EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

EU HEALTH PREPAREDNESS

EU Common list of COVID-19 antigen tests

Agreed by the Health Security Committee

Last update: 14 October 2022

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1. Introduction

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 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 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.

COVID-19 rapid antigen tests

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**. Examples of rapid antigen tests are lateral flow immunoassays that give results in < 30 minutes.

The devices included in the EU common list of COVID-19 rapid antigen tests were meeting 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 (see 2.2). 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.

Since its first publication in February 2021, the EU common list was 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.

As of 1 July 2021, and as determined by Regulation (EU) 2021/953 on the **EU Digital COVID Certificate**, all devices included in the EU common list of COVID-19 antigen tests and carried out by health professionals or by skilled testing personnel, could be used by EU Member States to issue EU Digital COVID test certificates. Moreover, as of 22 February 2022[3], 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 also became possible for EU Member States to issue EU Digital COVID recovery certificates. These certificates could be issued retroactively, based on rapid antigen tests carried out from 1 October 2021.

COVID-19 laboratory-based antigenic assays

In addition to the COVID-19 rapid antigen tests, since October 2021, the Health Security Committee has also agreed on a list of **mutually recognised COVID-19 laboratory-based**

[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://health.ec.europa.eu/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).

antigenic assays, such as enzyme-linked immunosorbent assays or automated immunoassays for the detection of antigens. These devices, meeting the same criteria as the COVID-19 rapid antigen tests, were until 30 June 2022 not eligible for the issuance of EU Digital COVID test and/or recovery certificates.

The first list of mutually recognised COVID-19 laboratory-based antigenic assays was agreed by the Health Security Committee on 20 October 2021. A first update was agreed on 10 February 2022, a second update on 8 April 2022, and a third update on 10 June 2022.

The EU common list of COVID-19 antigen tests

As of 1 July 2022, as determined by Regulation (EU) 2022/1034[4], both COVID-19 rapid antigen tests and COVID-19 laboratory-based antigenic assays are eligible for issuing EU Digital COVID test and recovery certificates. Therefore, on 22 July 2022, the Health Security Committee agreed that the EU common list of COVID-19 rapid antigen tests and the list of mutually recognised COVID-19 laboratory-based antigenic assays should be merged into one list: **the EU common list of COVID-19 antigen tests** (see Annex I).

All devices included in the EU common list of COVID-19 antigen tests are meeting the criteria as defined by the Council Recommendation of 21 January 2021 and further criteria agreed by the Health Security Committee on 21 September 2021 (see section 2.2.). All devices included in the EU common list of COVID-19 antigen tests and carried out by health professionals or by skilled testing personnel can be used by EU Member States to issue EU Digital COVID test and recovery certificates.

EU common list of COVID-19 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; Sixteenth update: 22 July 2022; Seventeenth update: 5 October 2022; Eighteenth update: 14 October 2022.

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of 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 antigen tests, both rapid antigen tests and laboratory-based antigenic assays, 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 antigen tests of which Member States mutually recognise the test results for public health measures.

[4] Regulation (EU) 2022/1034 of the European Parliament and of the Council of 29 June 2022 amending 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 173, 30.6.2022, p. 37–45).

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

2.1 Category A and Category B devices

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

- **Category A**: Antigen tests for which their performance has been evaluated through prospective clinical field studies and that meet the criteria agreed on 21 September 2021 (see section 2.2) have been placed under the "A-category" of the EU common list. **Category A.1** sets out the eligible COVID-19 rapid antigen tests and **Category A.2** sets out the eligible COVID-19 laboratory-based antigenic assays.
- **Category B**: Antigen tests for which their performance has been evaluated through retrospective in vitro studies and that meet the criteria agreed on 21 September 2021 (see section 2.2) have been placed under the "B-category" of the EU common list. **Category B.1** sets out the eligible COVID-19 rapid antigen tests and **Category B.2** sets out the eligible COVID-19 laboratory-based antigenic assays.

EU Member States are strongly encouraged to use, in particular, 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 antigen tests has been evaluated.

Thirdly, EU Member States are strongly encouraged to ensure that only test results from the evaluated specimen type(s) as indicated for Category A devices are used for the issuance of EU Digital COVID test and recovery certificates. As regards the Category B devices, in general, retrospective in vitro studies do not aim to evaluate the clinical performance of an 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 EU Member States when using these antigen tests for the issuance of EU Digital COVID certificates.

2.2 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 following section sets out the scope, definitions and criteria that were agreed by the Health Security Committee agreed on 21 September 2021 and that should be met by devices in order to be included in the EU common list of COVID-19 antigen tests.

