EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security and Vaccination

EU health preparedness:

A common list of COVID-19 rapid antigen tests, including those of which their test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee

This document was agreed by the HSC on 17 February 2021

A first update to Annex II was agreed by the HSC on 19 March 2021

A first update to Annex I was agreed by the HSC on 10 May 2021

I. Introduction

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. Also in the context of the circulation of SARS-CoV-2 variants of concern, surge testing in addition to existing testing deployment has proven to be key for controlling and suppressing further spread of the virus.

While the reverse transcription real-time polymerase chain reaction (RT-PCR) assay, which is a nucleic acid amplification test (NAAT) remains the 'gold standard' for COVID-19 diagnosis, new tests are rapidly entering the market, allowing faster and cheaper ways to detect ongoing infection. Rapid antigen tests, which detect the presence of viral proteins (antigens), are increasingly being used by Member States as a way of further strengthening countries' overall testing capacity, particularly in case of limited NAAT capacities or where prolonged testing turnaround times results in no clinical utility.

The Health Security Committee agreed on 17 September 2020 on Recommendations for a common EU testing approach for COVID-19[1], setting out various actions for consideration by countries when updating or adapting their testing strategies. The Recommendations included Member States' first experiences with rapid antigen tests and their deliberations concerning the settings and situations in which these tests should be used. Since then, the Committee has been discussing the use and application of rapid antigen tests in great depth, and has brought together a wealth of (technical) information on the types of tests used in European countries and the conditions applied.

On 21 January 2021, Member States unanimously agreed on a Council Recommendation setting a common framework for the use of rapid antigen tests and the mutual recognition of COVID-19 test results across the EU[2]. The Council Recommendation called on Member States to agree on three concrete deliverables:

1. **A common list of COVID-19 rapid antigen tests** that are considered appropriate for use in the context of the situations described in the Council Recommendation, that are in line with countries' testing strategies and that:
    a. carry CE marking;
    b. meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity; and
    c. 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

[1] https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/common_testingapproach_covid-19_en.pdf
[2] https://data.consilium.europa.eu/doc/document/ST-5451-2021-INIT/en/pdf

in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

2. A selection of rapid antigen tests of which Member States will **mutually recognise the test results for public health measures**.
3. **A common standardised set of data to be included in COVID-19 test result certificates**, further facilitating the mutual recognition of COVID-19 test results.

Based on the information collected by the Health Security Committee, and taking into consideration the current epidemiological situation and the testing strategies and approaches that have been put in place across the EU, this document sets out the three deliverables as agreed by Member States. Its content is prepared based on the criteria set out in the Council Recommendation and considers the relevant recommendations published by the Commission[3] and technical guidance issued the European Centre for Disease Prevention and Control (ECDC)[4] and the World Health Organization (WHO)[5].

II. Common list of rapid antigen tests

Point 11 of the Council Recommendation of 21 January 2021, calls on Member States to, without prejudice to Directive 98/79/EC, agree on and maintain a common and updated list of COVID-19 rapid antigen tests that are considered appropriate for use in the context of the situations described under point 6 and are in line with countries' testing strategies. Moreover, the antigen tests included in the list should:

(a) Carry CE marking;

(b) Meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity; and

(c) 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.

This list should be shared with ECDC and the Commission to prevent duplication of work and to feed into ongoing initiatives, particularly the "COVID-19 In Vitro Diagnostic Devices and Test Methods Database[6], hosted by the Joint Research Centre (JRC). Annex I to this document sets out a common list of rapid antigen tests that meet the criteria as specified above. This list has been incorporated by the JRC in its COVID-19 In Vitro Diagnostic Devices and Test Methods Database. An update to Annex I was agreed by the Health Security Committee on 10 May 2021.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1595 and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020H1743&from=EN
[4] https://www.ecdc.europa.eu/en/publications-data/options-use-rapid-antigen-tests-covid-19-eueea-and-uk
[5] https://www.who.int/publications/i/item/9789240017740
[6] https://covid-19-diagnostics.jrc.ec.europa.eu/devices

The common list of rapid antigen tests is regularly being reviewed by Member States in the context of Health Security Committee meetings, and, if necessary, be updated in line with new results from independent validation studies becoming available and new tests entering the markets. These updates are also taking into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARS-CoV-2 virus on the efficacy of NAAT, in particular RT-PCR assays, will also be kept under review.

III. Rapid antigen tests of which the test results are mutually recognised

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will **mutually recognise the test results for public health measures**, based on the information included in the common list (see Annex I).

The Health Security Committee agrees that, for rapid antigen test results to be mutually recognised, at least three Member States should be using a rapid antigen tests in practice. Based on this criterion, those rapid antigen tests for which Member States agree that their results will be mutually recognised for public health measures, are highlighted in yellow in Annex I[7]. An update to Annex I, including the selection of tests of which their results are mutually recognised, was agreed by the Health Security Committee on 10 May 2021.

