The EU has published a list of suitable antigen tests

Robust testing strategies are an essential aspect of preparedness and response to the COVID-19 pandemic, allowing for early detection of potentially infectious individuals and providing visibility on infection rates and transmission within communities. Moreover, they are a prerequisite to adequate contact tracing to limit the spread through prompt isolation.

The European Commission's Health Security Committee has published a list of rapid antigen tests for the presence of SARS-CoV-2 virus that are considered suitable for use in the situations described in the EU Council Recommendation and that are in line with country testing strategies.

The tests in the list meet the following conditions:

1. Carry CE marking
2. Meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity
3. Have been validated by at least one Member State as being appropriate for their use in the context of COVID-19, providing details on the methodology and results of such studies, such as the sample type used for validation, the setting in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements

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Common list of rapid antigen tests, as agreed by Member States on 17 February 2021

Manufacturer	RAT commercial name	CE marking	Clinical performance (JRC database)	Clinical performance (FIND database)	Clinical performance (Data used in BE)	Clinical performance (Data used in DE)	Clinical performance (Data used in SI)	MS using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS that are currently validating this RAT	In JRC database	In FIND database
Abbott Rapid Diagnostics	Panbio™ COVID-19 Ag Rapid Test	Yes	91.4% sensitivity, 99.8% specificity NP swab	FIND Evaluation - Studies in DE and CH, NP swab, 10 Dec 2020	93.3% sensitivity 99.4% specificity NP Swab 98.1% sensitivity 99.8% specificity Nasal swab	91.4% sensitivity 99.8% specificity		AT, BE, BG, CY, CZ, DE[2], EL, ES, FR[1], HR, IT, MT, NL[5], PL, PT, RO, SE, SK	CH, ME, MK, NO, UK, UA	DE, ES, NL[5], CH, NO	CY, ES, HR, HU, IE, LU, PT, SE	Yes	Yes
AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	Yes	97.3% sensitivity 100% specificity NP swab 97.3% sensitivity 98.8% specificity Nasal swab		97.3% sensitivity 100% specificity NP swab		97.3% sensitivity 100% specificity NP swab	BE, BG, DE[2] HR, SI,	CH, UA	DE	HR	Yes	Yes
Becton Dickinson	BD Veritor System for Rapid Deteciton os SARS-CoV-2	Yes	93.5% sensitivity 99.3% specificity Nasal swab					DE[2], ES, NL[5], SE	CH, UA	DE, ES, NL[5]	SE[3]	Yes	Yes
Beijing Lepu Medical Technology	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	Yes	92% sensitivity unknown specificity Nasal swab		92% sensitivity 99.3% specificity Nasal swab		92% sensitivity 99.2% specificity NP swab	BE, DE[2], SI	UA	DE		Yes	Yes
Beijing Wantai Biological Pharmacy Enterprise Co Ltd	WANTAI SARS-CoV-2 Ag Rapid Test (FIA)	Yes	96.6% sensitivity unknown specificity Nasal swab					DE[2]		DE		Yes	Yes
BIONOTE	NowCheck® COVID-19 Ag Test	Yes	89.2% sensitivity 97.6% specificity NP/Nasal swab	FIND Evaluation - Study in Brazil, NP swab, 10 Dec 2020				DE[2]	CH	DE		Yes	Yes

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BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	Yes	Not specified		96% sensitivity 100% specificity NP swab			BE, DE[2], FR, NL[5]	CH	DE, NL[5]		Yes	Yes
CerTest Biotect S.L.	CerTest SARS-CoV-2 CARD TEST	Yes	92.9% sensitivity 99.6% specificity NP swab		92.9% sensitivity 99.6% specificity NP swab		92.9% sensitivity 98.4% specificity NP/OP swab	DE[2], ES, SI		ES		Yes	No
GenBody Inc	GenBody COVID-19 Ag Test	Yes	90% sensitivity 98% specificity NP/OP swab	Withdrawn				DE[2]	UA	DE		Yes	Yes
Guangdong Wesail Biotech Co. Ltd	COVID-19 AG Test Kit	Yes	90% sensitivity 98% specificity NP/Nasal swab				90% sensitivity 98% specificity NP/Nasal swab	DE[2], SI		DE		Yes	No
Hangzhou Clongene Biotech	Clungene COVID-19 Antigen Rapid Test Kit	Yes	98.5% sensitivity unknown specificity Nasal swab		91.4% sensitivity 100% specificity NP/OP swab		91.4% sensitivity 100% specificity NP/OP swab	BE, DE[2], FR, SI	CH	DE	HR	Yes	No
Healgen Scientific Limited	Coronavirus Ag Rapid Test Cassette (Swab)	Yes					96.7% sensitivity 99.2% specificity NP/Nasal swab	DE[2], NL[5], SE, SI		NL[5]	SE[3]	No	No
Joinstar Biomedical Technology	COVID-19 Antigen Rapid Test (Colloidal Gold)	Yes	96.1% sensitivity 98.1% specificity Nasal swab				96.1% sensitivity 98.1% specificity NP swab	DE[2], SI		DE		Yes	Yes
LumiraDX UK LTd	LumiraDx SARS-CoV-2 Ag Test	Yes	97.6% sensitivity 96.7% specificity Nasal swab				97.6% sensitivity 97.7% specificity NP/Nasal swab	DE[2], ES, SI	CH	DE, ES		Yes	No
MEDsan GmbH	MEDsan® SARS-CoV-2 Antigen Rapid Test	Yes	92.5% sensitivity 99.8% specificity NP/OP swab		92.5% sensitivity 99.8% specificity Nasal/OP swab			BE, DE[2]	CH	DE		Yes	No

