EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security

EU health preparedness:

A common list of COVID-19 rapid antigen tests 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

Annex I

Common list of COVID-19 rapid antigen tests

A first update was agreed by the HSC on 10 May 2021
A second update was agreed by the HSC on 16 June 2021
A third update was agreed by the HSC on 7 July 2021

IMPORTANT: A (interim) grace period of 8 weeks applies whenever updates are made to Annex I, the common list of COVID-19 rapid antigen tests

Annex II

Common standardised data set of to be included in COVID-19 test result certificates

An update to Annex II was agreed by the HSC on 19 March 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, 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 in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

[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

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 (HSC), 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 deliverables as agreed by Member States. Its content is prepared based on the criteria set out in the Council Recommendation and further criteria agreed by Member States, and considers the relevant recommendations published by the Commission[3] as well as technical guidance issued the European Centre for Disease Prevention and Control (ECDC)[4] and the World Health Organization (WHO)[5].

II. Annex I: 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 meet the three performance criteria as outlined in section I of this document.

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

A first update to Annex I was agreed by the Health Security Committee on 10 May 2021, a second update on 16 June 2021, and a third update on 7 July 2021.

The common list of rapid antigen tests is regularly being reviewed by Member States, 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.

[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

On 7 July 2021, the HSC agreed that a (interim) grace period of 8 weeks applies whenever updates are made to Annex I, the common list of COVID-19 rapid antigen tests. The grace period, which will be further discussed by the HSC during summer 2021 and for which a new duration may be set in the future, applies to both the inclusion of new devices as well as the removal of rapid antigen tests that are included in the list. 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.

The Health Security Committee agrees that, considering that *all* of the rapid antigen tests included in the EU common list are eligible for a test certificate issued as part of the EU Digital COVID Certificate[7], the entire list is considered to consist of rapid antigen tests of which Member States mutually recognise the test results for public health measures.

III. HSC Technical Working Group on COVID-19 Diagnostic Tests

Based on the increasing political and commercial interest in the HSC agreed common list of rapid antigen tests, particularly in the context of the EU Digital COVID Certificate[8], there is a need to put in place a more structured, coherent and swift procedure for updating the common list of rapid antigen tests. As a first step, since 10 May 2021, it is now possible for manufacturers to submit data and information concerning rapid antigen tests that they believe should be considered for inclusion in the HSC agreed common list. This information will thus be reviewed and considered alongside the proposals put forward by EU Member States.

Secondly, a HSC Technical Working Group on COVID-19 Diagnostic Tests was set up. This Working Group, consisting of technical experts from EU and EEA Member States, will be responsible for reviewing the information submitted by countries and manufacturers, taking into account the latest result of independent validation studies and country practices and experiences. Based on this, the technical working group will present proposals to the HSC for further updates to the common list of rapid antigen tests. The HSC will thus remain the platform where agreement between Member States is reached for updates to the list.

On 29 June 2021, the experts of the Technical Working Group agreed on (interim) definitions and criteria that should be considered for independent validation studies assessing the clinical performance of rapid antigen tests for COVID-19 diagnosis. There was a strong need to set these further criteria in addition to the ones presented in Council Recommendation 2021/24/01 for the accurate assessment of proposals put forward. As of 29 June, the following additional criteria have been taken into account by the Technical Working Group during their review process, and will stay in place until further notice:

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0953
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0953&from=EN.

Agreed (interim) definition of an independent validation study:

- A study that may involve collaborations with or that may involve funding by private entities, however, there is always a public body involved and the study is performed objectively and in the public interest.

Agreed (interim) clinical performance criteria for independent validation studies:

- In independent evaluations of unselected participants, assays should have a sensitivity of 90% or greater for subjects with a Ct $\leq$ 25, in symptomatic people (positive samples from early infection within the first 7 days after symptom onset).
- When this data is not yet available, for an interim period, a sensitivity of over 80% when testing unselected symptomatic participants, where the diagnosis is confirmed by PCR in independent field studies, will be accepted.
- Target population considered in the context of an independent validation study should be based on at least 100 positive samples and at least 100 negative samples.
- In all cases: assays should have a specificity of at least 98%.
- In all cases: samples should have been compared against PCR / NP swab (gold standard).

As a wide range of different methodologies and protocols are being applied in countries, discussions on further criteria and definitions will continue, with the overall goal to agree on and develop an EU harmonised approach for validation studies assessing the clinical performance of COVID-19 rapid antigen tests. This guidance is expected to be agreed in the course of summer 2021, also taking into account the ongoing work by the In Vitro Diagnostics Working Group of the Medical Device Coordination Group (MDCG IVD WG) regarding guidance on the performance of COVID-19 tests in the context of CE-marking and common specifications under Article 9 of Regulation (EU) 2017/746[9].

Moreover, on 6 July 2021, the experts of the Technical Working Group agreed that:

- At the moment, the HSC agreed that the common list of rapid antigen tests only includes **rapid antigen tests for which their clinical performance was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens**.
- Rapid antigen tests that are based on other samples, such as saliva, sputum and/or faeces, are not included.
- The Technical Working Group will continue to monitor the development of these tests and will, if deemed necessary, consider their inclusion once relevant evidence and data has become available.

