



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management  
**Health Security**

## **EU health preparedness:**

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

*Agreed by the Health Security Committee*

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

*Agreed by the Health Security Committee on 17 February 2021.*

*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; Eighth update: 8 December 2021; Ninth update: 21 December 2021; Tenth update: 21 January 2022; Eleventh update: 10 February 2022; Twelfth update: 4 March 2022.*

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

*Agreed by the Health Security Committee on 17 February 2021.*

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

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

*Agreed by the Health Security Committee on 20 October 2021*

*First update: 10 February 2022.*

## I. Introduction

Robust testing strategies are an essential aspect of preparedness and response to the COVID-19 pandemic, allowing for early detection of potentially infectious individuals and providing visibility on infection rates and transmission within communities. Moreover, they are a prerequisite to adequate contact tracing to limit the spread through prompt isolation. Also in the context of the circulation of SARS-CoV-2 variants of concern, surge testing in addition to existing testing deployment has proven to be key for controlling and suppressing further spread of the virus.

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

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

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

1. **A common list of COVID-19 rapid antigen tests** that are considered appropriate for use in the context of the situations described in the Council Recommendation, that are in line with countries’ testing strategies.
2. A selection of rapid antigen tests of which Member States will **mutually recognise the test results for public health measures**.
3. **A common standardised set of data to be included in COVID-19 test result certificates**, further facilitating the mutual recognition of COVID-19 test results.

Based on the information collected by the HSC, and taking into consideration the current epidemiological situation and the testing strategies and approaches that have been put in place across the EU, this document sets out the deliverables as agreed by Member States.

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<sup>1</sup> [https://ec.europa.eu/health/sites/health/files/preparedness\\_response/docs/common\\_testingapproach\\_covid-19\\_en.pdf](https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/common_testingapproach_covid-19_en.pdf)

<sup>2</sup> <https://data.consilium.europa.eu/doc/document/ST-5451-2021-INIT/en/pdf>

This document is based on the content of the Council Recommendation and further criteria agreed by Member States, and considers the relevant recommendations published by the Commission<sup>3</sup> as well as the updated technical report issued the European Centre for Disease Prevention and Control (ECDC)<sup>4</sup> and the World Health Organization (WHO)<sup>5</sup>.

## II. Annex I: Common list of rapid antigen tests

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

This list should be shared with ECDC and the Commission to prevent duplication of work and to feed into ongoing initiatives, particularly the “COVID-19 In Vitro Diagnostic Devices and Test Methods Database<sup>6</sup>, hosted by the Joint Research Centre (JRC). **Annex I to this document sets out a common list of rapid antigen tests.** This list has been incorporated by the JRC in its COVID-19 In Vitro Diagnostic Devices and Test Methods Database.

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

A first update to Annex I was agreed by the Health Security Committee on 10 May 2021, a second update on 16 June 2021, a third update on 7 July 2021, a fourth update on 14 July 2021, a fifth update on 23 July 2021, a sixth update on 20 October 2021, a seventh update on 10 November 2021, an eight update on 8 December 2021, a ninth update on 21 December 2021, a tenth update on 21 January 2022, a eleventh update on 10 February 2022, and a twelfth update on 4 March 2022.

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will mutually recognise the test results for public health measures. The HSC agrees that, considering that *all* of the rapid antigen tests included in the EU common list are eligible for issuing EU Digital COVID test and recovery certificates<sup>7</sup>, the entire list is considered to consist of rapid antigen tests of which Member States mutually recognise the test results for public health measures.

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<sup>3</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1595> and <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020H1743&from=EN>

<sup>4</sup> <https://www.ecdc.europa.eu/sites/default/files/documents/Options-for-the-use-of-rapid-antigen-tests-for-COVID-19-first-update.pdf>

<sup>5</sup> <https://www.who.int/publications/i/item/9789240017740>

<sup>6</sup> <https://covid-19-diagnostics.jrc.ec.europa.eu/devices>

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

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

Based on the increasing political and commercial interest in the HSC agreed common list of rapid antigen tests, particularly in the context of the EU Digital COVID Certificate<sup>8</sup>, there was a need to put in place a more structured, coherent and swift procedure for updating the common list of rapid antigen tests.

As a first step, since 10 May 2021, it is possible for manufacturers to submit data and information concerning rapid antigen tests that they believe should be considered for inclusion in the HSC agreed common list. This information will thus be reviewed and considered alongside the proposals put forward by EU Member States.

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

Building on the interim definitions and criteria that were agreed by the experts on 29 June 2021, the Technical Working Group agreed on 21 September 2021 on further **definitions, scope, considerations and criteria** to be applied to independent validation studies assessing the clinical performance of rapid antigen tests for COVID-19 diagnosis. These further definitions, scope, considerations and criteria are used by the Technical Working Group in addition to the ones presented in Council Recommendation 2021/24/01 when assessing the proposals for new rapid antigen tests to be included in the EU common list. They have been applied to all proposals received after 12 July 2021. On 18 March 2022, the Health Security Committee agreed that for the rapid antigen tests included in the EU common list before 12 July 2021, the criteria agreed on 21 September 2021 will apply as of 1 June 2022.

On 6 July 2021, the Technical Working Group agreed that that the common list should not include rapid antigen self-tests. Moreover, on 10 November 2021, it was agreed rapid antigen tests that are using a mix of different sampling materials (i.e. nasal, oropharyngeal and/or nasopharyngeal swabs as well as other specimen types such as saliva) can be included in the EU common list, however, only the validation results 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. Rapid antigen tests that are solely based on sampling materials other than nasal, oropharyngeal and/or nasopharyngeal specimens (e.g. saliva, sputum, blood and/or faeces), are not included in the EU common list of antigen tests.

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

As of December 2021, the Technical Working Group has continuously been discussing the performance of rapid antigen tests in the context of the emerging **Omicron** variant of concern. In particular, concerns have been raised about rapid antigen devices that are solely targeting the spike protein (thus not combined with the nucleocapsid protein) as well as the viral load measured at different time points and at different sites (e.g. throat and nose) after Omicron infection. The Technical Working Group will continue monitoring the situation including emerging evidence on the potential impact of the Omicron variant of concern on the performance of COVID-19 rapid antigen tests and, if necessary, amend the agreed criteria accordingly.

For the time being, rapid antigen tests that target the S-protein or for which the target protein is unknown have been highlighted in the EU common list. Further details and information regarding the devices included in the EU common list and their performance in relation to Omicron and other lineages detected is available in the COVID-19 In Vitro Diagnostic Devices and Test Methods Database, hosted by the JRC.

On 18 March 2022, the Health Security Committee agreed that rapid antigen tests included in the EU common list should preferably be evaluated by **prospective clinical field studies**, testing unselected symptomatic or asymptomatic participants for SARS-CoV-2 infection. As of 1 June 2022, the EU common list will therefore be split up in two categories:

- An “**A-category**”, consisting of rapid antigen tests for which their performance has been evaluated through prospective clinical field studies meeting the criteria agreed on 21 September 2021 and testing unselected symptomatic or asymptomatic participants for SARS-CoV-2 infection; and
- A “**B-category**”, consisting of rapid antigen tests for which validation studies were carried out based on retrospective in vitro study designs meeting the criteria agreed on 21 September 2021 and testing the clinical performance by using SARS-CoV-2 reference panels.

While all rapid antigen tests included in the A-category and B-category lists will be eligible for issuing EU Digital COVID test and recovery certificates, Member States will be strongly encouraged to use, in particular, those devices listed under the A-category. Manufacturers will be able to continue submitting data and information on new evaluation studies, which may change the categorisation of their device in the EU common list.

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

- The EU common list includes rapid antigen tests that are used in practice in at least one EU Member State and that have been validated by at least one EU Member State.
- The EU common list includes rapid antigen tests for which their clinical performance was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens and that meet the criteria as further specified below.
- Rapid antigen tests that are solely based on other sampling materials, such as

saliva, sputum, blood and/or faeces, are not included in the EU common list of antigen tests. This is in line with current evidence and the technical recommendations provided by the European Centre for Disease Prevention and Control (ECDC)<sup>9</sup>.

- Rapid antigen tests that are using a mix of different sampling materials (i.e. nasal, oropharyngeal and/or nasopharyngeal swabs as well as other specimen types such as saliva) can be included in the EU common list. However, the validation studies of such tests should present the results and data for each specimen type separately. Only the validation results based on nasal, oropharyngeal and/or nasopharyngeal swabs of such devices will be reviewed by the Technical Working Group and assessed against the specified criteria.
- Only test results based on nasal, oropharyngeal and/or nasopharyngeal specimens should be valid for the issuance of test certificates for the EU Digital COVID Certificate.
- The EU common list of antigen tests does not include rapid antigen self-tests. It only includes those rapid antigen tests that are conducted by trained healthcare personnel or trained operators where appropriate (in line with Commission Recommendation (EU) 2020/1743 of 18 November 2020).
- The EU common list of antigen tests does not include pooled rapid antigen tests, which involve mixing of multiple samples together in a batch or pooled sample for testing.
- Only rapid antigen tests that carry CE marking are included in the EU common list of antigen tests.
- The Technical Working Group will continue to monitor the developments in the field of rapid antigen testing and will, if deemed necessary, reconsider the scope of the EU common list of rapid antigen tests once relevant evidence and data has become available. Particular attention will be paid to breakthrough infections among vaccinated individuals and the possible impact of such cases on the clinical performance of rapid antigen tests, as well as the performance of rapid antigen tests in the context of emerging SARS-CoV-2 variants.

#### ***Agreed definition and considerations of an independent validation study:***

- A study that may involve collaborations with or that may involve funding by private entities, however, there is always a public body involved from an EU Member State.
- Such study should be carried out in an EU Member State, and be performed objectively and in the public interest.
- Such 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 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.

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

- Such study should preferably be based on a **prospective clinical field study** design, testing *unselected* symptomatic and asymptomatic participants for SARS-CoV-2 infection. As of 1 June 2022, rapid antigen tests for which their performance has been evaluated through prospective clinical field studies that meet the criteria agreed on 21 September 2021 (see below) will be placed under the “A-category” of the EU common list.
- “Unselected” means no prior knowledge of SARS-CoV-2 diagnosis (e.g. determined by PCR); inclusion is allowed based on general possible COVID-like symptoms (or close contact with COVID-19 cases); and exclusion is allowed of children (e.g. <16 years) or for medical ethical permission reasons.
- The performance of rapid antigen tests can also be evaluated based on a **retrospective in vitro study design**, testing the clinical performance by using SARS-CoV-2 reference panels. As of 1 June 2022, rapid antigen tests for which their performance has been evaluated through retrospective in vitro studies that meet the criteria agreed on 21 September 2021 (see below) will be placed under the “B-category” of the EU common list.

### ***Agreed clinical performance criteria for independent validation studies:***

#### **Prospective clinical field studies:**

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

#### ***OR***

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

- The study population shall be clearly defined stating the inclusion criteria of participants (symptomatic individuals, close contacts or asymptomatic individuals without known exposure). Ideally, the sensitivity for each group should be discernible from the report. The RT-PCR protocol and the distribution of Ct values should be described. Samples should represent naturally occurring viral loads.
- Target population considered in the context of an independent validation study should be based on at least 100 RT-PCR positive samples and at least 300 RT-PCR negative samples. Each specimen type should be evaluated separately.
- In case of multiple smaller prospective clinical field studies that do not meet the minimum number of positive and/or negative samples separately but that do meet all the other criteria as agreed by the Technical Working Group, the number of samples may be combined, provided that the different studies applied the same or similar methodologies and that sufficient details are provided on their study design.
- Assays should have a specificity over 98%.
- In line with the *MDCG Guidance on performance evaluation of SARS-CoV-2 in*

*in vitro diagnostic medical devices*<sup>10</sup>, preference is given to samples being compared against RT-PCR results on nasopharyngeal swabs. However, in independent validation studies, samples can also be compared against RT-PCR results on oropharyngeal or nasal swabs if reasoning is provided (e.g. when assessing the clinical performance of rapid antigen tests among children).

### **Retrospective in vitro studies:**

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

#### **OR**

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

- The composition of the reference panel should be as follows:
  - A panel of at least 50 pooled clinical specimens that cover naturally occurring viral loads with SARS-CoV-2 concentration ranging from approximately  $1.1 \times 10^9$  to  $4.2 \times 10^2$  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; about 40% of the total number of pooled clinical specimens);
    - **High viral load** (Ct value 25-30; about 40% of the total number of pooled clinical specimens); and
    - **Moderate viral load** (Ct value 30-36; about 20% of the total number of pooled clinical specimens).
  - For each pool up to ten clinical respiratory specimens (nasopharyngeal/oropharyngeal) obtained for routine diagnostics with different virus loads may be used. The sample volume per panel member should be sufficient to allow comparative evaluation with different tests included in the evaluation.
  - RT-PCR needs to be applied to determine the RNA load per pool.
  - Ethical approval by an institutional review board is mandatory.
  - For each rapid antigen test and panel member, a pre-defined aliquot needs to be completely absorbed using the specimen collection device, e.g. swab, provided with the respective test.
  - Further steps needs to be strictly performed following the respective instructions for use (IFU).
  - The stability of the panel (antigen) must be considered throughout the preparation of the panel and the workflow up to the test.
- Assays should have a specificity over 98%, as measured through the retrospective in vitro evaluation study or as specified by the manufacturer in the IFU.
- In line with the *MDCG Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices*<sup>11</sup>, preference is given to samples being compared against RT-PCR results on nasopharyngeal swabs. However, in independent validation

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<sup>10</sup> [https://ec.europa.eu/health/sites/default/files/md\\_sector/docs/mdcg\\_2021-21\\_en.pdf](https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-21_en.pdf)



studies, samples can also be compared against RT-PCR results on oropharyngeal or nasal swabs if reasoning is provided (e.g. when assessing the clinical performance of rapid antigen tests among children).

As a wide range of different methodologies and protocols are being applied in countries, discussions on testing approaches will continue, with the overall goal for the Technical Working Group to develop and agree on an EU harmonised approach for validation studies assessing the clinical performance of COVID-19 rapid antigen tests. This work will take into account the ongoing work by the In Vitro Diagnostics Working Group of the Medical Device Coordination Group regarding guidance on the performance of COVID-19 tests in the context of CE-marking and common specifications under Article 9 of Regulation (EU) 2017/746<sup>11</sup>.

### ***Grace period***

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

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<sup>11</sup> 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.

#### **IV. Annex II: Common standardised set of data for COVID-19 test certificates**

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

Based on information that was submitted by members of the Health Security Committee in response to a survey on mutual recognition on COVID-19 test results and further discussions that took place in the context of the Health Security Committee, Member States agree on **the common standardised set of data for COVID-19 test result certificates as presented in Annex II**. Member States agree that COVID-19 test results should be made available in the national language(s) of the country where the test was taken, as well as English.

An update to this Annex was agreed by the Health Security Committee on 19 March 2021, addressing input received from the eHealth Network and in particular the Semantic Subgroup and based on discussions that took place in the context of the EU Digital COVID Certificate. The Health Security Committee will discuss, whenever relevant, possible updates to the agreed common standardised set of data for COVID-19 test certificates, and publish, if necessary, an updated agreed document.

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

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

Annex III sets out those laboratory-based antigenic assays that meet these criteria. A first update to Annex I was agreed by the Health Security Committee on 10 February 2022. Further criteria for lab-based antigenic assays may be defined at a later stage.

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

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

## ANNEX I: Common list of COVID-19 rapid antigen tests<sup>12</sup>

As agreed by EU Member States on 4 March 2022

***Disclaimer:** This list was agreed by the HSC based on a proposal by the Technical Working Group on COVID-19 Diagnostic Tests. Experts participating in the Technical Working Group strongly recommend that use of rapid antigen tests is primarily intended for preliminary testing for SARS-CoV-2 infection in symptomatic patients, and note that rapid antigen tests should in particular be used in the specific contexts and circumstances referred to by the Commission Recommendation (EU) 2020/1743 of 18 November 2020 and the updated technical report by ECDC on 26 October 2021. The content of the common list is based on the clinical performance data and information that is available at this moment in time. Updates to the common list are based on the criteria as described in Council Recommendation 2021/C 24/01 as well as the further criteria and definitions agreed by the Technical Working Group on 21 September 2021. The Medical Device Coordination Group Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices<sup>13</sup>, envisaged to form the basis for common specifications to be adopted according to Article 9 of Regulation (EU) 2017/746, has been taken into consideration in this regard.*

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

| Manufacturer | RAT commercial name | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i> | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup> | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>             | Included in EU common list since: |
|--------------|---------------------|---------------------------|--|---|------------------------------|---------------------------|------------------------------------|-----------------------------------|
| AAZ-LMB      | COVID-VIRO®         | 1833                      | Prospective clinical field study   | 96.6% sensitivity<br>100% specificity<br>Nasal swab, NP swab      | FR<br>CH                     | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab | 10 May 2021                       |

<sup>12</sup> This is the list of rapid antigen tests as referred to in Article 3 of the Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, OJ L 211, 15.6.2021, p. 1–22.

<sup>13</sup> [https://ec.europa.eu/health/sites/default/files/md\\_sector/docs/mdcg\\_2021-21\\_en.pdf](https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-21_en.pdf)

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

<sup>15</sup> As reported in the JRC database, see: <https://covid-19-diagnostics.jrc.ec.europa.eu/>.

