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; A common standardised set of data to be included in COVID-19 test result certificates; and A common list of COVID-19 laboratory based antigenic assays

Agreed by the Health Security Committee

Common list of COVID-19 rapid antigen tests (Annex I)

Agreed by the Health Security Committee on 17 February 2021.

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; A fourth update was agreed by the HSC on 14 July 2021; A fifth update was agreed by the HSC on 23 July 2021; A sixth update was agreed by the HSC on 20 October 2021.

Common standardised data set to be included in COVID-19 test result certificates (Annex II)

Agreed by the Health Security Committee on 17 February 2021.

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

Common list of COVID-19 laboratory based antigenic assays (Annex III)

Agreed by the Health Security Committee on 20 October 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 (HSC) 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 HSC 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.
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 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.

[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

This document is based on the content of 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.

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

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 rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of SARS-CoV-2 mutations on the efficacy of NAAT, in particular RT-PCR assays, will also be kept under review.

A first update to Annex I was agreed by the Health Security Committee on 10 May 2021, a second update on 16 June 2021, a third update on 7 July 2021, a fourth update on 14 July 2021, a fifth update on 23 July 2021, and a sixth update on 20 October 2021.

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 HSC 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.

[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
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0953

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 was 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 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, is 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 presents proposals to the HSC for further updates to the common list of rapid antigen tests. The HSC thus remains the platform where agreement between Member States is reached for updates to the list.

Building on the interim definitions and criteria that were agreed by the experts on 29 June 2021, the Technical Working Group agreed on 21 September 2021 on further **definitions, scope, considerations and criteria** to be applied to independent validation studies assessing the clinical performance of rapid antigen tests for COVID-19 diagnosis. These further definitions, scope, considerations and criteria are used by the Technical Working Group in addition to the ones presented in Council Recommendation 2021/24/01 when assessing the proposals for new rapid antigen tests to be included in the EU common list. They have been applied to all proposals received after 12 July 2021. Concerning the rapid antigen tests that were included in the EU common list of rapid antigen tests before this date, the criteria will apply as of May 2022.

Agreed scope of the EU common list of rapid antigen tests:

- The EU common list includes rapid antigen tests that are used in practice in at least one EU Member State and that have been validated by at least one EU Member State.
- The EU common list includes rapid antigen tests for which their clinical performance was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens and that meet the criteria as further specified below.
- Only test results based on nasal, oropharyngeal and/or nasopharyngeal specimens should be valid for the issuance of test certificates for the EU Digital COVID Certificate.
- Rapid antigen tests that are based on other sampling materials, such as saliva, sputum, blood and/or faeces, are not included in the EU common list of antigen

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

tests. This is in line with current evidence and technical recommendations provided by the European Centre for Disease Prevention and Control (ECDC)[9].

- The EU common list of antigen tests does not include rapid antigen self-tests. It only includes those rapid antigen tests that are conducted by trained healthcare personnel or trained operators where appropriate (in line with Commission Recommendation (EU) 20202/1743 of 18 November 2020).
- The EU common list of antigen tests does not include pooled rapid antigen tests, which involve mixing of multiple samples together in a batch or pooled sample for testing.
- Only rapid antigen tests that carry CE marking are included in the EU common list of antigen tests.
- The Technical Working Group will continue to monitor the developments in the field of rapid antigen testing and will, if deemed necessary, reconsider the scope of the EU common list of rapid antigen tests once relevant evidence and data has become available.

Agreed definition and considerations 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.
- Such study should be performed by an independent and accredited laboratory, which is a laboratory not owned nor operated by the manufacturer or sponsor of the test, and which is not related to the operator by ownership, familial relationships, nor contractual or other relationships that result in the laboratory being controlled by or being under the common control of the operator.
- Such study should preferably be based on a **prospective clinical field study** design, testing *unselected* symptomatic and asymptomatic participants for SARS-CoV-2 infection. Until May 2022, validation studies carried out based on retrospective in vitro study designs, testing the clinical performance of rapid antigen tests using SARS-CoV-2 reference panels, will be accepted too[10].
- "Unselected" means no prior knowledge of SARS-CoV-2 diagnosis (e.g. determined by PCR); inclusion is allowed based on general possible COVID-like symptoms (or close contact with COVID-19 cases); and exclusion is allowed of children (e.g. <16 years) or for medical ethical permission reasons.

[9] https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-use-saliva-sample-material-testing.pdf

[10] After May 2022, only rapid antigen tests of which their clinical performance has been evaluated through independent validation studies based on prospective clinical field study designs (in combination with retrospective in vitro studies) will be accepted for inclusion in the EU common list of rapid antigen tests.

Agreed clinical performance criteria for independent validation studies:

Prospective clinical field studies:

- A sensitivity over 80% when testing unselected symptomatic participants within the first seven days after symptom onset or asymptomatic participants, where the diagnosis is confirmed by RT-PCR in independent field studies, will be accepted.

  OR

  In independent evaluations of unselected participants, assays should have a sensitivity of 90% or greater for subjects with a Ct $\leq$ 25.

- The study population shall be clearly defined stating the inclusion criteria of participants (symptomatic individuals, close contacts or asymptomatic individuals without known exposure). Ideally, the sensitivity for each group should be discernible from the report. The RT-PCR protocol and the distribution of Ct values should be described. Samples should represent naturally occurring viral loads.

- Target population considered in the context of an independent validation study should be based on at least 100 RT-PCR positive samples and at least 300 RT-PCR negative samples. Each specimen type should be evaluated separately.

- In case of multiple smaller prospective clinical field studies that do not meet the minimum number of positive and/or negative samples separately but that do meet all the other criteria as agreed by the Technical Working Group, the number of samples may be combined, provided that the different studies applied the same or similar methodologies and that sufficient details are provided on their study design.

- Assays should have a specificity over 98%.

- In line with the *MDCG Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices*[11], preference is given to samples being compared against RT-PCR results on nasopharyngeal swabs. However, in independent validation studies, samples can also be compared against RT-PCR results on oropharyngeal or nasal swabs if reasoning is provided (e.g. when assessing the clinical performance of rapid antigen tests among children).

Retrospective in vitro studies:

- A sensitivity over 80% when testing all specimen in the reference panel will be accepted;

  OR

  Assays should have a sensitivity of 90% or greater for subjects with a Ct < 25.

- The composition of the reference panel should be as follows:
  - A panel of at least 50 pooled clinical specimens that cover naturally occurring viral loads with SARS-CoV-2 concentration ranging from approximately 1.1 x 10^9 to 4.2 x 10^2 genome copies per mL of specimen

[11] https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-21_en.pdf

and Ct values between 17 and 36.

- The whole evaluation panel should be subdivided into three subgroups: panel members, which are characterized by:
    - **Very high viral load** (Ct value 17-25; about 40% of the total number of pooled clinical specimens);
    - **High viral load** (Ct value 25-30; about 40% of the total number of pooled clinical specimens); and
    - **Moderate viral load** (Ct value 30-36; about 20% of the total number of pooled clinical specimens).
- For each pool up to ten clinical respiratory specimens (nasopharyngeal/oropharyngeal) obtained for routine diagnostics with different virus loads may be used. The sample volume per panel member should be sufficient to allow comparative evaluation with different tests included in the evaluation.
- RT-PCR needs to be applied to determine the RNA load per pool.
- Ethical approval by an institutional review board is mandatory.
- For each rapid antigen test and panel member, a pre-defined aliquot needs to be completely absorbed using the specimen collection device, e.g. swab, provided with the respective test.
- Further steps needs to be strictly performed following the respective instructions for use (IFU).
- The stability of the panel (antigen) must be considered throughout the preparation of the panel and the workflow up to the test.

- Assays should have a specificity over 98%, as measured through the retrospective in vitro evaluation study or as specified by the manufacturer in the IFU.
- In line with the *MDCG Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices*[11], preference is given to samples being compared against RT-PCR results on nasopharyngeal swabs. However, in independent validation studies, samples can also be compared against RT-PCR results on oropharyngeal or nasal swabs if reasoning is provided (e.g. when assessing the clinical performance of rapid antigen tests among children).

As a wide range of different methodologies and protocols are being applied in countries, discussions on testing approaches will continue, with the overall goal for the Technical Working Group to develop and agree on an EU harmonised approach for validation studies assessing the clinical performance of COVID-19 rapid antigen tests. This work will take into account the ongoing work by the In Vitro Diagnostics Working Group of the Medical Device Coordination Group 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[12].

[12] 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.

Grace period

Whenever updates are made to Annex I, a grace period of 8 weeks applies until the end of 2021. As of 1 January 2022, a grace period of 4 weeks will apply. The grace period applies to both the inclusion of new devices as well as the removal or rapid antigen tests that are included in the EU common list or rapid antigen tests.