- Similarly, at the moment, the HSC agreed that the common list of rapid antigen tests only includes those tests that are **conducted by trained healthcare personnel or**

[9] The Medical Device Coordination Group is set up according to Art. 103 of Regulation (EU) 2017/745 and Art. 98 of Regulation (EU) 2017/746. This group is also responsible for overseeing the implementation of Directive 98/79/EC. See also Register of Commission Expert Groups and Other Similar Entities, code number X03565, and its subgroups.

trained operators where appropriate (in line with Commission Recommendation (EU) 2020/1743 of 18 November 2020).

- Rapid antigen self-tests are not included.
- The Technical Working Group will continue to monitor the development of rapid antigen self-tests and will, if deemed necessary, consider their inclusion once relevant evidence and data has become available.

- **Laboratory-based antigenic assays** (e.g. enzyme immunoassays such as ELISA or automated tests) should also be included in the EU common list.
- As of July 2021, it will be possible for manufacturers and countries to put forward proposals for lab-based antigenic assays for inclusion in the list.
- These proposals will, in first instance, be assessed against the same criteria as described by Council Recommendation 2021/24/01 and as agreed by the experts of the Technical Working Group on 29 June 2021. Further criteria for lab-based antigenic assays may be defined at a later stage.

IV. Annex II: 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**. 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.

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 and based on discussions that took place in the context of the EU Digital COVID Certificate.

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.

ANNEX I: Common list of rapid antigen tests[10]

As agreed by Member States on 16 June 2201

***Disclaimer**: This list was agreed by the HSC based on a proposal by the Technical Working Group on COVID-19 Diagnostic Tests. Experts participating in the Technical Working Group strongly recommend that use of rapid antigen tests is primarily intended for preliminary testing for SARS-CoV-2 infection in symptomatic patients, and note that rapid antigen tests should in particular be used in the specific contexts and circumstances referred to by the Commission Recommendation (EU) 2020/1743 of 18 November 2020 and the technical guidance by ECDC on 19 November 2020. The content of the common list is based on the clinical performance data and information that is available at this moment in time. The common list of rapid antigen tests does not include rapid antigen self-tests nor rapid antigen tests that are based on samples other than those collected from nasal, oropharyngeal or nasopharyngeal specimens. Updates to the common list are based on the criteria as described in Council Recommendation 2021/C 24/01 as well as the additional criteria and definitions agreed by the Technical Working Group on 29 June 2021. Discussions on criteria and definitions will continue during summer 2021, also taking into consideration the work carried out by the In Vitro Diagnostics Working Group of the Medical Device Coordination Group[9] on guidance on the performance of COVID-19 tests in the context of CE-marking and common specifications under Article 9 of Regulation (EU) 2017/746.*

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
AAZ-LMB	COVID-VIRO® Rapid antigen test COVID-19	Yes	96.6% 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)
Abbott Rapid Diagnostics	Panbio™ COVID-19 Ag Rapid Test	Yes	91.4% sensitivity 99.8% specificity Nasopharyngeal swab (Ct values ≤ 33 98.1% sensitivity 99.8% specificity Nasal swab (Ct values ≤ 33	**BE**[6]: Small-scale head-to-head comparison of 5 RATs in Belgian hospital lab. Panbio overall sensitivity (Ct range 14,6 – 35,5): 45/57 samples (79%). Sensitivity for Ct≤25: 17/18 samples. Overall specificity 100%. **DE**: 91.4% sensitivity 99.8% specificity, NP swab 98.1% sensitivity, 99,8 specificity, Nasal swab	DE (10 Dec 2020) 1108 samples, NP swab Clinical sensitivities: - Days ≤ 7: 90.8%; - Ct ≤ 33: 88.3%; - Ct ≤ 25: 95.8%; Clinical specificity: 99.9% CH (10 Dec 2020) 535 samples, NP swab	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, FI, NL[5] CH, NO	CY, ES, HR, HU, IE, LU, PT, SE	Yes (1232)

[10] This is the list of rapid antigen tests as referred to in Article 3 of the Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, OJ L 211, 15.6.2021, p. 1–22.

