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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

EU HEALTH PREPAREDNESS

EU Common list of COVID-19 rapid antigen tests

and a list of mutually recognised COVID-19 laboratory based antigenic assays

Agreed by the Health Security Committee

Last update: 10 June 2022

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EU common list of COVID-19 rapid antigen tests

- Agreed by the Health Security Committee on 17 February 2021
- First update: 10 May 2021; Second update: 16 June 2021; Third update: 7 July 2021; Fourth update: 14 July 2021; Fifth update: 23 July 2021; Sixth update: 20 October 2021; Seventh update: 10 November 2021; Eight update: 8 December 2021; Ninth update: 21 December 2021; Tenth update: 21 January 2022; Eleventh update: 10 February 2022; Twelfth update: 4 March 2022; Thirteenth update: 8 April 2022; Fourteenth update: 6 May 2022; Fifteenth update: 10 June 2022.

List of mutually recognised COVID-19 laboratory based antigenic assays

- Agreed by the Health Security Committee on 20 October 2021
- First update: 10 February 2022; Second update: 8 April 2022; Third update: 10 June 2022.

1. Introduction

1.1 The EU common list of COVID-19 rapid antigen tests

This document builds on the Council Recommendation of 21 January 2021[1], for which EU Member States unanimously agreed to set a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results across the EU. The Council Recommendation called for a common framework that consists of COVID-19 rapid antigen tests that carry CE marking and that meet defined minimum performance requirements. Moreover, the devices should have been validated through an independent study carried out in at least one EU Member State, their use should be considered appropriate in the context of the COVID-19 pandemic, and their use should be in line with countries' national testing strategies.

On 17 February 2021, and on the basis of the Council Recommendation of 21 January 2021, the Health Security Committee agreed on a common list of COVID-19 rapid antigen tests (see Annex I). Since then, the EU common list has been regularly updated, taking into account the results of new validation studies and new rapid antigen test devices entering the market, as well as epidemiological developments and the emergence of SARS-CoV-2 variants.

The devices included in the EU common list of COVID-19 rapid antigen tests meet the criteria as defined by the Council Recommendation of 21 January 2021 as well as further criteria agreed by the Health Security Committee on 21 September 2021. A dedicated Technical Working Group on COVID-19 diagnostic tests[2] was set up by Health Security Committee with the objective to assess proposals submitted by countries and manufacturers for new devices to be included in the EU common list against these agreed criteria.

The EU common list of COVID-19 rapid antigen tests has been split up in two categories:

- Category A: COVID-19 rapid antigen tests evaluated by prospective clinical field studies; and
- Category B: COVID-19 rapid antigen tests evaluated by retrospective in vitro studies.

Since October 2021, the Health Security Committee has also agreed on a list of mutually recognised COVID-19 laboratory based antigenic assays (Annex II), which are meeting the same criteria as the COVID-19 rapid antigen tests.

1.2 EU Digital COVID Certificates

As determined by Regulation (EU) 2021/953[3], the devices included in the EU common list of COVID-19 rapid antigen tests (Annex I) and carried out by health professionals or by skilled testing personnel, can be used by EU Member States to issue EU Digital COVID test

[1] Council Recommendation of 21 January 2021 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (OJ C 24, 22.1.2021, p.1).

[2] https://ec.europa.eu/health/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en.

[3] 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).

certificates. Moreover, as of 22 February 2022[4], following a positive result of a COVID-19 rapid antigen test included in the EU common list and carried out by health professionals or by skilled testing personnel, it is possible for EU Member States to issue EU Digital COVID recovery certificates. These certificates may be issued retroactively, based on rapid antigen tests carried out from 1 October 2021. Both the EU Digital COVID test certificates and the EU Digital COVID recovery certificates should include specific data fields, as set out in the Annex to Regulation (EU) 2021/953.

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will mutually recognise the test results for public health measures. The Health Security Committee agrees that, considering that *all* of the rapid antigen tests included in the EU common list are eligible for issuing EU Digital COVID test and recovery certificates, the entire list is considered to consist of rapid antigen tests of which Member States mutually recognise the test results for public health measures.

EU Member States are strongly encouraged to use, in particular, rapid antigen tests included under Category A of the EU common list for the issuance of EU Digital COVID certificates. Secondly, EU Member States should pay particular attention to the issuance of EU Digital COVID recovery certificates based on the result of devices listed under Category B and that have solely been evaluated by the Paul-Ehrlich-Institut (PEI) in Germany, as only the sensitivity of these rapid antigen tests has been evaluated. Thirdly, EU Member States are strongly encouraged to ensure that only test results from the evaluated specimen type(s) are used for the issuance of EU Digital COVID test and recovery certificates.

It is important to note that results of COVID-19 laboratory based antigenic assays included in Annex II of this document are, at the moment, not eligible for the issuance of EU Digital COVID certificates.

2. The EU common list of COVID-19 rapid antigen tests

2.1 Criteria to be met

Based on a proposal by their Technical Working Group and taking into account the criteria presented by the Council Recommendation of 21 January 2021, the Health Security Committee agreed on 21 September 2021 on an updated scope and definitions of the EU common list of COVID-19 rapid antigen tests, as well as the criteria to be met by the applications for new rapid antigen tests to be possibly included in the EU common list.

The scope, definitions and criteria agreed on 21 September 2021 and as set out in this chapter have been applied to all proposals received by manufacturers and countries since the EU common list of COVID-19 rapid antigen tests was first agreed on 17 February 2021.

[4] Commission Delegated Regulation (EU) 2022/256 of 22 February 2022 amending Regulation (EU) 2021/953 of the European Parliament and of the Council as regards the issuance of certificates of recovery based on rapid antigen tests (OJ L 42, 23.2.2022, p. 4–8).

The Technical Working Group monitors technical and epidemiological developments in the field of rapid antigen testing on a continuous basis and will, if deemed necessary, reconsider the scope, definitions and criteria to be met by devices included in the EU common list. Particular attention will be paid to breakthrough infections among vaccinated individuals and the possible impact of such cases on the clinical performance of rapid antigen tests, as well as the performance of rapid antigen tests in the context of emerging SARS-CoV-2 variants. Moreover, 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[5] will be taken into account. If considered relevant, a proposal for an update of the below agreements will be put forward by the Technical Working Group to the Health Security Committee.

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

- Only rapid antigen tests that carry CE marking are included in the EU common list of rapid antigen tests.
- The EU common list includes rapid antigen tests that are used in practice in 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.
- Rapid antigen tests that are using a mix of different sampling materials (i.e. nasal, oropharyngeal and/or nasopharyngeal swabs as well as other specimen types such as saliva) can be included in the EU common list.
- In case rapid antigen tests are based on using multiple sampling materials, each specimen type should be evaluated separately and the results and data of validation studies should thus be presented per specimen type. The EU common list indicates for devices evaluated by prospective field studies, which of the specimen types have been evaluated and which of the specimen types meet the agreed criteria. Note that only the results of validation studies based on nasal, oropharyngeal and/or nasopharyngeal swabs of such devices will be reviewed by the Technical Working Group and assessed against the specified criteria.
- 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.

The EU common list of rapid antigen tests does **NOT** include, and therefore EU Digital COVID certificates cannot be issued based on a test result from:

- Rapid antigen tests that are solely based on sampling materials other than nasal, oropharyngeal or nasopharyngeal specimens, such as saliva, sputum, blood and/or faeces. This is in line with current evidence and the technical recommendations provided by the European Centre for Disease Prevention and Control (ECDC)[6].

[5] 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.

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

- Rapid antigen self-tests, including rapid antigen self-testing monitored by health professionals or by skilled testing personnel (either on site or remotely). The EU common list only includes 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).
- Pooled rapid antigen tests, which involve mixing of multiple samples together in a batch or pooled sample for testing.
- COVID-19 antibody tests, nor does the Technical Working Group assess the performance of these tests against the agreed criteria.

Agreed criteria and definitions of an independent validation study:

The clinical performance of rapid antigen tests included in the EU common list should have been evaluated by an independent validation study meeting the following criteria and definitions:

- The validation study should be performed by an independent laboratory, which is a laboratory not owned nor operated by the manufacturer or sponsor of the test, and which is not related to the manufacturer/sponsor of the test 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 manufacturer/sponsor of the test.
- The independent validation study should have been carried out in at least one of the 27 EU Member States[7], and be performed objectively and in the public interest.
- The independent validation study may involve collaborations with or may involve funding by private entities, however, there is always a public body involved from an EU Member State.
- The independent validation study should preferably be based on a **prospective clinical field study** design, testing *unselected* symptomatic and asymptomatic participants for SARS-CoV-2 infection. Rapid antigen tests for which their performance has been evaluated through prospective clinical field studies and that meet the criteria agreed on 21 September 2021 have been placed under the "**A-category**" of the EU common list.
- "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.
- The performance of rapid antigen tests can also be evaluated based on a **retrospective in vitro study design**, testing the clinical performance by using SARS-CoV-2 reference panels. Rapid antigen tests for which their performance has been evaluated through retrospective in vitro studies and that meet the criteria agreed on 21 September 2021 have been placed under the "**B-category**" of the EU common list.

[7] https://european-union.europa.eu/principles-countries-history/country-profiles_en.

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 should be based on at least 100 fresh RT-PCR positive samples and at least 300 fresh 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, are all carried out in EU Member States, 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*[8], 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 and Ct values between 17 and 36.

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

- 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).

2.2 Process to include devices in the EU common list

As called for by the Council Recommendation of 21 January 2021, the EU common list of rapid antigen tests should feed into the "COVID-19 In Vitro Diagnostic Devices and Test Methods Database[9], hosted by the Joint Research Centre (JRC). Therefore, as of May 2021, it is possible for EU Member States as well as manufacturers of COVID-19 rapid antigen tests to put forward proposals of rapid antigen tests to be included in the EU common list by submitting the relevant information to the COVID-19 In Vitro Diagnostic Devices and Test Methods Database.

After following the correct procedures and once verified against the source provider, the proposals will be forwarded to the Technical Working Group of the Health Security Committee for evaluation and review. Note that the submission of an application does not result in an

[9] https://covid-19-diagnostics.jrc.ec.europa.eu/devices.

immediate review, as the Technical Working Group assesses batches of proposals that have been submitted during a pre-defined period.

