# Clungene® COVID-19 IgG/IgM Rapid Test Cassette

On this page, we summarized the most important information on the serology (IgG/IgM) rapid test.

## **What is being detected?**

**The serology rapid test detects two antibodies produced by the human body exclusively to the novel coronavirus. These are called immunoglobulin G and immunoglobulin M, their common abbreviation are IgG and IgM, respectively. These are present in the human blood.**

IgM appears in the body in a detectable quantity on the 5–8th day after the infection. As the immune system fights off the virus, the amount of IgM decreases. In most cases, 4 weeks after the infection it cannot be detected anymore.

In contrast, IgG starts being produced typically 2 weeks after the infection. Its quantity peaks in the end of the first month, decreases afterwards – but it is detectable for a long time. (Currently there are insufficient data available but it is suspected that IgG is present in the blood for at least several months, maybe years.)

**What are the advantages of an IgG/IgM 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
* Collecting the specimen is much easier and less uncomfortable than that of PCR (and antigen) test. The blood specimen needed for the essay can be taken from finger-prick, as well.
* The results are obtained within 15 minutes
* An antibody test is the only way to detect a past infection even if it was symptomless

These advantages make antibody tests the **most capable for regular and systematic screening**. Testing the employees of a company or institution every week can identify those who are infected. By isolating then the spread of SARS-CoV-2 can be slowed down, which helps prevent the shutdown caused by the pandemic.

**Antibody tests are the most reliable from the second week after the onset day** (when the symptoms first appear). Therefore, to **detect the early phase of COVID-19 infection antigen or PCR tests are recommended.**

## **Whom is the IgG/IgM rapid test recommended?**

**Since performing antibody tests is easy and cost-effective, this is the most effective tool for screening large amount of people** – for example, the employees of an office or a company, the students of a school. The regular screening can help trace whether the virus is or has been already present in the community.

Moreover, IgG/IgM rapid tests are recommended for those,

* who have been in contact with confirmed infected people recently,
* in whose family/close relatives an illness of influenza-like symptoms has been or is present,
* who experience the mild form of the characteristic symptoms of COVID-19,
* who have recently been abroad or to a place where the risk of infection has been high,
* who experienced the typical symptoms of COVID-19 caused by the novel coronavirus and think they already came through the disease in the past – these people might be immune to the virus presently.

Rapid tests are **not recommended** for those who has had high temperature, severe cough or general sickness (may be related to COVID-19) in the last 7 days. In this case, voluntary quarantine, or – if the symptoms are severe – hospitalization is strongly recommended in order to ensure the convalescence. This also prevents the spreading of COVID-19.

## **How is the rapid test performed?**

**The blood specimen is being taken from finger prick or from the vein (used generally in blood-taking).** The test detects the presence of the antibodies in the blood (whole blood, serum or plasma). The interpretation of the results can take place on the spot or in a laboratory suitable for this process.

**No additional preparation is needed from the patient for having the test performed.**

## **How to interpret the results?**

**There are four possibilities.**

#### **(1) Neither IgM nor IgG is present in the specimen (IgM and IgG negative).**

This means that neither antibodies can be found in the blood in detectable quantity.

This can indeed happen because of the tested person is not infected, but that is not the only possibility.

* In case of a very early phase of the disease the production of IgM has not been started yet, therefore there is nothing to be detected.
* Also, some people who are already infected do not produce a detectable amount of IgM for some reason.

For these reasons, if someone with a negative test result shows the typical syndromes of COVID-19 and/or has been to a place with a high risk of infection, it is recommended to repeat the test in the future, or to confirm the result with another diagnostic method.

#### **(2) IgM is present in the specimen (IgM positive).**

It is very likely the sign of the infection. The virus appeared in the body 5–21 days before the testing since this antigen is usually detectable in this time range.

The typical syndromes of COVID-19 may be present or develop later. It is worth noting that the novel coronavirus does not always causes symptoms, but IgM positive people can still infect others. Therefore, the IgM positive have to be isolated immediately.

#### **(3) Both IgM and IgG are present (IgM and IgG positive).**

It is very likely the sign of the infection. The virus appeared in the body 14–28 before the testing since both antigens are usually detectable in this time range. (The exact amount of time may be different.)

The typical symptoms of COVID-19 have already developed by this time – if it has not happened, the tested person must have a symptomless infection.

Still, IgM+IgG positive people can infect others, therefore they must be isolated immediately.

#### **(4) IgG is present (IgG positive).**

The person has already fought off the infection, with or without symptoms.

According to our current knowledge this also means that the tested person has become immune to COVID-19. Should they get infected, their immune system fights off SARS-CoV-2 in maximum 1–2 days, with mild-to-no symptoms, in most cases.

However, they still can spread the virus. Whether SARS-CoV-2 is still present in their body, can be confirmed with a PCR or an antigen test. Should the virus be present, he/she must be isolated. If it is not present any more, he/she can return to work safely without the risk of infecting others.

**A summary of the possible results**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test image** |  |  |  |  |  |
| **Interpretation** | Negative | IgM positive | IgM and IgG positive | IgG positive | Invalid |
| **What does the result mean?** | Most likely, the person has not come across the virus so far | The person is in the early-to-mid phase of infection | The person is in the mid-phase of infection | The person is in the late phase of infection – or fought off the infection in the past | The appearance of the control line shows that the test has worked correctly. If the control line fails to appear, repeat the test with a new cassette regardless of any other lines appearing |
| **Can the person have symptoms?** | No | Yes, and they may become more severe later | Yes, but it is very unlikely that they will become more severe later | Yes, but if he/she has not had any symptoms so far, it is not likely they will have any later |
| **Can the person infect others?** | No | Yes | Most likely | Possible |
| **What to do?** | Nothing | Isolation and, if it is possible, the confirmation of the result with Ag or PCR test | Isolation and, if it is possible, the confirmation of the result with Ag or PCR test | Confirm the result with PCR test if it is possible – in case of a positive result, isolation, in case of negative, nothing to do |

## Code. C = Control; IgM = Immunoglobulin M; IgG = Immunoglobulin G. The appearance of any IgG or IgM lines refers to the presence of the antibody and has to be interpreted as a positive result (to the antibody in question) regardless of the intensity of the line(s).

## The intensity of the lines does not refer to the phase of the infection or 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 IgG/IgM Rapid Test Cassette**

[Videó helye]

The actual product might look different to the one appearing in the video.

## **Clungene® COVID-19 IgG/IgMTest 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-238321-1330-00. Its OGYÉI (National Institute of Pharmacy and Nutrition of Hungary) registration number is: HU/CA01/17106/20.

[User's Manual EN](https://covid-19.hbs.hu/web/content/489?unique=49ad4f2c6129696a6c44db8fdd68366ccfc4a15b&download=true)

[The diagnostic protocol of SmartBioma HU](https://covid-19.hbs.hu/web/content/709?unique=42a54df628361b8e6b407aa5f76c905c24817b61&download=true)

WARNING. COVID-19 IgG/IgM rapid test is to be qualified as a serological examination. The information it provides is for reference whether people are or have been infected or not. Applying an IgG/IgM 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).