[11] 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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
				FI: Validated in several laboratories (studies not published), meeting criteria.	Clinical sensitivities: - Days ≤ 7: 85.6%; - Ct ≤ 33: 89.7%; - Ct ≤ 25: 96.8%; Clinical specificity: 100% India (25 June 2021) 526 samples, NP swab Clinical sensitivities: - Days ≤ 7: 61.3%-100%; - Ct ≤ 33: 74.2%-86.7%; - Ct ≤ 25: 91.9%-100%; Clinical specificity: 100%					
ACON Laboratories, Inc.	Flowflex SARS-CoV-2 Antigen Rapid Test	Yes	96.9% sensitivity Nasal swab	**BE:** 96.9% sensitivity, 99.5% specificity, NP swab **DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 98,7%	CH (9 June 2021) 279 samples, nasal swab Clinical sensitivities: - Days ≤ 7: 92.2%; - Ct ≤ 33: 98.3%; - Ct ≤ 25: 100%; Clinical specificity: 99.5%	AT, BE, DE, LT, LV, SI		DE[2]		Yes (1468)
AESKU.DIAGNOSTICS GmbH & Co, KG	AESKU.RAPID SARS-CoV-2	Yes	96% sensitivity 98% specificity NP swab	**DE**: 96% sensitivity, 98% specificity **SI**: 96% sensitivity, 98% specificity, Nasal swab		AT, DE[2], SI		DE[2]		Yes (2108)
Affimedix Inc.	TestNOW® - COVID-19 Antigen Test	Yes	96.1% sensitivity 99.4% specificity NP swab, NP swab	**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,4%		DE[2]		DE[2]		Yes (2130)
AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	Yes	97.3% sensitivity NP swab 97.3% sensitivity Nasal swab 100% specificity	**BE**: 97.3% sensitivity, 100% specificity, NP swab **DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% **SI**: 97.3% sensitivity, 100% specificity, NP swab		AT, BG, DE[2] HR, SI	CH, UA	DE[2] CH	HR	Yes (1304)
Anbio (Xiamen) Biotechnology Co., Ltd	Rapid COVID-19 Antigen-Test (colloidal Gold)	Yes		**DE**: 99.27% sensitivity, 100% specificity		AT, DE[2]		DE[2]		Yes (1822)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
Anhui Deep Blue Medical Technology Co., Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)	Yes	Nasal swab: 96,4% sensitivity, 99,8% specificity NP swab: 95,7% sensitivity, 99,3% specificity OP swab: 96,4% sensitivity, 99,8% specificity	**BE**: 95% sensitivity, 99% specificity, NP/OP swab **DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: >99%		BE, DE[2]	UK	DE[2]		Yes (1736)
Anhui Deep Blue Medical Technology Co., Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Nasal swab	Yes	96.4 % sensitivity 99.8 % specificity Nasal swab	**DE:** 96,4 % sensitivity, 99,8 % specificity		DE[2]		DE[2]		Yes (1815)
ArcDia International Ltd	mariPOC SARS-CoV-2	Yes	92% sensitivity 100% specificity	**FI:** Meets the minimum performance requirements – see the report for details.		FI		FI		Yes (768)
Asan Pharmaceutical Co., Ltd	Asan Easy Test COVID-19 Ag	Yes		**DE**: 94.67% sensitivity, 97.71% specificity		DE[2]		DE[2]		Yes (1654)
Atlas Link Technology Co. Ltd.	NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	Yes	98.5 % sensitivity 99.4 % specificity Nasal swab, OP swab	**DE**: 97.6% sensitivity, 99.2% specificity		AT, DE[2], SI	CH	DE[2] CH		Yes (2010)
Avalun	Ksmart® SARS-COV2 Antigen Rapid Test	Yes	Clinical Sensitivity: 93.18 % Clinical Specificity: 99.32 % Specimen: NP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,32%		DE		DE[2]		Yes (1800)
AXIOM Gesellschaft für Diagnostica und Biochemica mbH	COVID-19 Antigen Rapid Test	Yes	98% sensitivity 100% specificity NP swab, Nasal swab, throat swab	**DE**: 98.1% sensitivity, 100% specificity		DE[2]		DE[2]		Yes (2101)
Azure Biotech, Inc.	COVID-19 Antigen Rapid Test Device	Yes	95% sensitivity 99.2% specificity NP swab	**DE**: 94.3% sensitivity, 99.1% specificity		DE[2]		DE[2]		Yes (1906)
Becton Dickinson	BD Veritor™ System for Rapid Detection of SARS CoV 2	Yes	Clinical Sensitivity: 91.1 % Clinical Specificity: 99.6 % Specimen: Nasal swab	**NL:** Independent field study in symptomatic individuals - sampling was Nasal mid-turbinate and OP swab. Sensitivity overall: 79.5% - Sensitivity Ct<30: 93.2% - Specificity overall: 99.8%		NL		NL		Yes (1065)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
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**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.76% **SI**: 96.6% sensitivity, 99.8% specificity, NP swab	*Ongoing*	AT, BE, DE[2], RO, SI		DE[2]		Yes (1870)
Beijing Lepu Medical Technology Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	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)
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)
Biomerica Inc.	Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab)	Yes	Clinical Sensitivity: 94.7 % Specimen: Nasal swab, NP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,7%		DE		DE[2]		Yes (1599)
BIONOTE	NowCheck COVID-19 Ag Test	Yes	Clinical Sensitivity: 90.91 % Clinical Specificity: 99.43 %	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 98,6%	**Brazil** (20 April 2021) 400 samples, NP swab Clinical sensitivities: - Days ≤ 7: 92.2%; - Ct ≤ 33: 91.4%; - Ct ≤ 25: 94.8%; Clinical specificity: 97.3% **Brazil** (30 March 2021) 218 samples, Nasal/NP swab. Clinical sensitivities: - Days ≤ 7: 92.5% (N/NP); - Ct ≤ 33: 97.2% (N/NP); - Ct ≤ 25: 100% (N/NP); Clinical specificity: 98.6%	DE		DE[2]		Yes (1242)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