Whenever Member States will review the common list of rapid antigen tests and consider whether any tests should be added or deleted, they will also take into account – also based on new results from independent national validation studies - whether any rapid antigen tests should be removed from or added to the selection of rapid antigen tests of which their results are being mutually recognised. This information will be provided to the JRC, who will update its database accordingly.

IV. Common standardised set of data for COVID-19 test certificates

In order to facilitate in practice the mutual recognition of results of rapid antigen tests as well as NAAT, including RT-PCR assays, point 18 of Council Recommendation 2020/1475 defines that Member States should agree on a common standardised set of data to be included in the form for test result certificates.

Based on information that was submitted by members of the Health Security Committee in response to a survey on mutual recognition on COVID-19 test results and further discussions that took place in the context of the Health Security Committee, Member States agree on the common standardised set of data for COVID-19 test result certificates as presented in Annex II. An update to this Annex was agreed by the Health Security Committee on 19 March 2021, addressing input received from the eHealth Network and in particular the Semantic Subgroup

[7] This list has been incorporated by the JRC in its COVID-19 In Vitro Diagnostic Devices and Test Methods Database.

and based on discussions that took place in the context of the EU Digital Green Certificate. Member States agree that COVID-19 test results should be made available in the national language(s) of the country where the test was taken, as well as English.

The Health Security Committee will discuss, whenever relevant, possible updates to the agreed common standardised set of data for COVID-19 test certificates, and publish, if necessary, an updated agreed document.

V. Continuous discussions and further work on the common rapid antigen tests list and common dataset for COVID-19 test result certificates

As described in the sections above, the content of this document, as agreed by the Health Security Committee on 17 February 2021, will continue to be discussed by Member States and updated whenever deemed relevant. Whenever updates are required, these will be published as an update to this current document and/or as an update to the JRC COVID-19 In Vitro Diagnostic Devices and Test Methods Database, depending on scope of the update.

Based on the increasing political and commercial interest in the HSC agreed common rapid antigen test list, including those of which their results are mutually recognised by EU Member States, on 21 April 2021, the Commission and JRC presented to the HSC a new procedure for updating the lists. This includes setting up a HSC Technical Working Group on rapid antigen tests, who will play a key role in reviewing the information submitted by EU countries (as well as manufactures) on the use and performance of rapid antigen tests that are available on the market. Once established, the HSC Technical Working Group will, in particular, address the following points:

Common RAT list

- **Sampling methods to be used**

The current HSC agreed common list of rapid antigen tests includes tests for which their clinical performance was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens. Other rapid antigen tests exist that have been validated in EU Member States based on alternative samples, such as saliva, sputum and/or faeces. Further discussions are required to reach consensus on whether these tests should also be included in the HSC agreed common RAT list.

- **Harmonised methodology for national validation studies on the clinical performance of rapid antigen tests**

This will be addressed by future guidelines to be developed by the JRC and the ECDC, also taking into consideration the implementation guide published by WHO on 21 December 2020 on SARS-CoV-2 antigen-detecting rapid diagnostic tests[8] as well as the guidance that is being developed by the MDCG-IVD Working Group.

[8] https://www.who.int/publications/i/item/9789240017740

Moreover, Member States will continue sharing details via the HSC on the implementation of national validation studies, particularly concerning the validation methodologies and protocols applied.

- **Quality of data produced through independent validation studies**

It is key that the sensitivity levels of the rapid antigen tests, as reported by independent national validation studies, reflect clinical performance as measures in practice, rather than the sensitivity reported by the manufacturer. In this context, the JRC is planning to verify the science behind the validation data that has been made available from the Member States through the Health Security Committee, and to verify the findings (eventually in laboratory settings). For the validation of rapid antigen tests, the JRC plans to use the "gold standard" method of NAAT, in particular RT-PCR, by benchmarking the antigen test samples against qPCR and digital PCR.

Moreover, Member States will continue sharing details via the HSC on the results produced by national validation studies, particularly concerning 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.

- **Occurrence of SARS-CoV-2 variants of concern**

Future updates to the common rapid antigen tests list should also take into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARS-CoV-2 virus on the efficacy of RT-PCR tests should also be kept under review. In particular, in the current context of circulation of variants of concern, the use of rapid antigen tests does not allow samples to be used for subsequent detection of new variants (by NAAT and/or sequencing).

Mutual recognition of COVID-19 test results

- **Criteria to be used for the mutual recognition of rapid antigen test results**

At the moment, the extent to which rapid antigen tests are being used in practice by Member States differs greatly. In this context, Member States have agreed that, for now, the criterion that at least 3 Member States should be using a specific type of rapid antigen test in practice for it to be mutually recognised, applies. Member States will further discuss and explore whether other criteria should be used in the future. It is key that such discussions are held in the context of quality assurance measures.