2.3 Updating of the EU common list

The Technical Working Group of the Health Security Committee meets, on average, once a month, during which the next batch of proposals by manufacturers and countries is reviewed and discussed. Based on these discussions, a proposal for a possible next update of the EU common list is forwarded to the Health Security Committee for review and formal agreement. Once the Health Security Committee has agreed with the update, it will be published on the Commission's website and the COVID-19 In Vitro Diagnostic Devices and Test Methods Database will be updated accordingly.

In parallel to the latest update of the EU common list, the Health Security Committee also agrees with the publication of an updated **addendum**. This document provides further background information to the decisions taken by the Technical Working Group in the context of the latest update to the common list of COVID-19 rapid antigen tests. It provides manufacturers and EU Member States with an overview of the devices of which their inclusion in the EU common list was rejected as well as the proposals that are still under review.

Apart from the inclusion of new devices, the Technical Working Group may also decide that certain rapid antigen tests should be removed from the EU common list. For example, this may happen in case new validation results are published, showing that the device no longer meets the agreed criteria or, in case a new variant emerges that affects the clinical performance of certain rapid antigen tests.

Grace period

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

3. A list of mutually recognised COVID-19 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 II sets out those laboratory-based antigenic assays that meet these criteria.

Currently, a negative test results produced by a lab-based antigenic assays <u>cannot</u> be used for the issuance of the EU Digital COVID Certificate.

4. Background information

COVID-19 rapid antigen tests

Robust and targeted testing strategies are an essential aspect of preparedness and response to the COVID-19 pandemic. Representative testing strategies provide useful indications on the epidemiological trends and of the intensity of community transmission, the impact of severe disease and on vaccine effectiveness. 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, testing is pivotal to ensuring representative and targeted genomic sequencing efforts.

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 being used by Member States as a way of further strengthening overall testing capacity, particularly in case of limited NAAT capacities or where clinical needs require faster testing turnaround times.

The Health Security Committee

The Health Security Committee, set up in 2001, is mandated to reinforce the coordination and sharing of best practice and information on national health security activities as well as the coordination of national responses to serious cross border threats to health, including events declared a public health emergency of international concern by World Health Organization in accordance with the International Health Regulations[10].

On 17 September 2020, the Health Security Committee agreed on Recommendations for a common EU testing approach for COVID-19[11], which 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 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.

In May 2021, the Health Security Committee set up a **Technical Working Group on COVID-19 Diagnostic Tests**, consisting of technical experts from EU and EEA Member States, as well as representatives from the Directorate-General for Health and Food Safety (DG SANTE), the Commission's Joint Research Centre (JRC) and the European Centre for Disease Prevention and Control (ECDC). The Technical Working Group 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 for further updates to the common list of rapid antigen tests to the Health Security Committee for agreement.

[10] https://ec.europa.eu/health/health-security-and-infectious-diseases/preparedness-and-response/health-security-committee-hsc_en.

[11] https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/common_testingapproach_covid-19_en.pdf

ANNEX I: EU common list of COVID-19 rapid antigen tests [12]

***Disclaimer**: The Technical Working Group strongly recommends that rapid antigen tests are primarily used for preliminary testing for SARS-CoV-2 infection in symptomatic patients, and notes that rapid antigen tests should in particular be used in the specific contexts and circumstances referred to by the Commission Recommendation (EU) 2020/1743 and the updated technical report by ECDC on 26 October 2021. The content of the EU common list is based on the clinical performance data and information that is available at this moment in time. The Medical Device Coordination Group Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices[13], 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.*

Category A: COVID-19 rapid antigen tests evaluated by prospective clinical field studies

EU Member States are strongly encouraged to use, in particular, the rapid antigen tests included under "Category A" of the EU common list for the issuance of EU Digital COVID certificates. The clinical performance of these devices – for the specimen type as indicated in the corresponding column - has been evaluated by (at least) one prospective clinical field study meeting the criteria and definitions as agreed by the Health Security Committee on 21 September 2021.

EU Member States are strongly encouraged to ensure that only test results from the evaluated specimen type(s) are used to issue EU Digital COVID certificates.

Devices highlighted in blue are identical in design and construction but are, for example, branded or distributed under a different name. The results of validation studies may be transferred between devices that are identical in design and construction.

Device ID # [14]	**Name of submitting company** ***(and role)*** [15]	**Commercial name of the device** [15]	**Clinical performance of the device** *As evaluated by independent validation studies, meeting the agreed criteria*	**Evaluated specimen type(s)** *Eligible for issuing EU Digital COVID certificates*	**Other specimen type(s)** [15] *Not evaluated*	**SARS-CoV-2 Target protein**	**Included in the EU common list since** *D/M/Y*
1833	**AAZ-LMB**	**COVID-VIRO®**	**Prospective clinical field study** Prospective study carried out in the "Centre Hospitalier d'Orléans" on nasopharyngeal swabs, simultaneously tested by RT PCR: sensitivity <7 days after onset of symptoms: 94.7%, specificity: 100%.	**Nasopharyngeal**	Nasal	Nucleocapsid protein	10/05/2021
1232	**Abbott Rapid Diagnostics** (manufacturer)	**Panbio™ COVID-19 Ag Rapid Test**	**Prospective clinical field study** Study enrolling 1367 and 208 subjects in Utrecht (NL) and Aruba, respectively. NP swabs.	**Nasopharyngeal**	Nasal	Nucleocapsid protein	17/02/2021

12 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.

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

14 As registered in and used by the JRC database; see: https://covid-19-diagnostics.jrc.ec.europa.eu/.

15 Identical to what is included in the Instructions For Use (IFU) and/or labelling of the rapid antigen test.

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Specificity 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. Source. **FIND prospective evaluation study** Germany (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%. Source. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity* of 99.8%.				
2079	**ArcDia International Ltd**	**mariPOC Quick Flu+**	**Prospective clinical field study** Clinical performance of the test was evaluated in Finland against qRT-PCR with NP 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 was 100.0% (201/201). Source. **Prospective clinical field study** Clinical performance of the test was evaluated in Finland against RT-PCR with specimens from 962 symptomatic and asymptomatic individuals. Among the symptomatic subjects, overall sensitivity was 82.5% (33/40), which increased to 97.1% (33/34) in samples with a Ct value <30. The specificity was 100% (916/916). Source.	**Nasopharyngeal**	-	Nucleocapsid protein	14/07/2021
2078	**ArcDia International Ltd**	**mariPOC Respi+**	**Prospective clinical field study** Clinical performance of the test was evaluated in Finland against qRT-PCR with NP swab specimens collected from patients suspected of acute SARS-CoV-2 infection. Sensitivity of the mariPOC test was 100.0% (13/13) directly from	**Nasopharyngeal**	-	Nucleocapsid protein	14/07/2021

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			swab specimens and 84.4% (38/45) from swab specimens in undefined transport mediums. Specificity was 100.0% (201/201). Source. **Prospective clinical field study** Clinical performance of the test was evaluated in Finland against RT-PCR with specimens from 962 symptomatic and asymptomatic individuals. Among the symptomatic subjects, overall sensitivity was 82.5% (33/40), which increased to 97.1% (33/34) in samples with a Ct value <30. The specificity was 100% (916/916). Source.				
768	**ArcDia International Ltd**	**mariPOC SARS-CoV-2**	**Prospective clinical field study** Clinical performance of the test was evaluated in Finland against qRT-PCR with NP 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 was 100.0% (201/201). Source. **Prospective clinical field study** Clinical performance of the test was evaluated in Finland against RT-PCR with specimens from 962 symptomatic and asymptomatic individuals. Among the symptomatic subjects, overall sensitivity was 82.5% (33/40), which increased to 97.1% (33/34) in samples with a Ct value <30. The specificity was 100% (916/916). Source.	**Nasopharyngeal**	-	Nucleocapsid protein	10/05/2021
2282	**Becton Dickinson** (manufacturer)	*BD Kit for Rapid Detection of SARS-CoV-2*	**Prospective clinical field study** Study in four Spanish hospitals (n = 476); 108 positive samples, 368 negative samples. Sensitivity: 92%, specificity: 98.6%. **Prospective clinical field study** Independent study in the Netherlands including symptomatic individuals (n=979, PCR positive n=161). Sampling: Nasal mid-turbinate and OP swabs. Sensitivity overall: 79.5%; Sensitivity Ct<30: 93.2%; Specificity overall: 99.8%.	**Nasal**	-	Nucleocapsid protein	10/11/2021
1065		*BD Veritor™ System for Rapid Detection of SARS CoV 2*					07/07/2021

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1778	**Beijing Kewei Clinical Diagnostic Reagent Inc**	**COVID19 Antigen Rapid Test Kit**	**Prospective clinical field study** Study at the General Hospital Jesenice in Slovenia: 103 RT-PCR positives and 450 RT-PCR negative subjects; symptomatic patients only. Overall sensitivity: 91.26%; specificity: 99.33%. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	**Nasal**	-	Nucleocapsid protein	21/12/2021
1485	**Beijing Wantai Biological Pharmacy Enterprise Co., Ltd**	**Wantai SARS-CoV-2 Ag Rapid Test (colloidal gold)**	**Prospective clinical field study** Independent prospective study by Public Health Institute Ostrava (Czechia), including nasopharyngeal swabs from unselected symptomatic and asymptomatic participants. Sensitivity 80.6%, specificity 98.5% on 155 positive and 325 negative samples against RT-PCR (N total = 480). **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.2%.*	**Nasopharyngeal**	Nasal	Nucleocapsid protein	14/07/2021
2519	**BIOLAN HEALTH, S.L.**	**COVID-19 Antigen Rapid Test (Colloidal Gold Method)**	**Prospective clinical field study** Prospective study performed in Hospital Universitario de Cruces (Spain). Nasal specimen, 314 negative samples and 116 positive samples. Sensitivity 98.1% at Ct<25; overall sensitivity 81%; specificity 98.1%.	**Nasal**	-	Nucleocapsid protein	04/03/2022
2035	**BioMaxima SA**	**SARS-CoV-2 Ag Rapid Test**	**Prospective clinical field study** Study in Poland performed on 480 samples of NP swabs taken from symptomatic patients and from asymptomatic people in contact with an infected person. Positive results were obtained in 205 patients and in the molecular test 213 people. Negative results were obtained in 275 people and in the molecular test 267 people. Diagnostic sensitivity: 93.43% (95% CI: 91.61%~97.19%) and diagnostic specificity: 97.75% (95% CI: 93.74%~98.92%). Source. **Retrospective in vitro study**	**Nasopharyngeal**	-	Nucleocapsid protein	23/07/2021