BIO-RAD	CORONAVIRUS AG RAPID TEST CASSETTE	Yes	Clinical Sensitivity: 98 % (NP Swab: 98,32% / Nasal Swab: 97,25%) Clinical Specificity: 99 % (NP Swab: 99,6% / Nasal Swab: 100%)	**ES:** NP swab: sensitivity 98,3%; specificity 99,6% (119 positive samples, 746 negative samples) Nasal swab: sensitivity 97,2%; specificity 100% (109 positive samples, 128 negative samples)		ES		ES		Yes (2031)
BIOSYNEX S.A.	BIOSYNEX COVID-19 Ag BSS	Yes	96% sensitivity, 100% specificity, NP swab	**BE[6]**: Small-scale head-to-head comparison of 5 RATs in Belgian hospital lab. Biosynex overall sensitivity (Ct range 14,6 – 35,5): 52/58 samples (89,7%). Sensitivity for Ct≤25: 18/18 samples. Overall specificity only 46,2%, but this is probably linked to the use of transport medium instead of the swab included in the kit. **DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% **NL**: Independent field study, mainly symptomatic individuals, sensitivity Ct≤30: 96.0%; specificity overall: 100%		AT, BE, DE[2], DK,FR, NL[5], PT	CH	DE, NL[5], CH	DK	Yes (1223)
BIOSYNEX SA	BIOSYNEX COVID-19 Ag+ BSS	Yes	Clinical Sensitivity: 97.5 %	**FR**: Validation study data: 125 positive and 118 negative samples; sensitivity 96%, specificity: 99%		FR		FR		Yes (1494)
BTNX Inc	Rapid Response COVID-19 Antigen Rapid Test	Yes	90.2% sensitivity 100% specificity NP swab, NP swab, OP swab	**DE**: 94.55% sensitivity, 100% specificity		AT, DE[2], SI		DE[2]		Yes (1236)
CerTest Biotec	CerTest SARS-CoV-2 Card test	Yes	92.9% sensitivity 99.6% specificity NP swab	**ES**: Ct ≤ 25, sensitivity: 94,0%; sensitivity for samples within the first 5 days after symptom onset: 84,8%		ES, PT, SI		DE[2], ES		Yes (1173)
Core Technology Co., Ltd	Coretests COVID-19 Ag Test	Yes	98.1% sensitivity 99.6% specificity NP swab	**DE**: 98.1% sensitivity, 99.6% specificity		AT, DE[2], RO		DE[2]		Yes (1919)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
CTK Biotech, Inc	OnSite COVID-19 Ag Rapid Test	Yes	Clinical Sensitivity: 92.3 % Clinical Specificity: 100 % Specimen: Nasal swab, NP swab	**ES:** 219 samples; Nasal swab - Clinical sensitivity 86% (90%: Ct <30) Specificity: 100% (Method B) **DK:** 107 samples; Nasal swab - clinical sensitivity 86%; (from asymptomatic and mild symptomatic individuals), Clinical specificity: 100%	*To start*	DK		DK, ES		Yes (1581)
DDS DIAGNOSTIC	Test Rapid Covid-19 Antigen (tampon nazofaringian)	Yes	98.77% sensitivity 99.03% specificity Nasal swab	**RO:** Meets the minimum performance requirements.		RO		RO China	RO	Yes (1225)
DIALAB GmbH	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)
Eurobio Scientific	EBS SARS-CoV-2 Ag Rapid Test	Yes	Clinical Sensitivity: 95.7 % Specimen: Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,1% **FR**: Validation study data: 119 positive and 125 negative samples; sensitivity 93%, specificity: 99%		DE, FR		DE[2], FR		Yes (1739)
Fujirebio	ESPLINE SARS-CoV-2	Yes	Clinical Sensitivity: 87.8 % ((n=98, Ct<33)) Clinical Specificity: 100 % Specimen: NP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,13%	DE (29 March 2021) 723 samples, NP swab Clinical sensitivities: - Days ≤ 7: 88.5%; - Ct ≤ 33: 87.8%; - Ct ≤ 25: 92.4%; Clinical specificity: 100%	DE		DE[2]		Yes (2147)
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)
Genrui Biotech Inc	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Yes	Clinical Sensitivity: 91.15 %	**DE:** Positive evaluation by Paul-Ehrlich-Institut		DE		DE[2]		Yes (2012)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
			Clinical Specificity: 99.02 % Specimen: Nasal swab, NP swab, OP swab	(sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,02%						
GenSure Biotech Inc	GenSure COVID-19 Antigen Rapid Test Kit	Yes	96.86% sensitivity, 100% specificity Nasal swab	**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 100%		DE[2]		DE[2]		Yes (1253)
Getein Biotech, Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	Yes	97.06% sensitivity 98.71% specificity Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 90% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		Yes (2183)
Green Cross Medical Science Corp.	GENEDIA W COVID-19 Ag	Yes	100% sensitivity 90.1% sensitivity NP swab, Anterior nasal swab	**BE**: 90.2% sensitivity, 100% specificity, NP swab **DE**: 90.1% sensitivity, 100% specificity		AT, BE, DE[2]		DE[2]		Yes (1144)
Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	Yes	96.23% sensitivity Nasal swab	**DE**: 96.6% sensitivity, 99.07% specificity		AT, DE[2]		DE[2]		Yes (1747)
Guangdong Wesail Biotech Co. Ltd	COVID-19 Ag Test Kit	Yes	90% sensitivity 98% specificity Nasal swab	**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 98% **SI**: 90% sensitivity, 98% specificity, NP/Nasal swab		DE[2], SI		DE[2]		Yes (1360)