The Technical Working Group of the Health Security Committee monitors technical and epidemiological developments in the field of 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

antigen tests, as well as the performance of 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 COVID-19 antigen tests:

- Only antigen tests that carry CE marking are included in the EU common list of COVID-19 antigen tests.
- The EU common list includes antigen tests that are used in practice in and that have been validated by at least one of the 27 EU Member States[6].
- The EU common list includes 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.
- 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 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.
- Multiplex antigen assays that simultaneously detect multiple pathogens – e.g. SARS-CoV-2 and Influenza A/B - can be included in the EU common list, but only their performance regarding their detection of SARS-CoV-2 will be assessed.

The EU common list of COVID-19 antigen tests does **NOT** include, and therefore EU Digital COVID certificates cannot be issued based on a test result from:

- 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)[7].

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

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

- Antigen self-tests, including antigen self-testing monitored by health professionals or by skilled testing personnel (either on site or remotely). The EU common list only includes 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 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 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[8], 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.
- "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 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.

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.

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

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*[9], 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 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.
  - The whole evaluation panel should be subdivided into three subgroups: panel members, which are characterized by:
    - **Very high viral load:** Ct value 17-25; 35% (+/- 2%) of the total number of (pooled) clinical specimens);
    - **High viral load** (Ct value 25-30; 45% (+/- 2%) of the total number of (pooled) clinical specimens); and
    - **Moderate viral load** (Ct value 30-36; 20% (+/- 2%) of the total number of (pooled) clinical specimens).

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

- 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 recommended.
- For each 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 antigen tests among children).

2.3 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 COVID-19 antigen tests should feed into the "COVID-19 In Vitro Diagnostic Devices and Test Methods Database[10], 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 antigen tests to put forward proposals of 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.

Manufacturers and EU Member States can (1) submit **new applications** for (twin) devices to be included in the EU common list; (2) **resubmit** an application (e.g. to update a previous submission of devices rejected by the HSC or removed from the EU common list, or to update a previous submission not yet evaluated by the TWG); **update** information concerning a device already included in the EU common list.

Twin devices are the same in design and construction but are, for example, branded or distributed under a different name. The results of validation studies may be transferred between such devices. In case a manufacturer wishes to submit an application for a twin device, a declaration stating that the devices are exactly the same should be provided by the manufacturer(s) legally responsible for the products in the framework of the CE marking.

10 https://covid-19-diagnostics.jrc.ec.europa.eu/devices.

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

2.4 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 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 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 SARS-CoV-2 variant emerges that affects the clinical performance of certain 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 antigen tests that are included in the EU common list or COVID-19 antigen tests.

3. Background information

COVID-19 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, 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[11].

On 17 September 2020, the Health Security Committee agreed on Recommendations for a common EU testing approach for COVID-19[12], which included Member States' first experiences with 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 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 COVID-19 antigen tests to the Health Security Committee for agreement.

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

12 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 antigen tests [13, 14]

***Disclaimer**: The Technical Working Group strongly recommends that antigen tests are primarily used for preliminary testing for SARS-CoV-2 infection in symptomatic patients, and notes that 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 Technical Working Group stresses that the clinical performance data of devices included in the EU common list, resulting from independent validation studies meeting the agreed criteria, cannot be directly compared as absolute numbers.*

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

EU Member States are strongly encouraged to use, in particular, the 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.

CATEGORY A.1: COVID-19 RAPID ANTIGEN TESTS

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1833	AS-COV-008, AS-COV-009	**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

[13] This is the list of COVID-19 antigen tests as referred to in Article 3 of the Regulation (EU) 2022/1034 of the European Parliament and of the Council of 29 June 2022, amending 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 173, 30.6.2022, p. 37–45.

[14] The Medical Device Coordination Group Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices, which will form the basis for common specifications to be adopted according to Article 9 of Regulation (EU) 2017/746, has been considered by the Technical Working Group for the development of the EU common list of COVID-19 antigen tests.

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

[16] The reference number is the identification number issued by the manufacturer to identify the device. It is usually included in the device's labelling, instructions for use and/or declaration of conformity, and often preceded by the symbol 'REF'. Synonyms for reference numbers are: catalogue numbers, commercial product codes or reorder numbers. The reference number may vary in different markets. The REF number included in the EU common list may be followed by "{…}", which means this is generic number that will, in practice, be followed by further references, depending on the packaging, box, national market, etc. When a reference number is not issued, the device is typically identified by its commercial product name.