<sup>16</sup> Only test results based on nasal, oropharyngeal and/or nasopharyngeal specimens should be valid for the issuance of test certificates for the EU Digital COVID Certificate. The information included in this column is based on the information provided by manufacturers to the JRC database.

| Manufacturer             | RAT commercial name            | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies  | SARS-CoV-2 Target protein | Specimen <sup>16</sup>          | Included in EU common list since: |
|--------------------------|--------------------------------|---------------------------|--|--|---|---------------------------|---------------------------------|-----------------------------------|
| Abbott Rapid Diagnostics | Panbio™ COVID-19 Ag Rapid Test | 1232                      | <i>Prospective clinical field studies</i>  |  |   |                           |                                 |                                   |
|                          |                                |                           | <p><b>BE:</b><br/>Small-scale head-to-head comparison of 5 RATs in Belgian hospital lab. Panbio overall sensitivity (Ct range 14,6 – 35,5): 45/57 samples (79%). Sensitivity for Ct≤25: 17/18 samples. Overall specificity 100%.</p> <p><b>NL:</b><br/>1367 and 208 subjects were enrolled in Utrecht and Aruba, respectively. Specificity of the Panbio™ COVID-19 Ag Rapid Test was 100% (95%CI: 99.7–100%) in both settings. Test sensitivity was 72.6% (95%CI: 64.5–79.9%) in the Netherlands and 81.0% (95% CI: 69.0–89.8%) in Aruba. Restricting RT-qPCR test positivity to Ct-values &lt;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.</p> <p><b>PT:</b><br/>83 samples from symptomatic individuals (27 PCR positive and 56 negative by PCR) were tested. Sensitivity 63% (95%IC 42-81); specificity 100% (95%IC 94-100). LoD TCID50/ml 1,38 x 10<sup>2</sup> and CT&lt;24.</p> <p><b>SE:</b><br/>Karolinska hospital evaluation of Lot 41ADF061A. Patient samples: 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 59%, specificity 100%. Sensitivity Ct&lt;25 = 90.2%.</p> <p><b>FIND evaluation studies</b><br/><b>DE</b> (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%<br/><b>CH</b> (10 Dec 2020): 535 samples, NP swab. Clinical sensitivities: Days ≤7: 85.6%; Ct ≤33: 89.7%; Ct ≤25: 96.8%. Clinical specificity: 100%<br/><b>India</b> (25 June 2021): 526 samples, NP swab. Clinical sensitivities: Days ≤7: 61.3%-100%; Ct ≤33: 74.2%-86.7%; Ct ≤25: 91.9%-100%. Specificity: 100%</p> | <p>91.4% sensitivity<br/>99.8% specificity<br/>NP swab (Ct ≤ 33)</p> <p>98.1% sensitivity<br/>99.8% specificity<br/>Nasal swab (Ct ≤ 33)</p> | <p><b>BE</b>, <b>DE</b><sup>[2]</sup>, <b>ES</b>, <b>FI</b>, <b>NL</b><sup>[5]</sup>, <b>PT</b>, <b>SE</b></p> <p><b>CH</b>, <b>India</b>, <b>NO</b>, <b>UK</b></p> | Nucleo-protein            | Nasal swab, Nasopharyngeal swab | 17 February 2021                  |

| Manufacturer                     | RAT commercial name                                   | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>                    | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>  | Included in EU common list since: |
|----------------------------------|---|---------------------------|---|--|------------------------------|---------------------------|---|-----------------------------------|
|                                  |   |                           | <i>Retrospective in vitro studies</i>   |  |                              |                           |   |                                   |
|                                  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity of 99.8%                          |  |                              |                           |   |                                   |
| ABIOTEQ                          | Cora Gentest-19                                       | 2374                      | <i>Retrospective in vitro study</i>   | Sensitivity 98,7%,<br>Specificity 99,8%  | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab, Throat swab | 20 October 2021                   |
|                                  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.8%                            |  |                              |                           |   |                                   |
| AccuBioTech Co.,Ltd              | Accu-Tell SARS-CoV-2 Ag Cassette                      | 2579                      | <i>Retrospective in vitro study</i>   | Sensitivity: 95.7%<br>Specificity: 99.2%   | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasopharyngeal swab   | 20 October 2021                   |
|                                  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%                            |  |                              |                           |   |                                   |
| Acon Biotech (Hangzhou) Co., Ltd | Flowflex SARS-CoV-2 Antigen Rapid Test                | 1457                      | <i>Prospective clinical field study</i>   | Nasal swab<br>Clinical Sensitivity: 97.1 %<br>Clinical Specificity: 99.5 %           | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab   | 14 July 2021                      |
|                                  |   |                           | <b>FIND evaluation</b><br><b>CH</b> (9 June 2021)<br>279 samples, nasal swab. Sensitivities: Days ≤ 7: 92.2%; Ct ≤ 33: 98.3%; Ct ≤ 25: 100%. Specificity: 99.5% |  |                              |                           |   |                                   |
|                                  |   |                           | <i>Retrospective in vitro study</i>   | NP swab<br>Clinical Sensitivity: 97.6 %<br>Clinical Specificity: 99.4 %              | CH, <a href="#">UK</a>       |                           |   |                                   |
|                                  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99.54%                          |  |                              |                           |   |                                   |
| ACON Biotech(Hangzhou) Co., Ltd. | Flowflex SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) | 1865                      | <i>Retrospective in vitro study</i>   | Clinical Sensitivity 97.1 % (Nasal Swab)<br>Clinical Specificity 99.5 % (Nasal Swab) | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab<br><b>! Saliva</b>   | 10 February 2022                  |
|                                  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99.5%                           |  |                              |                           |   |                                   |
| ACON Laboratories, Inc.          | Flowflex SARS-CoV-2 Antigen Rapid Test                | 1468                      | <i>Retrospective in vitro study</i>   | 96.9% sensitivity<br>98.7% specificity<br>Nasal swab                                 | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab  | 10 May 2021                       |
|                                  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 98,7%                           |  |                              |                           |   |                                   |

| Manufacturer                                | RAT commercial name  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>                                      | Completed validation studies                    | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                       | Included in EU common list since: |
|---|--|---------------------------|---|--|---|---------------------------|--|-----------------------------------|
| AESKU.DIAGNOSTICS GmbH & Co, KG             | AESKU.RAPID SARS-CoV-2   | 2108                      | <i>Retrospective in vitro study</i>   | 96% sensitivity<br>98% specificity<br>NP swab  | DE <sup>[2]</sup>                               | Nucleo-protein            | Nasal swab, Throat swab                      | 10 May 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 84% at Ct ≤ 25; Manufacturer specificity: 98%    |  |   |                           |  |                                   |
| Affimedix Inc.                              | TestNOW® - COVID-19 Antigen Test   | 2130                      | <i>Retrospective in vitro study</i>   | NP swab: 95% sensitivity<br>99.2% specificity<br><br>Nasal swab: 98.1% sensitivity<br>100% specificity | DE <sup>[2]</sup>                               | Nucleo-protein            | Nasal swab, Nasopharyngeal swab              | 10 May 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,2% |  |   |                           |  |                                   |
| AMEDA Labordiagnostik GmbH                  | AMP Rapid Test SARS-CoV-2 Ag   | 1304                      | <i>Retrospective in vitro study</i>   | 97.3% sensitivity<br>NP swab<br>97.3% sensitivity<br>Nasal swab<br>100% specificity                    | DE <sup>[2]</sup><br><br>CH, <a href="#">UK</a> | Nucleo-protein            | Nasal swab, Nasopharyngeal swab              | 17 February 2021                  |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%  |  |   |                           |  |                                   |
| Anbio (Xiamen) Biotechnology Co., Ltd       | Rapid COVID-19 Antigen-Test (colloidal Gold)   | 1822                      | <i>Retrospective in vitro study</i>   | 99.27% sensitivity, 100% specificity, Nasal swab<br><br>98.33% sensitivity, 100% specificity, NP swab  | DE <sup>[2]</sup>                               | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab, Throat swab | 10 May 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%  |  |   |                           |  |                                   |
| Anhui Deep Blue Medical Technology Co., Ltd | COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)  | 1736                      | <i>Retrospective in vitro study</i>   | Nasal/OP swab: 96,4% sensitivity, 99,8% specificity<br>NP swab: 95,7% sensitivity, 99,3% specificity   | DE <sup>[2]</sup><br><br><a href="#">UK</a>     | Nucleo-protein            | Nasal swab, <b>! Other</b>                   | 10 May 2021                       |
|   | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: >99% |                           |   |  |   |                           |  |                                   |
| Anhui Formaster Biosci Co., Ltd.            | COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Nasal swab   | 1815                      | <i>Retrospective in vitro study</i>   | 96.4 % sensitivity<br>99.8 % specificity<br>Nasal swab   | DE <sup>[2]</sup><br><br><a href="#">UK</a>     | Nucleo-protein            | Anterior nasal swab, Nasal swab              | 10 May 2021                       |
|   | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: >99% |                           |   |  |   |                           |  |                                   |
| Anhui Formaster Biosci Co., Ltd.            | New Coronavirus (COVID-19) Antigen Rapid Test  | 2089                      | <i>Retrospective in vitro study</i>   | sensitivity: 95.15%, specificity: 98.5%  | DE <sup>[2]</sup>                               | Nucleo-protein            | Nasopharyngeal swab, Oropharyngeal swab      | 20 October 2021                   |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.5% |  |   |                           |  |                                   |

| Manufacturer                | RAT commercial name          | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>                                   | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>             | Included in EU common list since: |
|-----------------------------|------------------------------|---------------------------|---|---|------------------------------|---------------------------|------------------------------------|-----------------------------------|
| ArcDia International Ltd    | mariPOC SARS-CoV-2           | 768                       | <p><i>Prospective clinical field study</i></p> <p><b>FI:</b> Clinical performance of the test was evaluated against qRT-PCR with nasopharyngeal swab specimens collected from patients suspected of acute SARS-CoV-2 infection. Sensitivity of the mariPOC test was 100.0% (13/13) directly from swab specimens and 84.4% (38/45) from swab specimens in undefined transport mediums. Specificity was 100.0% (201/201).</p> | 100% sensitivity<br>100% specificity<br>Nasopharyngeal swab   | <a href="#">FI</a>           | Nucleo-protein            | Nasopharyngeal swab                | 10 May 2021                       |
| ArcDia International Oy Ltd | mariPOC Respi+               | 2078                      | <p><i>Prospective clinical field study</i></p> <p><b>FI:</b> Clinical performance of the test was evaluated against qRT-PCR with nasopharyngeal swab specimens collected from patients suspected of acute SARS-CoV-2 infection. Sensitivity of the mariPOC test was 100.0% (13/13) directly from swab specimens and 84.4% (38/45) from swab specimens in undefined transport mediums. Specificity was 100.0% (201/201).</p> | 100 % sensitivity<br>100 % specificity<br>NP swab   | <a href="#">FI</a>           | Nucleo-protein            | Nasopharyngeal swab                | 14 July 2021                      |
| ArcDia International Oy Ltd | mariPOC Quick Flu+           | 2079                      | <p><i>Prospective clinical field study</i></p> <p><b>FI:</b> Clinical performance of the test was evaluated against qRT-PCR with nasopharyngeal swab specimens collected from patients suspected of acute SARS-CoV-2 infection. Sensitivity of the mariPOC test was 100.0% (13/13) directly from swab specimens and 84.4% (38/45) from swab specimens in undefined transport mediums. Specificity was 100.0%.</p>           | 100 % sensitivity<br>100 % specificity<br>NP swab   | <a href="#">FI</a>           | Nucleo-protein            | Nasopharyngeal swab                | 14 July 2021                      |
| Artron Laboratories Inc.    | Artron COVID-19 Antigen Test | 1618                      | <p><i>Retrospective in vitro study</i></p> <p><b>DE:</b> Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%</p>   | 91.59% sensitivity, Nasal swab<br>91.67% sensitivity, NP swab<br>100 % specificity<br>Nasal/NP swab | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab,<br>Nasopharyngeal swab | 14 July 2021                      |

| Manufacturer  | RAT commercial name                        | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup> | Completed validation studies            | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                                    | Included in EU common list since: |
|---|--|---------------------------|--|---|---|---------------------------|---|-----------------------------------|
| Asan Pharmaceutical Co., Ltd                          | Asan Easy Test COVID-19 Ag                 | 1654                      | <i>Retrospective in vitro study</i>  | 94.67% sensitivity, 97.71% specificity<br>Nasal swab              | DE <sup>[2]</sup>                       | Unknown                   | Nasal swab  | 10 May 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 97.71%  |   |   |                           |   |                                   |
| Assure Tech. (Hangzhou) Co., Ltd.                     | ECOTEST COVID-19 Antigen Rapid Test Device | 770                       | <i>Retrospective in vitro study</i>  | 92.5 % sensitivity<br>99.2 % specificity<br>Nasal/NP/OP swab      | DE <sup>[2]</sup><br><a href="#">UK</a> | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab | 14 July 2021                      |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 99.2%    |   |   |                           |   |                                   |
|   | ECOTEST COVID-19 Antigen Rapid Test Device | 2350                      | <i>Retrospective in vitro study</i>  | Sensitivity: 97.7%,<br>Specificity: 99.1%<br>NP and OP swab       | DE <sup>[2]</sup><br>UK                 | Nucleo-protein            | Nasopharyngeal swab,<br>Oropharyngeal swab                | 23 July 2021                      |
| Avalun  | Ksmart® SARS-COV2 Antigen Rapid Test       | 1800                      | <i>Retrospective in vitro study</i>  | Sensitivity: 93.18%<br>Specificity: 99.32%<br>NP swab             | DE <sup>[2]</sup>                       | Unknown                   | Nasopharyngeal swab                                       | 7 July 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,32% |   |   |                           |   |                                   |
| AXIOM Gesellschaft für Diagnostica und Biochemica mbH | COVID-19 Antigen Rapid Test                | 2101                      | <i>Retrospective in vitro study</i>  | 98% sensitivity<br>100% specificity<br>NP/Nasal swab              | DE <sup>[2]</sup>                       | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab, Throat swab           | 10 May 2021                       |



| Manufacturer     | RAT commercial name                                  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>          | Completed validation studies   | SARS-CoV-2 Target protein | Specimen <sup>16</sup> | Included in EU common list since: |
|------------------|--|---------------------------|--|--|--------------------------------|---------------------------|------------------------|-----------------------------------|
| Becton Dickinson | BD Veritor™ System for Rapid Detection of SARS CoV 2 | 1065                      | <i>Prospective clinical field studies</i>  | Clinical Sensitivity: 91.1 %<br>Clinical Specificity: 99.6 %<br>Nasal swab | DE <sup>[2]</sup> , ES, NL, SE | Nucleo-protein            | Nasal swab             | 7 July 2021                       |
|                  |  |                           | <p><b>ES:</b><br/>Prospective study in four Spanish hospitals (n = 476); 108 positive samples, 368 negative samples. Sensitivity: 92%, specificity: 98.6%.</p> <p><b>NL:</b><br/>Independent field study in symptomatic individuals (n=979, PCR positive n=161) - sampling was Nasal mid-turbinate + OP swab. Sensitivity overall: 79.5% - Sensitivity Ct&lt;30: 93.2% - Specificity overall: 99.8%</p> <p><b>SE:</b><br/>Karolinska hospital evaluation of Lot 0255648. Patient samples: 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 45%, specificity 97%. Sensitivity Ct&lt;25 = 87.8%.</p> |  |                                |                           |                        |                                   |
|                  |  |                           | <i>Retrospective in vitro study</i>  |  |                                |                           |                        |                                   |
|                  |  |                           | <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 99.6%</p>   |  |                                |                           |                        |                                   |
| Becton Dickinson | BD Kit for Rapid Detection of SARS-CoV-2             | 2282                      | <i>Prospective clinical field studies</i>  | Clinical Sensitivity: 91.1 %<br>Clinical Specificity: 99.6 %<br>Nasal swab | ES, NL                         | Nucleo-protein            | Nasal swab             | 10 November 2021                  |
|                  |  |                           | <p><b>ES:</b><br/>Prospective study in four Spanish hospitals (n = 476); 108 positive samples, 368 negative samples. Sensitivity: 92%, specificity: 98.6%.</p> <p><b>NL:</b><br/>Independent field study in symptomatic individuals (n=979, PCR positive n=161) - sampling was Nasal mid-turbinate + OP swab. Sensitivity overall: 79.5% - Sensitivity Ct&lt;30: 93.2% - Specificity overall: 99.8%</p>  |  |                                |                           |                        |                                   |

| Manufacturer                                       | RAT commercial name                                       | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup> | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>  | Included in EU common list since: |
|--|---|---------------------------|--|---|------------------------------|---------------------------|---|-----------------------------------|
| Beijing Hotgen Biotech Co., Ltd                    | Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) | 1870                      | <i>Prospective clinical field study</i>  | 97.1% sensitivity<br>99.76% specificity                           | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swabs,<br>Throat swabs,<br><b>! Saliva</b>  | 10 May 2021                       |
|  |   |                           | <b>FIND evaluation</b><br><b>Brazil</b> (15 September 2021)<br>453 samples, nasal swab. Clinical sensitivities:<br>Days $\leq$ 7: 90.1%; Ct $\leq$ 33: 89.5%; Ct $\leq$ 25: 95.5%.<br>Clinical specificity: 100%<br><b>UK</b> (15 September 2021)<br>248 samples, NP swab. Clinical sensitivities:<br>Days $\leq$ 7: 84.4%; Ct $\leq$ 33: 80.6%; Ct $\leq$ 25: 82.8%.<br>Clinical specificity: 99.4% |   |                              |                           |   |                                   |
|  |   |                           | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct $\leq$ 25; Manufacturer specificity: 99.76%  |   |                              |                           |   |                                   |
| Beijing Hotgen Biotech Co., Ltd                    | Coronavirus (2019-nCoV)-Antigentest                       | 2807                      | <i>Retrospective in vitro study</i>  | Clinical sensitivity: 96.95%<br>Clinical specificity: 98.88%      | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab  | 21 January 2022                   |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct $\leq$ 25; Manufacturer specificity: 98.88%   |   |                              |                           |   |                                   |
| Beijing Jinwofu Bioengineering Technology Co.,Ltd. | Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit     | 2072                      | <i>Retrospective in vitro study</i>  | 96.88 % sensitivity<br>100 % specificity<br>Nasal/ NP/ OP swab    | DE <sup>[2]</sup>            | Nucleo-protein            | Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab<br><b>! Saliva</b> | 14 July 2021                      |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct $\leq$ 25 + Manufacturer specificity: 100%  |   |                              |                           |   |                                   |
| Beijing Kewei Clinical Diagnostic Reagent Inc      | COVID19 Antigen Rapid Test Kit                            | 1778                      | <i>Retrospective in vitro study</i>  | Clinical Sensitivity: 96.18 %<br>Specificity: 100%                | DE <sup>[2]</sup>            | <b>Unknown</b>            | Nasal swab  | 21 December 2021                  |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct $\leq$ 25 + Manufacturer specificity: 100%  |   |                              |                           |   |                                   |
| Beijing Lepu Medical Technology Co., Ltd           | SARS-CoV-2 Antigen Rapid Test Kit                         | 1331                      | <i>Retrospective in vitro study</i>  | 92.00% sensitivity,<br>99.26% specificity<br>Nasal swab           | DE <sup>[2]</sup>            | <b>Unknown</b>            | Nasal swab,<br>Nasopharyngeal swab  | 17 February 2021                  |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct $\leq$ 25; Manufacturer specificity: 99.26%   |   |                              |                           |   |                                   |