Guangzhou Decheng Biotechnology CO., Ltd	V-CHEK, 2019-nCoV Ag Rapid Test Kit (Immunochromatography)	Yes	Clinical Sensitivity: 96.67 % Specimen: Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,5%		DE		DE[2]		Yes (1324)
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	**CH** (25 Feb 2020) 328 samples, NP swab Clinical sensitivities: - Days ≤ 7: 85.7%; - Ct ≤ 33: 92.2%; - Ct ≤ 25: 100%; Clinical specificity: 100%	AT, BE, BG, DE[2], FR	CH	DE[2]		Yes (1437)
Hangzhou Lysun Biotechnology Co. Ltd	COVID-19 Antigen Rapid Test Device (Colloidal Gold)	Yes	96.46% sensitivity 100% specificity Nasal swab	**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100%		DE[2]	CH	DE[2]		Yes (2139)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
Hangzhou AllTest Biotech Co., Ltd	COVID-19 Antigen Rapid Test	Yes	NP swab	**DE:** 93,40% sensitivity, 99,90% specificity		AT, BE, BG, FR, SI, RO	CH	DE	AT	Yes (1257)
Hangzhou Clongene Biotech Co., Ltd	COVID-19 Antigen Rapid Test Casette	Yes	Clinical Sensitivity: 91.4 % Clinical Specificity: 100 % NP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,4% at <Ct25) + Manufacturer specificity: 100%		DE		DE[2]		Yes (1610)
Hangzhou Clongene Biotech Co., Ltd.	Covid-19 Antigen Rapid Test Kit	Yes	98.5% (Ct<33) 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)
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)
Hangzhou Immuno Biotech Co., Ltd	Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)	Yes	94% sensitivity 100% specificity Nasal swab, NP	**DE**: 94.39% sensitivity 97.67% specificity		DE[2]		DE[2]		Yes (1844)
Hangzhou Immuno Biotech Co., Ltd	SARS-CoV2 Antigen Rapid Test	Yes	Clinical Sensitivity 98 % Clinical Specificity 100 %	**DE**: 95.6% sensitivity, 100% specificity		AT, DE[2]		DE[2]		Yes (2317)
Hangzhou Laihe Biotech Co.	LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Yes	Clinical Sensitivity: 95.07% % Clinical Specificity: 99.74% Nasal swab	**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,7%		AT, DE	CH	DE[2]		Yes (1215)
Hangzhou Testsea Biotechnology Co., Ltd.	Covid-19 Antigen Test Cassette	Yes	92.1% sensitivity 98.1% specificity Nasal swab	**DE**: 97.6% sensitivity 98.4% specificity		DE[2]		DE[2]		Yes (1392)
Healgen Scientific	Coronavirus Ag Rapid Test Cassette	Yes	80.6 % sensitivity 99.7% specificity NP swab	**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)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
Humasis	Humasis COVID-19 Ag Test	Yes	95.3% sensitivity Nasal swab	**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)
Jiangsu Medomics medical technology Co.,Ltd.	SARS-CoV-2 antigen Test Kit (LFIA)	Yes	Clinical Sensitivity: 97.73 % Clinical Specificity: 99.51 % Specimen: Anterior nasal swab, NP swab, Throat swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,51%		DE		DE[2]		Yes (2006)
Joinstar Biomedical Technology Co. Ltd	COVID-19 Rapid Antigen 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)
JOYSBIO (Tianjin) Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	Yes	98.13% sensitivity Nasal swab	**CZ:** Meets the minimum performance requirements – see the report for details.	CH (11 Feb 2021) 265 samples, Nasal swab Clinical sensitivities: - Days ≤ 7: 74.2%; - Ct ≤ 33: 78.9%; - Ct ≤ 25: 91.3%; Clinical specificity: 99.1%	AT, CZ, SI		CZ, DE[2] CH		Yes (1764)
Labnovation Technologies Inc.	SARS-CoV-2 Antigen Rapid Test Kit	Yes	NP/OP swab	**DE**: 96.3% sensitivity, 97.3% specificity **SI**: 96.3% sensitivity, 97.3% specificity, NP/OP swab		DE[2], SI		DE[2]		Yes (1266)
Lumigenex (Suzhou) Co., Ltd	PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Yes	93.33% sensitivity 99.16% specificity Nasal swab, NP/ OP swab	**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,16%		DE[2]		DE[2]		Yes (2128)
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)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
LumiraDX	LumiraDx SARS-CoV-2 Ag Test	Yes	97.6% sensitivity 96.6% specificity Nasal swab	**DE**: 93.8% sensitivity, 98.8% specificity **SI**: 97.6% sensitivity, 97.7% specificity, NP/Nasal swab **SKUP/2021/124**: 90% sensitivity, 97,8% specificity, NP swab	*To start*	DE[2], ES, SI	CH	DE[2], ES, SKUP – (Scandinavian evaluation of laboratory equipment for point of care testing) CH		Yes (1268)
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)
Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	Yes	95.05% sensitivity 98.99% specificity Nasal swab, NP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 90% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		Yes (2029)
MEXACARE GmbH	MEXACARE COVID-19 Antigen Rapid Test	Yes	Clinical Sensitivity: 96.17 % Specimen: Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,1%		DE		DE[2]		Yes (1775)
möLab	mö-screen Corona Antigen Test	Yes	NP swab	**DE**: 97.25% sensitivity , 99.99% specificity		DE[2], IE		DE[2], IE		Yes (1190)