- **Context in which mutual recognition should be applied**

Member States should further discuss the situation in which there is a need for mutual recognition of rapid antigen test results (as well as other COVID-19 test results). In addition to the context of travel, it is relevant to further discuss between countries when the list of rapid antigen tests of which their results will be mutually recognised should be applied.

ANNEX I: Common list of rapid antigen tests[9]

As agreed by Member States on 17 February 2021 and updated on 10 May 2021

The entries highlighted in yellow are the RATs of which Member States have agreed to mutually recognise their test results for public health measures

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
AAZ-LMB	COVID-VIRO® Rapid antigen test COVID-19	Yes	96.1% sensitivity 100% specificity	**BE**: 96.6% sensitivity, 100% specificity, NP swab **FR:** >95%% sensitivity, 100% specificity **SI**: 96.6% sensitivity, 100% specificity, NP swab		BE, FR, SI	CH	FR CH		Yes (1833)	Yes
Abbott Rapid Diagnostics	Panbio™ COVID-19 Ag Rapid Test	Yes	91.4% sensitivity 99.8% specificity Nasal/NP swab	**BE**: 93.3% sensitivity, 99.4% specificity, NP Swab 98.1% sensitivity, 99.8% specificity, Nasal swab **DE**: 91.4% sensitivity 99.8% specificity, NP swab 98.1% sensitivity, 99,8 specificity, Nasal swab	FIND Evaluation - Studies in DE and CH, NP swab, 10 Dec 2020	AT, BE, BG, CY, CZ, DE[2], DK, EE, EL, ES, FR[1], HR, IT, LT, LV, MT, NL[5], PL, PT, RO, SE, SK	CH, ME, MK, NO, UK, UA	DE[2], ES, NL[5] CH, NO	CY, ES, HR, HU, IE, LU, PT, SE	Yes (1232)	Yes
Acon Biotech (Hangzhou) Co., Ltd	Flowflex SARS-CoV-2 Antigen Rapid Test	Yes	97.1% sensitivity 99.6% specificity Nasal swab	**BE:** 96.9% sensitivity, 99.5% specificity, NP swab **DE**: 97.1% sensitivity, 99.5% specificity, NP/Nasal swab	Ongoing	AT, BE, LT, LV, SI		DE[2]		Yes (1468)	Yes
AESKU.DIAGNOSTICS GmbH & Co, KG	AESKU.RAPID SARS-CoV-2	Yes		**DE**: 96% sensitivity, 98% specificity **SI**: 96% sensitivity, 98% specificity, Nasal swab		AT, DE[2], SI		DE[2]		No	No

[9] This is the list of RATs as referred to by the Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate), COM/2021/130 final, of 17 March 2021, which is currently being negotiated in the European Parliament and the Council. Member States shall issue and accept Digital Green Certificates based on this list (and subsequent updates).

[10] In case rapid antigen tests are not included in the JRC Database, manufacturers are invited to submit this information here: https://covid-19-diagnostics.jrc.ec.europa.eu/contact/feedback_ant.