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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
3037	TR-COV-008	**AAZ-LMB**	**COVID-VIRO ALL IN**	**Prospective clinical field study** Prospective study carried out in the "Centre Hospitalier d'Orléans" on nasal swabs, simultaneously tested by RT PCR on NP swabs: sensitivity: 94.4% (101/107), specificity: 100% (505/505).	**Nasal**	-	Nucleocapsid protein	05/10/2022
1232	41FK10	**Abbott Rapid Diagnostics**	**Panbio™ COVID-19 Ag Rapid Test**	**Prospective clinical field study** Study enrolling 1367 and 208 subjects in Utrecht (NL) and Aruba, respectively. NP swabs. 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%.	**Nasopharyngeal**	Nasal	Nucleocapsid protein	17/02/2021
1457	L031-11815, L031-125A5	**Acon Biotech (Hangzhou) Co., Ltd**	**Flowflex SARS-CoV-2 Antigen Rapid Test**	**Prospective clinical field study** Independent prospective study carried out by University Magna Graecia of Catanzaro, Italy. Unselected nasal samples: 144 positive and 342 negative samples. Sensitivity: 97.22%, specificity: 99.71%. Unselected NP samples: 145 positive and 332 negative samples. Sensitivity: 96.55%, specificity: 100%. **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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2108	REF 840001, REF 840003, REF 840005, REF 840007	**AESKU.Diagnostics GmbH & Co KG**	**AESKU.RAPID SARS-CoV-2**	**Prospective clinical field study** Prospective study carried out in Germany, Nasal swab, study size: 130 positive samples and 460 negative samples. Overall sensitivity: 88,5%, sensitivity Ct ≤ 25: 100%, specificity: 98,8%.	Nasal	-	Nucleocapsid protein	14/10/2022
1822	A6061251, A6061252, A6061253	**Anbio (Xiamen) Biotechnology Co., Ltd**	**Rapid COVID-19 Antigen-Test (colloidal Gold)**	**Prospective clinical field study** Prospective study carried out in France, NP swab, sensitivity: 90.16% (110/122), specificity: 99.67% (302/303). **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
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	1184M	**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 swab specimens and 84.4% (38/45) from swab specimens in undefined transport mediums. Specificity was 100.0% (201/201). Source.	**Nasopharyngeal**	-	Nucleocapsid protein	14/07/2021

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
				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	1204S	**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
2538	RTA0301, RTA0302, RTA0303, RTA0304, RTA0305	**AUTOBIO DIAGNOSTICS., LTD.**	**SARS-CoV-2 Ag Rapid Test**	**Prospective clinical field study** Study carried out in France (Orléans hospital), Nasal samples. Overall sensitivity: 88.25% (105/119), specificity: 100% (300/300).	**Nasal**	-	Nucleocapsid protein	05/10/2022
2282	256091, 256113, 256114	**Becton Dickinson**	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1065	256089	**Becton Dickinson**	**BD Veritor™ System 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	07/07/2021
1778	601460, 601540	**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	WJ-2950	**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
3099	CIBG-20211012	**BioDetect (Xiamen) Biotechnology Co., Ltd.**	**RAPID SARS-COV-2 ANTIGEN TEST CARD**	**Prospective clinical field study** Prospective study in Slovenia, General Hospital Jesenice. Nasal swab, symptomatic and asymptomatic patients. Positive samples: 200, negative samples: 404. Sensitivity: 90% (180/200), specificity: 99.75% (403/404).	**Nasal**	-	Nucleocapsid protein	22/07/2022