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.

V. Annex III: Common list of laboratory-based antigenic assays

In addition to COVID-19 rapid antigen tests, as of 8 July 2021, it is possible for manufacturers and countries to put forward proposals for laboratory-based antigenic assays (e.g. enzyme immunoassays such as ELISA or automated tests) for review by the Technical Working Group. These proposals are reviewed by the experts against the same criteria used for the review of rapid antigen tests.

Annex III sets out those laboratory-based antigenic assays that meet these criteria. Further criteria for lab-based antigenic assays may be defined at a later stage.

The Technical Working Group on COVID-19 diagnostic devices does not, at the moment, review proposals for inclusion of antibody tests in the EU common list.

ANNEX I: Common list of rapid antigen tests[13]

As agreed by EU Member States on 20 October 2021

***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. Updates to the common list are based on the criteria as described in Council Recommendation 2021/C 24/01 as well as the further criteria and definitions agreed by the Technical Working Group on 21 September 2021. The Medical Device Coordination Group Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices[14], envisaged to form the basis for common specifications to be adopted according to Article 9 of Regulation (EU) 2017/746, has been taken into consideration in this regard.*

Rapid antigen tests presented in boxes are so-called 'twin tests'. These are rapid antigen tests that are identical in design and construction but, for example, branded or distributed under a different name. The results of independent validation studies may be transferred between twin tests.

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
AAZ-LMB	COVID-VIRO® Rapid antigen test COVID-19	1833	*Prospective clinical field study* **FR:** Prospective study carried out in the "Centre Hospitalier d'Orléans" on NP swabs simultaneously tested by RT PCR : sensitivity <7 days after onset of symptoms : 94,7% (72/76), specificity : 100%.	96.6% sensitivity 100% specificity Nasal swab, NP swab	BE, FR, SI	CH	FR CH	Nucleo-protein	10 May 2021

[13] 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.

[14] https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-21_en.pdf

[15] As registered in and used by the JRC database, see: https://covid-19-diagnostics.jrc.ec.europa.eu/.

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Abbott Rapid Diagnostics	Panbio™ COVID-19 Ag Rapid Test	1232	*Prospective clinical field studies* **BE**: 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%. **NL**: 1367 and 208 subjects were enrolled in Utrecht and Aruba, respectively. Specificity of the Panbio™ COVID-19 Ag Rapid Test was 100% (95%CI: 99.7–100%) in both settings. Test sensitivity was 72.6% (95%CI: 64.5–79.9%) in the Netherlands and 81.0% (95% CI: 69.0–89.8%) in Aruba. Restricting RT-qPCR test positivity to Ct-values <32 yielded test sensitivities of 95.2% (95%CI: 89.3–98.5%) in Utrecht and 98.0% (95%CI: 89.2–99.95%) in Aruba. **PT:** 83 samples from symptomatic individuals (27 PCR positive and 56 negative by PCR) were tested. Sensitivity 63% (95%IC 42-81); specificity 100% (95%IC 94-100). LoD TCID50/ml 1,38 x 102 and CT<24. **SE:** Karolinska hospital evaluation of Lot 41ADF061A. Patient samples: 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 59%, specificity 100%. Sensitivity Ct<25 = 90.2%. **FIND evaluation studies** **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. 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%	91.4% sensitivity 99.8% specificity NP swab (Ct ≤ 33) 98.1% sensitivity 99.8% specificity Nasal swab (Ct ≤ 33)	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	BE, DE[2], ES, FI, NL[5], PT, SE CH, India, NO, UK	Nucleo-protein	17 February 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
			Retrospective in vitro studies **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity of 99.8% **FI:** Validated in several laboratories (studies not published), meeting criteria.						
ABIOTEQ	Cora Gentest-19	2374	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.8%	Sensitivity 98,7%, Specificity 99,8%	DE[2]		DE[2]	Nucleo-capsid protein	20 October 2021
AccuBioTech Co.,Ltd	Accu-Tell SARS-CoV-2 Ag Cassette	2579	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	Sensitivity: 95.7% Specificity: 99.2%	DE[2]		DE[2]	Nucleo-capsid protein	20 October 2021
Acon Biotech (Hangzhou) Co., Ltd	Flowflex SARS-CoV-2 Antigen Rapid Test	1457	*Prospective clinical field study* **FIND evaluation** 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% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99.54%	Clinical Sensitivity 97.1 % (Nasal Swab) Clinical Sensitivity 97.6 % (NP Swab) Clinical Specificity 99.5 % (Nasal Swab) Clinical Specificity 99.4 % (NP Swab)	DE[2], FR, PT		DE[2] CH, UK	*Unknown*	14 July 2021
ACON Laboratories, Inc.	Flowflex SARS-CoV-2 Antigen Rapid Test	1468	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 98,7%	96.9% sensitivity 98.7% specificity Nasal swab	AT, BE, DE[2], LT, LV, SI		DE[2]	Nucleo-protein	10 May 2021
AESKU.DIAGNOSTICS GmbH & Co, KG	AESKU.RAPID SARS-CoV-2	2108	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 84% at Ct ≤ 25; Manufacturer specificity: 98%	96% sensitivity 98% specificity NP swab	AT, DE[2], SI		DE[2]	*Unknown*	10 May 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Affimedix Inc.	TestNOW® - COVID-19 Antigen Test	2130	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,4%	96.1% sensitivity 99.4% specificity NP swab	DE[2]		DE[2]	*Unknown*	10 May 2021
AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	1304	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	97.3% sensitivity NP swab 97.3% sensitivity Nasal swab 100% specificity	AT, BG, DE[2] HR, SI	CH, UA	DE[2] CH, UK	Nucleo-protein	17 February 2021
Anbio (Xiamen) Biotechnology Co., Ltd	Rapid COVID-19 Antigen-Test (colloidal Gold)	1822	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	99.27% sensitivity, 100% specificity Nasal swab	AT, DE[2]		DE[2]	*Unknown*	10 May 2021
Anhui Deep Blue Medical Technology Co., Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)	1736	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: >99%	Nasal/OP swab: 96,4% sensitivity, 99,8% specificity NP swab: 95,7% sensitivity, 99,3% specificity	BE, DE[2]	UK	DE[2] UK	Nucleo-protein	10 May 2021
	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Nasal swab	1815	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: >99%	96.4 % sensitivity 99.8 % specificity Nasal swab	DE[2]	UK	DE[2] UK	Nucleo-protein	10 May 2021
Anhui Formaster Biosci Co., Ltd.	New Coronavirus (COVID-19) Antigen Rapid Test	2089	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.5%	sensitivity: 95.15%, specificity: 98.5%	DE[2]		DE[2]	Nucleo-protein	20 October 2021
ArcDia International Ltd	mariPOC SARS-CoV-2	768	*Prospective clinical field study* **FI:** Clinical performance of the test was evaluated against qRT-PCR with nasopharyngeal swab specimens collected from patients suspected of acute SARS-CoV-2 infection. Sensitivity of the mariPOC test was 100.0% (13/13) directly from swab specimens and 84.4% (38/45) from swab specimens in undefined transport mediums. Specificity of the test was 100.0% (201/201).	92% sensitivity 100% specificity Nasopharyngeal swab	FI		FI	*Unknown*	10 May 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
ArcDia International Oy Ltd	mariPOC Respi+	2078	*Retrospective in vitro study* **FI:** Validated in several laboratories (studies not published), meeting criteria.	100 % sensitivity 100 % specificity NP swab	FI, PT		FI	*Unknown*	14 July 2021
ArcDia International Oy Ltd	mariPOC Quick Flu+	2079	*Retrospective in vitro study* **FI:** Validated in several laboratories (studies not published), meeting criteria.	100 % sensitivity 100 % specificity NP swab	FI, PT		FI	*Unknown*	14 July 2021
Artron Laboratories Inc.	Artron COVID-19 Antigen Test	1618	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	96.67% sensitivity, Nasal swab 91.67% sensitivity, NP swab 100 % specificity Nasal/NP swab	DE[2]		DE[2]	*Unknown*	14 July 2021
Asan Pharmaceutical Co., Ltd	Asan Easy Test COVID-19 Ag	1654	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 97.71%	94.67% sensitivity, 97.71% specificity Nasal swab	DE[2]		DE[2]	*Unknown*	10 May 2021
Assure Tech. (Hangzhou) Co., Ltd.	ECOTEST COVID-19 Antigen Rapid Test Device	770	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 99.2%	92.5 % sensitivity 99.2 % specificity Nasal/NP/OP swab	DE[2]		DE[2] UK	*Unknown*	14 July 2021
	ECOTEST COVID-19 Antigen Rapid Test Device	2350	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 99.1%	Sensitivity: 97.7%, Specificity: 99.1% NP and OP swab	CZ, DE[2]		DE[2] UK	*Unknown*	23 July 2021
Atlas Link Technology Co. Ltd.	NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	2010	**DE**: 97.6% sensitivity, 99.2% specificity	98.5 % sensitivity 99.4 % specificity Nasal/OP swab	AT, DE[2], SI	CH	DE[2] CH	*Unknown*	10 May 2021
Avalun	Ksmart® SARS-COV2 Antigen Rapid Test	1800	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,32%	Sensitivity: 93.18% Specificity: 99.32% NP swab	DE[2]		DE[2]	*Unknown*	7 July 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
AXIOM Gesellschaft für Diagnostica und Biochemica mbH	COVID-19 Antigen Rapid Test	2101	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	98% sensitivity 100% specificity NP/Nasal swab	DE[2]		DE[2]	*Unknown*	10 May 2021
Azure Biotech, Inc.	COVID-19 Antigen Rapid Test Device	1906	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 86% at Ct ≤ 25; Manufacturer specificity: 99.2%	95% sensitivity 99.2% specificity NP swab	DE[2]		DE[2]	*Unknown*	10 May 2021
Becton Dickinson	BD Veritor™ System for Rapid Detection of SARS CoV 2	1065	*Prospective clinical field study* **NL:** Independent field study in symptomatic individuals (n=979, PCR positive n=161) - sampling was Nasal mid-turbinate + OP swab. Sensitivity overall: 79.5% - Sensitivity Ct<30: 93.2% - Specificity overall: 99.8% **SE**: Karolinska hospital evaluation of Lot 0255648. Patient samples: 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 45%, specificity 97%. Sensitivity Ct<25 = 87.8%. *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 99.6%	Clinical Sensitivity: 91.1 % Clinical Specificity: 99.6 % Nasal swab	DE, NL		DE[2], NL, SE	*Unknown*	7 July 2021
Beijing Hotgen Biotech Co., Ltd	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	1870	*Prospective clinical field study* **FIND evaluation** **Brazil** (15 September 2021) 453 samples, nasal swab. Clinical sensitivities: Days ≤ 7: 90.1%; Ct ≤ 33: 89.5%; Ct ≤ 25: 95.5%. Clinical specificity: 100% **UK** (15 September 2021) 248 samples, NP swab. Clinical sensitivities: Days ≤ 7: 84.4%; Ct ≤ 33: 80.6%; Ct ≤ 25: 82.8%. Clinical specificity: 99.4% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.76%	97.1% sensitivity 99.76% specificity	AT, BE, DE[2], RO, SI		DE[2]	Nucleo-protein	10 May 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Beijing Jinwofu Bioengineering Technology Co.,Ltd.	Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit	2072	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25 + Manufacturer specificity: 100%	96.88 % sensitivity 100 % specificity Nasal/ NP/ OP swab	DE[2]		DE[2]	*Unknown*	14 July 2021
Beijing Lepu Medical Technology Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	1331	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.26%	92.00% sensitivity, 99.26% specificity Nasal swab	AT, BE, DE[2], SI, RO	UA	DE[2]	*Unknown*	17 February 2021
Beijing O&D Biotech Co., Ltd.	COVID-19 Antigen Rapid Test	2494	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.67%	sensitivity: 92.17%, specificity: 98.67 %	DE[2]		DE[2]	Nucleo-capsid protein	20 October 2021
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd	*Wantai SARS-CoV-2 Ag Rapid Test (FIA)*	*1484*	*No data available*	*96.6% sensitivity, Nasal swab*	*DE[2]*			*Nucleo-protein*	*17 February 2021*[16]
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd	Wantai SARS-CoV-2 Ag Rapid Test (colloidal gold)	1485	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	96.1 % sensitivity 99% specificity Nasal swab	DE[2]		DE[2]	*Unknown*	14 July 2021
BioGnost Ltd	CoviGnost AG Test Device 1x20	2247	*Retrospective in vitro study* **HR:** 300 NP samples (retrospective), symptomatic (<7 dps): 200 PCR+ samples (range Ct 16-30), Ct<30: sensitivity 96.5% 100 PCR- samples: specificity 100%	Sensitivity: 96%, Specificity: 99% NP swab	HR		HR	*Unknown*	23 July 2021
BIOHIT HealthCcare (Hefei) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromato-graphy)	1286	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.9%	Sensitivity: 96.77% Specificity: 98.9% NP/OP swab	DE[2]		DE[2]	*Unknown*	23 July 2021

