



## Instructions for using SARS-CoV-2 rapid antigen tests in work collectives

### Warning

- The procedure is potentially infectious!
- The rapid antigen test is not designed to be used as a basis for diagnosing or issuing certificates.
- The rapid antigen test provides the most reliable results when the individual has just fallen ill and the viral load in the body is at its highest, meaning within five days after first developing symptoms. The test is less sensitive when the viral load is low, prior to the first symptoms appearing and when the patient has begun to recover.
- A negative rapid antigen test result does not exempt the individual from any self-isolation or quarantining requirements.
- In the event of experiencing any symptoms, the individual must immediately contact their family physician, irrespective of their rapid antigen test result.

The target group for these instructions are those individuals who are conducting testing procedures but who are not healthcare professionals.

### Who should be tested with the rapid antigen test?

**Asymptomatic individuals** in the case of regular testing (two or three times a week) for the early detection of any infection:

- students, teachers, kindergarten teachers, and other related staff, work collectives (including providers of critical services);
- in enclosed institutions (such as prisons, Defence Force bases, care homes, etc).

As the sensitivity of the rapid antigen tests is lower when compared to the sensitivity levels of the RT-PCR test, the tests must be carried out regularly, two or three times a week in the case of negative results being achieved.

### **1. Selecting a rapid antigen test**

It is advisable to choose one of those rapid antigen tests which has been verified within European Union member states. This guarantees that the test is reliable within the ranges which have been declared by the manufacturer.

The [Health Security Committee's](#) list of tests which have been approved in at least three countries (as of 17 February 2021):

- Abbott Rapid Diagnostics, Panbio™ COVID-19 Ag Rapid Test
- AMEDA Labordiagnostik GmbH, AMP Rapid Test SARS-CoV-2 Ag
- Becton Dickinson, BD Veritor System for the Rapid Detection of SARS-CoV-2
- Beijing Lepu Medical Technology, SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)
- BIOSYNEX SWISS SA, BIOSYNEX COVID-19 Ag BSS



- CerTest Biotect SL, CerTest SARS-CoV-2 CARD TEST
- Hangzhou Clongene Biotech, Clungene COVID-19 Antigen Rapid Test Kit
- Healgen Scientific Limited, Coronavirus Ag Rapid Test Cassette (Swab)
- LumiraDX UK Ltd, LumiraDx SARS-CoV-2 Ag Test
- Nal von Minden GmbH, NADAL COVID-19 Ag Test
- Quidel Corporation, Sofia 2 SARS Antigen FIA
- SD BIOSENSOR Inc, Roche, STANDARD F COVID-19 Ag FIA
- SD BIOSENSOR Inc, Roche, STANDARD Q COVID-19 Ag Test
- Siemens Healthineers, CLINITEST Rapid COVID-19 Antigen Test
- Xiamen Boson Biotech Co, Rapid SARS-CoV-2 Antigen Test card
- Zhejiang Orient Gene Biotech Co Ltd, Coronavirus Ag Rapid Test Cassette (Swab)

There is no verified information available about any other tests, and the performance of such tests can therefore not be relied upon.

## **2. Suitable samples for testing**

Each manufacturer must specify on the packaging leaflet for which types of samples their test has been designed and approved. The accuracy of the test result cannot be guaranteed in the case of using a sample for which the test has not been designed.

Samples must be collected by using a process which follows the manufacturer's instructions. Some techniques which may be used for the collection of different types of samples have also been described in an annexe to these instructions (Annexe 1).

## **3. The precautions which must be taken during sampling**

All infection prevention measures must be taken during the collection of samples in order to prevent any spread of the infection as a result of the rapid testing process.

- A separate room must be chosen for collecting samples. This room should not be used for eating, but must be well-ventilated, and all surfaces in the room must be easy to clean and disinfect.
- Prior to commencing sampling, the individual who is conducting testing must verify that the packaging for the test is undamaged, that the test itself is intact, and that the test has been stored in conditions which are compliant with the manufacturer's instructions as provided on the packaging.
- No unmasked or unauthorised persons may be present during the sampling process.
- The instructions which have been supplied with the packaging must be read first.
- Make sure that you have everything that is needed for testing within reach. Do not open the sampling swab packaging.
- Label all samples with the names or initials of all individuals who have been tested (the latter option is to ensure anonymity), or in any other manner which makes it possible to connect the samples with the individuals who have provided those samples.



- The individual who is collecting the samples must always use personal protective equipment: a respirator (FFP2), a facial shield or goggles, a plastic apron, and gloves.
- The individual who is collecting the samples must put on a new pair of gloves and sanitise their hands after collecting each sample.
- The test is supplied with instructions which aid in interpreting the results. The waiting time which has been specified by the manufacturer must be observed before interpreting the results.
- Any equipment which is being used for sampling and the tests themselves must be collected in a bag or container which can be sealed, in order to make sure that third parties will not have access to potentially infectious materials, and that such bagged items may then be disposed of alongside domestic waste.
- All surfaces must be cleaned and disinfected after testing.
- The person who conducted the testing process must remove their plastic apron, gloves, facial shield and/or goggles and, finally, their respirator, before sanitising their hands, and then putting on a surgical mask.