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2519	KACOV19-5, KACOV19-25, KACOV19-25C	**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	1-367-K020	**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** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99%.*	**Nasopharyngeal**	-	Nucleocapsid protein	23/07/2021
2031	12015553	**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	BSD_0503-10, BSD_0503-25	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1494	SW40010	**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 in a French public health hospital (centre cardiologique du Nord): sensitivity 100% (188/188), specificity 100% (313/313).	**Nasopharyngeal**	Nasal	Nucleocapsid protein	07/07/2021
1223	SW40006	**BIOSYNEX SWISS S.A.**	**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** 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%.*	**Nasopharyngeal**	Nasal	Nucleocapsid protein	17/02/2021
1989	SMFP-71	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1647		**CALTH Inc.**	**AllCheck COVID19 Ag**	**Prospective clinical field study** Independent prospective study carried out in the laboratory of a public hospital in Italy. Sample size: 136 positive and 520 negative samples. Overall sensitivity: 95.6%; Sensitivity 98.9% for Ct ≤ 25; specificity: 100%.	**Nasopharyngeal**	-	Nucleocapsid protein	22/07/2022
2691		**CALTH Inc.**	**AllCheck COVID19 Ag Nasal**	**Prospective clinical field study** Independent prospective study carried out in the laboratory of a public hospital in Italy. Sample size: 130 positive and 530 negative samples. Overall sensitivity: 95.4% (124/130), specificity: 99.8% (519/530).	**Nasal**	-	Nucleocapsid protein	22/07/2022
1173	SC820001PC	**CerTest Biotec**	**CerTest SARS-CoV-2 Card test**	**Prospective clinical field study** Clinical study in Spain by Hospital Universitario Príncipe de Asturias (Madrid) during January/February 2021 and May 2022. Sample size: 98 positive and 242 negative samples; NP swabs. Overall sensitivity: 65% (92% for Ct ≤ 25), specificity: 98%. **Prospective clinical field study** Prospective study on NP samples by Laboratoire de Virologie CHU (Amiens, France) during October/November 2020. Sample size: 96 positive and 62 negative samples. Sensitivity 92% for Ct ≤ 25, specificity: 98%.	**Nasopharyngeal**	Nasal	Nucleocapsid protein	17/02/2021
2449	ICOV-502	**Citest Diagnostics Inc.**	**COVID-19 Antigen Rapid Test (Swab)**	**Prospective clinical field study** Prospective study conducted at General Hospital Jesenice in Slovenia. Unselected participants, nasal samples compared against Nasopharyngeal samples (RT-PCR). Sensitivity: 96.72% (118/122), specificity: 99.72% (354/355). **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 # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1225	04 nCov	**DDS DIAGNOSTIC**	**Test Rapid Covid-19 Antigen (tampon nazofaringian)**	**Prospective clinical field study** Clinical study in Romania; 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
1375	Z20401CE (rev17), Z20999CE (rev 16), Z20601CE (rev13)	**DIALAB GmbH**	*DIAQUICK COVID -19 Ag Cassette*	**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	10/06/2022
2147	231906	**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%. 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
3190	643K	**Green Cross Medical Science Corp.**	**GENEDIA W COVID-19 Ag 643K**	**Prospective clinical field study** Independent prospective study by University Hospital Sant'Andrea in Rome, Italy. Sample size: 117 positive and 400 negative samples, unselected population. Overall sensitivity: 78.6% and sensitivity Ct < 25: 93.75%, specificity: 100%.	**Nasal**	-	Nucleocapsid protein	05/10/2022
1144	643G	**Green Cross Medical Science Corp.**	**GENEDIA W COVID-19 Ag**	**Prospective clinical field study** Independent prospective study by University Hospital Sant'Andrea in Rome, Italy. Sample size: 117 positive and 400 negative samples, unselected population. Overall sensitivity: 82.05%, specificity: 100%	**Nasopharyngeal**	Anterior nasal	Nucleocapsid protein	10/05/2021
1747	JT04-20	**Guangdong Hecin Scientific, Inc.**	**2019-nCoV Antigen Test Kit (colloidal gold method)**	**Prospective clinical field study** Study in a public hospital in Slovenia with acute symptomatic patients, Nasal samples. Sensitivity: 97.09% (100/103) and specificity: 99.78% (449/450).	**Nasal**	Nasopharyngeal	Nucleocapsid protein	10/05/2021

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1437		**Guangzhou Wondfo Biotech Co., Ltd**	**Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)**	**Prospective clinical field study** Independent prospective study in Germany (NP swabs). Sample size: 114 positive samples, 426 negative samples. Sensitivity at Ct < 25: 98%, specificity: 99%.	**Nasopharyngeal**	Oropharyngeal	Nucleocapsid protein	14/10/2022
2302	FI-NCP-502	**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	INCP-502	**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	**Hangzhou AllTest Biotech Co., Ltd**	**CVAG4080A – GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP 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	10/06/2022
1767	GCCOV-502a	**Healgen Scientific**	**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:	**Nasopharyngeal**	Nasal	Nucleocapsid protein	17/02/2021

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
				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%.*				
3153	CY-F006-AG01P, CY-F006-AG05P, CY-F006-AG25P	**Huachenyang (Shenzhen) Technology Co., Ltd.**	**COVID-19 Ag Rapid Test Kit**	**Prospective clinical field study** Prospective study in Germany, sample size (Nasal samples): 100 positive, 300 negative. Sensitivity 91%, specificity: 100%.	**Nasal**	-	Nucleocapsid protein	14/10/2022
1791	RTVI039AG	**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	BCOV-502	**Inzek International Trading B.V.**	**Biozek covid-19 Antigen Rapidtest BCOV-502**	**Prospective clinical field study** Study in Dutch local public health authority (n=950, PCR positive = 61), NP swab; sensitivity overall: 85.25%; specificity: 99.78%. **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%.	**Nasopharyngeal**	-	Nucleocapsid protein	04/03/2022
2107	SC30107W {…}	**Jiangsu Bioperfectus Technologies Co., Ltd.**	**Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit**	**Prospective clinical field study** Study in Orleans Hospital (France). Evaluations for Nasopharyngeal and Nasal samples meet the criteria. NP samples - sensitivity: 84.92% (107/126), specificity: 100% (301/301). Nasal samples – sensitivity: 81% (92/113), specificity: 100% (305/305).	**Nasal, Nasopharyngeal**	Oropharyngeal	Nucleocapsid protein	14/07/2021

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
				Retrospective in vitro study Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.15%.*				
1764	G10313	**JOYSBIO (Tianjin) Biotechnology Co., Ltd.**	**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	AGSWNSA21-01, AGSWNSA21-02, AGSWNSA21-04, AGSWNSA21-05	**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
1268	SPEC-32312 R7 ART-00571 R13	**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.	**Nasal**	-	Nucleocapsid protein	17/02/2021