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MP Biomedicals Germany	Rapid SARS-CoV-2 Antigen Test Card	Yes	96.39% sensitivity 99.03% specificity Nasal swab		96.4% sensitivity 99% specificity NP/OP swab			BE, DE[2]	CH	DE		Yes	No
nal von minden GmbH	NADAL COVID -19 Ag Test	Yes	97.6% sensitivity 99.9% specificity Nasal swab		97.6% sensitivity 99.9% specificity NP/OP swab		97.6% sensitivity 99.9% specificity NP/OP swab	AT, BE, DE[2], SI		DE	HR	Yes	No
Precision Biosensor Inc (Axon Lab SG)	Exdia COVI-19 Ag Test	Yes	93.9% sensitivity 98% specificity NP swab				93.9% sensitivity 98% specificity NP swab	SI	CH	DE		Yes	Yes
Qingdao Hightop Biotech Co Ltd	SARS-CoV-2 Antigen Rapid Test	Yes	95% sensitivity unknown specificity Nasal swab					DE[2]		DE		Yes	No
Quidel Corporation	Sofia 2 SARS Antigen FIA	Yes	96.7% sensitivity 100% specificity NP/Nasal swab		96.7% sensitivity 100% specificity NP/nasal swab		96.7% sensitivity 100% specificity NP/Nasal swab	AT, BE, DE[2], FI, NL[5], SI	CH	DE, NL[5]	SI	Yes	Yes
Safecare Biotech Hangzhou Co	COVID-19 Ag Rapid Test Kit (Swab)	Yes	97.04% sensitivity unknown specificity Nasal swab					DE[2], FR	CH	DE		Yes	No
SD BIOSENSOR, Inc.; Roche	STANDARD F COVID-19 Ag FIA	Yes		FIND Evaluation - Studies in DE and Brazil, 10 Dec 2020	96.5% sensitivity 99.7% specificity NP swab			BE, BG, DE[2], IT , LU, LV, NL[5], PT, RO, SK		DE, IT, NL[5]	LU, PT	No	Yes
SD BIOSENSOR, Inc.; Roche	STANDARD Q COVID-19 Ag Test	Yes	96.52% sensitivity 99.68% specificity NP swab	FIND Evaluation - Studies in DE, CH and Brazil, 10 Dec 2020	96.5% sensitivity 99.7% specificity NP swab		96.5% sensitivity 99.7% specificity NP swab	AT, BE, BG, CY, DE[2], ES, FI, FR, HR, IT, LU, LV, MT, NL[5], RO, SE, SK, SI	ME, NO, CH	DE, ES, IT, NL[5], CH, UA	HR, IE, LU, SI, SE	Yes	Yes

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Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	Yes	96.72% sensitivity 96.72% specificity Nasal swab		98.32% sensitivity 99.6% specificity NP swab 97.25% sensitivity 100% specificity Nasal swab		96.7% sensitivity 99.2% specificity NP/Nasal swab	AT, BE, DE[2], FR, HR, NL[5], SE, SI		DE, NL[5]	ES, HR, PT, SE[3]	Yes	Yes
Xiamen Boson Biotech Co	Rapid SARS-CoV-2 Antigen Test card	Yes	Not specified		93.8% sensitivity 100% specificity NP swab			BE, BG, DE[2], FR	CH	DE		Yes	Yes
Zhejiang Orient Gene Biotech Co.,Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	Yes	96.72% sensitivity unknown specificity Nasal swab		98.32% sensitivity 99.6% specificity NP swab 97.25% sensitivity 100% specificity Nasal swab			AT, BE, BG, DE[2]	UK	DE	SE[3]	Yes	No

Notes:

[1] FR: Reference to validation study (not specifying which specific RAT is being recommended or was tested in practice): https://www.has-sante.fr/upload/docs/application/pdf/2020-10/synthese_tests_antigeniques_vd.pdf

[2] DE: Rapid antigen tests that fulfils the defined minimum criteria for reimbursement in Germany. See: https://antigentest.bfarm.de/ords/antigen/r/antigentests-auf-sars-cov-2/liste-der-antigentests?session=13130597074531

[3] SE: Smaller evaluations ongoing in some of the regions.

[4] BE: In the clinical performance study performed in three different clinical laboratories during the ascendant phase of the epidemiological curve, we found an overall sensitivity and specificity of 57.6 and 99.5%, respectively with an accuracy of 82.6%.

[5] NL: Collected validation data from accredited laboratories in the Netherlands. The report includes evaluations of various RAT that labs performed at their own initiative. https://lci.rivm.nl/antigeensneltesten