| Manufacturer   | RAT commercial name  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>  | Included in EU common list since: |
|--|--|---------------------------|--|--|------------------------------|---------------------------|---|-----------------------------------|
| Beijing O&D Biotech Co., Ltd.                          | COVID-19 Antigen Rapid Test  | 2494                      | <i>Retrospective in vitro study</i><br><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.67%  | <b>Nasal swab:</b><br>sensitivity: 92.17% (95% CI: 85.26%-96.13% )<br>specificity: 98.67 % (95% CI: 96.39%-99.57%)<br><b>OP swab:</b><br>sensitivity: 93.04% (95% CI: 86.33%-96.73% );<br>specificity: 99% (95% CI: 96.86%-99.74%)<br><b>NP swab:</b><br>sensitivity: 93.91% (95% CI: 87.86%-97.52% )<br>specificity: 99.33% (95% CI: 97.61%-99.92%) | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab, Oropharyngeal swab, Nasopharyngeal swab   | 20 October 2021                   |
| Beijing Wantai Biological Pharmacy Enterprise Co., Ltd | Wantai SARS-CoV-2 Ag Rapid Test (colloidal gold)                       | 1485                      | <i>Prospective clinical field study</i><br><b>CZ:</b><br>Independent prospective study by Public Health Institute Ostrava (CZ), including NP swabs from unselected symptomatic and asymptomatic participants. Sensitivity 80.6%, specificity 98.5% on 155 pos. and 325 neg. samples (as resulting by RT-PCR). Ct not reported. N total = 480<br><i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.2% | 93.2% sensitivity<br>98.2% specificity<br>Nasal swab   | CZ, DE <sup>[2]</sup>        | <b>Unknown</b>            | Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab<br><br><b>! Saliva</b> | 14 July 2021                      |
| BioGnost Ltd   | CoviGnost AG Test Device 1x20  | 2247                      | <i>Retrospective in vitro study</i><br><b>HR:</b><br>300 NP samples (retrospective), symptomatic (<7 dps): 200 PCR+ samples (range Ct 16-30), Ct<30: sensitivity 96.5%. 100 PCR- samples: specificity 100%   | Sensitivity: 96%,<br>Specificity: 99%<br>NP swab   | HR                           | <b>Unknown</b>            | Nasopharyngeal swab   | 23 July 2021                      |
| Biohit Healthcare (Hefei) Co., Ltd.                    | SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromato-graphy) | 1286                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.9%   | Sensitivity: 96.77%<br>Specificity: 98.9%<br>NP/OP swab  | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Anterior nasal swab   | 23 July 2021                      |

| Manufacturer                        | RAT commercial name                                   | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup> | Included in EU common list since: |
|-------------------------------------|---|---------------------------|--|--|------------------------------|---------------------------|------------------------|-----------------------------------|
| Biohit Healthcare (Hefei) Co., Ltd. | SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method) | 2230                      | <i>Retrospective in vitro study</i>  | Sensitivity: 96.12%, Specificity: 99.49 %  | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab             | 8 December 2021                   |
|                                     |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.49%   |  |                              |                           |                        |                                   |
| BIOLAN HEALTH, S.L.                 | COVID-19 Antigen Rapid Test (Colloidal Gold Method)   | 2519                      | <i>Prospective clinical field study</i>  | Clinical sensitivity 96.5 % (within 5 days of symptom onset).<br>Clinical sensitivity 91.6 % (7 days)<br>Clinical Specificity 98.3 % | ES                           | Nucleo-capsid protein     | Nasal swab             | 4 March 2022                      |
|                                     |   |                           | <b>ES:</b><br>Prospective study performed in Hospital Universitario de Cruces (independent public institution). Nasal specimen, 314 negative samples and 116 positive samples. CT distribution described. Sensitivity 98,1% at Ct<25; overall sensitivity 81%; specificity 98,1%.  |  |                              |                           |                        |                                   |
| BioMaxima SA                        | SARS-CoV-2 Ag Rapid Test                              | 2035                      | <i>Prospective clinical field studies</i>  | Sensitivity: 95%<br>Specificity: 99%<br>NP Swab  | DE <sup>[2]</sup> , FR, PL   | Nucleo-protein            | Nasopharyngeal swab    | 23 July 2021                      |
|                                     |   |                           | <b>FR:</b><br>NP swabs, Diagnostic sensitivity: 96,4% (80/83) (95% CI: 89,8-99,2%); diagnostic specificity: 99,2%, (120/121)   |  |                              |                           |                        |                                   |
|                                     |   |                           | <b>PL:</b><br>Evaluation of the test was performed on 480 samples of NP swabs taken from patients with symptoms of COVID-19 and from people in contact with an infected person but without symptoms of infection. Positive results 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. The above results permitted calculation of diagnostic sensitivity, which was 93.43% (95% CI: 91.61%~97.19%) and diagnostic specificity, which was 97.75% (95% CI: 93.74%~98.92%) |  |                              |                           |                        |                                   |
|                                     |   |                           | <i>Retrospective in vitro study</i>  |  |                              |                           |                        |                                   |
|                                     |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%  |  |                              |                           |                        |                                   |

| Manufacturer             | RAT commercial name   | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>   | Completed validation studies    | SARS-CoV-2 Target protein | Specimen <sup>16</sup>             | Included in EU common list since: |
|--------------------------|---|---------------------------|--|---|---------------------------------|---------------------------|------------------------------------|-----------------------------------|
| Biomerica Inc.           | Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab) | 1599                      | <i>Retrospective in vitro study</i>  | Clinical Sensitivity: 94.7%;<br>Clinical specificity: 99.7%<br>Nasal/NP swab                                  | DE <sup>[2]</sup>               | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab | 7 July 2021                       |
|                          |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,7%   |   |                                 |                           |                                    |                                   |
| BIONOTE                  | NowCheck COVID-19 Ag Test                                   | 1242                      | <i>Prospective clinical field study</i>  | Clinical Sensitivity: 90.91 %<br>Clinical Specificity: 99.43 %<br>Nasal swab, NP swab                         | DE <sup>[2]</sup><br><br>Brazil | Unknown                   | Nasal swab,<br>Nasopharyngeal swab | 7 July 2021                       |
|                          |   |                           | <b>FIND evaluation</b><br><b>Brazil</b> (20 April 2021)<br>400 samples, NP swab. Clinical sensitivities:<br>Days ≤ 7: 92.2%; Ct ≤ 33: 91.4%; Ct ≤ 25: 94.8%.<br>Clinical specificity: 97.3%<br><b>Brazil</b> (30 March 2021)<br>218 samples, Nasal/NP swab. Clinical sensitivities: Days ≤ 7: 92.5% (N/NP); Ct ≤ 33: 97.2% (N/NP); Ct ≤ 25: 100% (N/NP); Clinical specificity: 98.6%                                     |   |                                 |                           |                                    |                                   |
|                          |   |                           | <i>Retrospective in vitro study</i>  |   |                                 |                           |                                    |                                   |
|                          |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98,6%   |   |                                 |                           |                                    |                                   |
| BIO-RAD                  | CORONAVIRUS AG RAPID TEST CASSETTE                          | 2031                      | <i>Prospective clinical field studies</i>  | Clinical Sensitivity: 98% (NP: 98,32% / Nasal: 97,25%)<br>Clinical Specificity: 99% (NP: 99,6% / Nasal: 100%) | ES                              | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab | 7 July 2021                       |
|                          |   |                           | <b>ES<sup>7</sup>:</b><br><ul style="list-style-type: none"> <li>Prospective study; 96 positive samples and 269 negative samples. Sensitivity 94%. Specificity 99.2%. No Ct distribution specified.</li> <li>NP swab: sensitivity 98,3%; specificity 99,6% (119 positive samples, 746 negative samples)</li> <li>Nasal swab: sensitivity 97,2%; specificity 100% (109 positive samples, 128 negative samples)</li> </ul> |   |                                 |                           |                                    |                                   |
|                          |   |                           | <b>ES<sup>7</sup>:</b><br><ul style="list-style-type: none"> <li>Prospective study; 96 positive samples and 269 negative samples. Sensitivity 94%. Specificity 99.2%. No Ct distribution specified.</li> <li>NP swab: sensitivity 98,3%; specificity 99,6% (119 positive samples, 746 negative samples)</li> <li>Nasal swab: sensitivity 97,2%; specificity 100% (109 positive samples, 128 negative samples)</li> </ul> |   |                                 |                           |                                    |                                   |
| BioSpeedia International | COVID19Speed-Antigen Test BSD_0503                          | 2380                      | <i>Prospective clinical field studies</i>  | Clinical sensitivity: 97.5%<br>Clinical specificity: 99.3%  | FR                              | Nucleo-capsid protein     | Nasopharyngeal swab                | 21 January 2022                   |
|                          |   |                           | <b>FR:</b><br>Independent prospective study by the University Hospital of Saint-Etienne: samples from unselected symptomatic and asymptomatic individuals (255 pos., 365 neg.), overall sensitivity: 95.29% (sensitivity Ct<25: 97.72%), specificity: 99.73%.  |   |                                 |                           |                                    |                                   |
|                          |   |                           | <b>FR:</b><br>Independent prospective study by the University Hospital of Saint-Etienne: samples from unselected symptomatic and asymptomatic individuals (255 pos., 365 neg.), overall sensitivity: 95.29% (sensitivity Ct<25: 97.72%), specificity: 99.73%.  |   |                                 |                           |                                    |                                   |

| Manufacturer        | RAT commercial name       | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>       | Completed validation studies                             | SARS-CoV-2 Target protein | Specimen <sup>16</sup>          | Included in EU common list since: |
|---------------------|---------------------------|---------------------------|---|---|--|---------------------------|---------------------------------|-----------------------------------|
| BIOSYNEX SWISS S.A. | BIOSYNEX COVID-19 Ag BSS  | 1223                      | <i>Prospective clinical field studies</i>   | 96% sensitivity, 100% specificity, NP/Nasal swab                        | BE, DE <sup>[2]</sup> , FR, NL <sup>[5]</sup> , SE<br>CH | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab | 17 February 2021                  |
|                     |                           |                           | <p><b>BE<sup>[6]</sup>:</b><br/>Small-scale head-to-head comparison of 5 RATs in Belgian hospital lab. Biosynex overall sensitivity (Ct range 14.6 – 35.5): 52/58 samples (89.7%). Sensitivity for Ct≤25: 18/18 samples. Overall specificity only 46.2%, probably linked to the use of transport medium instead of the swab included in the kit.</p> <p><b>FR:</b><br/>NP swabs, prospective study (71/71) : sensitivity 100% (45/45, specificity 100%</p> <p><b>NL:</b><br/>Independent field study, mainly symptomatic individuals (n=568, PCR positive n=39), NP swab; sensitivity Ct≤30: 96.0%, sensitivity ≤25: 100%; specificity overall: 100%</p> <p><b>NL:</b><br/>Independent field study, symptomatic individuals (n=270, PCR positive n=17), NP+OP swab; sensitivity Ct≤30: 94.1%, sensitivity Ct≤25: 100%; specificity overall: 100%</p> <p><b>SE:</b><br/>Karolinska hospital evaluation of Lot 20100103. Patient samples; 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 76%, specificity 96%. Sensitivity Ct&lt;25 = 100%.</p> |   |  |                           |                                 |                                   |
|                     |                           |                           | <i>Retrospective in vitro study</i>   |   |  |                           |                                 |                                   |
|                     |                           |                           | <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%</p>  |   |  |                           |                                 |                                   |
| BIOSYNEX SA         | BIOSYNEX COVID-19 Ag+ BSS | 1494                      | <i>Prospective clinical field study</i>   | Clinical Sensitivity: 97.5 %<br>Specificity: 99%<br>Nasal swab, NP swab | FR<br><a href="#">UK</a>                                 | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab | 7 July 2021                       |

| Manufacturer  | RAT commercial name                                   | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>                                  | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                                    | Included in EU common list since: |
|---|---|---------------------------|--|--|------------------------------|---------------------------|---|-----------------------------------|
| BIOTEKE CORPORATION (WUXI) CO., LTD   | SARS-CoV-2 Antigen Test Kit (colloidal gold method)   | 2067                      | <i>Retrospective in vitro study</i>  | 96.49 % sensitivity<br>99.28 % specificity<br>OP/NP swab   | DE <sup>[2]</sup>            | Nucleo-protein            | Nasopharyngeal swab,<br>Oropharyngeal swab                | 14 July 2021                      |
|   |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 99.28%  |  |                              |                           |   |                                   |
| Biotical Health S.L.U.BIOTICAL HEALTH S.L.U   | biotical SARS-CoV-2 Ag Card                           | 2013                      | <i>Retrospective in vitro study</i>  | Sensitivity: 96%,<br>Specificity: 99%<br>NP swab   | BE                           | Nucleo-protein            | Nasopharyngeal swab                                       | 23 July 2021                      |
|   |   |                           | <b>BE:</b><br>Validation study 1: sensitivity 91.7% for Ct<25; Validation study 2: 94% for Ct<25. Manufacturer specificity: 99%  |  |                              |                           |   |                                   |
| Boditech Med Inc  | AFIAS COVID-19 Ag                                     | 1989                      | <i>Prospective clinical field study</i>  | Sensitivity: 91.9% (95%CI: 86.0% ~ 95.4%),<br>Specificity: 98.8% (95%CI: 95.6% - 99.7%)<br>NP swab | NL                           | Nucleo-capsid protein     | Nasopharyngeal swab                                       | 23 July 2021                      |
|   |   |                           | <b>NL:</b><br>Independent field study in mild symptomatic (n= 427, PCR positive: 106); unknown swab, overall sensitivity: 81.1%, sensitivity Ct <30: 96.4%; specificity: 100%, |  |                              |                           |   |                                   |
| BTNX Inc  | Rapid Response COVID-19 Antigen Rapid Test            | 1236                      | <i>Retrospective in vitro study</i>  | 90.2% sensitivity 100% specificity NP swab, NP swab, OP swab                                       | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab | 10 May 2021                       |
|   |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%   |  |                              |                           |   |                                   |
| CerTest Biotec  | CerTest SARS-CoV-2 Card test                          | 1173                      | <i>Prospective clinical field study</i>  | 92.9% sensitivity<br>99.6% specificity<br>NP swab  | DE <sup>[2]</sup> , ES       | Nucleo-capsid protein     | Nasopharyngeal swab                                       | 17 February 2021                  |
|   |   |                           | <b>ES:</b><br>Ct ≤ 25, sensitivity: 94,0%; sensitivity for samples within the first 5 days after symptom onset: 84,8%; 150 positive samples, 170 negative samples              |  |                              |                           |   |                                   |
| Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sist.İnş.Müh.Dan.San.Tic.Ltd. Şti. | CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST          | 2696                      | <i>Retrospective in vitro study</i>  | Clinical Sensitivity: 99.3 %<br>Clinical Specificity: 98.8 %                                       | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab  | 21 December 2021                  |
|   |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.8%  |  |                              |                           |   |                                   |
| Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sist.İnş.Müh.Dan.San.Tic.Ltd. Şti. | CHECK UP SARS-COV-2 NASOPHARYNGEAL RAPID ANTIGEN TEST | 2746                      | <i>Retrospective in vitro study</i>  | Clinical Sensitivity: 99.3 %<br>Clinical Specificity: 99.7 %                                       | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasopharyngeal swab                                       | 21 December 2021                  |
|   |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.7%  |  |                              |                           |   |                                   |

| Manufacturer   | RAT commercial name  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>             | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                     | Included in EU common list since: |
|--|--|---------------------------|---|---|------------------------------|---------------------------|--|-----------------------------------|
| Chil Tibbi Malzeme Sanayi ve Ticaret Limited Şirketi | CHIL COVID-19 Antigen Rapid Test (Nasopharyngeal / Oropharyngeal Swab-Casette) | 1691                      | <i>Retrospective in vitro study</i>   | Sensitivity 99.01%<br>Specificity: 99.57%                                     | DE <sup>[2]</sup>            | Nucleo-protein            | Nasopharyngeal swab,<br>Oropharyngeal swab | 20 October 2021                   |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.57%  |   |                              |                           |  |                                   |
| Chongqing M&D Biotechnology Co. Ltd                  | 2019-nCoV Antigen Test Kit   | 2150                      | <i>Retrospective in vitro study</i>   | sensitivity: 91.53%,<br>specificity:100%                                      | DE <sup>[2]</sup>            | Nucleo-protein            | Nasopharyngeal swab                        | 20 October 2021                   |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 100%   |   |                              |                           |  |                                   |
| Core Technology Co., Ltd                             | Coretests COVID-19 Ag Test   | 1919                      | <i>Retrospective in vitro study</i>   | 98.1% sensitivity<br>99.6% specificity<br>NP swab                             | DE <sup>[2]</sup>            | Nucleo-protein            | Nasopharyngeal swab                        | 10 May 2021                       |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 99.6%  |   |                              |                           |  |                                   |
| CTK Biotech, Inc                                     | OnSite COVID-19 Ag Rapid Test  | 1581                      | <i>Prospective clinical field study</i>   | Clinical Sensitivity: 92.3 %<br>Clinical Specificity: 100 %<br>Nasal, NP swab | DK, ES                       | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab         | 7 July 2021                       |
|  |  |                           | <b>DK:</b><br>107 samples; Nasal swab - clinical sensitivity 86%; (from asymptomatic and mild symptomatic individuals), Clinical specificity: 100%  |   |                              |                           |  |                                   |
|  |  |                           | <i>Retrospective in vitro study</i>   |   |                              |                           |  |                                   |
| DDS DIAGNOSTIC                                       | Test Rapid Covid-19 Antigen (tampon nazofaringian)                             | 1225                      | <i>Prospective clinical field study</i>   | 99.6% sensitivity<br>99.67% specificity NP swab                               | RO<br>China                  | Nucleo-capsid protein     | Nasopharyngeal swab                        | 10 May 2021                       |
|  |  |                           | <b>RO:</b><br>Clinical study based on 228 COVID-19 positive samples and 597 COVID-19 negative samples. All the samples were confirmed using PCR (Applied Biosystems™ 7500 and SLAN®- 96P) and clinical symptoms. The relative sensitivity of Rapid Test COVID-19 Antigen (Nasopharyngeal Swab) was 99.56%, the relative specificity was 99.66%, and the accuracy was 99.64% compared to the qRT-PCR result. |   |                              |                           |  |                                   |