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Affimedix	TestNOW® - COVID-19 Antigen	Yes		**DE**: 93.7% sensitivity, 99.2% specificity		DE[2]		DE[2]		No	No
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	**BE**: 97.3% sensitivity, 100% specificity, NP swab **DE**: 97.3% sensitivity, 100% specificity **SI**: 97.3% sensitivity, 100% specificity, NP swab		AT, BE, BG, DE[2] HR, PT, SI	CH, UA	DE[2] CH	HR	Yes (1304)	Yes
AmonMed Xiamen Biotechnology Co., Ltd.	COVID-19 Antigen Rapid Test Kit (Collodial Gold)	Yes	95.05% sensitivity Nasal swab	**DE**: 98.02% sensitivity , 99.6% specificity		DE[2]		DE[2]		Yes (1763)	Yes
Anbio (Xiamen) Biotechnology Co., Ltd.	Rapid COVID-19 Antigen-Test (colloidal Gold)	Yes	99.2% sensitivity 100% specificity	**DE**: 99.27% sensitivity, 100% specificity		AT, DE[2]		DE[2]		Yes (1822)	No
Anhui DeepBlue Medical Technology Co. Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)	Yes		**BE**: 95% sensitivity, 99% specificity, NP/OP swab **DE**: 97.1% sensitivity, 99.8% specificity		BE, DE[2]	UK	DE[2]		Yes (1589 or 1736)	Yes
ArcDia International Ltd	mariPOC SARS-CoV-2	Yes	92.3% sensitivity 100% specificity	**FI:** Meets the minimum performance requirements – see the report for details.		FI		FI		No	Yes
Asan Pharmaceutical CO., LTD	Asan Easy Test COVID-19 Ag	Yes	94.7% sensitivity 97.7% specificity	**DE**: 94.67% sensitivity, 97.71% specificity		DE[2]		DE[2]		Yes (1654)	Yes
Atlas-Link (Beijing) Technology Co. Ltd	NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	Yes		**DE**: 97.6% sensitivity, 99.2% specificity		AT, DE[2]	CH	DE[2] CH		Yes (2010)	Yes
AXIOM Gesellschaft für Diagnostica und Biochemica mbH	COVID-19 Antigen Rapid Test	Yes		**DE**: 98.1% sensitivity, 100% specificity		DE[2]		DE[2]		No	No
Azure Biotech, Inc.	Dia Sure COVID-19 Antigen Rapid Test Device	Yes		**DE**: 94.3% sensitivity, 99.1% specificity		DE[2]		DE[2]		No	No
Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Yes	97.1% sensitivity 99.76% specificity	**BE**: 98.6% sensitivity, 100% specificity, NP Swab 97.3% sensitivity, 99.2% specificity. OP swab **DE**: 95.37% sensitivity, 99.13% specificity **SI**: 96.6% sensitivity, 99.8% specificity, NP swab	Validation study to start	AT, BE, DE[2], RO, SI		DE[2]		Yes (1870)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Beijing Lepu Medical Technology	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	Yes	92% sensitivity unknown specificity Nasal swab	**BE**: 92% sensitivity, 99.3% specificity, Nasal **DE**: 92.0% sensitivity, 99.26% specificity **SI**: 92% sensitivity, 99.2% specificity, NP swab		AT, BE, DE[2], SI, RO	UA	DE[2]		Yes (1331)	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**: 96.6% sensitivity, 96.9% specificity		DE[2]		DE[2]		Yes (1484)	Yes
BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	Yes		**BE**: 96% sensitivity, 100% specificity, NP swab **DE**: 96% sensitivity, 100% specificity		AT, BE, DE[2], DK,FR, NL[5], PT	CH	DE, NL[5], CH		Yes (1223)	Yes
BTNX Inc.	Rapid Response COVID-19 Antigen Rapid Test Device	Yes	94.55% sensitivity 100% specificity	**DE**: 94.55% sensitivity, 100% specificity		AT, DE[2]		DE[2]		Yes (1236)	No
CerTest Biotect S.L.	CerTest SARS-CoV-2 CARD TEST	Yes	92.9% sensitivity 99.6% specificity NP swab	**BE**: 92.9% sensitivity, 99.6% specificity, NP swab **SI**: 92.9% sensitivity, 98.4% specificity, NP/OP swab		ES, PT, SI		ES		Yes (1173)	Yes
Core Technology Co., ltd	Canea Covid-19 Antigen Rapid Test	Yes		**DE**: 97.5% sensitivity, 100% specificity		DE[2]		DE[2]		No	No
Core Technology Co., ltd	Coretests COVID-19 Ag Test	Yes	98.1% sensitivity	**DE**: 98.1% sensitivity, 99.6% specificity		AT, DE[2], RO		DE[2]		Yes (1786)	No
Dialab	DIAQUICK COVID -19 Ag Cassette	Yes		**BE**: Z20401CE: 93.2% sensitivity, 100% specificity, NP swab Z20601CE: 96.4% sensitivity, 99.2% specificity, NP swab **DE**: 97.3% sensitivity, 100% specificity		AT, BE, DE[2]		DE[2]		Yes (1375)	Yes
DDS DIAGNOSTIC	Test Rapid Covid-19 Antigen (tampon nazofaringian)	Yes	98.77% sensitivity 99.03% specificity	**RO:** Meets the minimum performance requirements.		RO		RO China	RO	Yes (1225)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
GenBody Inc	GenBody COVID-19 Ag Test	Yes	90% sensitivity 98% specificity NP/OP swab	**DE**: 90% sensitivity 98% specificity	Withdrawn	DE[2]	UA	DE[2]		Yes (1244)	Yes