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
				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%.*				
2640	11811125	**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
1162	243103N-20	**nal von minden GmbH**	**NADAL® COVID-19 Ag Test**	**Prospective clinical field study** Prospective study in Germany; NP swab. Sample size: 137 positive samples, 401 negative samples. Sensitivity 95.7% (Ct<25), Specificity 99.8%.	**Nasopharyngeal**	-	Nucleocapsid protein	14/10/2022
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	NGB-COV-S23-202 (FR market), NGB-COV-S23-203 (DE market)	**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
1646	NGB-COV-S23-024	**NG Biotech**	**NG-Test SARS-CoV-2 Ag**	**Prospective clinical field study** Independent prospective study carried out in Greece, NP samples. Sample size: 121 positive and 305 negative samples. Overall sensitivity: 84.3%, specificity: 99.7%.	**Nasopharyngeal**	-	Nucleocapsid protein	05/10/2022
1762	MY28	**Novatech Tıbbi Cihaz Ürünleri Sanayi ve Ticaret A.Ş.**	**SARS-CoV-2 Antigen Rapid Test**	**Prospective clinical field study** Independent prospective study carried out in Germany. Sample size: 119 positive and 363 negative samples. Sensitivity at Ct ≤ 25: 98.36%, specificity: 98.3%.	**Nasopharyngeal**	Nasal	Nucleocapsid protein	14/07/2021

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
				Retrospective in vitro study Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 100%.*				
1593		**OSANG Healthcare Co., Ltd.**	**GeneFinder COVID-19 Ag Rapid Test**	**Prospective clinical field study** Independent prospective study carried out in a public hospital in Italy. Sample size: 100 positive and 450 negative samples. Overall sensitivity: 96%, specificity: 99.8%.	**Nasopharyngeal**	-	Nucleocapsid protein	22/07/2022
2741	O1-01SA-SN	**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%. **Prospective clinical field study** Independent prospective field study in Italy: 151 positive samples, 452 negative samples. Sensitivity: 96.03%; Specificity: 99.78%.	**Nasopharyngeal**	Nasal, Oropharyngeal	Nucleocapsid protein	21/12/2021
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
2685	200063-20P	**PRIMA Lab SA**	**COVID-19 Antigen Rapid Test**	**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). **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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1962	G61RHA20, G61RHA20C	**Rapigen Inc.**	**BIOCREDIT COVID-19 Ag**	**Prospective clinical field study** Prospective clinical field study in Italy, 146 positive samples and 302 negative samples, NP swab. Overall sensitivity: 87.67% and sensitivity Ct ≤ 25: 92.5%. Specificity: 98.34%.	**Nasopharyngeal**	-	Nucleocapsid protein	05/10/2022
1963	G69RHA20, G69RHA20C	**Rapigen Inc.**	**BIOCREDIT COVID-19 Ag Test Nasal**	**Prospective clinical field study** Prospective clinical field study in Italy, 146 positive samples and 302 negative samples, Nasal swab. Overall sensitivity: 93.15% and sensitivity Ct ≤ 25: 97.5%. Specificity: 98.34%.	**Nasal**	-	Nucleocapsid protein	14/10/2022
1604	9901-NCOV-01G	**Roche (SD BIOSENSOR)**	**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	9901-NCOV-03G	**Roche (SD BIOSENSOR)**	**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
344	F-NCOV-01G	**SD BIOSENSOR Inc.**	**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	Q-NCOV-01G	**SD BIOSENSOR Inc.**	**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.	**Nasopharyngeal**	-	Nucleocapsid protein	17/02/2021

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
				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.				
2052	Q-NCOV-04G	**SD BIOSENSOR Inc.**	**STANDARD Q COVID-19 Ag 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	22/07/2022
1592	H-07-0000000-00380	**Shenzhen Lifotronic Technology Co., Ltd.**	**Antigen Rapid Test Ag SARS-CoV-2**	**Prospective clinical field study** Independent prospective study carried out at a public hospital in Catanzaro, Italy. Sample size: 100 positive and 450 negative samples. Sensitivity: 93% (95% CI: 86.25% - 96.57%), specificity: 99.78% (95% CI: 98.75% - 99.96%).	**Nasopharyngeal**	-	Nucleocapsid protein	22/07/2022
2017	SC0201	**Shenzhen Ultra-Diagnostics Biotec Co., Ltd.**	**SARS-CoV-2 Antigen Test Kit**	**Prospective clinical field study** Study in Slovenia: sensitivity in unselected symptomatic population: 86.4% (172 RAT pos. / 199 RT-PCR pos.), sensitivity of 97.8% at Ct ≤ 25. Specificity: 99.1% (1972 RAT neg. / 1990 RT-PCR neg.), NP swab.	**Nasopharyngeal**	Nasal ! Saliva	Nucleocapsid protein	10/05/2021
1218	GCCOV-502a	**Siemens Healthineers**	**CLINITEST Rapid COVID-19 Antigen Test**	**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	**Nasopharyngeal**	Nasal	Nucleocapsid protein	17/02/2021