| Manufacturer                               | RAT commercial name   | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>          | Completed validation studies                | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                              | Included in EU common list since: |
|--|---|---------------------------|--|--|---|---------------------------|---|-----------------------------------|
| DNA Diagnostic                             | COVID-19 Antigen Detection Kit  | 2242                      | <i>Retrospective in vitro study</i>  | Sensitivity: 93.8%, Specificity: 99.6%<br>Nasal swab                       | DE <sup>[2]</sup><br><br><a href="#">UK</a> | Nucleo-protein            | Nasal swab  | 23 July 2021                      |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.56%   |  |   |                           |   |                                   |
| DNA Diagnostic                             | SARS-CoV-2 Antigen Rapid Test   | 2756                      | <i>Retrospective in vitro study</i>  | Clinical sensitivity: 93.4%<br>Clinical specificity: 99.3%                 | DE <sup>[2]</sup>                           | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab                     | 21 January 2022                   |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.3%  |  |   |                           |   |                                   |
| Dräger Safety AG & Co. KGaA                | Dräger Antigen Test SARS-CoV-2  | 2273                      | <i>Prospective clinical field studies</i>  | Sensitivity: 96.8% (Ct values <26) Specificity: 99.7%                      | DE <sup>[2]</sup><br><br>CH                 | Nucleo-capsid protein     | Nasal swab  | 20 October 2021                   |
|  |   |                           | <b>DE:</b><br>Independent prospective study, mainly symptomatic <7 dps (n=378, PCR positive = 70), self-collected nasal swab; sensitivity overall: 88.6%, sensitivity Ct<26: 96.8%; specificity overall: 99.7% |  |   |                           |   |                                   |
|  |   |                           | <b>CH:</b><br>Independent prospective study, mainly symptomatic ≤7 dps (n=464, PCR positive = 57), self-collected nasal swab; sensitivity Ct<30: 85.1%, sensitivity Ct<26: 90.0%; specificity overall: 100%    |  |   |                           |   |                                   |
|  |   |                           | <i>Retrospective in vitro study</i>  |  |   |                           |   |                                   |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct < 25; Manufacturer specificity: 99.6%   |  |   |                           |   |                                   |
| Dynamiker Biotechnology(Tianjin) Co., Ltd. | Dynamiker SARS-CoV-2 Ag Rapid Test                                    | 2533                      | <i>Retrospective in vitro study</i>  | sensitivity: 95.7%, specificity: 99.1%                                     | DE <sup>[2]</sup>                           | Nucleo-capsid protein     | Nasopharyngeal swab, Oropharyngeal swab             | 20 October 2021                   |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer Specificity: 99.1%  |  |   |                           |   |                                   |
| Edinburgh Genetics Limited                 | Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit | 1243                      | <i>Prospective clinical field study</i>  | Clinical Sensitivity 97.27% NP swab<br>Clinical Specificity 99.62% NP swab | DE <sup>[2]</sup><br><br>Peru               | Nucleo-protein            | Nasal swab, Nasopharyngeal swab, Oropharyngeal swab | 14 July 2021                      |
|  |   |                           | <b>FIND evaluation</b><br><a href="#">Peru</a> (26 April 2021)<br>120 samples, NP swab. Clinical sensitivities: Days ≤7: 62%; Ct ≤33: 75%; Ct ≤ 25: 100%.<br>Clinical specificity: 100%                        |  |   |                           |   |                                   |

| Manufacturer                                 | RAT commercial name          | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>                          | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup> | Included in EU common list since: |
|--|------------------------------|---------------------------|---|--|------------------------------|---------------------------|------------------------|-----------------------------------|
|  |                              |                           | <i>Retrospective in vitro study</i>   | Clinical Sensitivity 95.63% OP swab<br>Clinical Specificity 99.24% OP swab                 |                              |                           |                        |                                   |
|  |                              |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer Specificity: 99,24%                                    |  |                              |                           |                        |                                   |
| Fosun Diagnostics (Shanghai) Co.,Ltd., China | Fosun Covid-19 Ag Card       | 2724                      | <i>Retrospective in vitro study</i>   | Clinical Sensitivity 97.7 %<br>Clinical Specificity 98.7 %                                 | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasopharyngeal swab    | 4 March 2022                      |
|  |                              |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer Specificity: 99,7%                                     |  |                              |                           |                        |                                   |
| Eurobio Scientific                           | EBS SARS-CoV-2 Ag Rapid Test | 1739                      | <i>Prospective clinical field study</i>   | Clinical Sensitivity: 95.7 %<br>Nasal swab   | DE <sup>[2]</sup> , FR       | Nucleo-protein            | Nasal swab             | 7 July 2021                       |
|  |                              |                           | <b>FR:</b><br>Validation study data: 119 positive and 125 negative samples; sensitivity 93%, specificity: 99%   |  |                              |                           |                        |                                   |
|  |                              |                           | <i>Retrospective in vitro study</i>   |  |                              |                           |                        |                                   |
|  |                              |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,1%                                    |  |                              |                           |                        |                                   |
| Fujirebio                                    | ESPLINE SARS-CoV-2           | 2147                      | <i>Prospective clinical field study</i>   | Clinical Sensitivity: 87.8 %<br>( (n=98, Ct<33))<br>Clinical Specificity: 100 %<br>NP swab | DE <sup>[2]</sup>            | Nucleo-protein            | Nasopharyngeal swab    | 7 July 2021                       |
|  |                              |                           | <b>FIND evaluation</b><br><b>DE</b> (29 March 2021)<br>723 samples, NP swab. Sensitivities: Days ≤7: 88.5%; Ct ≤33: 87.8%; Ct ≤ 25: 92.4%. Clinical specificity: 100% |  |                              |                           |                        |                                   |
|  |                              |                           | <b>South Africa</b> (6 Oct 2021)<br>494 samples, NP swab. Sensitivities: Days ≤7: 75%; Ct ≤33: 78.9%; Ct ≤ 25: 90.1%. Clinical specificity: 99.7%                     |  |                              |                           |                        |                                   |
|  |                              |                           | <i>Retrospective in vitro study</i>   |  |                              |                           |                        |                                   |
|  |                              |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,13%                                   |  |                              |                           |                        |                                   |
| GA Generic Assays GmbH                       | GA CoV-2 Antigen Rapid Test  | 1855                      | <i>Retrospective in vitro study</i>   | Sensitivity: 97.059%,<br>Specificity: 99.2%<br>NP swab                                     | DE <sup>[2]</sup>            | Nucleo-protein            | Nasopharyngeal swab    | 23 July 2021                      |
|  |                              |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%                                     |  |                              |                           |                        |                                   |

| Manufacturer                     | RAT commercial name  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>   | Completed validation studies                     | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                                    | Included in EU common list since: |
|----------------------------------|--|---------------------------|---|---|--|---------------------------|---|-----------------------------------|
| Genobio Pharmaceutical Co., Ltd. | Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)                              | 2642                      | <i>Retrospective in vitro study</i>   | OP: sensitivity: 97.14%, specificity: 99.28%<br>NP: sensitivity: 97.22%, specificity: 99.23%                                | DE <sup>[2]</sup>                                | Nucleo-capsid protein     | Oropharyngeal swab;<br>Nasopharyngeal swab                | 8 December 2021                   |
|                                  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%                     |   |  |                           |   |                                   |
| Genrui Biotech Inc               | SARS-CoV-2 Antigen Test Kit (Colloidal Gold)   | 2012                      | <i>Retrospective in vitro study</i>   | Sensitivity: 91.15%<br>Specificity: 99.02%<br>Nasal/NP/OP swab  | DE <sup>[2]</sup>                                | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab | 7 July 2021                       |
|                                  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,02%                   |   |  |                           |   |                                   |
| GenSure Biotech Inc              | GenSure COVID-19 Antigen Rapid Test Kit  | 1253                      | <i>Retrospective in vitro study</i>   | 96.86% sensitivity<br>100% specificity<br>Nasal swab  | DE <sup>[2]</sup><br><a href="#">UK</a>          | <b>Unknown</b>            | Nasal swab  | 10 May 2021                       |
|                                  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 100%                     |   |  |                           |   |                                   |
| GenSure Biotech Inc.             | GenSure COVID-19 Antigen Rapid Test Kit  | 2853                      | <i>Retrospective in vitro study</i>   | Clinical Sensitivity 96.73 %<br>Clinical Specificity 100 %  | DE <sup>[2]</sup>                                | Nucleo-capsid protein     | Nasal swab<br><b>! Saliva</b>                             | 10 February 2022                  |
|                                  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 100%                     |   |  |                           |   |                                   |
| Getein Biotech, Inc              | SARS-CoV-2 Antigen (Colloidal Gold)  | 1820                      | <i>Retrospective in vitro study</i>   | 97.06% sensitivity<br>98.71% specificity<br>Nasal swab  | DE <sup>[2]</sup>                                | Nucleo-protein            | Nasal swab<br><b>! Saliva</b>                             | 14 July 2021                      |
|                                  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.71%                    |   |  |                           |   |                                   |
| Getein Biotech, Inc.             | One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)                                | 2183                      | <i>Retrospective in vitro study</i>   | 97.06% sensitivity<br>98.71% specificity<br>Nasal swab  | DE <sup>[2]</sup><br><a href="#">UK</a>          | Nucleo-protein            | Nasal swab<br><b>! Saliva</b>                             | 16 June 2021                      |
|                                  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 98.71% |   |  |                           |   |                                   |
| Glallergen CO., LTD.             | Novel Coronavirus (2019-nCoV) Antigen Test Kit (Colloidal gold immunochromatography) | 2695                      | <i>Retrospective in vitro study</i>   | Clinical Sensitivity: 94.44 %<br>Clinical Specificity: 99.02 %  | DE <sup>[2]</sup>                                | Nucleo-capsid protein     | Nasal swab  | 21 December 2021                  |
|                                  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.02%                    |   |  |                           |   |                                   |
| Goldsite Diagnostic Inc.         | SARS-CoV-2 Antigen Kit (Colloidal Gold)  | 1197                      | <i>Retrospective in vitro study</i>   | <b>Nasal:</b> Clinical sensitivity: 93.04% (95% CI: 86.75 – 96.95%); Clinical specificity: 100.00% (95% CI: 98.56 – 100.0%) | FR, DE <sup>[2]</sup> , ES<br><a href="#">UK</a> | Nucleo-capsid protein     | Nasal swab,<br>Nasopharyngeal swab<br><b>! Other</b>      | 14 July 2021                      |
|                                  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%                      |   |  |                           |   |                                   |

| Manufacturer                             | RAT commercial name   | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                              | Included in EU common list since: |
|--|---|---------------------------|---|--|------------------------------|---------------------------|---|-----------------------------------|
|  |   |                           |   | Nasopharyngeal: Clinical sensitivity: 97.14% (95% CI: 91.88 – 99.41%); Clinical specificity: 99.60% (95% CI: 98.58 – 99.95%)   |                              |                           |   |                                   |
| Green Cross Medical Science Corp.        | GENEDIA W COVID-19 Ag                                       | 1144                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 100%    | 100% sensitivity 90.1% sensitivity<br>100% specificity<br>NP swab, Anterior nasal swab   | DE <sup>[2]</sup>            | Nucleo-protein            | Anterior nasal swab, Nasopharyngeal swab            | 10 May 2021                       |
| Guangdong Hecin Scientific, Inc.         | 2019-nCoV Antigen Test Kit (colloidal gold method)          | 1747                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 82% at Ct ≤ 25; Manufacturer specificity: 99.07%  | 96.83% sensitivity<br>99.39% specificity<br>Nasal swab   | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasopharyngeal swab                                 | 10 May 2021                       |
| Guangdong Longsee Biomedical Co., Ltd.   | 2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)    | 1216                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%  | <u>OP swab</u> : sensitivity 95.22%, specificity 99.72%<br><u>Nasal swab</u> : sensitivity 94.15%, specificity 99.68%<br><u>NP swab</u> : sensitivity 95.51%, specificity 99.72% | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasopharyngeal swab, Oropharyngeal swab, Nasal swab | 14 July 2021                      |
| Guangdong Wesail Biotech Co. Ltd         | COVID-19 Ag Test Kit  | 1360                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98%    | 90% sensitivity<br>98% specificity<br>Nasal swab   | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab, Nasopharyngeal swab                     | 17 February 2021                  |
| Guangzhou Decheng Biotechnology CO., Ltd | V-CHEK, 2019-nCoV Ag Rapid Test Kit (Immuno-chromatography) | 1324                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct < 25; Manufacturer specificity: 99,5% | Clinical Sensitivity: 95.83%<br>Specificity 99.57%<br>Nasal swab   | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab  | 7 July 2021                       |

| Manufacturer                      | RAT commercial name                                 | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup> | Completed validation studies                    | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                    | Included in EU common list since: |
|-----------------------------------|---|---------------------------|--|---|---|---------------------------|---|-----------------------------------|
| Guangzhou Wondfo Biotech Co., Ltd | Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) | 1437                      | <i>Prospective clinical field study</i>  | Sensitivity: 98.11%<br>Specificity: 99.72%                        | DE <sup>[2]</sup><br><br>CH, <a href="#">UK</a> | Nucleo-capsid protein     | Nasopharyngeal swab<br>Oropharyngeal swab | 10 May 2021                       |
|                                   |   |                           | <b>FIND evaluation</b><br><a href="#">CH</a> (25 Feb 2020)<br>328 samples, NP swab. Clinical sensitivities:<br>Days ≤ 7: 85.7%; Ct ≤ 33: 92.2%; Ct ≤ 25: 100%.<br>Clinical specificity: 100%<br><a href="#">Brazil</a> (10 Oct 2021)<br>237 samples, NP swab. Clinical sensitivities:<br>Days ≤ 7: 90.4%; Ct ≤ 33: 89.3%; Ct ≤ 25: 96.7%.<br>Clinical specificity: 98.8% |   |   |                           |   |                                   |
|                                   |   |                           | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 99.74%  |   |   |                           |   |                                   |
| Hangzhou AllTest Biotech Co., Ltd | COVID-19 Antigen Rapid Test                         | 1257                      | <i>Prospective clinical field study</i><br><b>FR:</b><br>Prospective study, sensitivity 96,4% (80/83), specificity 99,2% (120/121)   | 93,40% sensitivity,<br>99,90% specificity<br>NP swab              | FR  | Nucleo-capsid protein     | Nasopharyngeal swab                       | 10 May 2021                       |
| Hangzhou AllTest Biotech Co., Ltd | SARS-CoV-2 Antigen Rapid Test (Nasal Swab)          | 2257                      | <i>Prospective clinical field study</i>  | Clinical Sensitivity<br>97.4 %<br>Clinical Specificity<br>99.9 %  | DE <sup>[2]</sup> , PL                          | Nucleo-capsid protein     | Nasal swab                                | 4 March 2022                      |
|                                   |   |                           | <b>PL:</b><br>Prospective study performed in Polish university, nasal specimen, 300 negative samples and 200 positive samples. CT distribution described. Overall sensitivity: 97,3%, overall specificity: 98,70%  |   |   |                           |   |                                   |
|                                   |   |                           | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99.9%   |   |   |                           |   |                                   |
| Hangzhou Biotest Biotech Co., Ltd | COVID-19 Antigen Rapid Test Cassette (Nasal Swab)   | 1876                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%  | Sensitivity: 93.2%,<br>Specificity: 99.2%<br>Nasal swab           | DE <sup>[2]</sup>                               | Nucleo-capsid protein     | Nasal swab                                | 8 December 2021                   |

| Manufacturer                        | RAT commercial name   | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>                                   | Completed validation studies            | SARS-CoV-2 Target protein | Specimen <sup>16</sup>  | Included in EU common list since: |
|-------------------------------------|---|---------------------------|--|---|---|---------------------------|---|-----------------------------------|
| Hangzhou Clongene Biotech Co., Ltd. | COVID-19 Antigen Rapid Test Casette   | 1610                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,4% at Ct ≤ 25; Manufacturer specificity: 100% | Clinical Sensitivity: 91.4 %<br>Clinical Specificity: 100 %<br>NP swab                              | DE <sup>[2]</sup><br><a href="#">UK</a> | Nucleo-protein            | Nasopharyngeal swab   | 7 July 2021                       |
|                                     | Covid-19 Antigen Rapid Test Kit   | 1363                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,4% at Ct ≤ 25; Manufacturer specificity: 100% | 98.5% (Ct<33) sensitivity<br>Nasal swab   | DE <sup>[2]</sup><br>CH                 | Nucleo-protein            | Nasal swab  | 17 February 2021                  |
|                                     | COVID-19/Influenza A+B Antigen Combo Rapid Test                               | 1365                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,4% at Ct ≤ 25; Manufacturer specificity: 100% | 91% sensitivity<br>100% specificity<br>NP swab  | DE <sup>[2]</sup>                       | Nucleo-protein            | Nasopharyngeal swab   | 10 May 2021                       |
| Hangzhou Immuno Biotech Co., Ltd    | Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive) | 1844                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%   | 94% sensitivity<br>100% specificity<br>Nasal swab, NP swab  | DE <sup>[2]</sup>                       | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab  | 10 May 2021                       |
|                                     | SARS-CoV2 Antigen Rapid Test  | 2317                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%   | Clinical Sensitivity: 98 %<br>Clinical Specificity: 100 %<br>Anterior nasal swab, NP swab, OP swab, | DE <sup>[2]</sup>                       | Nucleo-protein            | Anterior nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab<br><b>! Sputum</b> | 10 May 2021                       |
| Sigmed Sp. z o.o.                   | Redtest Professional Sars-CoV-2 Antigen Rapid Test (Covid-19 Ag)              | 2256                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%   | sensitivity: 98,13%,<br>specificity: 100%   | DE <sup>[2]</sup>                       | Nucleo-capsid protein     | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab                             | 8 December 2021                   |