[16] This rapid antigen test, device ID 1484, was removed from the EU common list on 20 October 2021. The grace period will end on 15 Dec 2021, 23:59 CET

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
BioMaxima SA	SARS-CoV-2 Ag Rapid Test	2035	*Prospective clinical field studies* **FR**: NP swabs, Diagnostic sensitivity: 96,4% (80/83) (95% CI: 89,8-99,2%); diagnostic specificity: 99,2%, (120/121) **PL**: Evaluation of the test was performed on 480 samples of nasopharyngeal swabs taken from patients with symptoms of COVID-19 and from people in contact with an infected person but without symptoms of infection. Positive results of the antigen test were obtained in 205 patients and in the molecular test 213 people. On the other hand, negative results of the antigen test were obtained in 275 people and in the molecular test 267 people. The above results permitted calculation of diagnostic sensitivity, which was 93.43% (95% CI: 91.61%~97.19%) and diagnostic specificity, which was 97.75% (95% CI: 93.74%~98.92%) *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	Sensitivity: 95% Specificity: 99% NP Swab	PL		DE[2], FR, PL	*Unknown*	23 July 2021
Biomerica Inc.	Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab)	1599	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,7%	Clinical Sensitivity: 94.7%; Clinical specificity: 99.7% Nasal/NP swab	DE[2]		DE[2]	*Unknown*	7 July 2021
BIONOTE	NowCheck COVID-19 Ag Test	1242	*Prospective clinical field study* **FIND evaluation** **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% *Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98,6%	Clinical Sensitivity: 90.91 % Clinical Specificity: 99.43 % Nasal swab, NP swab	DE[2]		DE[2] Brazil	*Unknown*	7 July 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
BIO-RAD	CORONAVIRUS AG RAPID TEST CASSETTE	2031	*Prospective clinical field studies* **ES[7]:** • [12 May 2021]: Prospective study; 96 positive samples and 269 negative samples. Sensitivity 94%. Specificity 99.2%. No Ct distribution specified. • 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)	Clinical Sensitivity: 98% (NP: 98,32% / Nasal: 97,25%) Clinical Specificity: 99% (NP: 99,6% / Nasal: 100%)	ES		ES	*Unknown*	7 July 2021
BIOSYNEX S.A.	BIOSYNEX COVID-19 Ag BSS	1223	*Prospective clinical field studies* **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. **FR**: NP swabs, prospective study (71/71) : sensitivity 100% (45/45, specificity 100% **NL**: Independent field study, mainly symptomatic individuals (n=568, PCR positive n=39), NP swab; sensitivity Ct≤30: 96.0%, sensitivity ≤25: 100%; specificity overall: 100% **NL**: Independent field study, symptomatic individuals (n=270, PCR positive n=17), NP+OP swab; sensitivity Ct≤30: 94.1%, sensitivity Ct≤25: 100%; specificity overall: 100% **SE**: Karolinska hospital evaluation of Lot 20100103. Patient samples; 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 76%, specificity 96%. Sensitivity Ct<25 = 100%. *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	96% sensitivity, 100% specificity, NP swab	AT, BE, DE[2], DK,FR, NL[5], PT	CH	BE, DE[2], FR, NL[5], SE CH	Nucleo-protein	17 February 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
BIOSYNEX SA	BIOSYNEX COVID-19 Ag+ BSS	1494	*Prospective clinical field study* **FR**: Validation study data: 125 positive and 118 negative samples; sensitivity 96%, specificity: 99%	Clinical Sensitivity: 97.5 % Specificity: 99% Nasal swab, NP swab	FR		FR UK	*Unknown*	7 July 2021
BIOTEKE CORPORATION (WUXI) CO., LTD	SARS-CoV-2 Antigen Test Kit (colloidal gold method)	2067	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 99.28%	96.49 % sensitivity 99.28 % specificity OP/NP swab	DE[2]		DE[2]	*Unknown*	14 July 2021
Biotical Health S.L.U.BIOTICAL HEALTH S.L.U	biotical SARS-CoV-2 Ag Card	2013	*Retrospective in vitro study* **BE**: Validation study 1: sensitivity 91.7% for Ct<25; Validation study 2: 94% for Ct<25. Manufacturer specificity: 99%	Sensitivity: 96%, Specificity: 99% NP swab	BE		BE	*Unknown*	23 July 2021
Boditech Med Inc	AFIAS COVID-19 Ag	1989	*Prospective clinical field study* **NL**: Independent field study in mild symptomatic (n= 427, PCR positive: 106); unknown swab, overall sensitivity: 81.1%, sensitivity Ct <30: 96.4%; specificity: 100%,	Sensitivity: 91.7%, Specificity: 98.7% NP swab	FR, NL		NL	*Unknown*	23 July 2021
BTNX Inc	Rapid Response COVID-19 Antigen Rapid Test	1236	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	90.2% sensitivity 100% specificity NP swab, NP swab, OP swab	AT, DE[2], ES, SI		DE[2]	Nucleo-protein	10 May 2021
CerTest Biotec	CerTest SARS-CoV-2 Card test	1173	*Prospective clinical field study* **ES**: Ct ≤ 25, sensitivity: 94,0%; sensitivity for samples within the first 5 days after symptom onset: 84,8%; 150 positive samples, 170 negative samples	92.9% sensitivity 99.6% specificity NP swab	ES, PT, SI		DE[2], ES	*Unknown*	17 February 2021
Chil Tıbbi Malzeme Sanayi ve Ticaret Limited Şirketi	CHIL COVID-19 Antigen Rapid Test (Nasopharyngeal / Oropharyngeal Swab-Casette)	1691	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.57%	Sensitivity 99.01% Specificity: 99.57%	DE[2]		DE[2]	Nucleo-protein	20 October 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Chongqing M&D Biotechnology Co. Ltd	2019-nCoV Antigen Test Kit	2150	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 100%	sensitivity: 91.53%, specificity:100%	DE[2]		DE[2]	Nucleo-protein	20 October 2021
Core Technology Co., Ltd	Coretests COVID-19 Ag Test	1919	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 99.6%	98.1% sensitivity 99.6% specificity NP swab	AT, DE[2], RO		DE[2]	Nucleo-protein	10 May 2021
CTK Biotech, Inc	OnSite COVID-19 Ag Rapid Test	1581	*Prospective clinical field study* **DK:** 107 samples; Nasal swab - clinical sensitivity 86%; (from asymptomatic and mild symptomatic individuals), Clinical specificity: 100%	Clinical Sensitivity: 92.3 % Clinical Specificity: 100 % Nasal, NP swab	DK		DK, ES	*Unknown*	7 July 2021
DDS DIAGNOSTIC	Test Rapid Covid-19 Antigen (tampon nazofaringian)	1225	*Prospective clinical field study* **RO:** Clinical study based on 228 COVID-19 positive samples and 597 COVID-19 negative samples. All the samples were confirmed using PCR (Applied Biosystems™ 7500 and SLAN®-96P) and clinical symptoms. The relative sensitivity of Rapid Test COVID-19 Antigen (Nasopharyngeal Swab) was 99.56%, the relative specificity was 99.66%, and the accuracy was 99.64% compared to the qRT-PCR result.	98.77% sensitivity 99.03% specificity Nasal swab	RO		RO China	*Unknown*	10 May 2021
DIALAB GmbH	DIAQUICK COVID -19 Ag Cassette	1375	**BE**: Z20401CE: 93.2% sensitivity, 100% specificity, NP swab Z20601CE: 96.4% sensitivity, 99.2% specificity, NP swab	NP swab	AT, BE, DE[2]		BE	*Unknown*	10 May 2021
DNA Diagnostic	COVID-19 Antigen Detection Kit	2242	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.56%	Sensitivity: 93.8%, Specificity: 99.6% Nasal swab	DE[2]		DE[2] UK	*Unknown*	23 July 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Dräger Safety AG & Co. KGaA	Dräger Antigen Test SARS-CoV-2	2273	*Prospective clinical field studies* **DE:** Independent prospective study, mainly symptomatic <7 dps (n=378, PCR positive = 70), self-collected nasal swab; sensitivity overall: 88.6%, sensitivity Ct<26: 96.8%; specificity overall: 99.7% **CH:** Independent prospective study, mainly symptomatic ≤7 dps (n=464, PCR positive = 57), self-collected nasal swab; sensitivity Ct<30: 85.1%, sensitivity Ct<26: 90.0%; specificity overall: 100% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 95% at Ct < 25; Manufacturer specificity: 99.6%	Sensitivity: 96.1% (Ct values ≤25) Specificity: 99.6%	DE[2]		DE[2] CH	Nucleo-capsid protein	20 October 2021
Dynamiker Biotechnolgy(Tianjin) Co., Ltd.	Dynamiker SARS-CoV-2 Ag Rapid Test	2533	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer Specificity: 99.1%	sensitivity: 95.7%, specificity: 99.1%	DE[2]		DE[2]	Nucleo-capsid protein	20 October 2021
Edinburgh Genetics Limited	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	1243	*Prospective clinical field study* **FIND evaluation** Peru (26 April 2021) 120 samples, NP swab. Clinical sensitivities: Days ≤ 7: 62%; Ct ≤ 33: 75%; Ct ≤ 25: 100%. Clinical specificity: 100% *Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer Specificity: 99,24%	Clinical Sensitivity 97.27% NP swab Clinical Specificity 99.62% NP swab Clinical Sensitivity 95.63% OP swab Clinical Specificity 99.24% OP swab	DE[2]		DE[2] Peru	Nucleo-protein	14 July 2021
Eurobio Scientific	EBS SARS-CoV-2 Ag Rapid Test	1739	*Prospective clinical field study* **FR**: Validation study data: 119 positive and 125 negative samples; sensitivity 93%, specificity: 99%	Clinical Sensitivity: 95.7 % Nasal swab	DE[2], FR		DE[2], FR	*Unknown*	7 July 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
			Retrospective in vitro study **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,1%						
Fujirebio	ESPLINE SARS-CoV-2	2147	*Prospective clinical field study* **FIND evaluation** 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% South Africa (6 Oct 2021) 494 samples, NP swab. Clinical sensitivities: Days ≤ 7: 75%; Ct ≤ 33: 78.9%; Ct ≤ 25: 90.1%. Clinical specificity: 99.7% *Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,13%	Clinical Sensitivity: 87.8 % ((n=98, Ct<33)) Clinical Specificity: 100 % NP swab	DE[2]		DE[2]	*Unknown*	7 July 2021
GA Generic Assays GmbH	GA CoV-2 Antigen Rapid Test	1855	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	Sensitivity: 97.059%, Specificity: 99.2% NP swab	DE[2]		DE[2]	*Unknown*	23 July 2021
GenBody Inc	*Genbody COVID-19 Ag Test*	*1244*	*No data available*	*90% sensitivity* *98% specificity* *NP/OP swab*	*DE[2]*	*UA*		*Unknown*	*17 February 2021*[17]
Genrui Biotech Inc	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	2012	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,02%	Sensitivity: 91.15% Specificity: 99.02% Nasal/NP/OP swab	DE[2]		DE[2]	*Unknown*	7 July 2021

[17] This rapid antigen test, device ID 1244, was removed from the EU common list on 20 October 2021. The grace period will end on 15 Dec 2021, 23:59 CET.