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99%.*				
2031	**BIO-RAD**	**CORONAVIRUS AG RAPID TEST CASSETTE**	**Prospective clinical field study** Study carried out in Spain; 96 positive samples and 269 negative samples. Sensitivity 94%. Specificity 99.2%. **Prospective clinical field study** Study carried out in Spain; nasopharyngeal swabs, sensitivity 98.3%; specificity 99.6% (119 positive samples, 746 negative samples). **Prospective clinical field study** Study carried out in Spain; nasal swabs, sensitivity 97.2%; specificity 100% (109 positive samples, 128 negative samples).	**Nasopharyngeal, Nasal**	-	Nucleocapsid protein	07/07/2021
2380	**BioSpeedia International**	**COVID19Speed-Antigen Test BSD_0503**	**Prospective clinical field study** Independent prospective study by the University Hospital of Saint-Etienne (France): samples from unselected symptomatic and asymptomatic individuals (255 pos., 365 neg.), overall sensitivity: 95.29% (sensitivity Ct<25: 97.72%), specificity: 99.73%.	**Nasopharyngeal**	-	Nucleocapsid protein	21/01/2022
1494	**BIOSYNEX SA**	**BIOSYNEX COVID-19 Ag+ BSS**	**Prospective clinical field study** Validation study carried out in France: 125 positive and 118 negative samples; sensitivity 96%, specificity: 99%. **Prospective clinical field study** Clinical study carried out in a public health hospital in France (centre cardiologique du Nord): sensitivity 100% (188/188), specificity 100% (313/313).	**Nasopharyngeal**	Nasal	Nucleocapsid protein	07/07/2021
1223	**BIOSYNEX SWISS S.A.** (manufacturer)	**BIOSYNEX COVID-19 Ag BSS**	**Prospective clinical field study** Independent field study in the Netherlands, involving mainly symptomatic individuals (n=568, PCR positive n=39), NP swab; sensitivity Ct ≤ 30: 96.0%, sensitivity Ct ≤ 25: 100%; specificity overall: 100%. **Prospective clinical field study**	**Nasopharyngeal**	Nasal	Nucleocapsid protein	17/02/2021

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Independent field study in the Netherlands, symptomatic individuals (n=270, PCR positive n=17), NP+OP swab; sensitivity Ct ≤ 30: 94.1%, sensitivity Ct ≤ 25: 100%; specificity: 100%. **Prospective clinical field study** Prospective study in France, nasopharyngeal swabs (n=71/71): sensitivity 100% (45/45, specificity 100%. **Prospective clinical field study** Evaluation in Karolinska hospital (Sweden) of Lot 20100103. Patient samples; 95 PCR positive, 150 negative. Sensitivity 76%, specificity 96%. Sensitivity Ct<25 = 100%. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*				
1989	**Boditech Med Inc**	**AFIAS COVID-19 Ag**	**Prospective clinical field study** Independent field study in the Netherlands in mild symptomatic (n= 427, PCR positive: 106); overall sensitivity: 81.1%, sensitivity Ct <30: 96.4%; specificity: 100%.	**Nasopharyngeal**	-	Nucleocapsid protein	23/07/2021
1173 [16]	*CerTest Biotec*	*CerTest SARS-CoV-2 Card test*	*Prospective clinical field study* *Clinical study in Spain: Ct ≤ 25, sensitivity: 94.0%; sensitivity for samples within the first 5 days after symptom onset: 84.8%; 150 positive samples, 170 negative samples.*	*Nasal, Nasopharyngeal*	-	*Nucleocapsid protein*	*17/02/2021*
1225	**DDS DIAGNOSTIC**	**Test Rapid Covid-19 Antigen (tampon nazofaringian)**	**Prospective clinical field study** Clinical study in Romania based on 228 positive samples and 597 negative samples. All the samples were confirmed using PCR (Applied Biosystems™ 7500 and SLAN®- 96P) and clinical symptoms. The relative sensitivity (nasopharyngeal Swab) was 99.56%, the relative specificity was 99.66%.	**Nasopharyngeal**	-	Nucleocapsid protein	10/05/2021

[16] This rapid antigen test, device ID 1173, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2147	**Fujirebio**	**ESPLINE SARS-CoV-2**	**FIND prospective evaluation study** Germany (29 March 2021): 723 samples, NP swab. Sensitivities: Days < 7: 88.5%; Ct < 33: 87.8%; Ct < 25: 92.4%. Clinical specificity: 100%. Source. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.13%.*	**Nasopharyngeal**	-	Nucleocapsid protein	07/07/2021
2302	**Hangzhou AllTest Biotech Co., Ltd**	**COVID-19 Antigen Test Cassette (Nasopharyngeal Swab) (FIA)**	**Prospective clinical field study** Study in a public hospital in Slovenia, unselected patients, NP samples, 102 positive samples and 312 negative samples. Sensitivity: 95.1% and specificity: 100%.	**Nasopharyngeal**	-	Nucleocapsid protein	08/04/2022
1257	**Hangzhou AllTest Biotech Co., Ltd**	*SARS-CoV-2 Antigen Rapid Test (COVID-19 Antigen Rapid Test) (Swab)*	**Prospective clinical field study** Study at General Hospital Jesenice in Slovenia, unselected asymptomatic and symptomatic participants. Sample size: 127 positive, 316 negative. Sensitivity: 97.6% (124/127); specificity: 99.7% (315/316).	**Nasopharyngeal**	-	Nucleocapsid protein	10/05/2021
2319		*CVAG4080A – GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP Swab)*					10/06/2022
1375	**DIALAB GmbH**	*DIAQUICK COVID -19 Ag Cassette*					10/06/2022

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1767	**Healgen Scientific** (manufacturer)	*Coronavirus Ag Rapid Test Cassette*	**Prospective clinical field study** Clinical field study in the Netherlands including 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: 100%. **Prospective clinical field study** Clinical field study in the Netherlands including 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: 100%. **Prospective clinical field study** Clinical field study in the Netherlands including 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: 97.3%. **Prospective clinical field study** Independent prospective study in Spain: 192 positive and 258 negative samples (NP swab). Sensitivity: 93.3%, specificity: 99.2%, compared against NP PCR. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	**Nasopharyngeal**	Nasal	Nucleocapsid protein	17/02/2021
1218	**Siemens Healthineers** (manufacturer)	*CLINITEST Rapid COVID-19 Antigen Test*					17/02/2021
1343	**Zhejiang Orient Gene Biotech Co., Ltd** (manufacturer)	*Coronavirus Ag Rapid Test Cassette (Swab)*					17/02/2021
1791	**Immunospark s.r.l.**	**Rapid SARS-Cov2 Antigen Test**	**Prospective clinical field study** Study with unselected individuals (with delayed antigen testing), supervised by a public university in Italy. Sample size (NP samples): 120 positive, 320 negative. Sensitivity overall: 75.8% (91/120), sensitivity at Ct<25: 98.8% (86/87). Specificity: 100% (320).	**Nasopharyngeal**	-	*Unknown*	06/05/2022
1988	**Inzek International Trading B.V.**	**Biozek covid-19 Antigen Rapidtest BCOV-502**	**Prospective clinical field study** Study in the Netherlands involving a local public health authority (n=950, PCR positive = 61), NP swab; sensitivity overall: 85.25%; specificity: 99.78%.	**Nasopharyngeal**	-	Nucleocapsid protein	04/03/2022

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Prospective clinical field study Study in the Netherlands among healthcare workers (n=294, PCR positive = 44), NP swab; sensitivity overall: 81.8%, sensitivity Ct<30: 91.9%; specificity: 99.7%.				
2151 [17]	*JINAN BABIO BIOTECHNOLOGY CO., LTD., China*	*SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method)*	*Prospective clinical field study* *Prospective study with frozen nasal samples in a Polish hospital; 210 positive samples, overall sensitivity 96.7%; 450 negative samples. Specificity 100%.*	*Nasal*	-	*Nucleocapsid protein*	*10/02/2022*
1764	**JOYSBIO (Tianjin) Biotechnology Co., Ltd.** (manufacturer)	**SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)**	**Prospective clinical field study** Study in Czechia, N=225 (90 RT-PCR positive), 60.3% symptomatic patients. Test parameters for a subgroup of symptomatic patients: sensitivity 92% (80.8–97.8), specificity 97.6% (91.5–99.7). Test parameters for a subgroup of asymptomatic patients: sensitivity 100% (54.1–100), specificity 100% (95.5–100). Source. **Prospective clinical field study** Study in Italy (nasal swab) including asymptomatic or mild symptomatic participants, compared against RT-PCR from NP swab. Sample size: 115 positive, 386 negative samples. Overall sensitivity: 98.3%, specificity 99.2%	**Nasal**	-	Nucleocapsid protein	10/05/2021
1353	**LINKCARE (NANTONG DIAGNOS BIO)**	**COVID-19 Antigen Test Kit (Colloidal Gold)**	**Prospective clinical field study** Prospective study in Spain, N = 504 nasal samples (385 negative and 115 positive), performed by University Hospital Son Espases. Sensitivity: 96.33% (CI95 0.91-0.99); specificity: 100%; compared against PCR Ct ≤ 30. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.04%.*	**Nasal, Nasopharyngeal**	-	Nucleocapsid protein	21/12/2021