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
				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%.*				
1466	2276, 2276/20	**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
3143	RGP- {…}	**VivaChek Biotech (Hangzhou) Co., Ltd.**	**Rapid Gold Pro SARS-CoV-2 AG Test**	**Prospective clinical field study** Independent prospective study in Germany: 160 positive and 300 negative samples (Nasal swab). Sensitivity at Ct ≤ 25: 91.9%, specificity: 100%.	**Nasopharyngeal**	Nasal, Oropharyngeal	Nucleocapsid protein	14/10/2022
2111	VCD 16 {…}	**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 protein	10/06/2022
2100	VCD 16 {…}	**VivaChek Biotech (Hangzhou) Co., Ltd, China**	**Verino Pro SARS CoV 2 Ag Rapid Test**	**Prospective clinical field study** Independent prospective study in Germany: 104 positive and 304 negative samples (Nasal swab). Sensitivity at Ct ≤ 25: 100%, specificity: 98.7%. **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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1456	518328 {…}	**Xiamen Wiz Biotech Co., Ltd.**	**SARS-CoV-2 Antigen Rapid Test**	**Prospective clinical field study** Prospective study in Germany, NP swab: 107 positive samples, 338 negative samples. Sensitivity Ct ≤ 25: 100%; specificity: 98.8%.	**Nasopharyngeal**	Nasal, Oropharyngeal	Nucleocapsid protein	14/10/2022
1343	GCCOV-502a	**Zhejiang Orient Gene Biotech Co., Ltd**	**Coronavirus Ag Rapid Test Cassette (Swab)**	**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
1957	LCV03 {…}	**Zhuhai Lituo Biotechnology Co., Ltd.**	**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)	**Nasal, Nasopharyngeal**	-	Nucleocapsid protein	14/07/2021

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
				in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*				
2201	2061708 (1test/kit), 2061701 (20tests/kit),	**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 A.2: COVID-19 LABORATORY-BASED ANTIGENIC ASSAYS

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1960	311490 (reagent), 311491 (control), 311492 (buffer)	**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 ≤ 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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	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) [17] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2124	260340	**Fujirebio**	**Lumipulse G SARS-CoV-2 Ag**	**Prospective clinical field study** Study in Belgium, NP samples: 102 positive 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).	**Nasopharyngeal**	-	Nucleocapsid protein	08/04/2022
1200	619 9941 (reagent pack), 619 9942 (calibrator)	**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	09345299190	**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

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

The clinical performance of the following 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.

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 an 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 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.

CATEGORY B.1: COVID-19 RAPID ANTIGEN TESTS

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2374	7427245282658	**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	ABT-IDT-B367	**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
1865	L031-12515, L031-125D5	**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	L031-11815	**ACON Laboratories, Inc.**	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2130	1166-25	**Affimedix Inc.**	**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	RT2950 (1 cassette), RT2955 (5 cassettes), RT2951 (10 cassettes)	**AMEDA Labordiagnostik GmbH**	**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
1736		**Anhui Deep Blue Medical Technology Co., Ltd**	**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		**Anhui Deep Blue Medical Technology Co., Ltd**	**COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Nasal swab**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.8%.*	Nasal, Anterior nasal	Nucleocapsid protein	10/05/2021
2089	FCB-103	**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
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	A03-50-422	**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	AM3474-K (20T), AM3476-K (25T)	**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	COV-S23	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2350	COV-S23	**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%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	23/07/2021
1800	03760097080046	**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	88 99 19	**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[18]	*HGCG134S01 {…}*	*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	AT120/20 (Model A/B)	**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	C3042	**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; *Manufacturer specificity of 100%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal ! Saliva	Nucleocapsid protein	14/07/2021
1331	CG27 {…}	**Beijing Lepu Medical Technology 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 99.26%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	17/02/2021
2494	00013C	**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

[18] This rapid antigen test, device ID 2807, was removed from the EU common list on 14 October 2022. The grace period will end on 11 November 2022, 23:59 CET.