GenSure Biotech Inc	Gensure COVID-19 Antigen Rapid Test Kit (REF: P2004) (DIA-COVID - 19 Ag Rapid Test)	Yes		**DE**: 96.86% sensitivity, 100% specificity		DE[2]		DE[2]		Yes (1253)	Yes
Green Cross Medical Science Corp.	GENEDIA W COVID-19 Ag	Yes		**BE**: 90.2% sensitivity, 100% specificity, NP swab **DE**: 90.1% sensitivity, 100% specificity		AT, BE, DE[2]		DE[2]		Yes (1144)	Yes
Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	Yes	96.23% sensitivity 98.51% specificity Nasal swab	**DE**: 96.6% sensitivity, 99.07% specificity		AT, DE[2]		DE[2]		Yes (1747)	No
Guangdong Wesail Biotech Co. Ltd	COVID-19 AG Test Kit	Yes	90% sensitivity 98% specificity NP/Nasal swab	**DE**: 90% sensitivity, 99.2% specificity **SI**: 90% sensitivity, 98% specificity, NP/Nasal swab		DE[2], SI		DE[2]		Yes (1360)	No
Guangzhou Wondfo Biotech Co., Ltd	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Yes		**BE**: 96.2% sensitivity, 99.7% specificity, NP/OP swab **DE**: 96.18 % sensitivity, 99.72% specificity		AT, BE, BG, DE[2], FR	CH	DE[2]		Yes (1437)	Yes
Hangzhou AllTest Biotech Co., Ltd	ALL TEST Covid 19 Antigen- Rapidtest (Swab)	Yes		**AT:** 96,4% sensitivity, 99,0% specificity, specimen type: NP; if N sens reduced to: 92,9%		AT		AT	AT	Yes (1256)	Yes
Hangzhou Clongene Biotech Co., Ltd.	COVID-19 Antigen Rapid Test Kit	Yes	98.5% sensitivity unknown specificity Nasal swab	**BE**: 91.4% sensitivity, 100% specificity, NP/OP swab **DE**: 91.4% sensitivity, 99.4% specificity **SI**: 91.4% sensitivity, 100% specificity, NP/OP swab		AT,BE, DE[2], FR, SI	CH	DE[2] CH	HR	Yes (1363)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Hangzhou Clongene Biotech Co., Ltd.	COVID-19/Influenza A+B Antigen Combo Rapid Test	Yes	91% sensitivity 100% specificity NP swab	**DE**: 97.7% sensitivity, 99.8% specificity		DE[2]		DE[2]		Yes (1365)	Yes
Hangzhou Laihe Biotech Co.	LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Yes		**DE**: 96.29% sensitivity, 100% specificity		AT	CH	DE[2]		Yes (1215)	No
Hangzhou Lysun Biotechnology Co., Ltd.	COVID-19 antigen Rapid Test Device (Colloidal Gold)	Yes		**DE**: 96.29% sensitivity, 100% specificity		DE[2]	CH	DE[2]		No	No
Hangzhou Testsea Biotechnology Co., Ltd.	Testsealabs Covid-19 Antigen Rapid Test Cassette	Yes	92.1% sensitivity 98.1% specificity Nasal swab	**DE**: 97.6% sensitivity 98.4% specificity		DE[2]		DE[2]		Yes (1392)	No
Hangzhou Immuno BiotechCo., Ltd	SARS-CoV2 Antigen Rapid Test	Yes		**DE**: 95.6% sensitivity, 100% specificity		AT, DE[2]		DE[2]		No	No
Hangzhou Immuno BiotechCo., Ltd	Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasiv)	Yes	94% sensitivity 100% specificity Nasal swab, NP	**DE**: 94.39% sensitivity 97.67% specificity		DE[2]		DE[2]		Yes (1844)	No
Healgen Scientific Limited	Coronavirus Ag Rapid Test Cassette (Swab)	Yes		**DE**: 97.25% sensitivity, 100% specificity **SI**: 96.7% sensitivity, 99.2% specificity, NP/Nasal swab		AT, DE[2], NL[5], SE, SI	CH	DE[2], NL[5]	SE[3]	Yes (1767)	No
Humasis Co. Ltd	HUMASIS COVID-19 Ag test	Yes		**BE**: 95.5% sensitivity, 100% specificity, NP swab **DE**: 95.5% sensitivity, 100% specificity **SI**: 95.5% sensitivity, 100% specificity, NP swab		AT, BE, BG, DE[2], FR, HR, SE, SI		DE[2]	HR, SE	Yes (1263)	Yes
Joinstar Biomedical Technology	COVID-19 Antigen Rapid Test (Colloidal Gold)	Yes	96.1% sensitivity 98.1% specificity Nasal swab	**DE**: 96.1% sensitivity, 98.1% specificity **SI**: 96.1% sensitivity, 98.1% specificity, NP swab		AT, DE[2], PT, SI		DE[2]		Yes (1333)	Yes
JOYSBIO (Tianjin) Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	Yes	98.13% sensitivity	**SI:** Meets the minimum performance requirements – see the report for details.	FIND evaluation studies in CH 11 Feb 2021	CZ, SI		SI CH		Yes (1764)	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Labnovation Technologies Inc.	SARS-CoV-2 Antigen Rapid Test Kit	Yes		**DE**: 96.3% sensitivity, 97.3% specificity **SI**: 96.3% sensitivity, 97.3% specificity, NP/OP swab		DE[2], SI		DE[2]		Yes (1266)	Yes
Lumigenex (Suzhou) Co., Ltd	PocRoc SARS-Cov-2 Antigen Schnellnachweiskit (Gold kolloidal)	Yes		**DE**: 93.33% sensitivity , 99.16% specificity		DE[2]		DE[2]		No	No
LumiQuick Diagnostics Inc.	QuickProfile™ COVID-19 ANTIGEN Test	Yes		**BE**: 94% sensitivity, 99% specificity, NP swab **DE**: 93.7% sensitivity, 98.8% specificity **SI**: 93.7% sensitivity, 98.8% specificity, NP swab		BE, DE[2] ,FR, SI,		DE[2]		Yes (1267)	Yes