| Manufacturer                                    | RAT commercial name  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>   | Completed validation studies          | SARS-CoV-2 Target protein             | Specimen <sup>16</sup>  | Included in EU common list since: |
|---|--|---------------------------|---|---|---------------------------------------|---------------------------------------|---|-----------------------------------|
| Hangzhou DIAN Biotechnology Co., Ltd.           | COVID-19 Antigen Test Cassette                                       | 2629                      | <i>Retrospective in vitro study</i>   | Clinical Sensitivity: 97.6 %<br>Clinical Specificity: 98.4 %  | DE <sup>[2]</sup>                     | Unknown                               | Nasal swab,<br>Nasopharyngeal swab                                  | 21 December 2021                  |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 98.4%  |   |                                       |                                       |   |                                   |
| Hangzhou Laihe Biotech Co.                      | LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) | 1215                      | <i>Retrospective in vitro study</i>   | OP: Sensitivity 95.49%, Specificity 99.32%<br>NP: Sensitivity 97.47%, Specificity 100.00%                 | DE <sup>[2]</sup><br><br>UK           | Nucleo-capsid protein                 | For professional use:<br>Nasopharyngeal swab,<br>Oropharyngeal swab | 10 May 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,7%  |   |                                       |                                       |   |                                   |
| Hangzhou Lysun Biotechnology Co. Ltd            | COVID-19 Antigen Rapid Test Device (Colloidal Gold)                  | 2139                      | <i>Retrospective in vitro study</i>   | 96.46% sensitivity<br>100% specificity<br>Nasal swab  | DE <sup>[2]</sup>                     | Nucleo-protein                        | Nasal swab  | 10 May 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%  |   |                                       |                                       |   |                                   |
| Hangzhou Sejoy Electronics & Instruments Co.Ltd | SARS-CoV-2 Antigen Rapid Test Cassette                               | 1945                      | <i>Retrospective in vitro study</i>   | Sensitivity: 94.5%,<br>Specificity:100%<br>Nasal swab   | DE <sup>[2]</sup>                     | Nucleo-capsid protein                 | Nasal swab  | 8 December 2021                   |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%  |   |                                       |                                       |   |                                   |
| Hangzhou Testsea Biotechnology Co., Ltd.        | Covid-19 Antigen Test Cassette                                       | 1392                      | <i>Retrospective in vitro study</i>   | 92.1% sensitivity<br>98.1% specificity<br>Nasal swab  | DE <sup>[2]</sup>                     | Nucleo-protein                        | Nasal swab,<br>Nasopharyngeal swab                                  | 10 May 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.4%   |   |                                       |                                       |   |                                   |
| Healgen Scientific                              | Coronavirus Ag Rapid Test Cassette                                   | 1767                      | <i>Prospective clinical field studies</i>   | 98.32 % sensitivity<br>99.6% specificity (NP swab)<br>97.25% sensitivity<br>100% specificity (Nasal swab) | DE <sup>[2]</sup> , NL <sup>[5]</sup> | Nucleo-proteins,<br>S1, S1-RBD,<br>S2 | Nasal swab,<br>Nasopharyngeal swab                                  | 17 February 2021                  |
|   |  |                           | <b>NL:</b><br><b>1):</b> Clinical field study, symptomatic individuals (n=417, PCR positive n=70), NP swab; sensitivity overall: 75.7%, sensitivity Ct≤30: 85.2%, sensitivity Ct≤25: 90.7%; specificity: 100%<br><b>2):</b> Clinical field study, symptomatic individuals (n=240, PCR positive n=21), NP+OP swab; sensitivity overall: 85.7%, sensitivity Ct≤30: 89.5%, sensitivity Ct≤25: 100%; specificity: 100%<br><b>3):</b> Clinical field study, symptomatic individuals (n=94, PCR positive n=18), NP+OP swab in VTM; sensitivity overall: 90.0%, sensitivity Ct≤30: 100%, sensitivity Ct≤25: 100%; specificity: 97.3% |   |                                       |                                       |   |                                   |

| Manufacturer                          | RAT commercial name                       | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>                   | Completed validation studies                  | SARS-CoV-2 Target protein       | Specimen <sup>16</sup>          | Included in EU common list since: |
|---------------------------------------|---|---------------------------|---|---|---|---------------------------------|---------------------------------|-----------------------------------|
|                                       |   |                           | <i>Retrospective in vitro study</i>   |   |   |                                 |                                 |                                   |
|                                       |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25;<br>Manufacturer specificity: 100%   |   |   |                                 |                                 |                                   |
|                                       |   |                           | <i>Prospective clinical field studies</i>   |   |   |                                 |                                 |                                   |
|                                       |   |                           | <b>NL:</b><br><b>1):</b> Clinical field study, symptomatic individuals (n=417, PCR positive n=70), NP swab; sensitivity overall: 75.7%, sensitivity Ct≤30: 85.2%, sensitivity Ct≤25: 90.7%; specificity: 100%<br><b>2):</b> Clinical field study, symptomatic individuals (n=240, PCR positive n=21), NP+OP swab; sensitivity overall: 85.7%, sensitivity Ct≤30: 89.5%, sensitivity Ct≤25: 100%; specificity: 100%<br><b>3):</b> Clinical field study, symptomatic individuals (n=94, PCR positive n=18), NP+OP swab in VTM; sensitivity overall: 90.0%, sensitivity Ct≤30: 100%, sensitivity Ct≤25: 100%; specificity: 97.3% |   |   |                                 |                                 |                                   |
| Siemens Healthineers                  | CLINITEST Rapid COVID-19 Antigen Test     | 1218                      | <b>ES:</b><br>Independent prospective study; 192 positive and 258 negative samples (NP swab). Sensitivity: 93,3%, Specificity. 99.2%, compared against NP PCR.<br><b>IE</b><br>Independent prospective study: overall sensitivity 79,4% and among Ct ≤25 89,7% (34 samples). Overall specificity 98.8% (249 samples) and in only the symptomatic cohort 98% (153 samples).  | 98.32% sensitivity (NP swab)<br>97.25% sensitivity (Nasal swab)<br>100% specificity | DE <sup>[2]</sup> , ES, IE, NL <sup>[5]</sup> | Nucleo-proteins, S1, S1-RBD, S2 | Nasal swab, Nasopharyngeal swab | 17 February 2021                  |
|                                       |   |                           | <i>Retrospective in vitro study</i>   |   |   |                                 |                                 |                                   |
|                                       |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25;<br>Manufacturer specificity: 100%   |   |   |                                 |                                 |                                   |
|                                       |   |                           | <i>Prospective clinical field studies</i>   |   |   |                                 |                                 |                                   |
| Zhejiang Orient Gene Biotech Co., Ltd | Coronavirus Ag Rapid Test Cassette (Swab) | 1343                      | <b>NL:</b><br><b>1):</b> Clinical field study, symptomatic individuals (n=417, PCR positive n=70), NP swab; sensitivity overall: 75.7%, sensitivity Ct≤30: 85.2%,   | 98.32 % sensitivity<br>99.6 % specificity<br>Nasal/NP swab                          | DE <sup>[2]</sup><br><a href="#">UK</a>       | Nucleo-protein                  | Nasal swab, Nasopharyngeal swab | 17 February 2021                  |



| Manufacturer                       | RAT commercial name   | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>                              | Completed validation studies            | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                     | Included in EU common list since: |
|------------------------------------|---|---------------------------|--|--|---|---------------------------|--|-----------------------------------|
|                                    |   |                           | <p>sensitivity Ct<sub>≤</sub>25: 90.7%; specificity: 100%</p> <p><b>2)</b>: Clinical field study, symptomatic individuals (n=240, PCR positive n=21), NP+OP swab; sensitivity overall: 85.7%, sensitivity Ct<sub>≤</sub>30: 89.5%, sensitivity Ct<sub>≤</sub>25: 100%; specificity: 100%</p> <p><b>3)</b>: Clinical field study, symptomatic individuals (n=94, PCR positive n=18), NP+OP swab in VTM; sensitivity overall: 90.0%, sensitivity Ct<sub>≤</sub>30: 100%, sensitivity Ct<sub>≤</sub>25: 100%; specificity: 97.3%</p> <p><i>Retrospective in vitro study</i></p> <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.6%</p> |  |   |                           |  |                                   |
| Hoyotek Biomedical Co.,Ltd.        | Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)       | 1929                      | <p><i>Retrospective in vitro study</i></p> <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99%</p>  | NP swab - Sensitivity: 96%, Specificity: 99%<br>OP swab - Sensitivity: 93%, Specificity: 97.5% | DE <sup>[2]</sup>                       | <b>Unknown</b>            | Nasopharyngeal swab,<br>Oropharyngeal swab | 20 October 2021                   |
| Hubei Jinjian Biology Co., Ltd     | SARS-CoV-2 Antigen Test Kit                                       | 1759                      | <p><i>Retrospective in vitro study</i></p> <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.3%</p>   | Sensitivity: 98.02%<br>Nasal Swab  | DE <sup>[2]</sup>                       | Nucleo-protein            | Nasopharyngeal swab                        | 23 July 2021                      |
| Humasis                            | Humasis COVID-19 Ag Test  | 1263                      | <p><i>Retrospective in vitro study</i></p> <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%</p>   | 95.3% sensitivity<br>100% specificity<br>Nasal swab  | DE <sup>[2]</sup><br><a href="#">UK</a> | <b>Unknown</b>            | Nasal swab                                 | 10 May 2021                       |
| Innova Medical Group.Inc           | Innova SARS-CoV-2 Antigen Rapid Qualitative Test                  | 1801                      | <p><i>Retrospective in vitro study</i></p> <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%</p>   | Sensitivity 94.0% : CI 95% (86.7%-98.0%)<br>Specificity: 99.6% - CI:95%(99.4%-99.8%)           | DE <sup>[2]</sup>                       | Nucleo-capsid protein     | Anterior nasal swab, Nasal swab            | 20 October 2021                   |
| Innovation Biotech(Beijing) Co.Ltd | Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Nasal swab) | 2278                      | <p><i>Retrospective in vitro study</i></p> <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%</p>   | Sensitivity: 95.6%<br>Specificity: 100%  | DE <sup>[2]</sup>                       | Nucleo-protein            | Nasal swab                                 | 20 October 2021                   |

| Manufacturer   | RAT commercial name                                     | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>   | Included in EU common list since: |
|--|---|---------------------------|--|--|------------------------------|---------------------------|--|-----------------------------------|
| InTec PRODUCTS, INC.                                   | Rapid SARS-CoV-2 Antigen Test (nasopharyngeal specimen) | 2419                      | <i>Retrospective in vitro study</i>  | Sensitivity 90.2% (95% CI: 83.1% to 95.0%); Specificity 100.0% (95% CI: 96.5% - 100.00%)   | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasopharyngeal swab  | 20 October 2021                   |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%   |  |                              |                           |  |                                   |
| Inzek International Trading B.V.                       | Biozek covid-19 Antigen Rapidtest BCOV-502              | 1988                      | <i>Prospective clinical field studies</i>  | Clinical Sensitivity: 93.63%<br>Clinical Specificity: 99.73%   | NL                           | Nucleo-capsid protein     | Nasopharyngeal swab  | 4 March 2022                      |
|  |   |                           | <b>NL:</b><br>Independent prospective study, local public health authority involved (n=950, PCR positive = 61), NP swab; sensitivity overall: 85.25%; specificity: 99.78%<br><b>NL:</b><br>Independent prospective study, healthcare workers (n=294, PCR positive = 44), NP swab; sensitivity overall: 81.8%, sensitivity Ct<30: 91.9%; specificity: 99.7% |  |                              |                           |  |                                   |
| Jiangsu Bioperfectus Technologies Co., Ltd.            | Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit       | 2107                      | <i>Retrospective in vitro study</i>  | Sensitivity: NP: 96.67% (95% CI: 88.64%~99.08%), Nasal: 97.06% (95% CI: 93.30%~98.74%)<br>Specificity: NP: 97.87% (95% CI: 95.12%~99.09%), Nasal: 99.15% (95% CI: 98.25%~99.59%) | DE <sup>[2]</sup><br><br>UK  | Nucleo-protein            | Nasal swab, Nasopharyngeal swab,                                 | 14 July 2021                      |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.15%   |  |                              |                           |  |                                   |
| Jiangsu Diagnostics Biotechnology Co., Ltd             | COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)   | 1920                      | <i>Retrospective in vitro study</i>  | 97.58 % sensitivity<br>100 % specificity<br>Nasal/NP/ OP swab  | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab, Nasopharyngeal swab, Oropharyngeal swab, Throat swab | 14 July 2021                      |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%   |  |                              |                           |  |                                   |
| Jiangsu Konsung Bio-Medical Science and Technology Co. | COVID-19 Antigen Rapid Test Kit (Colloidal Gold)        | 1899                      | <i>Retrospective in vitro study</i>  | Clinical Sensitivity 97.14 %<br>Clinical Specificity 99.34 %   | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab, Oropharyngeal swab              | 10 February 2022                  |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.34%   |  |                              |                           |  |                                   |
| Jiangsu Medomics medical technology Co.,Ltd.           | SARS-CoV-2 antigen Test Kit (LFIA)                      | 2006                      | <i>Retrospective in vitro study</i>  | Sensitivity: 97.73%<br>Specificity: 99.51%<br>Anterior nasal swab, NP swab   | DE <sup>[2]</sup>            | Nucleo-protein            | Anterior nasal swab, Nasopharyngeal swab, Throat swab            | 7 July 2021                       |
|  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,51%  |  |                              |                           |  |                                   |

| Manufacturer                               | RAT commercial name  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>                               | Completed validation studies    | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                              | Included in EU common list since: |
|--|--|---------------------------|--|---|---------------------------------|---------------------------|---|-----------------------------------|
| Jiangsu Mole Bioscience CO., LTD.          | SARS-CoV-2 Antigen Test Cassette                               | 2586                      | <i>Retrospective in vitro study</i>  | sensitivity: 98.31 %, specificity: 99.17 %  | DE <sup>[2]</sup>               | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab                     | 8 December 2021                   |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,17%   |   |                                 |                           |   |                                   |
| Jiangsu Well Biotech Co., Ltd.             | COVID-19 Ag Rapid Test Device                                  | 2144                      | <i>Retrospective in vitro study</i>  | sensitivity: 94.74%, specificity: 99%   | DE <sup>[2]</sup>               | Nucleo-protein            | Nasal swab  | 20 October 2021                   |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%  |   |                                 |                           |   |                                   |
| JINAN BABIO BIOTECHNOLOGY CO., LTD., China | SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method) | 2151                      | <i>Prospective clinical field study</i>  | Clinical Sensitivity 96.67 %<br>Clinical Specificity 100 %                                      | PL                              | Nucleo-capsid protein     | Nasal swab  | 10 February 2022                  |
|  |  |                           | <b>PL:</b><br>Prospective study with nasal samples in a Polish hospital; 210 positive samples, overall sensitivity 96,7%; 450 negative samples, including 100 hospitalized patients and 50 potentially cross-reacting samples. Specificity 100%.   |   |                                 |                           |   |                                   |
| Joinstar Biomedical Technology Co. Ltd     | COVID-19 Rapid Antigen Test (Colloidal Gold)                   | 1333                      | <i>Retrospective in vitro study</i>  | 96.1% sensitivity<br>98.1% specificity<br>Nasal swab  | DE <sup>[2]</sup>               | Nucleo-protein            | Nasal swab, Nasopharyngeal swab, Oropharyngeal swab | 17 February 2021                  |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.1%  |   |                                 |                           |   |                                   |
| IEDAU INTERNATIONAL GMBH                   | Covid-19 Antigen Schnelltest (Colloidal Gold)                  | 2555                      | <i>Retrospective in vitro study</i>  | OP/Nasal: sensitivity: 96,1%, specificity: 99,2%<br>NP: sensitivity: 97,1%, specificity: 99,2 % | DE <sup>[2]</sup>               | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab, Oropharyngeal swab | 8 December 2021                   |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%  |   |                                 |                           |   |                                   |
| JOYSBIO (Tianjin) Biotechnology Co., Ltd.  | SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)             | 1764                      | <i>Prospective clinical field studies</i>  | 98.13% sensitivity<br>Nasal swab  | CZ, DE <sup>[2]</sup><br><br>CH | Nucleo-capsid protein     | Nasal swab  | 10 May 2021                       |
|  |  |                           | <b>CZ</b><br>N=225 (90 RT-PCR positive), 60.3% symptomatic patients. Test parameters for a subgroup of symptomatic patients (estimates and 95% confidence intervals): sensitivity 92% (80.8–97.8), specificity 97.6% (91.5–99.7).<br>Test parameters for a subgroup of asymptomatic patients (estimates and 95% confidence intervals): sensitivity 100% 100 (54.1–100), specificity 100% (95.5–100). |   |                                 |                           |   |                                   |

| Manufacturer                     | RAT commercial name  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup> | Completed validation studies                 | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                              | Included in EU common list since: |
|----------------------------------|--|---------------------------|---|---|--|---------------------------|---|-----------------------------------|
|                                  |  |                           | <b>FIND Evaluation</b><br><a href="#">CH</a> (11 Feb 2021)<br>265 samples, Nasal swab. Clinical sensitivities: Days $\leq$ 7: 74.2%; Ct $\leq$ 33: 78.9%; Ct $\leq$ 25: 91.3%; Clinical specificity: 99.1%  |   |  |                           |   |                                   |
| Labnovation Technologies Inc.    | SARS-CoV-2 Antigen Rapid Test Kit                          | 1266                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94% at Ct $\leq$ 25; Manufacturer specificity: 97.3%  | 96.3% sensitivity, 97.3% specificity<br>NP/OP swab                | DE <sup>[2]</sup>                            | Nucleo-protein            | Nasopharyngeal swab, Oropharyngeal swab             | 10 May 2021                       |
| LINKCARE (NANTONG DIAGNOSIS BIO) | COVID-19 Antigen Test Kit (Colloidal Gold)                 | 1353                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct $\leq$ 25; Manufacturer specificity: 99.04%  | Clinical Sensitivity: 92.59 %<br>Specificity: 99.04%              | DE <sup>[2]</sup>                            | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab                     | 21 December 2021                  |
| Lumigenex (Suzhou) Co., Ltd      | PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) | 2128                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct $\leq$ 25; Manufacturer specificity: 99,16%  | 93.33% sensitivity<br>99.16% specificity<br>Nasal/NP/OP swab      | DE <sup>[2]</sup>                            | Nucleo-protein            | Nasal swab, Nasopharyngeal swab, Oropharyngeal swab | 10 May 2021                       |
| LumiQuick Diagnostics Inc.       | QuickProfile™ COVID-19 Antigen Test                        | 1267                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct $\leq$ 25; Manufacturer specificity: 98.8%   | 93.7% sensitivity, 98.8% specificity<br>NP swab                   | DE <sup>[2]</sup>                            | <b>Unknown</b>            | Nasopharyngeal swab                                 | 10 May 2021                       |
| LumiraDX                         | LumiraDx SARS-CoV-2 Ag Test                                | 1268                      | <i>Prospective clinical field study</i><br><b>SKUP/2021/124:</b><br>448 samples: 83 positive samples and 365 negative samples. Nasal specimen: diagnostic sensitivity of 87% (79-92) and diagnostic specificity of 99,5% (98,3-99,9). NP specimen: diagnostic sensitivity of 90% (83-95) and diagnostic specificity of 97,8% (96,0-98,8) (Scandinavian evaluation of laboratory equipment for point of care testing)<br><b>FIND Evaluation</b><br><b>DE</b> (8 Oct 2021)<br>761 samples, NP swab. Clinical sensitivities: Days $\leq$ 7: 86.4%; Ct $\leq$ 33: 87.2%; Ct $\leq$ 25: 92.6%; Clinical specificity: 99.3% | 97.6% sensitivity<br>96.6% specificity<br>Nasal swab              | DE <sup>[2]</sup> , ES<br><br>SKUP<br><br>CH | Nucleo-protein            | Nasal swab  | 17 February 2021                  |