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
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	COVAG0 {…}	**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	209.01.25.01	**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	AT043/20 (Ref 34)	**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	1509A-I	**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	RG1901DG	**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	400-678-8982	**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 Germany: Sensitivity of 95% at Ct ≤ 25; *Manufacturer specificity of 99.28%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	14/07/2021
2013	RTB25CoV2C	**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	COV-19C25	**BTNX Inc**	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2696	C2104N01	**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	C2104N02	**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	CCOV-201	**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
1581	R0182C	**CTK Biotech, Inc**	**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	CV19IC	**DNA Diagnostic**	**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	CV19AG	**DNA Diagnostic**	**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	3715270	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2533	DNK-1425-1	**Dynamiker Biotechnolgy(Tianjin) Co., Ltd.**	**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	EGCV0101 {…}	**Edinburgh Genetics Limited**	**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	PCSYHN02	**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
1739	EBS 1020	**Eurobio Scientific**	**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	3985	**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	COVAG025	**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	CoVSLFA-20	**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	52025 {…} 52026 {…} 52027 {…} 52104 {…} 52112 {…} 52129 {…}	**Genrui Biotech Inc**	**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	P2004	**GenSure Biotech Inc**	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2853	P2004s	**GenSure Biotech Inc**	**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	CG2061	**Getein Biotech, Inc.**	**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	CG20615	**Getein Biotech, Inc.**	**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
2695	600008	**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	CG123005	**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
1216	LS-C-T-009	**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	BE0040, BE0041	**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	0555C2X {…}	**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
2257	INCP-502-N	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2325	CVAG4080B (Nasal swab)	**Hangzhou AllTest Biotech Co., Ltd**	**GSD NovaGen SARS-CoV-2 Ag 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	22/07/2022
1876	302281	**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		**Hangzhou Clongene Biotech Co., Ltd.**	**COVID-19 Antigen Rapid Test Casette**	**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	Nucleocapsid protein	07/07/2021
1363	ICOV5002-B025	**Hangzhou Clongene Biotech Co., Ltd.**	**Covid-19 Antigen Rapid Test Kit**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.4% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	17/02/2021
1365		**Hangzhou Clongene Biotech Co., Ltd.**	**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	Nucleocapsid protein	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	INC-502	**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	P211138	**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
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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1215[19]	*303035*	*Hangzhou Laihe Biotech Co.*	*LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing*	*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	COV-201	**Hangzhou Lysun Biotechnology Co. Ltd**	**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	COVG-602	**Hangzhou Sejoy Electronics & Instruments 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 100%.*	Nasal	Nucleocapsid protein	08/12/2021
1952	COVG-602	**Hangzhou Sejoy Electronics & Instruments Co.Ltd**	**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
2063	COIF-522	**Hangzhou Sejoy Electronics & Instruments Co.,Ltd.**	**SARS-CoV-2 & Influenza A+B Antigen Combo 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 99.1%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	05/10/2022
1446	6936020115018, 6936020115025	**Hangzhou Singclean Medical Products Co., Ltd**	**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 99%.*	Nasal	Nucleocapsid protein	05/10/2022
1392	9010115	**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
2942	IFC-SCoV2-AG	**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

[19] This rapid antigen test, device ID 1215, was removed from the EU common list on 14 October 2022. The grace period will end on 11 November 2022, 23:59 CET.

