# Clungene® COVID-19 Antigen Rapid Test Cassette

Antigen (Ag) rapid tests complement IgG/IgM (antibody) rapid tests perfectly. On this page the most important information on the antigen test is summarized.

## **What is detected by an antigen rapid test?**

The substances recognized by the immune system and trigger the immune response are generally called antigens. An antigen test detects **directly of the presence of SARS-CoV-2**. This aspect is common with the PCR test. However, antigen tests detect **a specific protein of the virus**, not the RNA of it.

It must be pointed out that the virus antigen is present in a detectable amount **in the early phase of the infection** – antigen tests are thus the most reliable when they are used in the **first 7 days after the onset day** (when the symptoms first appear).

**What are the advantages of an antigen rapid test?**

* It is considerably cheaper than a PCR test
* Medical professionals can perform it at point-of-care (POC) sites, too, e.g. in a suitable room of a company
* No additional devices or disposables are needed for the test
* The results are obtained within 15–30 minutes

Although they are slightly less sensitive than PCR tests, they **can be used together with antibody tests**, since **they detect COVID-19 in the phase of the infection when antibody tests are not able to do so yet.**

## **Whom is an antibody test recommended?**

Assuming all the employees (or clients) are being screened systematically with antibody rapid tests at an institution, antigen tests mean the **next step of testing** in any case when performing a PCR test is not possible (e.g. lack of time or financial resources).

If a person has been tested positive with an antibody test, the antigen test **can be strengthen the diagnosis of an active infection**. In case of a confirmed new infection, with antigen tests **close contact can be tested** to discover whether they have got COVID-19, too in a cost-effective way. (Antibody tests often miss the early phase of the infection.)

Moreover, with an antigen test COVID-19 can be detected even if the antibody test has been negative but the person **shows the** (mild) **symptoms of the disease or have met confirmed COVID-19 people recently**.

Finally, having an antigen test made **is the best way of detection if it is crucial to get the result as quickly as possible – when there is no time for a PCR test**. For example, for employees having to start a business trip or at medical institution for patients whose treatment cannot be delayed.

An antigen test is **not recommended** if the symptoms have been persisting for a long time, and they cannot detect past infections. In these cases, an antibody test is to be performed.

## **How is an antigen test used?**

Nasopharyngeal or oropharyngeal swab has to be collected as specimen. Next, there are a couple of easy steps needed to be performed to prepare the specimen, which is placed on the test cassette. The result can be obtained in 15–30 minutes.

The test can be performed by a healthcare professional at any place, no additional devices or disposables are needed for that.

## **How can the results be interpreted?**

**There are two possible outcomes.**

#### **(1) Only the control line appears on the cassette – negative result.**

In this case the tested person is most likely not infected, the virus is not present in their body. However, a negative result cannot role out the infection totally, because

* it is possible that the viral protein is present in their system but its amount is so small that the antigen test cannot detect it;
* if the specimen collection or the text is performed incorrectly, there may be no viral protein in the sample.

***(2) Both the control line and the test line appear on the cassette – positive result.***

Since the SARS-CoV-2 nucleocapsid protein detected by the test is unique to this virus, the positive result means that the tested person is almost surely infected.

Infected people **must be isolated** even if they have no symptoms at all, because **they can infect others with the virus, too**.

**A summary of the possible test results**

|  |  |  |  |
| --- | --- | --- | --- |
| **Test image** |  |  |  |
| **Interpretation** | Negative | Positive | Invalid |
| **What does that mean?** | There is no detectable amount of virus (protein) in the tested person | The virus is present in the tested person | The appearance of the control line shows that the test has been performed well.If the control line fails to appear the test is invalid, regardless of any other lines. Repeat the test with a new cassette. |
| **Is the tested person infected?** | Unsure; if so, he/she must be in the late phase of the infection | Yes, he/she is in the early-to-mid phase of the infection |
| **Can the tested person infect others?** | If he/she is in the late phase of the infection, it is possible | Yes |
| **What to do?** | In case of typical symptoms confirm the result with another method | The person must be isolated, if possible, the result must be confirmed. |

## Code. C = control. Ag or T = antigen (or Test). If the Ag (T) line appears, the result is positive, regardless of the intensity of the line. The intensity of the Ag (T) line does not refer to the phase of the infection nor to the severity of the disease. This table is for reference only; it does not substitute the User’s Manual. This table cannot be used as a medical diagnostic guideline.

## **A video demonstration of the Clungene® COVID-19 Antigen Rapid Test Cassette**

## **Clungene® COVID-19 Rapid Test Cassette – References**

### **Further information and documentation**

Clungene® COVID-19 antigen rapid test cassette is registered in the European Union. Its DIMDI registration number is: DE/CA05/IvD-238321-1547-00. Its OGYÉI (National Institute of Pharmacy and Nutrition of Hungary) registration number is: HU/CA01=17106/20.

**Downloadable documents**

A brochure on the use of the product

User’s Manual (English)

WARNING. The information the antigen rapid test provides is for reference whether people are infected or not. Applying an antigen rapid test cannot be the sole base of diagnosing or excluding COVID-19. In case the findings of the contact tracing or the current symptoms refer to an infection, the result of the antigen rapid test has to be confirmed with other diagnostic methods, e.g. a molecular assay.

WARNING. This test is for professional use only. A short summary on the (Hungarian) legal background of diagnostic tests can be found [here](https://covid-19.hbs.hu/miert-nincsenek-a-piacon-otthoni-hasznalatra-is-alkalmas-covid-19-tesztek).