| Manufacturer                         | RAT commercial name                              | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup> | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                     | Included in EU common list since: |
|--------------------------------------|--|---------------------------|---|---|------------------------------|---------------------------|--|-----------------------------------|
|                                      |  |                           | <a href="#">Brazil</a> (8 Oct 2021)<br>251 samples, NP swab. Clinical sensitivities:<br>Days ≤7: 85.7%; Ct ≤33: 87.7%; Ct ≤25: 94.1%;<br>Clinical specificity: 99%  |   |                              |                           |  |                                   |
|                                      |  |                           | <i>Retrospective in vitro study</i>   |   |                              |                           |  |                                   |
|                                      |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.8%  |   |                              |                           |  |                                   |
| MEDsan GmbH                          | MEDsan SARS-CoV-2 Antigen Rapid Test             | 1180                      | <i>Retrospective in vitro study</i>   | 92.5% sensitivity<br>99.8% specificity<br>NP/OP swab              | DE <sup>[2]</sup><br>CH      | <b>Unknown</b>            | Nasopharyngeal swab,<br>Oropharyngeal swab | 17 February 2021                  |
|                                      |  |                           | <i>Retrospective in vitro study</i>   |   |                              |                           |  |                                   |
|                                      |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.8%  |   |                              |                           |  |                                   |
| Merlin Biomedical (Xiamen) Co., Ltd. | SARS-CoV-2 Antigen Rapid Test Cassette           | 2029                      | <i>Retrospective in vitro study</i>   | 95.05% sensitivity<br>98.99% specificity<br>Nasal/NP swab         | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab         | 16 June 2021                      |
|                                      |  |                           | <i>Retrospective in vitro study</i>   |   |                              |                           |  |                                   |
|                                      |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,1%  | Sensitivity: 96.17%<br>Specificity: 99,1%<br>Nasal swab           | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab                                 | 7 July 2021                       |
| MEXACARE GmbH                        | MEXACARE COVID-19 Antigen Rapid Test             | 1775                      | <i>Retrospective in vitro study</i>   |   |                              |                           |  |                                   |
|                                      |  |                           | <i>Retrospective in vitro study</i>   |   |                              |                           |  |                                   |
|                                      |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,99%   | Sensitivity: 97.25%<br>Specificity: 99.99%<br>NP swab             | DE <sup>[2]</sup> , IE       | <b>Unknown</b>            | Nasopharyngeal swab                        | 10 May 2021                       |
| möLab                                | mö-screen Corona Antigen Test                    | 1190                      | <i>Retrospective in vitro study</i>   |   |                              |                           |  |                                   |
|                                      |  |                           | <i>Prospective clinical field study</i>   |   |                              |                           |  |                                   |
|                                      |  |                           | <b>FIND evaluation</b><br><b>DE:</b> 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% | Sensitivity: 90.6%,<br>Specificity:100%<br>Nasal swab             | DE <sup>[2]</sup><br>UK      | Nucleo-capsid protein     | Nasal swab                                 | 8 December 2021                   |
| Mologic Ltd                          | COVIOS Ag COVID-19 Antigen Rapid Diagnostic Test | 2640                      |   |   |                              |                           |  |                                   |

| Manufacturer                                   | RAT commercial name  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies                    | SARS-CoV-2 Target protein | Specimen <sup>16</sup>  | Included in EU common list since: |
|--|--|---------------------------|--|--|---|---------------------------|---|-----------------------------------|
| MP Biomedicals                                 | Rapid SARS-CoV-2 Antigen Test Card                                 | 1481                      | <i>Retrospective in vitro study</i>  | 96.17% sensitivity<br>99.16% specificity<br>Nasal swab, Anterior nasal swab  | DE <sup>[2]</sup><br><br>CH, <a href="#">UK</a> | Nucleo-protein            | Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab            | 17 February 2021                  |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.03%   |  |   |                           |   |                                   |
| Multi-G bvba                                   | Covid19Check-NAS   | 2260                      | <i>Retrospective in vitro study</i>  | Clinical Sensitivity 97 % ( (99.35% for Ct values ≤25))<br>Clinical Specificity 99.5 %   | DE <sup>[2]</sup>                               | Nucleo-capsid protein     | Nasal swab  | 10 February 2022                  |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%  |  |   |                           |   |                                   |
| Nal von minden GmbH                            | NADAL COVID -19 Ag +Influenza A/B Test                             | 2104                      | <i>Retrospective in vitro study</i>  | 97% sensitivity<br>98% specificity<br>NP swab  | DE <sup>[2]</sup>                               | Nucleo-protein            | Nasopharyngeal swab   | 10 May 2021                       |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 99.9%   |  |   |                           |   |                                   |
| Nal von minden GmbH                            | NADAL COVID -19 Ag Test  | 1162                      | <i>Prospective clinical field study</i>  | 97.6% sensitivity<br>99.9% specificity<br>Nasal swab   | DE <sup>[2]</sup> , FR<br><br>China             | Nucleo-protein            | Nasal swab<br><br><b>! Serum, Whole blood</b>                                       | 17 February 2021                  |
|  |  |                           | <b>FIND evaluation</b><br><a href="#">CH</a> (26 April 2021)<br>462 samples, NP swab. Clinical sensitivities: Days ≤ 7: 88.5%; Ct ≤ 33: 92.4%; Ct ≤ 25: 97.8%; Clinical specificity: 99.2% |  |   |                           |   |                                   |
|  |  |                           | <i>Retrospective in vitro study</i>  |  |   |                           |   |                                   |
|  |  |                           | <i>Retrospective in vitro study</i>  | Sensitivity: 96.19 %, Specificity: 99.26 %<br>Nasal swab   | DE <sup>[2]</sup>                               | Nucleo-capsid protein     | Nasal swab  | 8 December 2021                   |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.26%   |  |   |                           |   |                                   |
| Nanjing Norman Biological Technology Co., Ltd. | Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold) | 2506                      | <i>Retrospective in vitro study</i>  | Clinical sensitivity: 91.13% (Saliva); 93.02% (Anterior Nasal); 93.21% (NP)<br>Clinical specificity: 93.02% (Anterior Nasal); 99.23% (Anterior Nasal); 99.29% (NP) | DE <sup>[2]</sup>                               | Nucleo-capsid protein     | Anterior nasal swab, Nasopharyngeal swab, Oropharyngeal swab<br><br><b>! Saliva</b> | 10 November 2021                  |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94% at Ct ≤ 25; Manufacturer specificity: 99.9%   |  |   |                           |   |                                   |

| Manufacturer                                   | RAT commercial name   | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>   | Included in EU common list since: |
|--|---|---------------------------|---|--|------------------------------|---------------------------|--|-----------------------------------|
| Nanjing Synthgene Medical Technology Co., Ltd. | SARS-COV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method) | 2164                      | <i>Retrospective in vitro study</i>   | Clinical sensitivity: 99.33%<br>Clinical specificity: 99.5%  | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasopharyngeal swab  | 21 January 2022                   |
|  |   |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%                      |  |                              |                           |  |                                   |
| NanoEntek                                      | FREND COVID-19 Ag   | 1420                      | <i>Retrospective in vitro study</i>   | 94.12% sensitivity<br>100% specificity<br>NP swab  | DE <sup>[2]</sup>            | Nucleo-protein            | Nasopharyngeal swab  | 10 May 2021                       |
|  |   |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%                        |  |                              |                           |  |                                   |
| NanoRepro AG                                   | NanoRepro SARS-CoV-2 Antigen Rapid Test   | 2200                      | <i>Retrospective in vitro study</i>   | 97.2 % sensitivity<br>98.4% specificity<br>Nasal/NP/OP swab  | DE <sup>[2]</sup>            | Nucleo-protein            | Anterior nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab | 14 July 2021                      |
|  |   |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 98.4%                     |  |                              |                           |  |                                   |
| Nantong Egens Biotechnology Co.,Ltd            | COVID-19 Antigen Rapid Test Kit   | 1573                      | <i>Retrospective in vitro study</i>   | sensitivity: 95.8 %, specificity: 99.5 %   | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab   | 10 February 2022                  |
|  |   |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%                      |  |                              |                           |  |                                   |
| NESAPOR EUROPA SL                              | MARESKIT COVID-19 ANTIGEN RAPID TEST KIT  | 2241                      | <i>Prospective clinical field study</i>   | Sensitivity: 95.24% (95% CI: 83.84% to 99.42%),<br>Specificity: 100% (95% CI: 97.22% to 100.00%)<br>Nasal swab | ES                           | Nucleo-protein            | Nasal swab   | 23 July 2021                      |
|  |   |                           | ES:<br>Independent validation study; Nasal test compared to nasal PCR. Sensitivity 95.24% (Ct<30), Specificity 100%.                            |  |                              |                           |  |                                   |
| Neo-nostics (Suzhou) Bioengineering Co., Ltd.  | COVID 19 Antigen Test Kit (Colloidal Gold Method)                               | 2608                      | <i>Retrospective in vitro study</i>   | Clinical Sensitivity 95.93 %<br>Clinical Specificity 99.19 %   | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab          | 10 February 2022                  |
|  |   |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.19%                     |  |                              |                           |  |                                   |
| New Gene (Hangzhou) Bioengineering Co., Ltd.   | COVID-19 Antigen Detection Kit  | 1501                      | <i>Retrospective in vitro study</i>   | 98% sensitivity<br>99.2% specificity<br>Nasal swab   | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab          | 16 June 2021                      |
|  |   |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 92,5% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.2% |  |                              |                           |  |                                   |

! Saliva, Sputum

| Manufacturer                                  | RAT commercial name                    | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>             | Included in EU common list since: |
|---|--|---------------------------|--|--|------------------------------|---------------------------|------------------------------------|-----------------------------------|
| NG Biotech                                    | Ninonasal                              | 1880                      | <i>Prospective clinical field study</i>  | Clinical sensitivity: 98%,<br>Clinical specificity: 99%  | FR                           | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab | 10 November 2021                  |
|   |  |                           | <b>FR:</b><br>Prospective validation study for NP and nasal swabs: NP sensitivity 89% (75/84) , specificity 99% (92/93). Nasal sensitivity 98% (125/128), specificity 99% (388/390)                |  |                              |                           |                                    |                                   |
| Novatech                                      | SARS-CoV-2 Antigen Rapid Test          | 1762                      | <i>Retrospective in vitro study</i>  | 95 % sensitivity<br>100% specificity<br>Nasal/ NP swab   | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab | 14 July 2021                      |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 100%  |  |                              |                           |                                    |                                   |
| Oncosem Onkolojik Sistemler San. ve Tic. A.S. | CAT                                    | 1199                      | <i>Retrospective in vitro study</i>  | 93.75% sensitivity<br>98.04% specificity<br>Nasal swab   | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab                         | 10 May 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 98,04%  |  |                              |                           |                                    |                                   |
| OSANG Healthcare Co., Ltd.                    | GeneFinder COVID-19 Ag Plus Rapid Test | 2741                      | <i>Prospective clinical field study</i>  | Clinical Sensitivity: 94%<br>(95% CI: 87.52% ~ 97.22%)<br>Clinical Specificity: 100%<br>(95% CI: 99.05% ~ 100.00%) | IT                           | Nucleo-capsid protein     | Nasopharyngeal swab                | 21 December 2021                  |
|   |  |                           | <b>IT:</b><br>Independent prospective evaluation study carried out in Hospital Pugliese Ciaccio, Italy. Sample type: NP swab; sample size: 100 pos., 400 neg.; Sensitivity: 94%; Specificity: 100% |  |                              |                           |                                    |                                   |
| PCL Inc.                                      | PCL COVID19 Ag Rapid FIA               | 308                       | <i>Prospective clinical field study</i>  | 94,92% sensitivity,<br>99,99% specificity  | DE <sup>[2]</sup> , FR       | Unknown                   | Nasopharyngeal Swab                | 10 May 2021                       |
|   |  |                           | <b>FR:</b><br>Validation study data: NP swabs, sensitivity 94.29% (33/35) and specificity 100% (70/70)   |  |                              |                           |                                    |                                   |
| PCL Inc.                                      | PCL COVID19 Ag Gold                    | 2243                      | <i>Prospective clinical field study</i>  | Clinical Sensitivity: 90.83 %<br>Clinical Specificity: 99.5 %  | FR                           | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab | 7 July 2021                       |
|   |  |                           | <b>FR:</b><br>Validation study data: 120 positive and 200 negative samples; sensitivity 92%, specificity: 100%   |  |                              |                           |                                    |                                   |



| Manufacturer                             | RAT commercial name  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>   | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>  | Included in EU common list since: |
|--|--|---------------------------|---|---|------------------------------|---------------------------|---|-----------------------------------|
| PerGrande Bio Tech Development Co., Ltd. | SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromato-graphic Assay) | 2116                      | <i>Retrospective in vitro study</i>   | 94.28% sensitivity<br>99.11% specificity<br>NP/Nasal/OP swab  | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab                                   | 10 May 2021                       |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.11%                     |   |                              |                           |   |                                   |
| Pierenkemper GmbH                        | (SARS-CoV-2) Antigen Rapid Test COVIDENT (SWAB) COVID-19                       | 2672                      | <i>Retrospective in vitro study</i>   | Clinical Sensitivity 99.27 %<br>Clinical Specificity 100 %  | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Anterior nasal swab, Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab, Throat swab | 4 March 2022                      |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%                       |   |                              |                           |   |                                   |
| Precision Biosensor Inc.                 | Exdia COVI-19 Ag   | 1271                      | <i>Retrospective in vitro study</i>   | 93.9% sensitivity<br>98% specificity<br>NP swab   | DE <sup>[2]</sup>            | Unknown                   | Nasopharyngeal swab   | 17 February 2021                  |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.3%                      |   | CH                           |                           |   |                                   |
| Prognosis Biotech                        | Rapid Test Ag 2019-nCov  | 1495                      | <i>Retrospective in vitro study</i>   | Clinical Sensitivity: 95.56 %<br>Specificity: 99,58%<br>Nasal swab  | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab  | 7 July 2021                       |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,58%                    |   |                              |                           |   |                                   |
| Qingdao Hightop Biotech Co. Ltd          | SARS-CoV-2 Antigen Rapid Test (Immunochromatography)                           | 1341                      | <i>Retrospective in vitro study</i>   | 98.04% sensitivity<br>100% specificity<br>Nasal, NP, OP swab  | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab                                   | 17 February 2021                  |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.75% |   |                              |                           |   |                                   |
| Qingdao Hightop Biotech Co., Ltd.        | SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test                                      | 2754                      | <i>Retrospective in vitro study</i>   | Clinical Sensitivity: 100 % (SARS-CoV-2 at Ct lower or equal to 25)<br>Clinical Specificity: 99.75 % (SARS-CoV-2) | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasopharyngeal swab   | 21 December 2021                  |
|  |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.75% |   |                              |                           |   |                                   |

| Manufacturer                  | RAT commercial name                  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup> | Completed validation studies                                    | SARS-CoV-2 Target protein | Specimen <sup>16</sup>             | Included in EU common list since: |
|-------------------------------|--------------------------------------|---------------------------|---|---|---|---------------------------|------------------------------------|-----------------------------------|
| Quidel Corporation            | Sofia SARS Antigen FIA               | 1097                      | <i>Prospective clinical field studies</i>   | 96.7% sensitivity<br>100% specificity<br>NP/Nasal swab            | DE <sup>[2]</sup> , NL <sup>[5]</sup> ,<br>PT<br><br>CH         | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab | 17 February 2021                  |
|                               |                                      |                           | <b>FR:</b><br>Validation study data: NP swabs sensitivity 84,44% (76/90), specificity 99,19 (491/495)<br><b>NL:</b><br>Independent prospective clinical field study in symptomatic (n=733, PCR positive 144); NP swab; sensitivity overall: 84.0%, sensitivity Ct<30: 90.1%, sensitivity Ct<25: 92.5%; specificity overall: 99.8%.<br><b>PT:</b><br>80 samples from symptomatic individuals (27 PCR positive and 53 negative by PCR) were tested. Sensitivity 70% (95%IC50-86); specificity 100% (95%IC 93-100). TCID50/ml 0,68x 102 and CT<25. |   |   |                           |                                    |                                   |
|                               |                                      |                           | <i>Retrospective in vitro study</i>   |   |   |                           |                                    |                                   |
|                               |                                      |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 89% at Ct ≤ 25; Manufacturer specificity: 100%   |   |   |                           |                                    |                                   |
| Rapid Pathogen Screening, Inc | LIAISON® Quick Detect Covid Ag Assay | 2290                      | <i>Retrospective in vitro study</i>   | Sensitivity: 96.1%,<br>Specificity: 97%<br>NP and Nasal swab      | IT  | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab | 23 July 2021                      |
| Roche (SD BIOSENSOR)          | SARS-CoV-2 Rapid Antigen Test        | 1604                      | <i>Prospective clinical field study</i>   | 96.52% sensitivity<br>99.2% specificity<br>NP swab                | DE <sup>[2]</sup> , FI, NL,<br>PT, SE<br><br><a href="#">UK</a> | Nucleo-protein            | Nasopharyngeal swab                | 10 May 2021                       |
|                               |                                      |                           | <b>NL:</b><br>Independent prospective clinical field study in symptomatic (n=970, PCR positive 186); NP swab; sensitivity overall: 84.9%, sensitivity Ct≤30: 94.3%, sensitivity Ct≤25: 99.1%; specificity overall: 99.5%<br><b>SE:</b><br>Karolinska hospital evaluation of Lot QCO3020109. Patient samples: 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 43%, specificity 100%. Sensitivity Ct<25 = 80.5%.   |   |   |                           |                                    |                                   |

