLLOIDAL GOLD)	2546	20 Oct 2021
Spartacus-Biomed	COVID-19 Antigen Rapid Test	2185	20 Oct 2021
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
Tody Laboratories Int.	Coronavirus (SARS-CoV 2) Antigen - Swab Specimen	1935	20 July 2021
TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.	Covid-19 Ag Test	1689	20 Oct 2021
TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.	TOYO Covid-19 Ag Test	1722	20 Oct 2021
TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.	RAPIDAN TESTER Covid-19 Ag Test	1751	20 Oct 2021
TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.	INFO Covid-19 Ag Test	2584	20 Oct 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
VEDALAB	COVID-19-CHECK-1 Antigen	1956	20 Oct 2021
Vitrosens Biyoteknoloji Ltd. Sti	RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	2180	20 July 2021
VivaChek Biotech (Hangzhou) Co., Ltd	Vivadiag SARS CoV 2 Ag Rapid Test	1246	15 June 2021 20 July 2021
VivaChek Biotech (Hangzhou) Co., Ltd	VivaDiag SARS-CoV-2 Ag Saliva Rapid Test	1980	15 June 2021
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag Wellion SARS-CoV-2 Antigen Rapid Test	2163	20 July 2021 20 Oct 2021

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MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	DEVICE ID	DATE(S) OF REJECTION
VivaChek Biotech (Hangzhou) Co., Ltd	Verino Pro SARS CoV 2 Ag Rapid Test	2100	15 June 2021 13 July 2021
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 FIA Test	2105	13 July 2021
VivaChek Biotech (Hangzhou) Co., Ltd, China	VivaDiag SARS-CoV-2 Ag Rapid Test	2102	20 Oct 2021
Wenzhou OJA Biotechnology Co.,Ltd	SARS CoV-2 Antigen Detection Kit (Colloidal Gold Method)	1575	15 June 2021 13 July 2021
Wuhan Healthcare Biotech CO. LTD	SARS CoV 2 Antigen Test Kit (Colloidal Gold)	2444	20 Oct 2021
Willi Fox GmbH	Willi Fox COVID-19 Antigen rapid test	1276	20 July 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
Zet Medikal Tekstil Dis Ticaret Ltd. STI.	softec SARS COV-2 (Covid-19) Antigen Test Kit	2226	13 July 2021
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
Zhejiang Hongyu Medical Commodity Co.,Ltd	SARS-CoV-2 Ag Rapid Test Kit	2309	20 Oct 2021
Zybio Inc.	SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)	2201	20 July 2021 20 Oct 2021

Rapid antigen tests under discussion

The following rapid antigen tests – submitted before 11 September 2021 - 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
Becton Dickinson	BD Kit for Rapid Detection of SARS-CoV-2	2282
BIOLAN HEALTH, S.L	COVID-19 Antigen Rapid Test (Colloidal Gold Method)	2519
Biopanda Reagents Ltd	COVID-19 Rapid Antigen Test	2034
BioSpeedia International	BioSpeedia COVID19 Non-Invasive Antigen Test BSD_0504	2379
BioSpeedia International	COVID19Speed-Antigen Test BSD_0503	2380
BioSpeedia International	BioSpeedia COVID19 Nasal Antigen Test BSD_0506	2381
Dia.Pro Diagnostic Bioprobes S.r.l.	SARS-CoV-2 Antigen	2457
Hangzhou GENESIS Biodetection and Biocontrol CO.,LTD	KaiBiLi COVID-19 Antigen	2085
innovative diagnostics	iD Rapid® COVID-19 Antigen	1728
Jiangsu Konsung Bio-Medical Science and Technology Co.	H+W_COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	1899

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Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	2066
Multi-G	Covid19Check-GEN	2258
Multi-G bvba	Covid19Check-NAS	2260
Nanjing Norman Biological Technology Co., Ltd.	Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)	2506
NG Biotech	Ninonasal	1880
Polonord Adeste Srl	POLOFLUOR 2	2583
RapiGEN Inc	BIOCREDIT COVID-19 Ag Test Nasal	1963
Rapigen Inc.	BIOCREDIT COVID-19 Ag - SARS-CoV 2 Antigen test	1606
Salofa OY	SIENNA Covid-19 Antigen Rapid Test	2127
Senova Gesellschaft für Biowissenschaft und Technik mbH	Senova Greenlight	1818
Shenzhen Microprofit Biotech Co., Ltd.	SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)	2231
Shenzhen Microprofit Biotech Co., Ltd.	SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)	1228
Sigmed Sp. z o.o.	Redtest Professional Sars-CoV-2 Antigen Rapid Test (Covid-19 Ag)	2256

PART II: LAB-BASED ANTIGENIC ASSAYS

Lab-based antigenic assays rejected for inclusion

The following lab-based antigenic assays – applications submitted until 10 September 2021 - 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 21 September 2021:

MANUFACTURER	COMMERCIAL NAME RAPID ANTIGEN TEST	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.	COVID-19 IgG Confirmation	539	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 Spike 1&2 IgG	2456	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 IgM	2464	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 Spike/RBD Ab	2478	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.	COVID-19 IgG/IgM Confirmation and Typing	2461	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 IgM	538	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 RNA Vs 2	2460	20 Oct 2021
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