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
GenSure Biotech Inc	GenSure COVID-19 Antigen Rapid Test Kit	1253	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 100%	96.86% sensitivity 100% specificity Nasal swab	DE[2]		DE[2] UK	*Unknown*	10 May 2021
Getein Biotech, Inc	SARS-CoV-2 Antigen (Colloidal Gold)	1820	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.71%	97.06% sensitivity 98.71% specificity Nasal swab	AT, DE[2]		DE[2]	*Unknown*	14 July 2021
Getein Biotech, Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	2183	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 90% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 98.71%	97.06% sensitivity 98.71% specificity Nasal swab	DE[2]		DE[2] UK	Nucleo-protein	16 June 2021
Goldsite Diagnostic Inc.	SARS-CoV-2 Antigen Kit (Colloidal Gold)	1197	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	93.04% sensitivity; 100% specificity Nasal swab	BE, BG, CY, FR, RO, SI, ES	UK	FR, DE[2], ES UK	*Unknown*	14 July 2021
Green Cross Medical Science Corp.	GENEDIA W COVID-19 Ag	1144	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 100%	100% sensitivity 90.1% sensitivity 100% specificity NP swab, Anterior nasal swab	AT, BE, DE[2]		DE[2]	Nucleo-protein	10 May 2021
Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	1747	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 82% at Ct ≤ 25; Manufacturer specificity: 99.07%	96.23% sensitivity 99.07% specificity Nasal swab	AT, DE[2]		DE[2]	Nucleo-protein	10 May 2021
Guangdong Longsee Biomedical Co., Ltd.	COVID-2019-nCoV Ag Rapid TestDetection Kit(Immuno-Chromatography)	1216	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%	99.72% specificity 99.5% specificity NP/OP swab	DE[2]		DE[2]	*Unknown*	14 July 2021
Guangdong Wesail Biotech Co. Ltd	COVID-19 Ag Test Kit	1360	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98%	90% sensitivity 98% specificity Nasal swab	DE[2], SI		DE[2]	Nucleo-protein	17 February 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Guangzhou Decheng Biotechnology CO., Ltd	V-CHEK, 2019-nCoV Ag Rapid Test Kit (Immuno-chromatography)	1324	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,5%	Clinical Sensitivity: 96.67 % Nasal swab	DE[2]		DE[2]	*Unknown*	7 July 2021
Guangzhou Wondfo Biotech Co., Ltd	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	1437	*Prospective clinical field study* **FIND evaluation** **CH** (25 Feb 2020) 328 samples, NP swab. Clinical sensitivities: Days ≤ 7: 85.7%; Ct ≤ 33: 92.2%; Ct ≤ 25: 100%. Clinical specificity: 100% **Brazil** (10 Oct 2021) 237 samples, NP swab. Clinical sensitivities: Days ≤ 7: 90.4%; Ct ≤ 33: 89.3%; Ct ≤ 25: 96.7%. Clinical specificity: 98.8% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 99.74%	Sensitivity: 87.12% Specificity: 99.74%	AT, BE, BG, DE[2], FR	CH	DE[2] CH, UK	*Unknown*	10 May 2021
Hangzhou Lysun Biotechnology Co. Ltd	COVID-19 Antigen Rapid Test Device (Colloidal Gold)	2139	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	96.46% sensitivity 100% specificity Nasal swab	DE[2]	CH	DE[2]	*Unknown*	10 May 2021
Hangzhou AllTest Biotech Co., Ltd	COVID-19 Antigen Rapid Test	1257	*Prospective clinical field study* **FR**: Prospective study, sensitivity 96,4% (80/83), specificity 99,2% (120/121)	93,40% sensitivity, 99,90% specificity NP swab	AT, BE, BG, FR, SI, RO	CH	FR	*Unknown*	10 May 2021
Hangzhou Clongene Biotech Co., Ltd.	COVID-19 Antigen Rapid Test Casette	1610	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,4% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity: 91.4 % Clinical Specificity: 100 % NP swab	DE[2]		DE[2] UK	Nucleo-protein	7 July 2021
	Covid-19 Antigen Rapid Test Kit	1363	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,4% at Ct ≤ 25; Manufacturer specificity: 100%	98.5% (Ct<33) sensitivity Nasal swab	AT,BE, DE[2], FR, SI	CH	DE[2] CH	Nucleo-protein	17 February 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
	COVID-19/Influenza A+B Antigen Combo Rapid Test	1365	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,4% at Ct ≤ 25; Manufacturer specificity: 100%	91% sensitivity 100% specificity NP swab	DE[2]		DE[2]	Nucleo-protein	10 May 2021
Hangzhou Immuno Biotech Co., Ltd	Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)	1844	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	94% sensitivity 100% specificity Nasal swab, NP swab	DE[2]		DE[2]	Nucleo-protein	10 May 2021
	SARS-CoV2 Antigen Rapid Test	2317	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity 98 % Clinical Specificity 100 % Anterior nasal swab, NP swab, OP swab,	AT, DE[2]		DE[2]	Nucleo-protein	10 May 2021
Hangzhou Laihe Biotech Co.	LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	1215	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,7%	Clinical Sensitivity: 95.07% % Clinical Specificity: 99.74% Nasal swab	AT, DE[2]	CH	DE[2] UK	*Unknown*	10 May 2021
Hangzhou Testsea Biotechnology Co., Ltd.	Covid-19 Antigen Test Cassette	1392	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.4%	92.1% sensitivity 98.1% specificity Nasal swab	DE[2]		DE[2]	Nucleo-protein	10 May 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Healgen Scientific	Coronavirus Ag Rapid Test Cassette	1767	*Prospective clinical field studies* **NL**: Independent clinical field study, symptomatic individuals (n=417, PCR positive n=70), NP swab; sensitivity overall: 75.7%, sensitivity Ct≤30: 85.2%, sensitivity Ct≤25: 90.7%; specificity overall: 100% **NL**: Independent clinical field study, symptomatic individuals (n=240, PCR positive n=21), NP+OP swab; sensitivity overall: 85.7%, sensitivity Ct≤30: 89.5%, sensitivity Ct≤25: 100%; specificity overall: 100% **NL**: Independent clinical field study, symptomatic individuals (n=94, PCR positive n=18), NP+OP swab in VTM; sensitivity overall: 90.0%, sensitivity Ct≤30: 100%, sensitivity Ct≤25: 100%; specificity overall: 97.3% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	98.32 % sensitivity 99.6% specificity (NP swab) 97.25% sensitivity 100% specificity (Nasal swab)	AT, DE[2], NL[5], SE, SI	CH	DE[2], NL[5]	Nucleo-proteins, S1, S1-RBD, S2	17 February 2021
Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	1218	*Prospective clinical field studies* **NL**: Independent clinical field study, symptomatic individuals (n=417, PCR positive n=70), NP swab; sensitivity overall: 75.7%, sensitivity Ct≤30: 85.2%, sensitivity Ct≤25: 90.7%; specificity overall: 100% **NL**: Independent clinical field study, symptomatic individuals (n=240, PCR positive n=21), NP+OP swab; sensitivity overall: 85.7%, sensitivity Ct≤30: 89.5%, sensitivity Ct≤25: 100%; specificity overall: 100% **NL**: Independent clinical field study, symptomatic individuals (n=94, PCR positive n=18), NP+OP swab in VTM; sensitivity overall: 90.0%, sensitivity Ct≤30: 100%, sensitivity Ct≤25: 100%; specificity overall: 97.3% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	98.32% sensitivity (NP swab) 97.25% sensitivity (Nasal swab) 100% specificity	AT, BE, DE[2], EE, FR, HR, NL[5], PT, SE, SI	CH	DE[2], ES, NL[5]	Nucleo-proteins, S1, S1-RBD, S2	17 February 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Hoyotek Biomedical Co.,Ltd.	Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)	1929	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99%	NP swab - Sensitivity: 96%, Specificity: 99% OP swab - Sensitivity: 93%, Specificity: 97.5%	DE[2]		DE[2]	*Unknown*	20 October 2021
Hubei Jinjian Biology Co., Ltd	SARS-CoV-2 Antigen Test Kit	1759	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.3%	Sensitivity: 98.02% Nasal Swab	DE[2]		DE[2]	*Unknown*	23 July 2021
Humasis	Humasis COVID-19 Ag Test	1263	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	95.3% sensitivity 100% specificity Nasal swab	AT, BE, BG, DE[2], FR, HR, SE, SI		DE[2] UK	*Unknown*	10 May 2021