#### **4. Procedure for a positive test result**

- **If the test result is positive or unclear.** The individual who provided the sample must self-isolate and contact their family physician so that they can book an RT-PCR test to confirm their result.
- **If the test result is negative.** If the individual does not have any symptoms, they may carry on with their normal routine, but must continue to use personal protective equipment (a mask). In order to ensure maximum confidence, the tests should be repeated up to two or three times a week.

#### **Bibliography:**

1. Guidelines for COVID-19 testing and the quarantining of air travellers. Addendum to the COVID-19 Aviation Health Safety Protocol. European Centre for Disease Prevention and Control 02.12.2020.
2. A common list of COVID-19 rapid antigen tests, including those for which test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates. Agreed by the Health Security Committee. European Commission Directorate-General for Health and Food Safety.
3. Options for the use of rapid antigen tests for COVID-19 in the EU/EAA and UK. European Centre for Disease Prevention and Control 19.11.2020.
4. Antigen detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. World Health Organization 11.09.2020.
5. Interim Guidance for Antigen Testing for SARS-CoV-2. Updated 16 December 2020, Centres for Disease Control and Prevention.
6. Considerations on the use of self-tests for COVID-19 within the EU/EEA. European Centre for Disease Prevention and Control, 17.03.2021.



7. ECDC response on the use of self-tests for COVID-19 in the EU/EEA. European Centre for Disease Prevention and Control, 08.03.2021.



## Annexe 1. A description of the techniques which are used for the collection of different sampling formats

### Nasal swabs

The purpose: to collect from nasal discharge any infected epithelial cells from the nostril or cells which have been detached from the mucosa.

The patient should blow or clean their nose before the procedure if necessary.

1. The patient's head is tilted slightly backwards and a dry swab is led into the nostril, parallel with the palate, and tipped slightly upwards. The swab is entered between 1-2cm into the nostril in the case of children and 3-5cm into the nostril in the case of adults.
2. Then the swab is left in place for a few seconds to allow it to absorb surrounding nasal discharge. Next the swab is rotated under pressure against the inferior nasal concha in order to remove infected epithelial cells from the nasal mucosa.
3. The same procedure is repeated with the same swab in the other nostril.

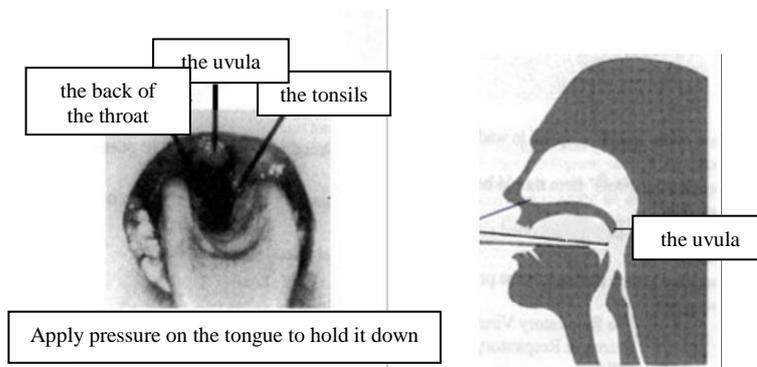
### Nasopharyngeal swabs

The purpose: to collect infected epithelial cells from the nose or cells which have detached into the pharyngeal secretion.



1. A swab on a thin, flexible shaft is led into the nostril until it reached an obstacle (the nasopharynx) and is left in place for a few seconds. Then the swab is slowly removed by rotating it in the nostril.
2. The same operation is repeated through the other nostril.
3. The shaft of the swab is snapped shorter and the swab is placed in a viral transportation medium.

### Nose swabs & throat swabs





1. The tip of the nose is lifted up and a dry swab is led into the nostril, parallel with the palate, and tipped slightly upwards. The swab is entered about 1-2cm into the nostril in the case of children and 3-5cm into the nostril in the case of adults.

Then the swab is left in place for a few seconds to allow it to absorb surrounding nasal discharge. Next the swab is rotated under pressure against the inferior nasal concha in order to remove infected epithelial cells from the nasal mucosa.

The same procedure is repeated with the same swab in the other nostril. The swab is removed from the nose, the shaft is snapped shorter, and the swab is placed in a viral transportation medium.

2. The patient is asked to open their mouth. The patient's tongue is held down with a spatula and another dry swab is used to collect culture from the back wall of the throat and tonsils, avoiding contact between the swab and the patient's palate, tongue, or the mucosa of the cheeks.

### Throat swabs

The purpose: to collect infected epithelial cells and secretions from the tonsils and from the back wall of the pharynx.

Attention: the procedure may trigger a vomiting reflex.

1. The individual who is providing the sample must be seated with their head tilted slightly backwards. The patient is asked to open their mouth.

2. The patient's tongue is held down with a spatula.

3. Both the tonsils and the back wall of the pharynx are swabbed (by moving the swab up and down and from left to right).

4. Touching the patient's tongue, palate, and the mucosa of the cheeks must be avoided during the withdrawal of the swab.

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