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1929	HYT-G01	**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
1801	BT1389	**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	IN4658I	**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	ITP16010-TC1, ITP16010-TC25	**InTec PRODUCTS, INC.**	**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	ITP16010-TC {…}	**InTec PRODUCTS, INC.**	**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	08/40/2022
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	1031-02	**Jiangsu Medomics medical technology Co.,Ltd.**	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2586	R220T001B0C0	**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	CO-05	**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		**Joinstar Biomedical Technology Co. Ltd**	**COVID-19 Rapid 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 98.1%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	17/02/2021
2555		**IEDAU INTERNATIONAL GMBH**	**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	08/12/2021
2038	NCV11 (25 tests), NCV12 (1 test)	**Koch Biotechnology (Beijing) 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; *Manufacturer specificity of 99.3%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	22/07/2022
1266	B63000, LX-401301	**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
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	P230 {…}	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1267	71110	**LumiQuick Diagnostics Inc**	**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	T00023 (single box), T00019 (25 pack)	**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	CP01810011, CP02150011	**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	3011035	**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	0230005SP	**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	07AG6020B	**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	MGJGEN	**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
2301	500200	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2164	RQ005 {…}	**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
2200	B66000	**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; *Manufacturer specificity of 99.5%.*	Nasal	Nucleocapsid protein	10/02/2022
2678		**NDFOS Co., Ltd.**	**ND COVID-19 Ag Test**	**Retrospective in vitro study** Independent retrospective study by the University of Geno, Italy; 100 positive and 300 negative samples. Overall sensitivity: 87% (79.02-92.24), sensitivity of 100% (91.24-100) at Ct ≤ 25, specificity: 100%.	Nasopharyngeal ! Saliva	Nucleocapsid protein	22/07/2022
2608	SVRAG	**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	COVID-19-NG08	**New Gene (Hangzhou) Bioengineering Co., Ltd.**	**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
1199	CMA-031	**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
2271	SARS-CoV-2019 Ag (N) {…}	**Pantest SA**	**Pantest Coronavirus Ag (Nasopharyngeal Swab)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99%.*	Nasopharyngeal	Nucleocapsid protein	08/12/2021
2116	67311, 67321, 67331, 67341, 67351, 67361, 67371	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
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	PR-FC13	**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
1495	V1320, V1340	**Prognosis Biotech**	**Rapid Test Ag 2019-nCov**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.58%.*	Nasal, Nasopharyngeal	Nucleocapsid protein	07/07/2021
1341	H100G	**Qingdao Hightop Biotech Co., Ltd**	**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	H100C	**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	311590	**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	COV Ag-6012	**Safecare Biotech (Hangzhou) Co. Ltd**	**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	FCO-6032a (multi-windows cassette)	**Safecare Biotech (Hangzhou) Co. Ltd**	**Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19)**	**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	10/05/2021
2097	S3109E	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1201	34	**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	36	**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	SCVC02	**SGA Medikal**	**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	SCVC02	**SGA Medikal**	**V-Chek SARS-CoV-2 Rapid Ag Test (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	07/07/2021
2936	MU003	**Shenzhen AMPER Biotechnology Co Ltd**	**AMPER COVID-19 Antigen Rapid Testing 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	Nucleocapsid protein	05/10/2022
2152	CG201A	**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	R0043, R0044, R0045, R0046	**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	HRK-66 {…}	**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	203-020	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2941	150129	**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	K602-20	**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	GF102B1	**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	MF-68	**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	MF-60	**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
1228	MF-63	**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	RNS92048B	**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	LFA0401-25N	**Shenzhen Watmind Medical Co., Ltd**	**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	LFB0401-25N	**Shenzhen Watmind Medical Co., Ltd**	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1347	G86255, G86254, G86247	**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
1780	SP-SW 106	**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	CAGT025E0	**Sugentech, Inc.**	**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
2297	COVID19AGVCG	**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	04A024	**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	C011906	**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	C011906	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1689	TICV03	**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	ICV03	**TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.**	**INFO 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	21/12/2021
1751	RTCV03	**TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.**	**RAPIDAN TESTER 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
1722	TCV03	**TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.**	**TOYO 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
1443	VSCD02	**Vitrosens Biotechnology Co., Ltd**	**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; *Manufacturer specificity of 99.05%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal Throat	Nucleocapsid protein	10/05/2021
1276	COVA1	**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	W-Ag03-20	**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	FP-318	**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	SF24025	**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

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2090	CoV2Ag-25	**Wuhan UNscience Biotechnology 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 99.57%.*	Nasal, Nasopharyngeal, Oropharyngeal Mid-turbinates	Nucleocapsid protein	07/07/2021
2143	COV-S31	**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	CG01Ag-25	**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	1N40C5	**Xiamen Boson Biotech Co. Ltd**	**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%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	17/02/2021
1296	3021902	**Zhejiang Anji Saianfu Biotech Co.., Ltd**	**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	COVG10 {…}	**Zhejiang Anji Saianfu Biotech Co.., Ltd**	**reOpenTest 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%.*	Nasopharyngeal	Nucleocapsid protein	10/05/2021
2687		**Zephyr Biomedicals - Tulip Diagnostics**	**PerkinElmer COVID 19 Antigen Test (NS, NP)**	**Retrospective in vitro study** Retrospective study by the University of Chieti-Pescara, Italy. NP samples, 155 positive samples with a Ct distribution in agreement with criteria. Overall sensitivity: 80.64%, sensitivity 100% at Ct ≤ 25, specificity: 99%.	Nasal, Nasopharyngeal	Nucleocapsid protein ! Spike glycoprotein	22/07/2022
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	RDC-802	**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

CATEGORY B.2: COVID-19 LABORATORY-BASED ANTIGENIC ASSAYS

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
1982	ABCVA-020, ABCVA-020W	**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

ANNEX II: 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 ANTIGEN TESTS

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

1. Is the device an **antibody test**?
2. Is the device a **antigen self-test**?
3. Is the device a **pooled antigen test**?
4. 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

5. Does the device carry **CE-marking**?
6. Is the device **in use** in at least one of the 27 EU Member States?
7. 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 (an authorised legal representative of) the laboratory that performed (part of) the study,** 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. As part of your application, you should provide a **written endorsement**, signed by (an authorised legal representative of) a public body, clearly stating the role of the public body in the design, oversight and/or analysis of the study. If relevant and in line with the applicable national legislation, references should be included to the ethical approval given by an institutional review board. 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.

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; **35% (+/- 2%)** of the total number of pooled clinical specimens);
     - **High viral load** (Ct value 25-30; **45% (+/- 2%)** of the total number of pooled clinical specimens); and
     - **Moderate viral load** (Ct value 30-36; **35% (+/- 2%)** 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 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.

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.*