MP Biomedicals	Rapid SARS-CoV-2 Antigen Test Card	Yes	96.17% sensitivity 99.16% specificity Nasal swab, Anterior 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)
Nal von minden GmbH	NADAL COVID -19 Ag +Influenza A/B Test	Yes	97% sensitivity 98% specificity NP swab	**DE**: 97.6% sensitivity, 99.9% specificity		DE[2]		DE[2]		Yes (2104)
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	**CH** (26 April 2021) 462 samples, NP swab Clinical sensitivities: - Days ≤ 7: 88.5%; - Ct ≤ 33: 92.4%; - Ct ≤ 25: 97.8%; Clinical specificity: 99.2%	AT, BE, CY DE[2], FR, PT, SI		DE[2], FR China	HR, SKUP	Yes (1162)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
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)
New Gene (Hangzhou) Bioengineering Co., Ltd.	COVID-19 Antigen Detection Kit	Yes	98% sensitivity Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 92,5% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		Yes (1501)
Oncosem Onkolojik Sistemler San. ve Tic. A.S.	CAT	Yes	93.75% sensitivity 98.04% specificity Nasal swab	**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 98,04%		DE[2]		DE[2]		Yes (1199)
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)
PCL Inc.	PCL COVID19 Ag Gold	Yes		**FR**: Validation study data: 120 positive and 200 negative samples; sensitivity 92%, specificity: 100%		FR		FR		Yes (2243)
PerGrande Bio Tech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromato-graphic Assay)	Yes	94.28% sensitivity 99.11% specificity NP swab, Nasal swab, OP swab	**DE**: 94.28% sensitivity, 99.11% specificity		AT, DE[2]		DE[2]		Yes (2116)
Precision Biosensor Inc.	Exdia COVI-19 Ag	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)
Prognosis Biotech	Rapid Test Ag 2019-nCov	Yes	Clinical Sensitivity: 95.56 % Specimen: Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,58%		CY, DE		DE[2]		Yes (1495)
Qingdao Hightop Biotech Co. Ltd	SARS-CoV-2 Antigen Rapid Test (Immunochromatography)	Yes	95% sensitivity unknown specificity Nasal swab	**DE**: 95% sensitivity 99.75% specificity		AT, DE[2]		DE[2]		Yes (1341)
Quidel Corporation	Sofia SARS Antigen FIA	Yes	96.7% sensitivity 100% specificity NP/Nasal swab	**BE**: 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)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
				DE: 96.7% sensitivity , 100% specificity **SI**: 96.7% sensitivity, 100% specificity, NP/Nasal swab						
Roche (SD BIOSENSOR)	SARS-CoV-2 Rapid AntigenTest	Yes	96.52% sensitivity 99.2% specificity NP	**DE**: 96.52% sensitivity, 99.68% specificity **FI:** Validated in several laboratories (studies not published), meeting criteria.		AT, DE[2], MT, NL, RO	CH, NO	DE[2], FI		Yes (1604)
Roche (SD BIOSENSOR)	SARS-CoV-2 Rapid Antigen Test Nasal	Yes	Clinical Sensitivity: 89.6 % ((Ct ≤ 30) and 93.1 % (for Ct below LOD 27)) Clinical Specificity: 99.1 % Specimen Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 89.6% at <Ct30)	**DE** (12 April 2021) 179 samples, nasal swab Clinical sensitivities: - Days ≤ 7: 81.2%; - Ct ≤ 33: 87.5%; - Ct ≤ 25: 100%; Clinical specificity: 99.3% **Brazil** (12 April 2021) 214 samples, nasal swab Clinical sensitivities: - Days ≤ 7: 81.2%; - Ct ≤ 33: 91.7%; - Ct ≤ 25: 100%; Clinical specificity: 99.3%	DK	CH, UK	DE[2]		Yes (2228)
Safecare Biotech (Hangzhou) Co. Ltd	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)
Safecare Biotech (Hangzhou) Co. Ltd	Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19)	Yes	97.04% sensitivity Nasal swab	**DE**: 97.04% sensitivity , 99.44% specificity		DE[2]		DE[2]		Yes (1490)
ScheBo Biotech AG	ScheBo SARS CoV-2 Quick Antigen	Yes	96.6% sensitivity (Ct 30) NP/ OP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		Yes (1201)
SD Biosensor Inc	STANDARD Q COVID-19 Ag Test Nasal	Yes	Clinical Sensitivity: 97.12 % Clinical Specificity: 100 %	**FI:** Validated in several laboratories (studies not published), meeting criteria.	**DE** (12 April 2021) 179 samples, nasal swab Clinical sensitivities: - Days ≤ 7: 81.2%;	FI		DE[2], FI, FR		Yes (2052)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
			Specimen: Nasal swab	**DE**: Published study: https://www.medrxiv.org/content/10.1101/2021.01.06.20249009v1	- Ct ≤ 33: 87.5%; - Ct ≤ 25: 100%; Clinical specificity: 99.3% **Brazil** (12 April 2021) 214 samples, nasal swab Clinical sensitivities: - Days ≤ 7: 81.2%; - Ct ≤ 33: 91.7%; - Ct ≤ 25: 100%; Clinical specificity: 99.3%					
SD BIOSENSOR Inc.	STANDARD F COVID-19 Ag FIA	Yes	94,09% sensitivity 98.52% specificity NP swab	**BE**: 96.5% sensitivity, 99.7% specificity, NP swab **DE**: 94% sensitivity 97% specificity	**DE** (10 Dec 2020) 676 samples, NP swab Clinical sensitivities: - Days ≤ 7: 81.2%; - Ct ≤ 33: 75%; - Ct ≤ 25: 100%; Clinical specificity: 96.9% **Brazil** (10 Dec 2020) 453 samples, NP swab Clinical sensitivities: - Days ≤ 7: 80.2%; - Ct ≤ 33: 80.9%; - Ct ≤ 25: 87.9%; Clinical specificity: 97.9% **India** (25 June 2020) 417 samples, NP swab Clinical sensitivities: - Days ≤ 7: 61.8%; - Ct ≤ 33: 53.6%; - Ct ≤ 25: 68.5%; Clinical specificity: 99.5%	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)