Innova Medical Group.Inc	Innova SARS-CoV-2 Antigen Rapid Qualitative Test	1801	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	Sensitivity 94.0% : CI 95% (86.7%-98.0%) – calculated for viral loads x10^6 copies RNA /mL Specificity: 99.6% - CI:95%(99.4%-99.8%)	DE[2]		DE[2]	Nucleo-capsid protein	20 October 2021
Innovation Biotech(Beijing) Co.Ltd	Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Nasal swab)	2278	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	Sensitivity: 95.6% Specificity: 100%	DE[2]		DE[2]	Nucleo-protein	20 October 2021
InTec PRODUCTS, INC.	Rapid SARS-CoV-2 Antigen Test (nasopharyngeal specimen)	2419	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Sensitivity 90.2% (95% CI: 83.1% to 95.0%); Specificity 100.0% (95% CI: 96.5% - 100.00%)	DE[2]		DE[2]	Nucleo-capsid protein	20 October 2021
Jiangsu Bioperfectus Technologies Co., Ltd.	Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit	2107	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.15%	97.06 % sensitivity 99.15 % specificity Nasal/NP/ OP swab	DE[2]		DE[2] UK	*Unknown*	14 July 2021
Jiangsu Diagnostics Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	1920	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	97.58 % sensitivity 100 % specificity Nasal/NP/ OP swab	DE[2]		DE[2]	*Unknown*	14 July 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Jiangsu Medomics medical technology Co.,Ltd.	SARS-CoV-2 antigen Test Kit (LFIA)	2006	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,51%	Sensitivity: 97.73% Specificity: 99.51% Anterior nasal swab, NP swab	DE[2]		DE[2]	*Unknown*	7 July 2021
Jiangsu Well Biotech Co., Ltd.	COVID-19 Ag Rapid Test Device	2144	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	sensitivity:94.74%, specificity:99%	DE[2]		DE[2]	Nucleo-protein	20 October 2021
Joinstar Biomedical Technology Co. Ltd	COVID-19 Rapid Antigen Test (Colloidal Gold)	1333	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.1%	96.1% sensitivity 98.1% specificity Nasal swab	AT, DE[2], PT, SI		DE[2]	Nucleo-protein	17 February 2021
JOYSBIO (Tianjin) Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	1764	*Prospective clinical field studies* **CZ** N=225 (90 RT-PCR positive), 60.3% symptomatic patients. Test parameters for a subgroup of symptomatic patients (estimates and 95% confidence intervals): sensitivity 92% (80.8–97.8), specificity 97.6% (91.5–99.7). Test parameters for a subgroup of asymptomatic patients (estimates and 95% confidence intervals): sensitivity 100% 100 (54.1–100), specificity 100% (95.5–100). **FIND Evaluation** **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%	98.13% sensitivity Nasal swab	AT, CZ, SI		CZ, DE[2] CH	*Unknown*	10 May 2021
Labnovation Technologies Inc.	SARS-CoV-2 Antigen Rapid Test Kit	1266	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94% at Ct ≤ 25; Manufacturer specificity: 97.3%	96.3% sensitivity, 97.3% specificity NP/OP swab	DE[2], IT, SI		DE[2]	Nucleo-protein	10 May 2021
Lumigenex (Suzhou) Co., Ltd	PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	2128	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,16%	93.33% sensitivity 99.16% specificity Nasal/NP/OP swab	DE[2]		DE[2]	*Unknown*	10 May 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
LumiQuick Diagnostics Inc.	QuickProfile™ COVID-19 Antigen Test	1267	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.8%	93.7% sensitivity, 98.8% specificity NP swab	BE, DE[2] ,FR, SI,		DE[2]	*Unknown*	10 May 2021
LumiraDX	LumiraDx SARS-CoV-2 Ag Test	1268	*Prospective clinical field study* **SKUP/2021/124**: 448 samples: 83 positive samples and 365 negative samples. Nasal specimen: diagnostic sensitivity of 87% (79-92) and diagnostic specificity of 99,5% (98,3-99,9). NP specimen: diagnostic sensitivity of 90% (83-95) and diagnostic specificity of 97,8% (96,0-98,8) (Scandinavian evaluation of laboratory equipment for point of care testing) **FIND Evaluation** **DE** (8 Oct 2021) 761 samples, NP swab. Clinical sensitivities: Days ≤ 7: 86.4%; Ct ≤ 33: 87.2%; Ct ≤ 25: 92.6%; Clinical specificity: 99.3% **Brazil** (8 Oct 2021) 251 samples, NP swab. Clinical sensitivities: Days ≤ 7: 85.7%; Ct ≤ 33: 87.7%; Ct ≤ 25: 94.1%; Clinical specificity: 99% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.8%	97.6% sensitivity 96.6% specificity Nasal swab	DE[2], ES, SI	CH	DE[2], ES SKUP CH	Nucleo-protein	17 February 2021
MEDsan GmbH	MEDsan SARS-CoV-2 Antigen Rapid Test	1180	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.8%	92.5% sensitivity 99.8% specificity NP/OP swab	AT, BE, DE[2]	CH	DE[2] CH	*Unknown*	17 February 2021
Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	2029	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 90% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 98.99%	95.05% sensitivity 98.99% specificity Nasal/NP swab	DE[2]		DE[2]	Nucleo-protein	16 June 2021
MEXACARE GmbH	MEXACARE COVID-19 Antigen Rapid Test	1775	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,1%	Sensitivity: 96.17% Specificity: 99,1% Nasal swab	DE[2]		DE[2]	*Unknown*	7 July 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
möLab	mö-screen Corona Antigen Test	1190	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,99%	Sensitivity: 97.25% Specificity: 99.99% NP swab	DE[2], IE		DE[2], IE	*Unknown*	10 May 2021
MP Biomedicals	Rapid SARS-CoV-2 Antigen Test Card	1481	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.03%	96.17% sensitivity 99.16% specificity Nasal swab, Anterior nasal swab	AT, BE, DE[2]	CH	DE[2] CH, UK	Nucleo-protein	17 February 2021
Nal von minden GmbH	NADAL COVID -19 Ag +Influenza A/B Test	2104	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 99.9%	97% sensitivity 98% specificity NP swab	DE[2]		DE[2]	*Unknown*	10 May 2021
Nal von minden GmbH	NADAL COVID -19 Ag Test	1162	*Prospective clinical field study* **FIND evaluation** 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% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 99.9%	97.6% sensitivity 99.9% specificity Nasal swab	AT, BE, CY DE[2], FR, PT, SI		DE[2], FR China	Nucleo-protein	17 February 2021
NanoEntek	FREND COVID-19 Ag	1420	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	94.12% sensitivity 100% specificity NP swab	DE[2]		DE[2]	Nucleo-protein	10 May 2021
NanoRepro AG	NanoRepro SARS-CoV-2 Antigen Rapid Test	2200	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at at Ct ≤ 25; Manufacturer specificity: 98.4%	97.2 % sensitivity 98.4% specificity Nasal/NP/OP swab	DE[2]		DE[2]	*Unknown*	14 July 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
NESAPOR EUROPA SL	MARESKIT COVID-19 ANTIGEN RAPID TEST KIT	2241	*Prospective clinical field study* **ES:** Independent validation study; Nasal test compared to nasal PCR. Sensitivity 95.24% (Ct<30), Specificity 100%.	Sensitivity: 95.24%, Specificity: 100% Nasal swab	ES		ES	*Unknown*	23 July 2021
New Gene (Hangzhou) Bioengineering Co., Ltd.	COVID-19 Antigen Detection Kit	1501	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 92,5% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	98% sensitivity 99.2% specificity Nasal swab	DE[2]		DE[2]	Nucleo-*protein*	16 June 2021
Novatech	SARS-CoV-2 Antigen Rapid Test	1762	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 100%	95 % sensitivity 100% specificity Nasal/ NP swab	DE[2]		DE[2]	*Unknown*	14 July 2021
Oncosem Onkolojik Sistemler San. ve Tic. A.S.	CAT	1199	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 98,04%	93.75% sensitivity 98.04% specificity Nasal swab	DE[2]		DE[2]	*Unknown*	10 May 2021
PCL Inc.	PCL COVID19 Ag Rapid FIA	308	*Prospective clinical field study* **FR**: Validation study data: NP swabs, sensitivity 94.29% (33/35) and specificity 100% (70/70)	94,92% sensitivity, 99,99% specificity	FR, DE[2], RO, SI		DE[2], FR	*Unknown*	10 May 2021