LumiraDX UK LTd	LumiraDx SARS-CoV-2 Ag Test	Yes	97.6% sensitivity 96.7% specificity Nasal swab	**DE**: 93.8% sensitivity, 98.8% specificity **SI**: 97.6% sensitivity, 97.7% specificity, NP/Nasal swab		DE[2], ES, SI	CH	DE[2], ES CH		Yes (1268)	No
MEDsan GmbH	MEDsan® SARS-CoV-2 Antigen Rapid Test	Yes	92.5% sensitivity 99.8% specificity NP/OP swab	**BE**: 92.5% sensitivity, 99.8% specificity, Nasal/OP swab **DE**: 92.5% sensitivity, 99.8% specificity		AT, BE, DE[2]	CH	DE[2] CH		Yes (1180)	No
MöLab	COVID-19 Rapid Antigen Test	Yes		**DE**: 97.25% sensitivity , 99.99% specificity		DE[2]		DE[2]		Yes (1190)	No
MP Biomedicals Germany	Rapid SARS-CoV-2 Antigen Test Card	Yes	96.39% sensitivity 99.03% specificity Nasal swab	**BE**: 96.4% sensitivity, 99% specificity, NP/OP swab **DE:** 96.39 % sensitivity, 99.03% specificity		AT, BE, DE[2]	CH	DE[2] CH		Yes (1481)	Yes
nal von minden GmbH	NADAL COVID -19 Ag +Influenza A/B Test	Yes		**DE**: 97.6% sensitivity, 99.9% specificity		DE[2]		DE[2]		No	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
nal von minden GmbH	NADAL COVID -19 Ag Test	Yes	97.6% sensitivity 99.9% specificity Nasal swab	**BE**: 97.6% sensitivity, 99.9% specificity, NP/OP swab **DE**:97.6% sensitivity, 99.9% specificity **SI**: 97.6% sensitivity, 99.9% specificity, NP/OP swab	FIND Evaluation studies 26 April 21	AT, BE, DE[2], PT, SI		DE[2], FR China	HR	Yes (1162)	No
NanoEntek	FREND Covid-19 Ag	Yes	94.12% sensitivity 100% specificity NP swab	**DE**: 94.12% sensitivity , 100% specificity		DE[2]		DE[2]		Yes (1420)	Yes
Oncosem Onkolojik Sistemler San. ve Tic. A.S.	CAT	Yes	93.75% sensitivity 98.04% specificity Nasal swab	**DE**: 96.36% sensitivity, 98.04% specificity		DE[2]		DE[2]		Yes (1199)	No
PCL Inc	PCL COVID19 Ag Rapid FIA	Yes		**DE**: 94,92 % sensitivity, 99,99 % specificity **SI**: 95.5% sensitivity, 98.6% specificity, NP/OP swab, sputum		FR, DE, RO, SI		DE[2]		Yes (308)	No
PerGrande Biotech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic assay)	Yes		**DE**: 94.28% sensitivity, 99.11% specificity		AT, DE[2]		DE[2]		No	No
Precision Biosensor Inc (Axon Lab SG)	Exdia COVI-19 Ag Test	Yes	93.9% sensitivity 98% specificity NP swab	**DE**: 93.88% sensitivity , 98% specificity **SI**:93.9% sensitivity, 98% specificity, NP swab		SI, DE[2]	CH	DE[2] CH		Yes (1271)	Yes
Qingdao Hightop Biotech Co Ltd	SARS-CoV-2 Antigen Rapid Test	Yes	95% sensitivity unknown specificity Nasal swab	**DE**: 95% sensitivity 99.75% specificity		AT, DE[2]		DE[2]		Yes (1341)	No
Quidel Corporation	Sofia 2 SARS Antigen FIA	Yes	96.7% sensitivity 100% specificity NP/Nasal swab	**BE**: 96.7% sensitivity, 100% specificity, NP/nasal swab **DE**: 96.7% sensitivity , 100% specificity **SI**: 96.7% sensitivity, 100% specificity, NP/Nasal swab		AT, BE, DE[2], FI, NL[5], PT, SI	CH	DE[2], NL[5] CH	SI	Yes (1097)	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Rapigen Inc.	BIOCREDIT COVID-19 Ag - SARS-CoV 2 Antigen test	Yes	90.2% sensitivity 100% specificity NP swab	**SI**: 90.2% sensitivity, 100% specificity, NP swab		AT, RO, SK, FR, SI		HU	PT	Yes (1606)	Yes
Roche (SD BIOSENSOR)	SARS-CoV-2 Antigen Rapid Test	Yes	96.52% sensitivity 99.2% specificity NP	**DE**: 96.52% sensitivity, 99.68% specificity		AT, DE[2], NL, RO	CH, NO	DE[2]		Yes (1604)	Yes
Safecare Biotech Hangzhou Co	COVID-19 Antigen Rapid Test Kit (Swab)	Yes	97.04% sensitivity unknown specificity Nasal swab	**DE**: 97.27 % sensitivity , 99.42% specificity		AT, DE[2], FR	CH	DE[2]		Yes (1489)	No
Safecare Biotech Hangzhou Co	Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19)	Yes	Sensitivity: 97.04%	**DE**: 97.04% sensitivity , 99.44% specificity		DE[2]		DE[2]		Yes (1490)	No
SD BIOSENSOR, Inc.; Roche	STANDARD F COVID-19 Ag FIA	Yes	94,09% sensitivity 98.52% specificity	**BE**: 96.5% sensitivity, 99.7% specificity, NP swab **DE**: 94% sensitivity 97% specificity	FIND Evaluation - Studies in DE and Brazil, 10 Dec 2020	AT, BE, BG, DE[2], IT , LU, LV, NL[5], PT, RO, SK	CH	DE[2], IT, NL[5], DK CH, UK, BR	LU, PT	Yes (344)	Yes
SD BIOSENSOR, Inc.; Roche	STANDARD Q COVID-19 Ag Test	Yes	96.52% sensitivity 99.68% specificity NP swab	**BE**: 96.5% sensitivity, 99.7% specificity, NP swab **DE**: 96.52% sensitivity, 99.68% specificity **SI**: 96.5% sensitivity, 99.7% specificity, NP swab	FIND Evaluation - Studies in DE, CH and Brazil, 10 Dec 2020	AT, BE, BG, CY, DE[2], DK, EE, ES, FI, FR, HR, IT, LU, LV, MT, NL[5], RO, SE, SK, SI	ME, NO, CH	DE[2], ES, IT, NL[5], DK CH, UA, UK, BR	HR, IE, LU, SI, SE	Yes (345)	Yes