| Manufacturer | RAT commercial name | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>   | Completed validation studies                        | SARS-CoV-2 Target protein | Specimen <sup>16</sup>             | Included in EU common list since: |
|--------------|---------------------|---------------------------|--|---|---|---------------------------|------------------------------------|-----------------------------------|
|              |                     |                           | <i>Retrospective in vitro studies</i>  |   |   |                           |                                    |                                   |
|              |                     |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 89% at Ct ≤ 25; Manufacturer specificity: 99.68%   |   |   |                           |                                    |                                   |
|              |                     |                           | <i>Prospective clinical field studies</i>  |   |   |                           |                                    |                                   |
|              |                     |                           | <b>FIND evaluation</b><br><b>DE</b> (12 April 2021)<br>179 samples, nasal swab. Clinical sensitivities:<br>Days ≤ 7: 81.2%; Ct ≤ 33: 87.5%; Ct ≤ 25: 100%;<br>Clinical specificity: 99.3%<br><b>Brazil</b> (12 April 2021)<br>214 samples, nasal swab. Clinical sensitivities:<br>Days ≤ 7: 81.2%; Ct ≤ 33: 91.7%; Ct ≤ 25: 100%;<br>Clinical specificity: 99.3% | Clinical Sensitivity: 89.6 %<br>( Ct ≤ 30) 93.1 % (Ct ≤ 27)<br>Clinical Specificity: 99.1 %<br>Nasal swab | DE <sup>[2]</sup><br><br>Brazil, <a href="#">UK</a> | Nucleo-protein            | Nasal swab                         | 7 July 2021                       |
|              |                     |                           | <i>Retrospective in vitro study</i>  |   |   |                           |                                    |                                   |
|              |                     |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 89.6% at Ct ≤ 30; Manufacturer specificity: 99.1%  |   |   |                           |                                    |                                   |
|              |                     |                           | <i>Retrospective in vitro study</i>  |   |   |                           |                                    |                                   |
|              |                     |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.42%  | 97.27% sensitivity<br>99.42% specificity<br>Nasal swab  | DE <sup>[2]</sup>                                   | Nucleo-protein            | Nasal swab                         | 17 February 2021                  |
|              |                     |                           | <i>Retrospective in vitro study</i>  |   |   |                           |                                    |                                   |
|              |                     |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.44%  | 97.04% sensitivity<br>99.44% specificity Nasal swab   | DE <sup>[2]</sup>                                   | Nucleo-protein            | Nasal swab                         | 10 May 2021                       |
|              |                     |                           | <i>Retrospective in vitro study</i>  |   |   |                           |                                    |                                   |
|              |                     |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.1%   | Clinical Sensitivity: 98.4 %<br>Clinical Specificity: 98.1 %  | DE <sup>[2]</sup>                                   | Nucleo-capsid protein     | Nasal swab,<br>Nasopharyngeal swab | 21 December 2021                  |

| Manufacturer     | RAT commercial name                                     | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>          | Completed validation studies                             | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                                       | Included in EU common list since: |
|------------------|---|---------------------------|--|--|--|---------------------------|--|-----------------------------------|
| ScheBo Biotech   | ScheBo SARS CoV-2 Quick Antigen                         | 1201                      | <i>Retrospective in vitro study</i>  | 96.6% sensitivity (Ct ≤ 30)<br>99.00% specificity<br>NP/ OP swab           | DE <sup>[2]</sup>  | Nucleo-protein            | Nasopharyngeal swab,<br>Oropharyngeal swab<br><b>! Serum</b> | 16 June 2021                      |
|                  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 95% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99%  |  |  |                           |  |                                   |
| ScheBo Biotech   | ScheBo SARS CoV-2 Quick ANTIGEN (Colloidal Gold Method) | 2763                      | <i>Retrospective in vitro study</i>  | Clinical sensitivity: 96.12%<br>Clinical specificity: 99.49%               | DE <sup>[2]</sup>  | Nucleo-capsid protein     | Nasal swab   | 21 January 2022                   |
|                  |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.49%  |  |  |                           |  |                                   |
| SD Biosensor Inc | STANDARD Q COVID-19 Ag Test Nasal                       | 2052                      | <i>Prospective clinical field studies</i>  | Clinical Sensitivity: 97.12 %<br>Clinical Specificity: 100 %<br>Nasal swab | DE <sup>[2]</sup> , FI, FR<br>Brazil, <a href="#">UK</a> | Nucleo-protein            | Nasal swab   | 7 July 2021                       |
|                  |   |                           | <b>DE</b><br>146 symptomatic adults, 40 (27.4%) were RT-PCR-positive for SARS-CoV-2. Sensitivity with 85.0% (34/40; 95% CI 70.9-92.9) with professional testing. At high viral load (>7.0 log <sub>10</sub> SARS-CoV-2 RNA copies/ml), sensitivity was 96.6% (28/29; 95% CI 82.8-99.8) for professional testing.<br><b>FIND evaluation</b><br><b>DE</b> (12 April 2021)<br>179 samples, nasal swab. Clinical sensitivities: Days ≤ 7: 81.2%; Ct ≤ 33: 87.5%; Ct ≤ 25: 100%; Clinical specificity: 99.3%<br><b>Brazil</b> (12 April 2021)<br>214 samples, nasal swab. Clinical sensitivities: Days ≤ 7: 81.2%; Ct ≤ 33: 91.7%; Ct ≤ 25: 100%; Clinical specificity: 99.3% |  |  |                           |  |                                   |

| Manufacturer      | RAT commercial name        | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup> | Completed validation studies  | SARS-CoV-2 Target protein | Specimen <sup>16</sup> | Included in EU common list since: |
|-------------------|----------------------------|---------------------------|---|---|---|---------------------------|------------------------|-----------------------------------|
| SD BIOSENSOR Inc. | STANDARD F COVID-19 Ag FIA | 344                       | <i>Prospective clinical field studies</i>   | 94,09% sensitivity<br>98.52% specificity NP swab                  | DE <sup>[2]</sup> , IT, NL <sup>[5]</sup> , DK<br><br>Brazil, CH, India, UK | Nucleo-protein            | Nasopharyngeal swab    | 17 February 2021                  |
|                   |                            |                           | <p><b>NL</b><br/>Independent prospective clinical field study in symptomatic (n=628, PCR positive 118); NP swab; sensitivity overall: 78.0%, sensitivity Ct&lt;30: 84.4%, sensitivity Ct&lt;25: 90.3%; specificity overall: 99.6%</p> <p><b>FIND evaluation</b><br/><b>DE</b> (10 Dec 2020)<br/>676 samples, NP swab. Clinical sensitivities: Days ≤7: 81.2%; Ct ≤33: 75%; Ct ≤ 25: 100%; Clinical specificity: 96.9%</p> <p><b>Brazil</b> (10 Dec 2020)<br/>453 samples, NP swab. Clinical sensitivities: Days ≤7: 80.2%; Ct ≤33: 80.9%; Ct ≤ 25: 87.9%; Clinical specificity: 97.9%</p> <p><b>India</b> (25 June 2020)<br/>417 samples, NP swab. Clinical sensitivities: Days ≤7: 61.8%; Ct ≤33: 53.6%; Ct ≤ 25: 68.5%; Clinical specificity: 99.5%</p> |   |   |                           |                        |                                   |
|                   |                            |                           | <i>Retrospective in vitro study</i>   |   |   |                           |                        |                                   |
|                   |                            |                           | <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.52%</p>  |   |   |                           |                        |                                   |

| Manufacturer      | RAT commercial name                                  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup> | Completed validation studies  | SARS-CoV-2 Target protein | Specimen <sup>16</sup> | Included in EU common list since: |
|-------------------|--|---------------------------|--|---|---|---------------------------|------------------------|-----------------------------------|
| SD BIOSENSOR Inc. | STANDARD Q COVID-19 Ag Test                          | 345                       | <i>Prospective clinical field studies</i>  | 96.52% sensitivity<br>99.68% specificity<br>NP swab               | DE <sup>[2]</sup> , ES, IT, NL <sup>[5]</sup> , DK, PT<br><br>Brazil, CH, India, NO, UA, UK | Unknown                   | Nasopharyngeal swab    | 17 February 2021                  |
|                   |  |                           | <p><b>PT</b><br/>80 samples from symptomatic individuals (27 PCR positive and 53 negative by PCR) were tested. Sensitivity 70% (95%IC50-86); specificity 100% (95%IC 93-100). TCID50/ml 0,68x 10<sup>2</sup> and CT&lt;25.</p> <p><b>FIND evaluation</b><br/><a href="#">DE</a> (10 Dec 2020)<br/>1263 samples, NP swab. Clinical sensitivities: Days ≤7: 80%; Ct ≤33: 87.8%; Ct ≤25: 100%; Clinical specificity: 99.3%</p> <p><a href="#">Brazil</a> (10 Dec 2020)<br/>400 samples, NP swab. Clinical sensitivities: Days ≤7: 90.7%; Ct ≤33: 91.9%; Ct ≤25: 95.9%; Clinical specificity: 97.6%</p> <p><a href="#">CH</a> (10 Dec 2020)<br/>529 samples, NP swab. Clinical sensitivities: Days ≤7: 89.8%; Ct ≤33: 91.8%; Ct ≤25: 97.2%; Clinical specificity: 99.7%</p> <p><a href="#">India</a> (22 April 2021)<br/>334 samples, NP swab. Clinical sensitivities: Days ≤7: 58.3%; Ct ≤33: 65.5%; Ct ≤25: 89.4%; Clinical specificity: 97.3%</p> <p><a href="#">Peru</a> (22 April 2021)<br/>335 samples, NP swab. Clinical sensitivities: Days ≤7: 81.4%; Ct ≤33: 83.3%; Ct ≤25: 96.2%; Clinical specificity: 99.6%</p> |   |   |                           |                        |                                   |
|                   |  |                           | <i>Retrospective in vitro studies</i>  |   |   |                           |                        |                                   |
|                   |  |                           | <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 89% at Ct ≤25; Manufacturer specificity: 99.68%</p>   |   |   |                           |                        |                                   |
| SGA Medikal       | V-Chek SARS-CoV-2 Ag Rapid Test Kit (Colloidal Gold) | 1319                      | <i>Retrospective in vitro study</i>  | 96.6% sensitivity,<br>99.5% specificity, Nasal swab               | DE <sup>[2]</sup>   | Nucleo-protein            | Nasal swab             | 10 May 2021                       |
|                   |  |                           | <p><b>DE:</b><br/>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤25; Manufacturer specificity: 99,5%</p>  |   |   |                           |                        |                                   |

| Manufacturer                                       | RAT commercial name                              | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>   | Included in EU common list since: |
|--|--|---------------------------|--|--|------------------------------|---------------------------|--|-----------------------------------|
|  | V-Chek SARS-CoV-2 Rapid Ag Test (colloidal gold) | 1357                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,5%  | 96.60% sensitivity: 99.5% specificity, Nasal swab  | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab   | 7 July 2021                       |
| Shenzhen Ultra-Diagnostics Biotec Co., Ltd         | SARS-CoV-2 Antigen Test Kit                      | 2017                      | <i>Prospective clinical field study</i><br><b>SI:</b><br>Sensitivity in unselected symptomatic population: 86.4% (172 RAT pos. / 199 RT-PCR pos.), sensitivity of 97.8% at Ct≤25. Specificity: 99.1% (1972 RAT neg. / 1990 RT-PCR neg.), NP swab | Clinical Sensitivity: 95.33 % (Nasal), 95.48(NP)<br>Clinical Specificity: 99.16 % (Nasal), 99.61 % (NP)                                      | BE, SI                       | Nucleo-protein            | Nasal swab, Nasopharyngeal swab<br><b>! Saliva</b>                       | 10 May 2021                       |
| Shenzhen CAS-Envision Medical Technology Co., Ltd. | SARS-CoV-2-Antigen Rapid Detection Kit           | 2152                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.5%   | OP: Sensitivity: 98.1% 94.7%-99.4%), Specificity: 99.5% 97.0%-99.9%)<br>NP: Sensitivity: 98.1% 94.7%-99.4%), Specificity: 99.5% 97.0%-99.9%) | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Oropharyngeal swab; Nasopharyngeal swab                                  | 8 December 2021                   |
| Shenzhen Dymind Biotechnology Co., Ltd             | SARS-CoV-2 Antigen Test Kit (Colloidal Gold)     | 2415                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 96.58%  | Sensitivity: 96.58%, Specificity: 98.37%   | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab, Nasopharyngeal swab  | 20 October 2021                   |
| Shenzhen Huian Biosci Technology Co., Ltd.         | SARS-CoV-2 Antigen Test Kit (Colloidal Gold)     | 2414                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.1%   | NP/OP swab: Sensitivity: 95.0%, Specificity: 99.1%<br>Nasal swab: Sensitivity: 94.6%, Specificity: 99.1%                                     | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab  | 20 October 2021                   |
| Shenzhen Kisshealth Biotechnology Co., Ltd         | SARS-CoV-2 Antigen Test Kit (GICA)               | 1813                      | <i>Retrospective in vitro study</i><br><b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%   | NP swabs: Sensitivity: 96.43%, Specificity: 100%.<br>Nasal (Anterior) swabs: Sensitivity: 99.43%, Specificity: 99.23%.                       | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab | 20 October 2021                   |

| Manufacturer                               | RAT commercial name  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>   | Completed validation studies | SARS-CoV-2 Target protein                | Specimen <sup>16</sup>   | Included in EU common list since: |
|--|--|---------------------------|---|---|------------------------------|--|--|-----------------------------------|
| Shenzhen Lvshiyuan Biotechnology Co., Ltd. | Green Spring SARS-CoV-2 Antigen-Rapid test-Set                                 | 2109                      | <i>Retrospective in vitro study</i>   |   |                              |  |  |                                   |
|  |  |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%   | 96.43% sensitivity<br>100% specificity<br>NP/OP/Nasal swab  | DE <sup>[2]</sup>            | Nucleo-protein                           | Anterior nasal swab,<br>Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab<br><b>! Saliva</b> | 10 May 2021                       |
| Shenzhen Microprofit Biotech Co., Ltd      | SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)       | 1967                      | <i>Retrospective in vitro study</i>   |   |                              |  |  |                                   |
|  |  |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%   | Sensitivity: 92.93%<br>Clinical Specificity: 100 %<br>Nasal/NP/OP swab  | DE <sup>[2]</sup>            | Nucleo-protein                           | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab  | 7 July 2021                       |
| Shenzhen Microprofit Biotech Co., Ltd.     | SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay) | 1178                      | <i>Retrospective in vitro study</i>   |   |                              |  |  |                                   |
|  |  |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 100%   | Sensitivity: 86.3%,<br>Specificity: 100%<br>Nasal Swab  | DE <sup>[2]</sup>            | <b>Spike protein</b>                     | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab  | 23 July 2021                      |
| Shenzhen Microprofit Biotech Co., Ltd      | SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)                   | 1228                      | <i>Retrospective in vitro study</i>   |   |                              |  |  |                                   |
|  |  |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 100%   | Sensitivity: 93.46%,<br>Specificity: 100%   | DE <sup>[2]</sup>            | Nucleo-protein,<br><b>S protein (S1)</b> | Nasopharyngeal swab  | 8 December 2021                   |
| Shenzhen Reagent Technology Co.,Ltd.       | SARS-CoV-2 antigen IVD kit SWAB  | 2026                      | <i>Retrospective in vitro study</i>   |   |                              |  |  |                                   |
|  |  |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 98.1%  | Sensitivity: 95.23 %,<br>specificity: 98.71 %   | DE <sup>[2]</sup>            | Nucleo-capsid protein                    | Nasopharyngeal swab,<br>Oropharyngeal swab   | 20 October 2021                   |
| Shenzhen Watmind Medical Co., Ltd          | SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)                             | 1769                      | <i>Retrospective in vitro study</i>   |   |                              |  |  |                                   |
|  |  |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.12% | NP/OP swab: Sensitivity 95.15%, specificity 99.12%.<br>Nasal swab: Sensitivity: 91.51% for onset of symptoms < 7 days, specificity: 99.02%. | DE <sup>[2]</sup>            | Nucleo-capsid protein                    | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab  | 10 May 2021                       |
| Shenzhen Watmind Medical Co., Ltd          | SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)                        | 1768                      | <i>Retrospective in vitro study</i>   |   |                              |  |  |                                   |
|  |  |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,13% | Clinical Sensitivity: 97.83 % (CT ≤ 33); Clinical Sensitivity: 90.08 % (Ct ≤ 36); Specificity: 99,13%<br>Nasal swab                         | DE <sup>[2]</sup>            | Nucleo-protein                           | Nasal swab   | 7 July 2021                       |



| Manufacturer                      | RAT commercial name                                 | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>   | Completed validation studies                | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                              | Included in EU common list since: |
|-----------------------------------|---|---------------------------|---|---|---|---------------------------|---|-----------------------------------|
| Shenzhen YHLO Biotech Co., Ltd.   | GLINE-2019-nCoV Ag                                  | 1347                      | <i>Retrospective in vitro study</i>   | Nasal: Sensitivity: 97.37% (95%CI: 92.50% - 99.45%); Specificity: 99.25% (95%CI: 97.82% - 99.85%); NP: Sensitivity: 96.49% (95%CI: 91.26% - 99.04%); Specificity: 99.25% (95%CI: 97.82% - 99.85%) | DE <sup>[2]</sup>                           | Nucleo-capsid protein     | Nasal swab; Nasopharyngeal swab                     | 8 December 2021                   |
|                                   |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 99.85%                     |   |   |                           |   |                                   |
| Shenzhen Zhenrui Biotech Co., Ltd | Zhenrui <sup>®</sup> COVID-19 Antigen Test Cassette | 1574                      | <i>Retrospective in vitro study</i>   | 96% sensitivity<br>97% specificity<br>Nasal swab  | DE <sup>[2]</sup>                           | Nucleo-protein            | Nasal swab<br><b>! Saliva</b>                       | 10 May 2021                       |
|                                   |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 82% at Ct ≤ 25; Manufacturer specificity: 97%                        |   |   |                           |   |                                   |
| Sugentech, Inc.                   | SGTI-flex COVID-19 Ag                               | 1114                      | <i>Retrospective in vitro study</i>   | NP: 95,07% sensitivity<br>99,38% specificity<br>Nasal swab: 95,06% sensitivity<br>99,29% specificity  | DE <sup>[2]</sup>                           | Nucleo-capsid protein     | Nasopharyngeal swab, Nasal swab                     | 10 May 2021                       |
|                                   |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.0% |   |   |                           |   |                                   |
| SureScreen Diagnostics            | SARS-CoV-2 Rapid Antigen Test Cassette              | 2297                      | <i>Retrospective in vitro study</i>   | Sensitivity: 96.1%,<br>Specificity: 99%   | DE <sup>[2]</sup><br><br><a href="#">UK</a> | Nucleo-protein            | Anterior nasal swab<br><b>! Other</b>               | 20 October 2021                   |
|                                   |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%                       |   |   |                           |   |                                   |
| Surge Medical Inc.                | COVID-19 Antigen Test Kit                           | 1942                      | <i>Retrospective in vitro study</i>   | Clinical sensitivity: 93.33%<br>Clinical specificity: 97.69%  | DE <sup>[2]</sup>                           | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab, Oropharyngeal swab | 21 January 2022                   |
|                                   |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 97.69%                    |   |   |                           |   |                                   |
| TODA PHARMA                       | TODA CORONADIAG Ag                                  | 1466                      | <i>Prospective clinical field study</i>   | 98.6% sensitivity<br>Nasal swab   | DE <sup>[2]</sup> , FR                      | Nucleo-protein            | Nasal swab, Nasopharyngeal swab                     | 10 May 2021                       |
|                                   |   |                           | <b>FR:</b><br>Validation data: NP swabs, sensitivity : 96,1-100%, specificity 99,2-100%   |   |   |                           |   |                                   |
|                                   |   |                           | <i>Retrospective in vitro study</i>   |   |   |                           |   |                                   |
|                                   |   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%                      |   |   |                           |   |                                   |