[17] This rapid antigen test, device ID 2151, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1268	**LumiraDX**	**LumiraDx SARS-CoV-2 Ag Test**	**Prospective clinical field study** Evaluation by SKUP - Scandinavian evaluation of laboratory equipment for point of care testing. Total sample size: 448; 83 positive samples and 365 negative samples. For nasal specimen: sensitivity of 87% (79-92) and specificity of 99.5% (98.3-99.9). For nasopharyngeal specimen: sensitivity of 90% (83-95) and specificity of 97.8% (96.0-98.8). Source. **FIND prospective evaluation study** Germany (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%. Source. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.8%.*	**Nasal**	-	Nucleocapsid protein	17/02/2021
2640	**Mologic Ltd**	**COVIOS Ag COVID-19 Antigen Rapid Diagnostic Test**	**FIND prospective evaluation study** Germany: Symptomatic and asymptomatic (n=649, PCR positive = 191), nasal and nasal-mouth-throat swab; sensitivity overall: 90.6%, sensitivity Ct ≤ 25: 96.4%; specificity: 100%.	**Nasal**	-	Nucleocapsid protein	08/12/2021
2241	**NESAPOR EUROPA SL**	**MARESKIT COVID-19 ANTIGEN RAPID TEST KIT**	**Prospective clinical field study** Prospective study in Spain; Nasal test compared to nasal PCR. Sensitivity 95.24% (Ct<30), Specificity 100%.	**Nasal**	-	Nucleocapsid protein	23/07/2021
1880	**NG Biotech**	**Ninonasal**	**Prospective clinical field study** Prospective study in France for NP and nasal swabs: NP sensitivity 89% (75/84), specificity 99% (92/93). Nasal sensitivity 98% (125/128), specificity 99% (388/390)	**Nasal, Nasopharyngeal**	-	Nucleocapsid protein	10/11/2021
2741	**OSANG Healthcare Co., Ltd.**	**GeneFinder COVID-19 Ag Plus Rapid Test**	**Prospective clinical field study** Independent prospective evaluation study carried out in Hospital Pugliese Ciaccio, Italy. Sample type: NP swab; sample size: 100 positive, 400 negative; sensitivity: 94%; specificity: 100%.	**Nasopharyngeal**	Nasal, Oropharyngeal	Nucleocapsid protein	21/12/2021

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Prospective clinical field study Independent prospective field study in Italy: 151 positive samples, 452 negative samples. Sensitivity: 96.03%; Specificity: 99.78%.				
2243 [18]	*PCL Inc.*	*PCL COVID19 Ag Gold*	*Prospective clinical field study* *Study in France: 120 positive and 200 negative samples; sensitivity 92%, specificity: 100%.*	*Nasal*	*Nasopharyngeal* *! Saliva*	*Nucleocapsid protein*	*07/07/2021*
308 [19]	*PCL Inc.*	*PCL COVID19 Ag Rapid FIA*	*Prospective clinical field study* *Validation study in France: NP swabs, sensitivity 94.29% (33/35) and specificity 100% (70/70).*	*Nasopharyngeal*	-	*Unknown*	*10/05/2021*
1097	**Quidel Corporation**	**Sofia SARS Antigen FIA**	**Prospective clinical field study** Validation study in France, nasopharyngeal swabs. Sensitivity 84.44% (76/90), specificity 99.19% (491/495). **Prospective clinical field study** Independent prospective clinical field study in the Netherlands among 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%	**Nasopharyngeal**	Nasal	Nucleocapsid protein	17/02/2021
1604	**Roche (SD BIOSENSOR)** (manufacturer)	**SARS-CoV-2 Rapid Antigen Test**	**Prospective clinical field study** Independent prospective clinical field study in the Netherlands among 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%. Source.	**Nasopharyngeal**	-	Nucleocapsid protein	10/05/2021
2228	**Roche (SD BIOSENSOR)** (manufacturer)	**SARS-CoV-2 Rapid Antigen Test Nasal**	**Prospective clinical field study** Study by the Charité Berlin in Germany for nasal samples and reference RT-PCR with NP/OP samples. Study size: 150 RT-PCR positive and 546 RT-PCR negative samples. Overall Sensitivity: 82.7% and of 97.8% for Ct ≤ 24 (91 samples). Overall Specificity: 99.1%	**Nasal**	-	Nucleocapsid protein	07/07/2021

[18] This rapid antigen test, device ID 2243, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

[19] This rapid antigen test, device ID 308, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
344	**SD BIOSENSOR Inc.** (manufacturer)	**STANDARD F COVID-19 Ag FIA**	**Prospective clinical field study** Independent prospective clinical field study in the Netherlands among 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%. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.52%.*	**Nasopharyngeal**	-	Nucleocapsid protein	17/02/2021
345	**SD BIOSENSOR Inc.** (manufacturer)	**STANDARD Q COVID-19 Ag Test**	**Prospective clinical field study** Study in Portugal: 80 samples from symptomatic individuals (27 PCR positive and 53 negative by PCR). Sensitivity: 70% (95%IC50-86); specificity: 100% (95%IC 93-100). TCID50/ml 0,68x 102 and CT<25. **FIND prospective evaluation study** Germany (10 Dec 2020): 1263 samples, NP swab. Clinical sensitivities: Days ≤ 7: 80%; Ct ≤ 33: 87.8%; Ct ≤ 25: 100%; Clinical specificity: 99.3%. Source.	**Nasopharyngeal**	-	Nucleocapsid protein	17/02/2021
2052 [20]	*SD BIOSENSOR Inc. (manufacturer)*	*STANDARD Q COVID-19 Ag Test Nasal*	*Prospective clinical field study* *Study in Germany: 146 symptomatic adults, 40 (27.4%) were RT-PCR-positive. Sensitivity: 85.0% (34/40; 95% CI 70.9-92.9). At high viral load (>7.0 log10 SARS-CoV-2 RNA copies/ml), sensitivity: 96.6% (28/29; 95% CI 82.8-99.8). Source.* *FIND prospective evaluation study* *Germany (12 April 2021): 179 samples, nasal swab. Clinical sensitivities: Days < 7: 81.2%; Ct < 33: 87.5%; Ct < 25: 100%; Clinical specificity: 99.3%. Source.*	*Nasal*	-	*Nucleocapsid protein*	*07/07/2021*
2017	**Shenzhen Ultra-Diagnostics Biotec Co., Ltd.**	**SARS-CoV-2 Antigen Test Kit**	**Prospective clinical field study** Study in Slovenia: sensitivity in unselected	**Nasopharyngeal**	Nasal	Nucleocapsid protein	10/05/2021

[20] This rapid antigen test, device ID 2052, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [14]	Name of submitting company *(and role)* [15]	Commercial name of the device [15]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [15] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
	(manufacturer)		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.		! Saliva		
1466	**TODA PHARMA**	**TODA CORONADIAG Ag**	**Prospective clinical field study** Study in France: NP swabs, sensitivity : 96.1-100%, specificity 99.2-100%. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	**Nasopharyngeal**	Nasal	Nucleocapsid protein	10/05/2021
2111	**VivaChek Biotech (Hangzhou) Co., Ltd**	**SARS-CoV-2 Ag Rapid Test**	**Prospective clinical field study** Study at General Hospital Jesenice in Slovenia; Nasal specimens. Total of 472 samples: 113 positive and 359 negative samples. Sensitivity: 85.84%, specificity: 99.72%.	**Anterior nasal**	-	Nucleocapsid	10/06/2022
1957	**Zhuhai Lituo Biotechnology Co., Ltd.** (manufacturer)	**COVID-19 Antigen Detection Kit (Colloidal Gold)**	**Prospective clinical field study** Independent prospective field study at a public hospital in Slovenia; Nasal specimens; sensitivity 189/191 PCR positives: 98.95%, specificity 403/404: 100%. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	**Nasal, Nasopharyngeal**	-	Nucleocapsid protein	14/07/2021
2201	**Zybio Inc.**	**SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)**	**Prospective clinical field study** Independent prospective field study at a public hospital in Slovenia; nasal samples. Study population: unselected hospital patients, 107 positive and 417 negative samples (as defined by RT-PCR testing of matched NP swabs). Sensitivity: 88.8%; specificity: 99%.	**Nasal**	-	Nucleocapsid protein	04/03/2022

Category B: COVID-19 rapid antigen tests evaluated by retrospective in vitro studies

The clinical performance of the following rapid antigen tests listed under "Category B" has been evaluated by retrospective in vitro studies, meeting the criteria and definitions as agreed by the Health Security Committee on 21 September 2021.

Devices highlighted in blue are identical in design and construction but are, for example, branded or distributed under a different name. The results of validation studies may be transferred between devices that are identical in design and construction.

Important notes to be taken into account by EU Member States:

- ➔ In case of retrospective in vitro evaluation studies carried out by the Paul-Ehrlich-Institut in Germany, only the sensitivity of the device has been evaluated. The specificity as reported by the manufacturer has been indicated in the corresponding column. EU Member States should pay particular attention to the issuance of EU Digital COVID recovery certificates based on the result of these devices, as the specificity of the device has thus not been evaluated by an independent validation study meeting the agreed criteria.
- ➔ In general, retrospective in vitro studies do not aim to evaluate the clinical performance of a rapid antigen test based on a specific specimen type. Therefore, the clinical performance of devices listed under Category B *cannot* be linked to a specific specimen type, which should be taken into consideration by countries when using these rapid antigen tests for the issuance of EU Digital COVID certificates. Instead, the table below makes a general reference to the specimen type(s) that can be used for the device as stated in the Instructions For Use of the device.

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2374	**ABIOTEQ**	**Cora Gentest-19**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.8%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal, Throat	Nucleocapsid protein	20/10/2021
2579	**AccuBioTech Co.,Ltd**	**Accu-Tell SARS-CoV-2 Ag Cassette**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Nasopharyngeal	Nucleocapsid protein	20/10/2021
1457	**Acon Biotech (Hangzhou) Co., Ltd** (manufacturer)	**Flowflex SARS-CoV-2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.54%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	14/07/2021

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

[22] Identical to what is included in the Instructions For Use (IFU) and/or labelling of the rapid antigen test.