SGA MÜHENDİSLİK DANIŞMANLIK EĞİTİM İÇ VE DIŞ TİC. A.Ş.	V-Chek SARS-CoV2- Rapid Ag Tets (Coloidal Gold)	Yes	96.6% sensitivity, Nasal swab	**DE**: 96.6% sensitivity, 99% specificity		DE[2]		DE[2]		Yes (1319)	No
Shenzen Ultra-Diagnostics Biotec Co.	SARS-COV-2 Antigen test Kit (colloidal gold)	Yes		**BE**: 92% sensitivity, 100% specificity, NP swab 100% sensitivity, 100% specificity, OP swab 96% sensitivity, 100% specificity, Saliva **SI**: 95.9% sensitivity, 99.9% specificity, NP/OP/Nasal swab, saliva		AT, BE, ES, SI		BE, SI		No	No
Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2-Antigen-Schnelltests-Set	Yes		**DE**: 98% sensitivity , 100% specificity		DE[2]		DE[2]		No	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Shenzhen Watmind Medical Co., Ltd	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	Yes	95.15% Sensitivity Nasal swab, Salvia	**DE**: 95.15% sensitivity , 99.12% specificity		AT, DE[2], FR		DE[2]		Yes (1769)	No
Shenzhen Zhenrui Biotech Co., Ltd	Zhenrui ®COVID-19 Antigen Test Cassette	Yes	96% sensitivity Nasal swab, Salvia	**DE**: 96% sensitivity 97% specificity		DE[2]		DE[2]		Yes (1574)	No
Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	Yes	96.72% sensitivity 96.72% specificity Nasal swab	**BE**: 98.32% sensitivity, 99.6% specificity, NP swab 97.25% sensitivity, 100% specificity, Nasal swab **SI**: 96.7% sensitivity, 99.2% specificity, NP/Nasal swab		AT, BE, DE[2], FR, HR, NL[5], PT, SE, SI	CH	DE[2], ES, NL[5]	HR, PT, SE[3]	Yes (1218)	Yes
Sugentech, Inc.	SGTi-flex COVID-19 Ag	Yes		**DE**: 95.1% sensitivity, 99% specificity		AT, DE[2]		DE[2]		Yes (1114)	No
TODA Pharma	TODA CORONADIAG Ag®	Yes	98.6% sensitivity unknown specificity Nasal swab	**BE**: 96.6% sensitivity, 100% specificity, NP/OP swab **DE**: 96.6% sensitivity, 100 specificity **SI**: 96.6% sensitivity, 100% specificity, NP/OP swab		BE, DE[2], SI		DE[2]		Yes (1466)	No
Tody Laboratories Int.	Coronavirus (SARS-CoV 2) Antigen - Oral Fluid	Yes	90.1% sensitivity 99.3% specificity	**RO**: Meets the minimum performance requirements.		RO		ES UA, China	RO	No	Yes
Vitrosens Biyoteknoloji Ltd. Şti.	RapidFor SARS-CoV-2 Ag Test Kit	Yes	97.3% sensitivity unknown specificity Nasal swab, saliva	**DE**: 97.3% sensitivity, 99% specificity **SI**: 97.3% sensitivity, 99% specificity, NP/OP/Nasal swab		DE[2], SI		DE[2]		Yes (1443)	Yes
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiagTM Pro SARS-CoV-2 Ag Rapid Test	Yes		**AT**: 97,06% sensitivity, 100% specificity, all specimen types, i.e. N&OP&NP swab		AT		AT	AT	Yes (1246)	Yes
Wuhan EasyDiagnosis Biomedicine Co., Ltd.	Antigen-Testkit für COVID-19 (SARS-Cov-2)	Yes		**DE**: 96.15% sensitivity , 99.26% specificity		DE[2]		DE[2]		No	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Xiamen Boson Biotech Co	Rapid SARS-CoV-2 Antigen Test card	Yes	Not specified	**BE**: 93.8% sensitivity, 100% specificity, NP swab **DE**: 96.49% sensitivity, 99.03% specificity		AT, BE, BG, DE[2], FR, RO	CH	DE[2] CH		Yes (1278)	Yes
Xiamen Wiz Biotech Co., Ltd.	SARS-CoV-2 Antigen Rapid Test	Yes		**DE**: 96.3% sensitivity, 100% specificity		AT, DE[2]		DE[2]		No	Yes
Xiamen Wiz Biotech Co., Ltd.	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	Yes		**DE**: 95.91% sensitivity , 100% specificity		AT, DE[2]		DE[2]		No	No
Zhejiang Anji Saianfu Biotech Co.., Ltd.	AndLucky COVID-19 Antigen Rapid Test	Yes	95.8% sensitivity, Nasal swab, Saliva	**DE**: 97.5% sensitivity, 99.1% specificity		AT, DE[2]		DE[2]		Yes (1296)	No
Zhejiang Anji Saianfu Biotech Co.., Ltd.	reOpenTest COVID-19 Antigen Rapid Test	Yes	95.8% sensitivity, Nasal swab, Saliva, Plasma	**DE**: 95.8% sensitivity, 99% specificity		DE[2]		DE[2]		Yes (1295)	No
Zhejiang Orient Gene Biotech Co., Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	Yes	96.72% sensitivity unknown specificity Nasal swab	**BE**: 98.32% sensitivity, 99.6% specificity, NP swab 97.25% sensitivity, 100% specificity, Nasal swab **DE**: 96.72% sensitivity, 99.22% specificity		AT, BE, BG, DE[2], PT	CH, UK	DE[2]	SE[3]	Yes (1343)	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 have completed practical validation studies in Germany: See: https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/evaluierung-sensitivitaet-sars-cov-2-antigentests-04-12-2020.pdf?__blob=publicationFile&v=43