| Manufacturer                                      | RAT commercial name               | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup> | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>16</sup>  | Included in EU common list since: |
|---|-----------------------------------|---------------------------|--|---|------------------------------|---------------------------|---|-----------------------------------|
| Triplex International Biosciences(China) CO.,LTD. | SARS-CoV-2 Antigen Rapid Test Kit | 2074                      | <i>Retrospective in vitro study</i>  | 98.51% sensitivity<br>99.91% specificity<br>Nasal/OP/NP swab      | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab<br>! Saliva                       | 16 June 2021                      |
|   |                                   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 92,5% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.91% |   |                              |                           |   |                                   |
| Triplex International Biosciences(China) CO.,LTD. | SARS-CoV-2 Antigen Rapid Test Kit | 1465                      | <i>Retrospective in vitro study</i>  | 98.51 % sensitivity<br>100% specificity Nasal swab                | DE <sup>[2]</sup>            | Nucleo-protein            | Nasal swab  | 14 July 2021                      |
|   |                                   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%                        |   |                              |                           |   |                                   |
| TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.        | INFO Covid-19 Ag Test             | 2584                      | <i>Retrospective in vitro study</i>  | Clinical Sensitivity: 92.71 %<br>Clinical Specificity: 99.54 %    | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab  | 21 December 2021                  |
|   |                                   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99.54%                       |   |                              |                           |   |                                   |
| TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.        | Covid-19 Ag Test                  | 1689                      | <i>Retrospective in vitro study</i>  | Clinical sensitivity: 92.71%<br>Clinical specificity: 99.54%      | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab,<br>Nasopharyngeal swab,   | 21 January 2022                   |
|   |                                   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99.54%                       |   |                              |                           |   |                                   |
| TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.        | RAPIDAN TESTER Covid-19 Ag Test   | 1751                      | <i>Retrospective in vitro study</i>  | Clinical sensitivity: 92.71%<br>Clinical specificity: 99.54%      | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab  | 21 January 2022                   |
|   |                                   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99.54%                       |   |                              |                           |   |                                   |
| TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.        | TOYO Covid-19 Ag Tes              | 1722                      | <i>Retrospective in vitro study</i>  | Clinical sensitivity: 92.71%<br>Clinical specificity: 99.54%      | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab,<br>Nasopharyngeal swab,   | 21 January 2022                   |
|   |                                   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99.54%                       |   |                              |                           |   |                                   |
| Vitrosens Biotechnology Co., Ltd                  | RapidFor SARS-CoV-2 Rapid Ag Test | 1443                      | <i>Retrospective in vitro study</i>  | 97.30% sensitivity<br>99.05% specificity                          | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Anterior nasal swab, Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab, Throat swab | 10 May 2021                       |
|   |                                   |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.05%  |   |                              |                           |   |                                   |

| Manufacturer                                      | RAT commercial name                                  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies            | SARS-CoV-2 Target protein | Specimen <sup>16</sup>   | Included in EU common list since: |
|---|--|---------------------------|--|--|---|---------------------------|--|-----------------------------------|
| VivaChek Biotech (Hangzhou) Co., Ltd, China       | Verino Pro SARS CoV 2 Ag Rapid Test                  | 2100                      | <i>Retrospective in vitro study</i>  | Clinical Sensitivity: 97.42%<br>Clinical Specificity: 99.9%  | DE <sup>[2]</sup>                       | Nucleo-protein            | Nasal swab, Nasopharyngeal swab, Oropharyngeal swab                      | 21 December 2021                  |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.9%  |  |   |                           |  |                                   |
| Wuhan EasyDiagnosis Biomedicine Co., Ltd.         | COVID-19 (SARS-CoV-2) Antigen-Test Kit               | 2098                      | <i>Retrospective in vitro study</i>  | 96.1% sensitivity<br>100% specificity<br>Nasal/OP/NP swab  | DE <sup>[2]</sup><br><a href="#">UK</a> | Nucleo-protein            | Nasal swab, Nasopharyngeal swab, Oropharyngeal swab                      | 10 May 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.26% |  |   |                           |  |                                   |
| Wuhan HealthCare Biotechnology Co. Ltd.           | SARS-CoV-2 Antigen Test Kit (Colloidal Gold)         | 2742                      | <i>Retrospective in vitro study</i>  | Clinical Sensitivity: 97.8 % (Nasal Swab)<br>Clinical Sensitivity: 96.7 % (NP Swab)<br>Clinical Specificity: 100 % (Nasal Swab)<br>Clinical Specificity: 100 % (NP Swab) | DE <sup>[2]</sup>                       | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab  | 4 March 2022                      |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 100%    |  |   |                           |  |                                   |
| Wuhan Life Origin Biotech Joint Stock Co., Ltd.   | SARS-CoV-2 Antigen Assay Kit (Immuno-chromatography) | 1773                      | <i>Retrospective in vitro study</i>  | 92.67% sensitivity Nasal swab  | DE <sup>[2]</sup>                       | <b>Unknown</b>            | Nasal swab   | 14 July 2021                      |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: %      |  |   |                           |  |                                   |
| Wuhan UNscience Biotechnology Co., Ltd.           | SARS-CoV-2 Antigen Rapid Test Kit                    | 2090                      | <i>Retrospective in vitro study</i>  | Sensitivity: 96.33%<br>Specificity: 99.57%<br>Nasal/NP/OP swab   | DE <sup>[2]</sup> , FR                  | Nucleo-protein            | Mid-turbinates swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab | 7 July 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,57% |  |   |                           |  |                                   |
| Wuxi Biohermes Bio & Medical Technology Co., Ltd. | SARS-CoV-2 Antigen Test Kit (Lateral Flow Assay)     | 2143                      | <i>Retrospective in vitro study</i>  | Sensitivity: 95.31 %,<br>Specificity: 98.02 %  | DE <sup>[2]</sup>                       | Nucleo-protein            | Nasopharyngeal swab, Oropharyngeal swab                                  | 20 October 2021                   |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.02% |  |   |                           |  |                                   |
| Xiamen AmonMed Biotechnology Co., Ltd             | COVID-19 Antigen Rapid Test Kit (Colloidal Gold)     | 1763                      | <i>Retrospective in vitro study</i>  | 93.2% sensitivity<br>99.55% specificity<br>Nasal swab  | DE <sup>[2]</sup>                       | Nucleo-protein            | Nasal swab   | 10 May 2021                       |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.55% |  |   |                           |  |                                   |

| Manufacturer                           | RAT commercial name                                       | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies                    | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                                    | Included in EU common list since: |
|--|---|---------------------------|--|--|---|---------------------------|---|-----------------------------------|
| Xiamen Boson Biotech Co. Ltd           | Rapid SARS-CoV-2 Antigen Test Card                        | 1278                      | <i>Retrospective in vitro study</i>  | NP swab<br>96.08% sensitivity<br>99.14% specificity<br>Nasal swab<br>96.19% sensitivity<br>99.2% specificity<br>OP swab<br>96.23% sensitivity<br>99.2% specificity | DE <sup>[2]</sup><br><br>CH, <a href="#">UK</a> | Nucleo-capsid protein     | Nasopharyngeal swab,<br>Oropharyngeal swab, Nasal swab    | 17 February 2021                  |
|  |   |                           | DE:<br>Positive evaluation by Paul-Ehrlich-Institut (PEI):<br>Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.03% |  |   |                           |   |                                   |
| Xiamen Wiz Biotech Co., Ltd            | SARS-CoV-2 Antigen Rapid Test                             | 1456                      | <i>Retrospective in vitro study</i>  | 96.3% sensitivity,<br>100% specificity Nasal swab  | DE <sup>[2]</sup>                               | Nucleo-protein            | Nasal swab<br><b>! Other</b>                              | 10 May 2021                       |
|  | SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)            | 1884                      | <i>Retrospective in vitro study</i>  | 95.91% sensitivity<br>100% specificity<br>Nasal swab   | DE <sup>[2]</sup>                               | Nucleo-capsid protein     | Anterior nasal swab                                       | 10 May 2021                       |
| Zhejiang Anji Saianfu Biotech Co., Ltd | AndLucky COVID-19 Antigen Rapid Test                      | 1296                      | <i>Retrospective in vitro study</i>  | 95.8% sensitivity,<br>99% specificity,<br>Nasal swab   | DE <sup>[2]</sup>                               | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab,<br>Oropharyngeal swab | 10 May 2021                       |
| Zhejiang Anji Saianfu Biotech Co., Ltd | reOpenTest COVID-19 Antigen Rapid Test                    | 1295                      | <i>Retrospective in vitro study</i>  | 95.8% sensitivity,<br>99% specificity,<br>Nasal swab   | DE <sup>[2]</sup>                               | Nucleo-protein            | Nasal swab,<br>Nasopharyngeal swab                        | 10 May 2021                       |
| Pantest SA                             | Pantest Coronavirus Ag (Nasopharyngeal Swab)              | 2271                      | <i>Retrospective in vitro study</i>  | sensitivity: 95,70%,<br>specificity: 99,10%  | DE <sup>[2]</sup>                               | Nucleo-capsid protein     | Nasopharyngeal swab                                       | 8 December 2021                   |
| Zhejiang GENE SCIENCE Co., Ltd         | Novel Coronavirus (COVID-19) Antigen Detection Kit (Swab) | 2684                      | <i>Retrospective in vitro study</i>  | OP: Sensitivity: 95.65%,<br>Specificity: 99.17%<br>NP: Sensitivity: 94.58%,<br>Specificity: 98.73%   | DE <sup>[2]</sup>                               | Nucleo-capsid protein     | Oropharyngeal swab;<br>Nasopharyngeal swab                | 8 December 2021                   |

| Manufacturer                              | RAT commercial name                                  | Device ID # <sup>14</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i> <sup>15</sup>  | Completed validation studies            | SARS-CoV-2 Target protein | Specimen <sup>16</sup>                       | Included in EU common list since: |
|---|--|---------------------------|--|--|---|---------------------------|--|-----------------------------------|
| Zhuhai Encode Medical Engineering Co.,Ltd | ENCODE SARS-COV-2 Antigen Rapid Test Device          | 1902                      | <i>Retrospective in vitro study</i>  | Throat swab/Nasal Swab: Sensitivity 96.49%, Specificity 100%<br>Anterior Swab: Sensitivity 94.74%, Specificity: 100% | DE <sup>[2]</sup><br><a href="#">UK</a> | Nucleo-capsid protein     | Anterior nasal swab, Nasal swab, Throat swab | 20 October 2021                   |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 100%  |  |   |                           |  |                                   |
| Zhuhai Lituo Biotechnology Co., Ltd.      | COVID-19 Antigen Detection Kit (Colloidal Gold)      | 1957                      | <i>Retrospective in vitro study</i>  | 96.12% sensitivity Nasal swab (CT≤33); 99.59% sensitivity NP swab; 100% specificity Nasal swab (CT≤33)               | DE <sup>[2]</sup>                       | Nucleo-protein            | Nasal swab, Nasopharyngeal swab              | 14 July 2021                      |
|   |  |                           | <b>DE:</b><br>Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%   |  |   |                           |  |                                   |
| Zybio Inc.                                | SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method) | 2201                      | <i>Prospective clinical field study</i>  | Clinical Sensitivity 97.87 %<br>Clinical Specificity 99.62 %   | SI                                      | Nucleo-capsid protein     | Anterior nasal swab                          | 4 March 2022                      |
|   |  |                           | <b>SI:</b><br>Independent prospective study by a public hospital, 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%. |  |   |                           |  |                                   |

*Notes:*

[1] FR: Reference to validation study (not specifying which specific RAT is being recommended or was tested in practice): [https://www.has-sante.fr/upload/docs/application/pdf/2020-10/synthese\\_tests\\_antigeniques\\_vd.pdf](https://www.has-sante.fr/upload/docs/application/pdf/2020-10/synthese_tests_antigeniques_vd.pdf)

[2] DE: Rapid antigen tests that have completed practical validation studies in Germany: See: [https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/evaluierung-sensitivitaet-sars-cov-2-antigentests-04-12-2020.pdf?\\_\\_blob=publicationFile&v=43](https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/evaluierung-sensitivitaet-sars-cov-2-antigentests-04-12-2020.pdf?__blob=publicationFile&v=43)

[3] SE: Smaller evaluations ongoing in some of the regions.

[4] BE: In the clinical performance study performed in three different clinical laboratories during the ascendant phase of the epidemiological curve, we found an overall sensitivity and specificity of 57.6 and 99.5%, respectively with an accuracy of 82.6%.

[5] NL: Collected validation data from accredited laboratories in the Netherlands. The report includes evaluations of various RAT that labs performed at their own initiative. <https://lci.rivm.nl/antigeensneltesten>

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

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

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

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

As agreed by Member States on 10 February 2022

| Manufacturer               | RAT commercial name                                 | Device ID # <sup>17</sup> | Clinical performance<br><i>As reported by independent validation studies</i>  | Clinical performance<br><i>Data by manufacturer</i>  | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>18</sup>          | Included in EU common list since: |
|----------------------------|---|---------------------------|---|--|------------------------------|---------------------------|---------------------------------|-----------------------------------|
| DIASORIN                   | LIAISON SARS-CoV-2 Ag assay                         | 1960                      | <i>Prospective clinical field studies</i>   |  |                              |                           |                                 |                                   |
|                            |   |                           | <p><b>BE:</b><br/>Independent prospective study (random selection), symptomatic and asymptomatic (n=414, PCR positive = 204, PCR negative = 210), NP swab; sensitivity Ct&lt;35: 73.4%, sensitivity Ct&lt;25: 96.4%; specificity: 100%</p> <p><b>FR:</b><br/>Independent prospective study, symptomatic and asymptomatic (n=378, PCR positive = 46), NP swab; overall sensitivity: 84.8%, sensitivity Ct&lt;25 100%; specificity: 99.4%</p> <p><b>IT:</b><br/>Independent prospective study, asymptomatic (n=1075, PCR positive = 23), NP swab; sensitivity Ct&lt;30 90.5%; specificity: 99.8%</p> <p><b>NL :</b><br/>Independent field study, mainly symptomatic individuals (n=980, PCR positive n=98), NP+OP swab; sensitivity overall 82.7%, sensitivity Ct&lt;30: 91.9%; specificity overall: 99.1%.</p> | <p>Nasal Swab:<br/>Sensitivity: 99/101 (98.0%, 95% CI: 93.1 – 99.5%).<br/>Specificity: 210/211 (99.5%, 95% CI: 97.4 – 99.9%).</p> <p>NP Swabs:<br/>Sensitivity: 108/109 (99.1%, 95% CI: 95.0 – 99.8%).<br/>Specificity: 295/299 (98.7%, 95% CI: 96.6 – 99.5%).</p> | BE, FR, IT, NL               | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab | 20 October 2021                   |
| Ortho Clinical Diagnostics | VITROS Immunodiagnostic Products SARS-CoV-2 Antigen | 1200                      | <p><i>Prospective clinical field studies</i></p> <p><b>BE:</b><br/>Independent prospective study: 80 positive NP samples (sensitivity 100%), 108 negative samples (specificity 100%).</p>   | <p>Clinical Sensitivity 95 % (CI: 92.0% - 100%)<br/>Clinical Sensitivity 98 % (95% CI: 92.2–99.4%)<br/>Clinical Specificity</p>  | BE, FR                       | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab | 10 February 2022                  |

<sup>17</sup> As registered in and used by the JRC database, see: <https://covid-19-diagnostics.jrc.ec.europa.eu/>.

<sup>18</sup> The information included in this column is based on the information provided by manufacturers to the JRC database.

| Manufacturer           | RAT commercial name         | Device ID # <sup>17</sup> | Clinical performance<br><i>As reported by independent validation studies</i>   | Clinical performance<br><i>Data by manufacturer</i>  | Completed validation studies | SARS-CoV-2 Target protein | Specimen <sup>18</sup>                              | Included in EU common list since: |
|------------------------|-----------------------------|---------------------------|--|--|------------------------------|---------------------------|---|-----------------------------------|
|                        |                             |                           | <p><b>FR:</b><br/>Independent prospective study: 107 positive NP samples with Ct<sub>≤</sub>35 (sensitivity 93,5% for Ct<sub>≤</sub>35), 1614 negative samples (specificity 100%).</p> <p style="text-align: center;"><i>Retrospective in vitro study</i></p> <p>A retrospective study including 134 positive NP samples with Ct&lt;35 (sensitivity 82,8% for Ct<sub>≤</sub>35).</p> | 98.9 % (95% CI: 96.3-99.9%)  |                              |                           |   |                                   |
| Roche Diagnostics GmbH | Elecsys® SARS-CoV-2 Antigen | 2156                      | <p style="text-align: center;"><i>Prospective clinical field study</i></p> <p><b>DE:</b><br/>Total N: 3139 (2747 negative, 392 positive) Germany participated in the validation. Roche coordinated and performed partially the data analysis. Relative specificity overall 99.9%; relative sensitivity (n=390) overall 92.5% (CT&lt;26).</p>   | <p>Sensitivity:<br/>NP/OP: 94.5 % (95% CI: 90.4-97.2);<br/>Nasal swabs: 96.8% (95% CI: 88.8-99.6%)<br/>Specificity: 99.9% (95 % CI: 99.6-100%)</p> | DE <sup>[2]</sup>            | Nucleo-capsid protein     | Nasal swab, Nasopharyngeal swab, Oropharyngeal swab | 20 October 2021                   |