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1865	**Acon Biotech (Hangzhou) Co., Ltd**	**Flowflex SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.5%.*	Nasal ! Saliva	Nucleocapsid protein	10/02/2022
1468	**ACON Laboratories, Inc.** (manufacturer)	**Flowflex SARS-CoV-2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 98.7%.*	Nasal	Nucleocapsid protein	10/05/2021
2108 [23]	*AESKU.DIAGNOSTICS GmbH & Co, KG*	*AESKU.RAPID SARS-CoV-2*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 84% at Ct ≤ 25;* *Manufacturer specificity of 98%.*	*Nasal*	*Nucleocapsid protein*	*10/05/2021*
2130	**Affimedix Inc.** (manufacturer)	**TestNOW® - COVID-19 Antigen Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	10/05/2021
1304	**AMEDA Labordiagnostik GmbH** (manufacturer)	**AMP Rapid Test SARS-CoV-2 Ag**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	17/02/2021
1822	**Anbio (Xiamen) Biotechnology Co., Ltd**	**Rapid COVID-19 Antigen-Test (colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal, Throat	Nucleocapsid protein	10/05/2021
1736	**Anhui Deep Blue Medical Technology Co., Ltd** (manufacturer)	*COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)*	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.8%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2021
1815		*COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Nasal swab*		Nasal, Anterior nasal		10/05/2021
2089	**Anhui Formaster Biosci Co., Ltd.**	**New Coronavirus (COVID-19) Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.5%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	20/10/2021

[23] This rapid antigen test, device ID 2108, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1926	**ARISTA Biotech Pte.LTD.**	**ARISTA™ COVID-19 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasopharyngeal	Nucleocapsid protein	08/04/2022
1618	**Artron Laboratories Inc.**	**Artron COVID-19 Antigen Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	14/07/2021
1654	**Asan Pharmaceutical Co., Ltd**	**Asan Easy Test COVID-19 Ag**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.7%.*	Nasal	*Unknown*	10/05/2021
770	**Assure Tech. (Hangzhou) Co., Ltd.**	*ECOTEST COVID-19 Antigen Rapid Test Device*	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 95% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	14/07/2021
2350		*ECOTEST COVID-19 Antigen Rapid Test Device*		Nasopharyngeal, Oropharyngeal		23/07/2021
1800	**Avalun**	**Ksmart® SARS-COV2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.32%.*	Nasopharyngeal	*Unknown*	07/07/2021
2101	**AXIOM Gesellschaft für Diagnostica und Biochemica mbH**	**COVID-19 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal, Throat	Nucleocapsid protein	10/05/2021
2807	**Beijing Hotgen Biotech Co., Ltd**	**Coronavirus (2019-nCoV)-Antigentest**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.88%.*	Nasal	Nucleocapsid protein	21/01/2022
1870	**Beijing Hotgen Biotech Co., Ltd**	**Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.76%.*	Nasal, Throat ! Saliva	Nucleocapsid protein	10/05/2021
2072	**Beijing Jinwofu Bioengineering Technology Co.,Ltd.**	**Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25;	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	14/07/2021

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Manufacturer specificity of 100%.	! Saliva		
1331	**Beijing Lepu Medical Technology Co., Ltd** (manufacturer)	**SARS-CoV-2 Antigen Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.26%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	17/02/2021
2494	**Beijing O&D Biotech Co., Ltd.**	**COVID-19 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.67%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	20/10/2021
2858	**Bioscience (Tianjin) Diagnostic Technology Co.,Ltd**	**Novel Coronavirus (2019-nCoV) Antigen Rapid Detection**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Nasal	Nucleocapsid protein	10/06/2022
2247	**BioGnost Ltd**	**CoviGnost AG Test Device 1x20**	**Retrospective in vitro study** Study in Croatia: 300 NP samples, symptomatic (<7 dps): 200 PCR+ samples (range Ct 16-30), Ct ≤ 30: sensitivity 96.5%. 100 PCR- samples: specificity 100%.	Nasopharyngeal	*Unknown*	23/07/2021
2230	**Biohit Healthcare (Hefei) Co., Ltd.**	**SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.49%.*	Nasal	Nucleocapsid protein	08/12/2021
1286	**Biohit Healthcare (Hefei) Co., Ltd.**	**SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromato-graphy)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.9%.*	Anterior Nasal	Nucleocapsid protein	23/07/2021
1599	**Biomerica Inc.**	**Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.7%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	07/07/2021
1242	**BIONOTE**	**NowCheck COVID-19 Ag Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.6%.*	Nasal, Nasopharyngeal	*Unknown*	07/07/2021
2067	**BIOTEKE CORPORATION (WUXI) CO., LTD**	**SARS-CoV-2 Antigen Test Kit (colloidal gold method)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	14/07/2021

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Germany: Sensitivity of 95% at Ct ≤ 25; *Manufacturer specificity of 99.28%.*			
2013	**Biotical Health S.L.U.BIOTICAL HEALTH S.L.U**	**biotical SARS-CoV-2 Ag Card**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 95% at Ct ≤ 25; *Manufacturer specificity of 99.28%.*	Nasopharyngeal	Nucleocapsid protein	23/07/2021
1236	**BTNX Inc** (manufacturer)	**Rapid Response COVID-19 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2021
2696	**Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sist.İnş.Müh.Dan.San.Tic.Ltd. Şti.**	**CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.8%.*	Nasal	Nucleocapsid protein	21/12/2021
2746	**Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sist.İnş.Müh.Dan.San.Tic.Ltd. Şti.**	**CHECK UP SARS-COV-2 NASOPHARYNGEAL RAPID ANTIGEN TEST**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.7%.*	Nasopharyngeal	Nucleocapsid protein	21/12/2021
2588	**Changzhou Biowin Pharmaceutical Co.,Ltd.**	**Novel Coronavirus(COVID-19) Antigen Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.3%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/06/2022
1691	**Chil Tıbbi Malzeme Sanayi ve Ticaret Limited Şirketi**	**CHIL COVID-19 Antigen Rapid Test (Nasopharyngeal / Oropharyngeal Swab-Casette)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.57%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	20/10/2021
2150	**Chongqing M&D Biotechnology Co. Ltd**	**2019-nCoV Antigen Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 95% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasopharyngeal	Nucleocapsid protein	20/10/2021
2449	**Citest Diagnostics Inc.**	**COVID-19 Antigen Rapid Test (Nasal Swab)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.9%.*	Nasal	Nucleocapsid protein	10/06/2022

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1919 [24]	*Core Technology Co., Ltd*	*Coretests COVID-19 Ag Test*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity of 99.6%.*	*Nasopharyngeal*	*Nucleocapsid protein*	*10/05/2021*
1581	**CTK Biotech, Inc** (manufacturer)	**OnSite COVID-19 Ag Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	07/07/2021
2242	**DNA Diagnostic** (manufacturer)	**COVID-19 Antigen Detection Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.56%.*	Nasal	Nucleocapsid protein	23/07/2021
2756	**DNA Diagnostic** (manufacturer)	**SARS-CoV-2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.3%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	21/01/2022
2273	**Dräger Safety AG & Co. KGaA**	**Dräger Antigen Test SARS-CoV-2**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 95% at Ct ≤ 25; *Manufacturer specificity of 99.6%.*	Nasal	Nucleocapsid protein	20/10/2021
2533	**Dynamiker Biotechnolgy(Tianjin) Co., Ltd.** (manufacturer)	**Dynamiker SARS-CoV-2 Ag Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.1%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	20/10/2021
1243	**Edinburgh Genetics Limited** (manufacturer)	**Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.24%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	14/07/2021
2724	**Fosun Diagnostics (Shanghai) Co.,Ltd., China**	**Fosun Covid-19 Ag Card**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.7%.*	Nasopharyngeal	Nucleocapsid protein	04/03/2022

[24] This rapid antigen test, device ID 1919, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1739	**Eurobio Scientific** (manufacturer)	**EBS SARS-CoV-2 Ag Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.1%.*	Nasal	Nucleocapsid protein	07/07/2021
1855	**GA Generic Assays GmbH**	**GA CoV-2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Nasopharyngeal	Nucleocapsid protein	23/07/2021
1244	**GenBody Inc**	**GenBody COVID-19 Ag Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94% at Ct ≤ 25; *Manufacturer specificity of 99.19%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	08/04/2022
2642	**Genobio Pharmaceutical Co., Ltd.**	**Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	08/12/2021
2012	**Genrui Biotech Inc** (manufacturer)	**SARS-CoV-2 Antigen Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.02%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	07/07/2021
1253	**GenSure Biotech Inc** (manufacturer)	**GenSure COVID-19 Antigen Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal	*Unknown*	10/05/2021
2853	**GenSure Biotech Inc** (manufacturer)	**GenSure COVID-19 Antigen Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal ! Saliva	Nucleocapsid protein	10/02/2022
2183	**Getein Biotech, Inc.** (manufacturer)	**One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.71%.*	Nasal ! Saliva	Nucleocapsid protein	16/06/2021
1820	**Getein Biotech, Inc.** (manufacturer)	**SARS-CoV-2 Antigen (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.71%.*	Nasal ! Saliva	Nucleocapsid protein	14/07/2021

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2695	**Glallergen CO., LTD.**	**Novel Coronavirus (2019-nCoV) Antigen Test Kit (Colloidal gold immunochromatography)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.02%.*	Nasal	Nucleocapsid protein	21/12/2021
1197	**Goldsite Diagnostic Inc.**	**SARS-CoV-2 Antigen Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal ! Other	Nucleocapsid protein	14/07/2021
1144 [25]	*Green Cross Medical Science Corp.*	*GENEDIA W COVID-19 Ag*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 83% at Ct ≤ 25;* *Manufacturer specificity of 100%.*	*Anterior nasal, Nasopharyngeal*	*Nucleocapsid protein*	*10/05/2021*
1747 [26]	*Guangdong Hecin Scientific, Inc.*	*2019-nCoV Antigen Test Kit (colloidal gold method)*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 82% at Ct ≤ 25;* *Manufacturer specificity of 99.07%.*	*Nasopharyngeal*	*Nucleocapsid protein*	*10/05/2021*
1216	**Guangdong Longsee Biomedical Co., Ltd.**	**2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.5%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	14/07/2021
1360	**Guangdong Wesail Biotech Co. Ltd** (manufacturer)	**COVID-19 Ag Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	17/02/2021
1324	**Guangzhou Decheng Biotechnology CO., Ltd**	**V-CHEK, 2019-nCoV Ag Rapid Test Kit (Immuno-chromatography)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.5%.*	Nasal	Nucleocapsid protein	07/07/2021
1437 [27]	*Guangzhou Wondfo Biotech Co., Ltd*	*Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 88% at Ct ≤ 25;*	*Nasopharyngeal, Oropharyngeal*	*Nucleocapsid protein*	*10/05/2021*

[25] This rapid antigen test, device ID 1144, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

[26] This rapid antigen test, device ID 1747, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