[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

ANNEX II: Common standardised set of data to be included in COVID-19 test result certificates, as agreed by Member States on 17 February 2021 and updated on 19 March 2021

Section	Data element	Description	Preferred Code System
Person identification	Person name	The legal name of the tested person. Surname(s) and forename(s), in that order.	
	Person identifier *(optional)*	An identifier of the tested person, according to the policies applicable in each country. Examples: citizen ID and/or document number (ID-card/passport).	
	Person date of birth *(optional)*	Tested person's date of birth. Mandatory if no Person identifier is provided.	Complete date, without time, following the ISO 8601.
Test information	Disease or agent targeted	Specification that it concerns the detection of SARS-CoV-2 infection.	ICD-10, SNOMED CT
	Type of test	Description of the type of test that was conducted, e.g. NAAT or rapid antigen test.	LOINC, NPU
	Test name *(optional for NAAT)*	Commercial or brand name of the test.	
	Test Manufacturer *(optional for NAAT)*	Legal manufacturer of the test.	
	Sample origin *(optional)*	The type of sample that was taken (e.g. nasopharyngeal swab, oropharyngeal swab, nasal swab, saliva).	SNOMED CT
	Date and time of the test sample collection	Date and time when the sample was collected.	Complete date, with time and time zone, following ISO 8601
	Date and time of the test result production *(optional)*	Date and time when the test result was produced.	Complete date, with time and time zone, following ISO 8601
	Result of the test	For example, negative, positive, inconclusive or void.	SNOMED CT
	Testing centre or facility *(mandatory for NAAT)*	Name/code of testing centre, facility or a health authority responsible for the testing event. *Optional*: address of the testing facility.	
	Health Professional identification *(optional)*	Name or health professional code responsible for conducting (and validating) the test. Surname(s) and forename(s), in that order.	
	Country where the test was taken	The country in which the individual was tested.	ISO 3166 Country Codes
Test certificate metadata	Test result certificate issuer	Entity that issued the COVID-19 test result certificate (allowing to check the certificate).	
	Certificate identifier	Reference of the COVID-19 test result certificate (unique identifier).	