SD BIOSENSOR Inc.	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	**DE** (10 Dec 2020) 1263 samples, NP swab Clinical sensitivities: - Days ≤ 7: 80%; - Ct ≤ 33: 87.8%; - Ct ≤ 25: 100%; Clinical specificity: 99.3%	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, NO	HR, IE, LU, SI, SE	Yes (345)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
				FI: Validated in several laboratories (studies not published), meeting criteria.	**Brazil** (10 Dec 2020) 400 samples, NP swab Clinical sensitivities: - Days ≤ 7: 90.7%; - Ct ≤ 33: 91.9%; - Ct ≤ 25: 95.9%; Clinical specificity: 97.6% **CH** (10 Dec 2020) 529 samples, NP swab Clinical sensitivities: - Days ≤ 7: 89.8%; - Ct ≤ 33: 91.8%; - Ct ≤ 25: 97.2%; Clinical specificity: 99.7% **India** (22 April 2021) 334 samples, NP swab Clinical sensitivities: - Days ≤ 7: 58.3%; - Ct ≤ 33: 65.5%; - Ct ≤ 25: 89.4%; Clinical specificity: 97.3% **Peru** (22 April 2021) 335 samples, NP swab Clinical sensitivities: - Days ≤ 7: 81.4%; - Ct ≤ 33: 83.3%; - Ct ≤ 25: 96.2%; Clinical specificity: 99.6%					
SGA Medikal	V-Chek SARS-CoV-2 Ag Rapid Test Kit (Colloidal Gold)	Yes	96.6% sensitivity, Nasal swab	**DE**: 96.6% sensitivity, 99% specificity		DE[2]		DE[2]		Yes (1319)
SGA Medikal	V-Chek SARS-CoV-2 Rapid Ag Test (colloidal gold)	Yes	Clinical Sensitivity: 96.60% Specimen: Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,5%		DE		DE[2]		Yes (1357)
Shenzen Ultra-Diagnostics Biotec Co., Ltd	SARS-CoV-2 Antigen Test Kit	Yes	Clinical Sensitivity: 95.33 % (Nasal), 95.48(NP) Clinical Specificity:	**BE**: 92% sensitivity, 100% specificity, NP swab 100% sensitivity, 100% specificity, OP swab		AT, BE, ES, SI		BE, SI		Yes (2017)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
			99.16 % (Nasal), 99.61 % (NP)	**SI**: 95.9% sensitivity, 99.9% specificity, NP/OP/Nasal swab						
Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2 Antigen-Rapid test-Set	Yes	98% sensitivity 100% specificity NP/ OP swab, Anterior nasal swab, Nasal swab	**DE**: 98% sensitivity , 100% specificity		DE[2]		DE[2]		Yes (2109)
Shenzhen Microprofit Biotech Co., Ltd	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	Yes	Clinical Sensitivity: 92.93 % Clinical Specificity: 100 % Specimen: Nasal swab, NP swab, OP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100%		DE, ES		DE[2]		Yes (1967)
Shenzhen Watmind Medical Co., Ltd	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	Yes	95.15% Sensitivity Nasal swab	**DE**: 95.15% sensitivity , 99.12% specificity		AT, DE[2], FR		DE[2]		Yes (1769)
Shenzhen Watmind Medical Co., Ltd	SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)	Yes	Clinical Sensitivity: 97.83 % (CT value ≤33) Clinical Sensitivity: 90.08 % (CT value ≤36) Specimen: Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,13%		DE		DE[2]		Yes (1768)
Shenzhen Zhenrui Biotech Co., Ltd	Zhenrui ®COVID-19 Antigen Test Cassette	Yes	96% sensitivity Nasal swab	**DE**: 96% sensitivity 97% specificity		DE[2]		DE[2]		Yes (1574)
Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	Yes	98.32% sensitivity (NP swab) 97.25% sensitivity 100% 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)
Sugentech, Inc.	SGTi-flex COVID-19 Ag	Yes	100% sensitivity 100% specificity OP/NP swab	**DE**: 95.1% sensitivity, 99% specificity		AT, DE[2]		DE[2]		Yes (1114)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
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)
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	Yes (1934)
Triplex International Biosciences Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	Yes	98.33% sensitivity 100% specificity Nasal/OP/NP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 92,5% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		Yes (2074)
Vitrosens Biotechnology Co., Ltd	RapidFor SARS-CoV-2 Rapid Ag Test	Yes	97.3% sensitivity unknown specificity Nasal swab	**DE**: 97.3% sensitivity, 99% specificity **SI**: 97.3% sensitivity, 99% specificity, NP/OP/Nasal swab		DE[2], SI		DE[2]		Yes (1443)
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	Yes	97.04% sensitivity 99.9% specificity Nasal/OP/NP swab	**AT**: 97,06% sensitivity, 100% specificity, all specimen types, i.e. N&OP&NP swab		AT, SI		AT, DE[2], SI	AT	Yes (2103)
Wuhan EasyDiagnosis Biomedicine Co., Ltd.	COVID-19 (SARS-CoV-2) Antigen-Test Kit	Yes	96.1% sensitivity 100% specificity Nasal/OP/NP swab	**DE**: 96.15% sensitivity , 99.26% specificity		DE[2]		DE[2]		Yes (2098)
Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	Yes	Clinical Sensitivity: 96.33 % Clinical Specificity: 99.57 % Specimen: Mid-turbinates swab, Nasal swab, NP swab, OP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,57%		DE		DE[2], FR		Yes (2090)
Xiamen AmonMed Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	Yes	93.2% sensitivity 99.55% specificity Nasal	**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.55%		DE[2]		DE[2]		Yes (1763)