PCL Inc.	PCL COVID19 Ag Gold	2243	*Prospective clinical field study* **FR**: Validation study data: 120 positive and 200 negative samples; sensitivity 92%, specificity: 100%		FR, PT		FR	*Unknown*	7 July 2021
PerGrande Bio Tech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromato-graphic Assay)	2116	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.11%	94.28% sensitivity 99.11% specificity NP/Nasal/OP swab	AT, DE[2]		DE[2]	*Unknown*	10 May 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Precision Biosensor Inc.	Exdia COVI-19 Ag	1271	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.3%	93.9% sensitivity 98% specificity NP swab	SI, DE[2]	CH	DE[2] CH	*Unknown*	17 February 2021
Prognosis Biotech	Rapid Test Ag 2019-nCov	1495	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,58%	Clinical Sensitivity: 95.56 % Specificity: 99,58% Nasal swab	CY, DE[2]		DE[2]	*Unknown*	7 July 2021
Qingdao Hightop Biotech Co. Ltd	SARS-CoV-2 Antigen Rapid Test (Immunochromatography)	1341	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.75%	95% sensitivity 99.75% specificity Nasal swab	AT, DE[2]		DE[2]	Nucleo-protein	17 February 2021
Quidel Corporation	Sofia SARS Antigen FIA	1097	*Prospective clinical field studies* **FR**: Validation study data: NP swabs sensitivity 84,44% (76/90), specificity 99,19 (491/495) **NL:** Independent prospective clinical field study in symptomatic (n=733, PCR positive 144); NP swab; sensitivity overall: 84.0%, sensitivity Ct<30: 90.1%, sensitivity Ct<25: 92.5%; specificity overall: 99.8%. **PT:** 80 samples from symptomatic individuals (27 PCR positive and 53 negative by PCR) were tested. Sensitivity 70% (95%IC50-86); specificity 100% (95%IC 93-100). TCID50/ml 0,68x 102 and CT<25. *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 89% at Ct ≤ 25; Manufacturer specificity: 100%	96.7% sensitivity 100% specificity NP/Nasal swab	AT, BE, DE[2], FI, NL[5], PT, SI	CH	DE[2], NL[5], PT CH	Nucleo-protein	17 February 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Rapid Pathogen Screening, Inc	LIAISON® Quick Detect Covid Ag Assay	2290	*Retrospective in vitro study* **IT:** Independent validation study, 100 pos. and 100 neg. samples; sensitivity: 92.7% with Ct<25; specificity: 100%.	Sensitivity: 96.1%, Specificity: 97% NP and Nasal swab	IT		IT	*Unknown*	23 July 2021
Roche (SD BIOSENSOR)	SARS-CoV-2 Rapid Antigen Test	1604	*Prospective clinical field study* **NL:** Independent prospective clinical field study in symptomatic (n=970, PCR positive 186); NP swab; sensitivity overall: 84.9%, sensitivity Ct≤30: 94.3%, sensitivity Ct≤25: 99.1%; specificity overall: 99.5% **SE**: Karolinska hospital evaluation of Lot QCO3020109. Patient samples: 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 43%, specificity 100%. Sensitivity Ct<25 = 80.5%. *Retrospective in vitro studies* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 89% at Ct ≤ 25; Manufacturer specificity: 99.68% **FI:** Validated in several laboratories (studies not published), meeting criteria.	96.52% sensitivity 99.2% specificity NP swab	AT, DE[2], MT, NL, PT, RO	CH, NO	DE[2], FI, NL, PT, SE UK	Nucleo-protein	10 May 2021
Roche (SD BIOSENSOR)	SARS-CoV-2 Rapid Antigen Test Nasal	2228	*Prospective clinical field studies* **FIND evaluation** **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% *Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 89.6% at Ct ≤ 30; Manufacturer specificity: 99.1%	Clinical Sensitivity: 89.6 % ((Ct ≤ 30) 93.1 % (Ct ≤ 27) Clinical Specificity: 99.1 % Nasal swab	DK, SK	CH, UK	DE[2] Brazil, UK	Nucleo-protein	7 July 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Safecare Biotech (Hangzhou) Co. Ltd	COVID-19 Antigen Rapid Test Kit (Swab)	1489	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.42%	97.27% sensitivity 99.42% specificity Nasal swab	AT, DE[2], FR	CH	DE[2]	Nucleo-protein	17 February 2021
	Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19)	1490	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.44%	97.04% sensitivity 99.44% specificity Nasal swab	DE[2]		DE[2]	Nucleo-protein	10 May 2021
ScheBo Biotech AG	ScheBo SARS CoV-2 Quick Antigen	1201	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 95% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99%	96.6% sensitivity (Ct ≤ 30) 99.00% specificity NP/ OP swab	DE[2]		DE[2]	Nucleo-protein	16 June 2021
SD Biosensor Inc	STANDARD Q COVID-19 Ag Test Nasal	2052	*Prospective clinical field studies* **DE** 146 symptomatic adults, 40 (27.4%) were RT-PCR-positive for SARS-CoV-2. Sensitivity with 85.0% (34/40; 95% CI 70.9-92.9) with professional testing. At high viral load (>7.0 log10 SARS-CoV-2 RNA copies/ml), sensitivity was 96.6% (28/29; 95% CI 82.8-99.8) for professional testing. **FIND evaluation** **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% *Retrospective in vitro study* **FI:** Validated in several laboratories (studies not published), meeting criteria.	Clinical Sensitivity: 97.12 % Clinical Specificity: 100 % Nasal swab	FI, PT, SK		DE[2], FI, FR Brazil, UK	*Unknown*	7 July 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
SD BIOSENSOR Inc.	STANDARD F COVID-19 Ag FIA	344	*Prospective clinical field studies* **NL** Independent prospective clinical field study in symptomatic (n=628, PCR positive 118); NP swab; sensitivity overall: 78.0%, sensitivity Ct<30: 84.4%, sensitivity Ct<25: 90.3%; specificity overall: 99.6% **FIND evaluation** **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% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.52%	94,09% sensitivity 98.52% specificity NP swab	AT, BE, BG, DE[2], IT , LU, LV, NL[5], PT, RO, SK	CH	DE[2], IT, NL[5], DK Brazil, CH, India, UK	Nucleo-protein	17 February 2021
SD BIOSENSOR Inc.	STANDARD Q COVID-19 Ag Test	345	*Prospective clinical field studies* **PT** 80 samples from symptomatic individuals (27 PCR positive and 53 negative by PCR) were tested. Sensitivity 70% (95%IC50-86); specificity 100% (95%IC 93-100). TCID50/ml 0,68x 102 and CT<25. **FIND evaluation** **DE** (10 Dec 2020) 1263 samples, NP swab. Clinical sensitivities: Days ≤ 7: 80%; - Ct ≤ 33: 87.8%; Ct ≤ 25: 100%; Clinical specificity: 99.3% **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%	96.52% sensitivity 99.68% specificity NP swab	AT, BE, BG, CY, DE[2], DK, EE, ES, FI, FR, HR, IT, LU, LV, MT, NL[5], PT, RO, SE, SK, SI	ME, NO, CH	DE[2], ES, IT, NL[5], DK, PT Brazil, CH, India, NO, UA, UK	*Unknown*	17 February 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
			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% *Retrospective in vitro studies* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 89% at Ct ≤ 25; Manufacturer specificity: 99.68% **FI:** Validated in several laboratories (studies not published), meeting criteria.						
SGA Medikal	V-Chek SARS-CoV-2 Ag Rapid Test Kit (Colloidal Gold)	1319	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,5%	96.6% sensitivity, 99.5% specificity, Nasal swab	DE[2]		DE[2]	Nucleo-protein	10 May 2021
	V-Chek SARS-CoV-2 Rapid Ag Test (colloidal gold)	1357	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,5%	96.60% sensitivity: 99.5% specificity, Nasal swab	DE[2]		DE[2]	Nucleo-protein	7 July 2021
Shenzen Ultra-Diagnostics Biotec Co., Ltd	SARS-CoV-2 Antigen Test Kit	2017	*Prospective clinical field study* **SI:** Sensitivity in unselected symptomatic population: 86.4% (172 RAT pos. / 199 RT-PCR pos.), sensitivity of 97.8% at Ct≤25. Specificity: 99.1% (1972 RAT neg. / 1990 RT-PCR neg.), NP swab	Clinical Sensitivity: 95.33 % (Nasal), 95.48(NP) Clinical Specificity: 99.16 % (Nasal), 99.61 % (NP)	AT, BE, ES, SI		BE, SI	Nucleo-protein	10 May 2021