[27] This rapid antigen test, device ID 1437, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Manufacturer specificity of 99.74%.			
2257	**Hangzhou AllTest Biotech Co., Ltd**	**SARS-CoV-2 Antigen Rapid Test (Nasal Swab)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 90% at Ct ≤ 25; *Manufacturer specificity of 99.9%.*	Nasal	Nucleocapsid protein	04/03/2022
1876	**Hangzhou Biotest Biotech Co., Ltd**	**COVID-19 Antigen Rapid Test Cassette (Nasal Swab)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Nasal	Nucleocapsid protein	08/12/2021
1610 **1363** **1365**	**Hangzhou Clongene Biotech Co., Ltd.** (manufacturer)	*COVID-19 Antigen Rapid Test Casette* *Covid-19 Antigen Rapid Test Kit* *COVID-19/Influenza A+B Antigen Combo Rapid Test*	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.4% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasopharyngeal Nasal, Nasopharyngeal Nasopharyngeal	Nucleocapsid protein	07/07/2021 17/02/2021 10/05/2021
2629	**Hangzhou DIAN Biotechnology Co., Ltd.**	**COVID-19 Antigen Test Cassette**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 90% at Ct ≤ 25; *Manufacturer specificity of 98.4%.*	Nasal, Nasopharyngeal	*Unknown*	21/12/2021
2862	**Hangzhou Funworld Biotech Co., Ltd**	**SARS-CoV-2 Antigen Rapid Test Device**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98%.*	Nasal, Nasopharyngeal ! Saliva	Nucleocapsid protein	08/04/2022
2885	**Hangzhou GENESIS Biodetection and Biocontrol CO.,LTD**	**KaiBiLi COVID-19 Antigen Pro**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	10/06/2022
1844 [28]	*Hangzhou Immuno Biotech Co., Ltd*	*Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in*	*Nasal, Nasopharyngeal*	*Nucleocapsid protein*	*10/05/2021*

[28] This rapid antigen test, device ID 1844, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2317 [29]		*SARS-CoV2 Antigen Rapid Test*	*Germany: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity of 100%.*	*Anterior nasal, Nasopharyngeal, Oropharyngeal* *! Sputum*		*10/05/2021*
2256 [30]	*Sigmed Sp. z o.o.*	*Redtest Professional Sars-CoV-2 Antigen Rapid Test (Covid-19 Ag)*		*Nasal, Nasopharyngeal, Oropharyngeal*		*08/12/2021*
2979	**Hangzhou Jucheng Medical Products Co., Ltd**	**SARS-CoV-2 Ag Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Anterior nasal	Nucleocapsid protein	08/04/2022
1215	**Hangzhou Laihe Biotech Co.**	**LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.7%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2022
2139	**Hangzhou Lysun Biotechnology Co. Ltd** (manufacturer)	**COVID-19 Antigen Rapid Test Device (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal	Nucleocapsid protein	10/05/2022
1945	**Hangzhou Sejoy Electronics & Instruments Co.Ltd** (manufacturer)	**SARS-CoV-2 Antigen Rapid Test Cassette**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal	Nucleocapsid protein	08/12/2021
1952	**Hangzhou Sejoy Electronics & Instruments Co.Ltd** (manufacturer)	**SARS-CoV-2 Antigen Rapid Test Cassette (nasal, nasopharyngeal, oropharyngeal, saliva)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.1%.*	Nasal, Nasopharyngeal, Oropharyngeal ! Saliva	Nucleocapsid protein	10/06/2022
1392	**Hangzhou Testsea Biotechnology Co., Ltd.**	**Covid-19 Antigen Test Cassette**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.4%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	10/05/2022

[29] This rapid antigen test, device ID 2317, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

[30] This rapid antigen test, device ID 2256, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2942	**Hangzhou Zheda Dixun Biological Gene Engineering Co., Ltd.**	**SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Test Cassette (Swab)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	06/05/2021
1929	**Hoyotek Biomedical Co., Ltd.**	**Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 90% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Nasopharyngeal, Oropharyngeal	*Unknown*	20/10/2021
1759	**Hubei Jinjian Biology Co., Ltd**	**SARS-CoV-2 Antigen Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.3%.*	Nasopharyngeal	Nucleocapsid protein	23/07/2021
1263 [31]	*Humasis*	*Humasis COVID-19 Ag Test*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 88% at Ct ≤ 25;* *Manufacturer specificity of 100%.*	*Nasal*	*Unknown*	*10/05/2021*
1801	**Innova Medical Group.Inc**	**Innova SARS-CoV-2 Antigen Rapid Qualitative Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Anterior nasal, Nasal	Nucleocapsid protein	20/10/2021
2278	**Innovation Biotech(Beijing) Co.Ltd**	**Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Nasal swab)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Nasal	Nucleocapsid protein	20/10/2021
2419	**InTec PRODUCTS, INC.** (manufacturer)	**Rapid SARS-CoV-2 Antigen Test (nasopharyngeal specimen)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasopharyngeal	Nucleocapsid protein	20/10/2021
1783	**InTec PRODUCTS, INC.** (manufacturer)	**Rapid SARS-CoV-2 Antigen Test (nasopharyngeal/nasal specimen)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	08/1040/2021

[31] This rapid antigen test, device ID 1263, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2107	**Jiangsu Bioperfectus Technologies Co., Ltd.** (manufacturer)	**Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.15%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	14/07/2021
1920	**Jiangsu Diagnostics Biotechnology Co., Ltd**	**COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal, Oropharyngeal, Throat	Nucleocapsid protein	14/07/2021
1899	**Jiangsu Konsung Bio-Medical Science and Technology Co**	**COVID-19 Antigen Rapid Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.34%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/02/2022
2006	**Jiangsu Medomics medical technology Co.,Ltd.** (manufacturer)	**SARS-CoV-2 antigen Test Kit (LFIA)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.51%.*	Anterior nasal, Nasopharyngeal, Throat	Nucleocapsid protein	07/07/2021
2586	**Jiangsu Mole Bioscience CO., LTD.**	**SARS-CoV-2 Antigen Test Cassette**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.17%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	08/12/2021
2144	**Jiangsu Well Biotech Co., Ltd.**	**COVID-19 Ag Rapid Test Device**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Nasal	Nucleocapsid protein	20/10/2021
2963	**Jiangxi Province JinHuan Medical Instrument Co., LTD.**	**DREHA Novel Coronavirus (SARS-CoV-2) Antigen Rapid Detection Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Nasal	Nucleocapsid protein	08/04/2022
1333 **2555**	**Joinstar Biomedical Technology Co. Ltd** (manufacturer) *IEDAU INTERNATIONAL GMBH*	*COVID-19 Rapid Antigen Test (Colloidal Gold)* *Covid-19 Antigen Schnelltest (Colloidales Gold)*	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.1%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	17/02/2021 08/12/2021
1266	**Labnovation Technologies Inc.**	**SARS-CoV-2 Antigen Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2021

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2866	**Lifecosm Biotech Limited**	**COVID-19 Antigen Test Cassette**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	06/05/2022
2128	**Lumigenex (Suzhou) Co., Ltd**	**PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.16%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2021
1267	**LumiQuick Diagnostics Inc** (manufacturer)	**QuickProfile™ COVID-19 Antigen Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.8%.*	Nasopharyngeal	*Unknown*	10/05/2021
1180	**MEDsan GmbH**	**MEDsan SARS-CoV-2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.8%.*	Nasopharyngeal, Oropharyngeal	*Unknown*	17/02/2021
2029	**Merlin Biomedical (Xiamen) Co., Ltd.**	**SARS-CoV-2 Antigen Rapid Test Cassette**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.99%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	16/06/2021
1775	**MEXACARE GmbH**	**MEXACARE COVID-19 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.1%.*	Nasal	Nucleocapsid protein	07/07/2021
1190	**möLab**	**mö-screen Corona Antigen Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.99%.*	Nasopharyngeal	*Unknown*	10/05/2021
1481	**MP Biomedicals**	**Rapid SARS-CoV-2 Antigen Test Card**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.03%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	17/02/2021
2260	**Multi-G bvba**	**Covid19Check-NAS**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.5%.*	Nasal	Nucleocapsid protein	10/02/2022

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2104 [32]	*Nal von minden GmbH*	*NADAL COVID -19 Ag +Influenza A/B Test*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity of 99.9%.*	*Nasopharyngeal*	*Nucleocapsid protein*	*10/05/2021*
1162 [33]	*Nal von minden GmbH*	*NADAL COVID -19 Ag Test*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity of 99.9%.*	*Nasal, Nasopharyngeal, Oropharyngeal*	*Nucleocapsid protein*	*17/02/2021*
2301	**Nanjing Liming Bio-Products Co., Ltd.**	**StrongStep® SARS-CoV-2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.26%.*	Anterior nasal, Nasopharyngeal, Oropharyngeal ! Saliva	Nucleocapsid protein	08/12/2021
2506	**Nanjing Norman Biological Technology Co., Ltd.**	**Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94% at Ct ≤ 25; *Manufacturer specificity of 99.9%.*	Nasopharyngeal	Nucleocapsid protein	10/11/2021
2164	**Nanjing Synthgene Medical Technology Co., Ltd.**	**SARS-COV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.5%.*	Nasopharyngeal	Nucleocapsid protein	21/01/2022
1420[34]	*NanoEntek*	*FREND COVID-19 Ag*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity of 100%.*	*Nasopharyngeal*	*Nucleocapsid protein*	*10/05/2021*
2200	**NanoRepro AG**	**NanoRepro SARS-CoV-2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 98.4%.*	Anterior nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	14/07/2021
1573	**Nantong Egens Biotechnology Co.,Ltd**	**COVID-19 Antigen Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25;	Nasal	Nucleocapsid protein	10/02/2022

[32] This rapid antigen test, device ID 2104, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

[33] This rapid antigen test, device ID 1162, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

[34] This rapid antigen test, device ID 1420, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Manufacturer specificity of 99.5%.			
2608	**Neo-nostics (Suzhou) Bioengineering Co., Ltd.**	**COVID 19 Antigen Test Kit (Colloidal Gold Method)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.19%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/02/2022
1501	**New Gene (Hangzhou) Bioengineering Co., Ltd.** (manufacturer)	**COVID-19 Antigen Detection Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Nasal, Nasopharyngeal, Oropharyngeal ! Saliva, Sputum	Nucleocapsid protein	16/06/2021
1762	**Novatech Tıbbi Cihaz Ürünleri Sanayi ve Ticaret A.Ş.**	**SARS-CoV-2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	14/07/2021
1199	**Oncosem Onkolojik Sistemler San. ve Tic. A.S.**	**CAT**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 98.04%.*	Nasal	Nucleocapsid protein	10/05/2021
2116	**PerGrande Bio Tech Development Co., Ltd.**	**SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromato-graphic Assay)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.11%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2021
2672	**Pierenkemper GmbH**	**(SARS-CoV-2) Antigen Rapid Test COVIDENT (SWAB) COVID-19**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal Throat	Nucleocapsid protein	04/03/2022
1271	**Precision Biosensor Inc.**	**Exdia COVI-19 Ag**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.3%.*	Nasopharyngeal	*Unknown*	17/02/2021
2685	**PRIMA Lab SA**	**COVID-19 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.3%.*	Nasopharyngeal	Nucleocapsid protein	08/04/2022
1495	**Prognosis Biotech** (manufacturer)	**Rapid Test Ag 2019-nCov**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in	Nasal, Nasopharyngeal	Nucleocapsid protein	07/07/2021