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	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
Xiamen Boson Biotech Co. Ltd	Rapid SARS-CoV-2 Antigen Test Card	Yes	Not specified NP swab	**BE**: 93.8% sensitivity, 100% specificity, NP swab **DE**: 96.49% sensitivity, 99.03% specificity		AT, BE, BG, CY, DE[2], FR, RO	CH	DE[2] CH		Yes (1278)
Xiamen Wiz Biotech Co., Ltd	SARS-CoV-2 Antigen Rapid Test	Yes	96.3% sensitivity, Nasal swab	**DE**: 96.3% sensitivity, 100% specificity		AT, DE[2]		DE[2]		Yes (1456)
Xiamen Wiz Biotech Co., Ltd	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	Yes	95.91% sensitivity 100% specificity Nasal swab	**DE**: 95.91% sensitivity , 100% specificity		AT, DE[2]		DE[2]		Yes (1884)
Zhejiang Anji Saianfu Biotech Co.., Ltd	AndLucky COVID-19 Antigen Rapid Test	Yes	95.8% sensitivity, Nasal swab	**DE**: 97.5% sensitivity, 99.1% specificity		AT, DE[2]		DE[2]		Yes (1296)
Zhejiang Anji Saianfu Biotech Co.., Ltd	reOpenTest COVID-19 Antigen Rapid Test	Yes	95.8% sensitivity, Nasal swab	**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99%		DE[2]		DE[2]		Yes (1295)
Zhejiang Orient Gene Biotech Co., Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	Yes	98.32 % sensitivity 99.6 % specificity Nasal/NP 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)

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

[6] BE: Van Honacker E. et al., Comparison of five SARS-CoV-2 rapid antigen detection tests in a hospital setting and performance of one antigen assay in routine practice: a useful tool to guide isolation precautions? J Hosp Infect. In press.

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).	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).	