Shenzhen Dymind Biotechnology Co., Ltd	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	2415	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct < 25; Manufacturer specificity: 96.58%	Sensitivity: 96.58%, Specificity: 98.37%	DE[2]		DE[2]	Nucleo-protein	20 October 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Shenzhen Huian Biosci Technology Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	2414	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.1%	NP/OP swab: Sensitivity: 95.0%, Specificity: 99.1% Nasal swab: Sensitivity: 94.6%, Specificity: 99.1%	DE[2]		DE[2]	Nucleo-capsid protein	20 October 2021
Shenzhen Kisshealth Biotechnology Co., Ltd	SARS-CoV-2 Antigen Test Kit (GICA)	1813	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	NP swabs: Sensitivity: 99.49%, Specificity: 99.24%. Nasal (Anterior) swabs: Sensitivity: 99.43%, Specificity: 99.23%.	DE[2]		DE[2]	Nucleo-capsid protein	20 October 2021
Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2 Antigen-Rapid test-Set	2109	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	98% sensitivity 100% specificity NP/OP/Nasal swab	DE[2]		DE[2]	Nucleo-protein	10 May 2021
Shenzhen Microprofit Biotech Co., Ltd	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	1967	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Sensitivity: 92.93% Clinical Specificity: 100 % Nasal/NP/OP swab	DE[2], ES		DE[2]	*Unknown*	7 July 2021
Shenzhen Microprofit Biotech Co., Ltd.	SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	1178	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct < 25; Manufacturer specificity: 100%	Sensitivity: 86.3%, Specificity: 100% Nasal Swab	DE[2]		DE[2]	*Unknown*	23 July 2021
Shenzhen Reagent Technology Co.,Ltd.	SARS-CoV-2 antigen IVD kit SWAB	2026	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct < 25; Manufacturer specificity: 98.1%	Sensitivity: 95.2 %, specificity: 98.1 %	DE[2]		DE[2]	Nucleo-protein	20 October 2021
Shenzhen Watmind Medical Co., Ltd	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	1769	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.12%	Sensitivity: 95.15% (for symptom onset within 7 days) Specificity: 99.12% Nasal swab	AT, DE[2], FR		DE[2]	Nucleo-capsid protein	10 May 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Shenzhen Watmind Medical Co., Ltd	SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)	1768	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,13%	Clinical Sensitivity: 97.83 % (CT ≤ 33) Clinical Sensitivity: 90.08 % (Ct ≤ 36) Specificity: 99,13% Nasal swab	DE[2]		DE[2]	*Unknown*	7 July 2021
Shenzhen Zhenrui Biotech Co., Ltd	Zhenrui ®COVID-19 Antigen Test Cassette	1574	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 82% at Ct ≤ 25; Manufacturer specificity: 97%	96% sensitivity 97% specificity Nasal swab	DE[2]		DE[2]	Nucleo-protein	10 May 2021
Sugentech, Inc.	SGTi-flex COVID-19 Ag	1114	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.0%	100% sensitivity 100% specificity OP/NP swab	AT, DE[2]		DE[2]	*Unknown*	10 May 2021
SureScreen Diagnostics	SARS-CoV-2 Rapid Antigen Test Cassette	2297	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	Sensitivity: 96.1%, Specificity: 99%	DE[2]		DE[2] UK	Nucleo-protein	20 October 2021
TODA PHARMA	TODA CORONADIAG Ag	1466	*Prospective clinical field study* **FR:** Validation data: NP swabs, sensitivity : 96,1-100%, specificity 99,2-100% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	98.6% sensitivity Nasal swab	BE, DE[2], SI		DE[2], FR	Nucleo-protein	10 May 2021
Triplex International Biosciences Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	2074	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 92,5% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.91%	98.51% sensitivity 99.91% specificity Nasal/OP/NP swab	DE[2]		DE[2]	Nucleo-capsid protein	16 June 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Triplex International Biosciences Co., Ltd, China	SARS-CoV-2 Antigen Rapid Test Kit	1465	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	98.51 % sensitivity 100% specificity Nasal swab	DE[2], FR, PT		DE[2]	*Unknown*	14 July 2021
Vitrosens Biotechnology Co., Ltd	RapidFor SARS-CoV-2 Rapid Ag Test	1443	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.05%	97.30% sensitivity 99.05% specificity NP swab	DE[2], SI		DE[2]	Nucleo-protein	10 May 2021
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	2103	**AT**: 97,06% sensitivity, 100% specificity, all specimen types, i.e. N&OP&NP swab	97.04% sensitivity 99.9% specificity Nasal/OP/NP swab	AT, SI		AT, DE[2], SI	*Unknown*	10 May 2021
Wuhan EasyDiagnosis Biomedicine Co., Ltd.	COVID-19 (SARS-CoV-2) Antigen-Test Kit	2098	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.26%	96.1% sensitivity 100% specificity Nasal/OP/NP swab	DE[2]		DE[2] UK	*Unknown*	10 May 2021
Wuhan Life Origin Biotech Joint Stock Co., Ltd.	SARS-CoV-2 Antigen Assay Kit (Immuno-chromatography)	1773	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: %	92.67% sensitivity Nasal swab	DE[2]		DE[2]	*Unknown*	14 July 2021
Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	2090	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,57%	Sensitivity: 96.33% Specificity: 99.57% Nasal/NP/OP swab	DE[2]		DE[2], FR	*Unknown*	7 July 2021
Wuxi Biohermes Bio & Medical Technology Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Lateral Flow Assay)	2143	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.02%	Sensitivity: 95.31 %, Specificity: 98.02 %	DE[2]		DE[2]	Nucleo-protein	20 October 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Xiamen AmonMed Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	1763	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.55%	93.2% sensitivity 99.55% specificity Nasal swab	DE[2]		DE[2]	Nucleo-protein	10 May 2021
Xiamen Boson Biotech Co. Ltd	Rapid SARS-CoV-2 Antigen Test Card	1278	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.03%	96.49% sensitivity 99.03% specificity NP swab	AT, BE, BG, CY, DE[2], FR, RO	CH	DE[2] CH, UK	*Unknown*	17 February 2021
Xiamen Wiz Biotech Co., Ltd	SARS-CoV-2 Antigen Rapid Test	1456	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	96.3% sensitivity, 100% specificity Nasal swab	AT, DE[2]		DE[2]	Nucleo-protein	10 May 2021
	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	1884	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	95.91% sensitivity 100% specificity Nasal swab	AT, DE[2]		DE[2]	Nucleo-protein	10 May 2021
Zhejiang Anji Saianfu Biotech Co.., Ltd	AndLucky COVID-19 Antigen Rapid Test	1296	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99%	95.8% sensitivity, 99% specificity, Nasal swab	AT, DE[2]		DE[2]	Nucleo-protein	10 May 2021
Zhejiang Anji Saianfu Biotech Co.., Ltd	reOpenTest COVID-19 Antigen Rapid Test	1295	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99%	95.8% sensitivity, 99% specificity, Nasal swab	DE[2]		DE[2]	Nucleo-protein	10 May 2021
Zhejiang Orient Gene Biotech Co., Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	1343	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.22%	98.32 % sensitivity 99.6 % specificity Nasal/NP swab	AT, BE, BG, DE[2], PT	CH, UK	DE[2] UK	Nucleo-protein	17 February 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Zhuhai Encode Medical Engineering Co.,Ltd	ENCODE SARS-COV-2 Antigen Rapid Test Device	1902	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 100%	Throat swab/Nasal Swab: Sensitivity 96.49%, Specificity 100% Anterior Swab: Sensitivity 94.74%, Specificity: 100%	DE[2]		DE[2] UK	Nucleo-capsid protein	20 October 2021
Zhuhai Lituo Biotechnology Co., Ltd.	COVID-19 Antigen Detection Kit (Colloidal Gold)	1957	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	96.12% sensitivity Nasal swab (CT≤33); 99.59% sensitivity NP swab; 100% specificity Nasal swab (CT≤33)	CZ, DE[2], SI		DE[2]	Nucleo-protein	14 July 2021