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.58%.*			
1341	**Qingdao Hightop Biotech Co., Ltd** (manufacturer)	**SARS-CoV-2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.75%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	17/02/2021
2754	**Qingdao Hightop Biotech Co., Ltd**	**SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.75%.*	Nasopharyngeal	Nucleocapsid protein	21/12/2021
2290	**Rapid Pathogen Screening, Inc**	**LIAISON® Quick Detect Covid Ag Assay**	**Retrospective in vitro study** Independent validation study, in Italy; 100 positive and 100 negative samples. Sensitivity: 92.7% with Ct<25; specificity: 100%.	Nasal, Nasopharyngeal	Nucleocapsid protein	23/07/2021
1489	**Safecare Biotech (Hangzhou) Co. Ltd** (manufacturer)	*COVID-19 Antigen Rapid Test Kit (Swab)*	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.4%.*	Nasal	Nucleocapsid protein	17/02/2021
1490		*Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19)*				10/05/2021
2097	**Sansure Biotech Inc**	**SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.1%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	21/12/2021
1201	**ScheBo Biotech**	**ScheBo SARS CoV-2 Quick Antigen**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Nasopharyngeal, Oropharyngeal ! Serum	Nucleocapsid protein	16/06/2021
2763	**ScheBo Biotech**	**ScheBo SARS CoV-2 Quick ANTIGEN (Colloidal Gold Method)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.49%.*	Nasal	Nucleocapsid protein	21/01/2022
1319	**SGA Medikal** (manufacturer)	*V-Chek SARS-CoV-2 Ag Rapid Test Kit (Colloidal Gold)*	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.5%.*	Nasal	Nucleocapsid protein	10/05/2021
1357		*V-Chek SARS-CoV-2 Rapid Ag Test (Colloidal gold)*				07/07/2021

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2152	**Shenzhen CAS-Envision Medical Technology Co., Ltd.**	**SARS-CoV-2-Antigen Rapid Detection Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.5%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	08/12/2021
2415	**Shenzhen Dymind Biotechnology Co., Ltd**	**SARS-CoV-2 Antigen Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.37%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	20/10/2021
2812	**Shenzhen Huaree Technology Co.,Ltd**	**SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal	Nucleocapsid protein	06/05/2022
2414	**Shenzhen Huian Biosci Technology Co., Ltd.**	**SARS-CoV-2 Antigen Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.1%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	20/10/2021
2941	**Shenzhen Kingfocus Biomedical Engineering Co., Ltd.**	**COVID-19 Antigen Detection Kit (Quantum Dots-Based Immunofluorescence Chromatography)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.28%.*	Nasal	Nucleocapsid protein	08/04/2022
1813	**Shenzhen Kisshealth Biotechnology Co., Ltd**	**SARS-CoV-2 Antigen Test Kit (GICA)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	20/10/2021
2109	**Shenzhen Lvshiyuan Biotechnology Co., Ltd.**	**Green Spring SARS-CoV-2 Antigen-Rapid test-Set**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal ! Saliva	Nucleocapsid protein	10/05/2021
1967	**Shenzhen Microprofit Biotech Co., Ltd**	**SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	07/07/2021
1178	**Shenzhen Microprofit Biotech Co., Ltd.**	**SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal, Oropharyngeal	Spike protein	23/07/2021

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1228	**Shenzhen Microprofit Biotech Co., Ltd.**	**SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasopharyngeal	Nucleocapsid protein, Spike protein (S1)	08/12/2021
2026	**Shenzhen Reagent Technology Co.,Ltd.**	**SARS-CoV-2 antigen IVD kit SWAB**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.1%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	20/10/2021
1769	**Shenzhen Watmind Medical Co., Ltd** (manufacturer)	**SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.12%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2021
1768	**Shenzhen Watmind Medical Co., Ltd** (manufacturer)	**SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.13%.*	Nasal	Nucleocapsid protein	07/07/2021
1347	**Shenzhen YHLO Biotech Co., Ltd.**	**GLINE-2019-nCoV Ag**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 90% at Ct ≤ 25; *Manufacturer specificity of 99.85%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	08/12/2021
1574 [35]	*Shenzhen Zhenrui Biotech Co., Ltd*	*Zhenrui ®COVID-19 Antigen Test Cassette*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 82% at Ct ≤ 25;* *Manufacturer specificity of 97%.*	*Nasal* *! Saliva*	*Nucleocapsid protein*	*10/05/2021*
1780	**Spring Healthcare Services AG**	**SARS-Cov-2 Antigen Rapid Test Cassette (swab)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.9%.*	Nasal	Nucleocapsid protein	10/06/2022
1114	**Sugentech, Inc.** (manufacturer)	**SGTi-flex COVID-19 Ag**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	10/05/2021

[35] This rapid antigen test, device ID 1574, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2297	**SureScreen Diagnostics**	**SARS-CoV-2 Rapid Antigen Test Cassette**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Nasal	Nucleocapsid protein	20/10/2021
1942	**Surge Medical Inc.**	**COVID-19 Antigen Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct < 25; *Manufacturer specificity of 99%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	21/01/2022
3015	**Suzhou Soochow University Saier Immuno Biotech Co., Ltd.**	**InstantSure Covid-19 Ag CARD**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.52%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	06/05/2022
3093	**TBG BIOTECHNOLOGY XIAMEN INC.**	**SARS-CoV-2 Antigen Rapid Test (Nasal Swab)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 95% at Ct ≤ 25; *Manufacturer specificity of 99.68%.*	Nasal	Nucleocapsid protein	10/06/2022
2074	**Triplex International Biosciences(China) CO.,LTD.**	**SARS-CoV-2 Antigen Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.91%.*	Nasal, Nasopharyngeal, Oropharyngeal ! Saliva	Nucleocapsid protein	16/06/2021
1465	**Triplex International Biosciences(China) CO.,LTD.**	**SARS-CoV-2 Antigen Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal	Nucleocapsid protein	14/07/2021
1689	**TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.**	*Covid-19 Ag Test*	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 90% at Ct ≤ 25; *Manufacturer specificity of 99.54%.*	Nasal	Nucleocapsid protein	21/01/2022
2584		*INFO Covid-19 Ag Test*				21/12/2021
1751		*RAPIDAN TESTER Covid-19 Ag Test*				21/01/2022
1722		*TOYO Covid-19 Ag Tes*				21/01/2022
1443	**Vitrosens Biotechnology Co., Ltd** (manufacturer)	**RapidFor SARS-CoV-2 Rapid Ag Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25;	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal Throat	Nucleocapsid protein	10/05/2021

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Manufacturer specificity of 99.05%.			
2100	**VivaChek Biotech (Hangzhou) Co., Ltd, China**	**Verino Pro SARS CoV 2 Ag Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.9%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	21/12/2021
1276	**Willi Fox GmbH**	**Willi Fox COVID-19 Antigen rapid test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.9%.*	Nasopharyngeal, Oropharyngeal ! Other	Nucleocapsid protein	10/06/2022
2098	**Wuhan EasyDiagnosis Biomedicine Co., Ltd.**	**COVID-19 (SARS-CoV-2) Antigen-Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.26%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2021
2742	**Wuhan HealthCare Biotechnology Co. Ltd.**	**SARS-CoV-2 Antigen Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 90% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	04/03/2022
1773	**Wuhan Life Origin Biotech Joint Stock Co., Ltd.**	**SARS-CoV-2 Antigen Assay Kit (Immuno-chromatography)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.13%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	14/07/2021
2090	**Wuhan UNscience Biotechnology Co., Ltd.** (manufacturer)	**SARS-CoV-2 Antigen Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.57%.*	Nasal, Nasopharyngeal, Oropharyngeal Mid-turbinates	Nucleocapsid protein	07/07/2021
2143	**Wuxi Biohermes Bio & Medical Technology Co., Ltd.**	**SARS-CoV-2 Antigen Test Kit (Lateral Flow Assay)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.02%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	20/10/2021
1763	**Xiamen AmonMed Biotechnology Co., Ltd** (manufacturer)	**COVID-19 Antigen Rapid Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.55%.*	Nasal	Nucleocapsid protein	10/05/2021
1278	**Xiamen Boson Biotech Co. Ltd**	**Rapid SARS-CoV-2 Antigen Test Card**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	17/02/2021

Device ID # [21]	Name of submitting company *(and role)* [22]	Commercial name of the device [22]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [22]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.03%.*			
1456 [36]	*Xiamen Wiz Biotech Co., Ltd*	*SARS-CoV-2 Antigen Rapid Test*	*Retrospective in vitro study* *Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity of 100%.*	*Nasal* *! Other*	*Nucleocapsid protein*	*10/05/2021*
1884 [37]		*SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)*		*Anterior nasal*		*10/05/2021*
1296	**Zhejiang Anji Saianfu Biotech Co.., Ltd** (manufacturer)	*AndLucky COVID-19 Antigen Rapid Test*	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2021
1295		*reOpenTest COVID-19 Antigen Rapid Test*		Nasal, Nasopharyngeal		10/05/2021
2271	**Pantest SA** (manufacturer)	*Pantest Coronavirus Ag (Nasopharyngeal Swab)*		Nasopharyngeal		08/12/2021
2684	**Zhejiang GENE SCIENCE Co., Ltd**	**Novel Coronavirus (COVID-19) Antigen Detection Kit (Swab)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.73%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	08/12/2021
1902	**Zhuhai Encode Medical Engineering Co.,Ltd**	**ENCODE SARS-COV-2 Antigen Rapid Test Device**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 95% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Anterior nasal, Nasal, Throat	Nucleocapsid protein	20/10/2021

[36] This rapid antigen test, device ID 1456, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

[37] This rapid antigen test, device ID 1884, was removed from the EU common list on 10 June 2022. The grace period will end on 8 July 2022, 23:59 CET.

ANNEX II: list of mutually recognised COVID-19 laboratory-based antigenic assays [38]

NB: The devices listed in the table below are *not* eligible for issuing EU Digital COVID test and recovery certificates.

Device ID # [39]	Name of submitting company *(and role)* [40]	Commercial name of the device [40]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [40] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1982	**Absology Co., Ltd.**	**Absoludy COVID-19 Ag**	**Retrospective in vitro study** Study in Italy, residual NP samples already tested by RT-PCR. Sample size: 148 positive samples (Ct ≤ 17-25: n=52; Ct ≤ 25-30: n=63; Ct ≤ 30-36: n=33); 300 negative samples. Sensitivity (overall): 80.4%; Specificity: 100%.	**Nasopharyngeal**	-	Nucleocapsid protein	10/06/2022
1960	**DIASORIN**	**LIAISON SARS-CoV-2 Ag assay**	**Prospective clinical field study** Study in Belgium (n=414, PCR positive = 204, PCR negative = 210), NP swab. Sensitivity Ct ≤ 35: 73.4%, sensitivity Ct ≤ 25: 96.4%; specificity: 100%. **Prospective clinical field study** Study in Italy, symptomatic and asymptomatic (n=378, PCR positive = 46), NP swab. Overall sensitivity: 84.8%, sensitivity Ct ≤ 25: 100%; specificity: 99.4%. **Prospective clinical field study** Study in Italy (n=1075, PCR positive = 23), NP swab; sensitivity Ct ≤ 30: 90.5%; specificity: 99.8%. **Prospective clinical field study** Independent field study in the Netherlands (n=980, PCR positive n=98), NP+OP swab; sensitivity overall: 82.7%, sensitivity Ct ≤ 30: 91.9%; specificity overall: 99.1%.	**Nasopharyngeal**	Nasal	Nucleocapsid protein	20/10/2021
2124	**Fujirebio**	**Lumipulse G SARS-CoV-2 Ag**	**Prospective clinical field study** Study in Belgium, NP samples: 102 positive	**Nasopharyngeal**	-	Nucleocapsid protein	08/04/2022

38 The devices included in this list cannot be used for the issuance EU Digital COVID certificates.
39 As registered in and used by the JRC database; see: https://covid-19-diagnostics.jrc.ec.europa.eu/.
40 Identical to what is included in the Instructions For Use (IFU) and/or labelling of the rapid antigen test.

Device ID # [39]	Name of submitting company *(and role)* [40]	Commercial name of the device [40]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [40] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
			samples, 400 negative samples (including 100 hospitalized patients). Sensitivity: 93%, specificity: 99%. **Prospective clinical field study** Study in Italy; sample size (NP): 194 positive and 400 negative. Sensitivity (overall): 79.9% (155/194); sensitivity (Ct ≤ 25): 100% (87/87); specificity: 99.3% (397/400).				
1200	**Ortho Clinical Diagnostics**	**VITROS Immunodiagnostic Products SARS-CoV-2 Antigen**	**Prospective clinical field study** Study in Belgium: 80 positive NP samples (sensitivity 100%), 108 negative samples (specificity 100%). **Prospective clinical field study** Study in France: 107 positive NP samples with Ct ≤ 35 (sensitivity 93.5%), 1614 negative samples (specificity 100%). **Retrospective in vitro study** A retrospective study including 134 positive NP samples with Ct ≤ 35 (sensitivity 82.8%).	**Nasopharyngeal**	Nasal	Nucleocapsid protein	10/02/2022
2156	**Roche Diagnostics GmbH**	**Elecsys® SARS-CoV-2 Antigen2156**	**Prospective clinical field study** Study in Germany: Total N: 3139 (2747 negative, 392 positive). Relative specificity overall 99.9%; relative sensitivity (n=390) overall 92.5% (Ct ≤ 26).	**Nasopharyngeal**	Nasal, Oropharyngeal	Nucleocapsid protein	20/10/2021

ANNEX III: Checklists and further guidance for manufacturers

CHECKLIST I

FOR MANUFACTURERS WISHING TO SUBMIT AN APPLICATION FOR A NEW DEVICE TO BE INCLUDED IN THE EU COMMON LIST OF COVID-19 RAPID ANTIGEN TESTS

For further details about the criteria and definitions referred to below, please see chapter 2.1

1. Is the device a **lab-based antigenic assay**?
2. Is the device an **antibody test**?
3. Is the device a **rapid antigen self-test**?
4. Is the device a **pooled rapid antigen test**?
5. Is the device solely based on **sampling materials other than nasal, oropharyngeal or nasopharyngeal specimens** (*e.g. is it a device that can only be used for saliva sampling*)?

YES

*If the answer to **any of these questions** is **YES**, this means that the device is not eligible to be included in the EU common list.*

Your application will be rejected by the HSC.

NO

6. Does the device carry **CE-marking**?
7. Is the device **in use** in at least one of the 27 EU Member States?
8. Has the clinical performance of the device, based on nasal, oropharyngeal and/or nasopharyngeal swabs, been evaluated in at least one of the 27 EU Member States through an **independent validation study**?

NO

*If the answer to **any of these questions** is **NO**, this means that the device is not eligible to be included in the EU common list.*

Your application will be rejected by the HSC.

YES

*If the answer to **all of these questions** is **YES**, please continue with CHECKLIST II.*

CHECKLIST II

INDEPENDENT VALIDATION STUDIES CARRIED OUT IN A EU MEMBER STATE

1. Has the validation study be performed by an **independent laboratory**? Do you have a signed **declaration of conflict of interest**?

   This 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.

   *As part of your application, you should provide a **declaration of conflict of interest**, signed by the laboratory involved, containing details whether funding from a private partner or the manufacturer was received and stating that no one has personal interest in the manufacturer company, stock papers, or have worked there within the previous 3 years.*

2. Has the validation study be performed **objectively** and in the **public interest**?

3. Was a **public body** involved in the validation study? Do you have a **written endorsement** of this body?

   A public body is a public entity (government institution, regional government office, public hospital) that is primarily state-funded and plays a role in public health.

   *Ideally, the public body should be involved in the design, oversight and analysis of the study. However, as arrangements vary in Member States, you may also provide a **written endorsement** as part of your application, signed by a public body in case the study was performed by other organisations. Note that written endorsement by individuals are not accepted.*

NO

*If the answer to **any of these questions** is **NO**, this means that the device is not eligible to be included in the EU common list.*

Your application will be rejected by the HSC.

YES

4. Is the validation study based on a **prospective clinical field study design**, testing *unselected* symptomatic and asymptomatic participants for SARS-CoV-2 infection?

   "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.

YES

Continue with CHECKLIST III.I

NO

5. Is the validation study based on a **retrospective in vitro study design**, testing the clinical performance of the device by using reference panels?

YES

Continue with CHECKLIST III.II

CHECKLIST III.I - PROSPECTIVE CLINICAL FIELD STUDIES

1. Does the study show a **sensitivity** of:
   a. ≥ **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; or
   b. ≥ **90 %** for subjects with a Ct ≤ 25, in independent evaluations of unselected participants?
2. Does the study show a **specificity** of ≥ **98 %**?
3. Has the **study population** been clearly defined in the study and application documents, stating the inclusion criteria of participants (symptomatic individuals, close contacts or asymptomatic individuals without known exposure)?

   Recommendations: Ideally, the study population would include a minimum of 30 participants with a Ct value ≤ 25. The distribution and the individual results of the Ct values of all positive PCR samples and the corresponding antigen test results must be provided. Positive samples should be taken within the first seven days after symptom onset or time of infection, if known, taking into account the incubation time.
4. Has the **study design** been clearly described (incl. RT-PCR protocol and the distribution of Ct values)? Samples should represent naturally occurring viral loads. Ideally, the sensitivity for stratified Ct values should be discernible from the report.

   Recommendations: An analysis of the correlation of PCR positive/antigen positive samples should be provided, stratified by Ct value or IU/mL. A correlation of antigen negative/PCR negative samples and results (Ct values or IU/mL) of antigen negative/PCR positive samples should be included. The PCR protocol, including the type of platform, the gene targets amplified, and any reference materials used should be described. Sampling should be matched for antigen and NAAT testing, e.g., two simultaneous samples from each individual or optimally NAAT- and antigen testing from the same sample (e.g. from the eluate of one swab); the buffer/transport medium should be compatible for both NAAT and antigen testing; any volume change in the buffer/medium for sample uptake different from that of the proprietary assay, and/or between antigen and NAAT test should be clearly communicated. Each specimen type should be evaluated separately. All claimed specimen types should be compared with paired NAAT results from nasopharyngeal or oropharyngeal specimens. The analysis and the sample storage should be clearly described and carried out in line with the IFU. Test and reference samples should preferably be taken sequentially.
5. Is the study based on a target population of at least **100 fresh RT-PCR positive samples**, and at least **300 fresh RT-PCR negative samples**? Note that this number of samples should be reached for each specimen type evaluated.

   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, the number of samples may be combined, provided that the different studies applied the same/similar methodologies and that sufficient details are provided on their study design.
6. Has **ethical approval** been provided by an institutional review board?

NO

*If the answer to **any of these questions** is **NO**, this means that the device is not eligible to be included in the EU common list.*

Your application will be rejected by the HSC.

YES

*If the answer to **all of these questions** is **YES**, the device may be eligible to be included in the EU common list.*

CHECKLIST III.II - RETROSPECTIVE IN VITRO STUDIES

1. Does the study show a **sensitivity** of:
   c. ≥ **80 %** when testing all specimen in the reference panel are accepted; or
   d. ≥ **90 %** for subjects with a Ct ≤ 25?
2. Does the study show a **specificity** of ≥ **98 %** (as measured through the retrospective in vitro evaluation study or as specified by the manufacturer in the IFU)?
3. Is the **composition of the reference panel** 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 109 to 4.2 x 102 genome copies per mL of specimen and Ct values between 17 and 36.
   - The whole evaluation panel has been 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.
   - 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.
4. Has **ethical approval** been provided by an institutional review board?

NO

*If the answer to **<u>any of these questions</u>** is **NO**, this means that the device is not eligible to be included in the EU common list.*

Your application will be rejected by the HSC.

YES

*If the answer to **<u>all of these questions</u>** is **YES**, the device may be eligible to be included in the EU common list.*