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).	

ANNEX III: Common list of COVID-19 laboratory based antigenic assays

As agreed by Member States on 20 October 2021

Manufacturer	RAT commercial name	Device ID # [18]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
DIASORIN	LIAISON SARS-CoV-2 Ag assay	1960	*Prospective clinical field studies* **BE**: Independent prospective study (random selection), symptomatic and asymptomatic (n=414, PCR positive = 204, PCR negative = 210), NP swab; sensitivity Ct<35: 73.4%, sensitivity Ct<25: 96.4%; specificity: 100% **FR**: Independent prospective study, symptomatic and asymptomatic (n=378, PCR positive = 46), NP swab; overall sensitivity: 84.8%, sensitivity Ct=<25 100%; specificity: 99.4% **IT**: Independent prospective study, asymptomatic (n=1075, PCR positive = 23), NP swab; sensitivity Ct=<30 90.5%; specificity: 99.8% **NL** : Independent field study, mainly symptomatic individuals (n=980, PCR positive n=98), NP+OP swab; sensitivity overall 82.7%, sensitivity Ct<30: 91.9%; specificity overall: 99.1%.	Nasal Swab: Sensitivity: 99/101 (98.0%, 95% CI: 93.1 – 99.5%). Specificity: 210/211 (99.5%, 95% CI: 97.4 – 99.9%). NP Swabs: Sensitivity: 108/109 (99.1%, 95% CI: 95.0 – 99.8%). Specificity: 295/299 (98.7%, 95% CI: 96.6 – 99.5%).	BE, CZ, FR, IT, NL		BE, FR, IT, NL	Nucleo-capside protein	20 October 2021
Roche Diagnostics GmbH	Elecsys® SARS-CoV-2 Antigen	2156	*Prospective clinical field study* **DE:** Total N: 3139 (2747 negative, 392 positive) Germany participated in the validation. Roche coordinated and performed partially the data analysis. Relative specificity overall 99.9%; relative sensitivity (n=390) overall 92.5% (CT<26).	Sensitivity: NP/OP: 94.5 % (95% CI: 90.4-97.2); Nasal swabs: 96.8% (95% CI: 88.8-99.6%) Specificity: 99.9% (95 % CI: 99.6-100%)	DE[2], EE, PL		DE[2]	Nucleo-capsid protein	20 October 2021

[18] As registered in and used by the JRC database, see: https://covid-19-diagnostics.jrc.ec.europa.eu/.