YES OR NO

# CORONA-Test COVID-19 IgG/IgM



*Please read these instructions for use carefully before starting the test!*

**IMPORTANT! PLEASE NOTE THE INFORMATION IN THIS SECTION**
The YES or NO Corona-Test COVID-19 IgG/IgM does not detect the actual corona virus (in this manual also called SARS-CoV-2), but it detects the antibodies that the body produces against this virus. Anyone infected with the Corona virus does not show any (!) symptoms in the first days after infection, but can still infect other people and thus spread the virus further if quarantine and hygiene measures are not observed. After a few days (between 2 and 14 days, on average after 5-6 days), symptoms that remind one of an incipient flu (coughing, scratching of the throat, slight fever) begin to appear. At this point your immune system starts to actively fight the virus. For this purpose, so-called antibodies are formed which bind to the surface of SARS-CoV-2 and thus serve to fight the disease! Two types of these antibodies (so-called IgM and IgG antibodies) can be detected with a very high probability with the YES or NO Corona-Test COVID-19 IgG/IgM.
**Therefore, you should only perform the YES or NO Corona-Test COVID-19 IgG/IgM after the appearance of symptoms.**

**IN CASE OF A NEGATIVE RESULT PLEASE NOTE THE FOLLOWING**
If your IgM and IgG test is negative, there are two possible causes:
Either
**a. You have not been infected with the corona virus,**
or
**b. You may already be infected with the corona virus, but your body has not yet developed an appropriate immune response. In this case, you can still be infectious and infect other people.**
**Therefore, even if your result should be negative: Always comply with the hygiene measures and regulations of the authorities and the Robert Koch Institute. Keep your distance to your fellow human beings and only leave your home for necessary errands! To be on the safe side, you should perform a new test after 3 days!**

## Area of Application and Test Principle

Coronaviruses are enveloped RNA viruses that are widely distributed in humans, other mammals and birds and cause respiratory, intestinal, liver and neurological diseases. Seven types of coronavirus are known to cause human disease. Four viruses - 229E, OC43, NL63 and HKU1 - are widespread and typically cause cold symptoms in individuals with an intact immune system.[4] The three other strains - the severe acute respiratory syndrome coronavirus (SARS-CoV), the Middle East respiratory syndrome coronavirus (MERS-CoV) and the novel coronavirus (SARS-CoV-2), which first appeared in 2019 - are of animal origin and are associated with a sometimes fatal disease. IgG and IgM antibodies against SARS-CoV-2 can be detected 1-3 weeks after infection. After the immune system starts fighting the virus you will develop symptoms. Antibody levels rise rapidly within the first two weeks. Some patients with negative PCR results could nevertheless be classified as positive by antibody tests in the past. The combination of PCR test and antibody test significantly increases the sensitivity for the detection of patients. Antibody detection is therefore an important complement to PCR detection during the course of the disease, particularly in that it can provide information on whether the patient has fully recovered from the disease and is no longer infectious.
The YES or NO Corona-Test COVID-19 IgG/IgM COVID-19 IgG/IgM is an immunochromatographic solid phase assay in lateral flow format for the rapid, qualitative and differential detection of IgG and IgM antibodies against SARS-CoV-2 in human blood. This test provides only a preliminary result. Therefore, any positive sample of YES or NO Corona-Test COVID-19 IgG/IgM COVID-19 IgG/IgM must be confirmed with alternative test methods and clinical findings.
Use for in vitro diagnostic purposes only!
The YES or NO Corona-Test COVID-19 IgG/IgM COVID-19 IgG/IgM uses anti-human IgM antibodies (M line), anti-human IgG (G line) and goat anti-rabbit IgG antibodies (control line C) immobilised on a cellulose strip. The burgundy conjugate pad contains colloidal gold bound to SARS-CoV-2 antigens (SARS-CoV-2 conjugates) and rabbit anti-IgG-gold conjugates. When a blood sample and then the enclosed test buffer are added to the sample, IgM and/or IgG antibodies, if present, bind to the SARS-CoV-2 conjugates and form an antigen-antibody complex. This complex migrates along the cellulose membrane by capillary action. When the complex encounters the line of the corresponding immobilized antibody (anti-human IgM and/or anti-human IgG), the complex is captured and forms a burgundy-colored band indicating a positive result. The absence of a coloured band in the test region indicates a negative test result. As a procedural control, a coloured line in the control line region always changes from blue to red, indicating that the correct amount of sample fluid has been added and the membrane has been soaked.

## Materials Provided

1. 1 x sealed pouch with YES or NO Corona-Test COVID-19 IgG/IgM-rapid test-cassette, pipette and desiccant. The desiccant is for storage purposes and is not used in the testing process
2. 1 x buffer
3. 1 x safety lancet
4. 1 x alcohol pad
5. 1 x package insert

## What else do I need?

A timer (Stop watch, kitchen alarm clock or similar)

## Precautions

1. This package insert must be read completely before performing the tests. Failure to follow the package insert will result in inaccurate test results
2. For vitro diagnostics use only! Do not use after the expiration date!
3. Do not use the test if the pouch is damaged or broken!
4. The test is intended for single use only. Do not reuse under any circumstances!
5. Please keep away from children!
6. Temperature can negatively affect the results.
7. Do not perform the test in a room with a strong air flow, i.e. with an electric fan or strong air conditioning.

## Test Procedure

Note: Do not remove the test from the foil pouch until immediately prior to use. To begin the test, read the instructions carefully and perform the test at room temperature (15 °C - 30 °C)!

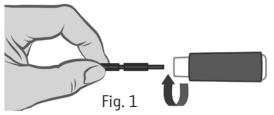


Fig. 1

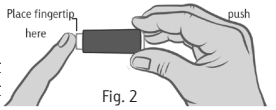


Fig. 2

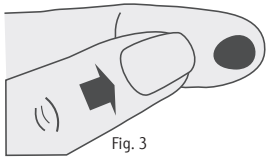


Fig. 3

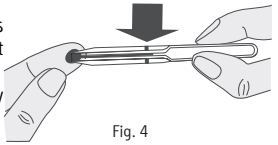


Fig. 4

1. Wash your hands with soap and then rinse them with clean water.
2. Remove the test device and pipette from the foil pouch and use within one hour. Best results are obtained if the test is performed immediately after opening the foil pouch. Discard the desiccant pouch.
3. Place the cassette firmly on a clean and level surface.
4. Massage the fingertip and then clean it with the cleaning pad. Wait until the finger is dry.
5. Take the safety lancet, unscrew the protective pin and pull it out (Fig.1). Press the safety lancet with the opening firmly against the clean fingertip to activate it (Fig.2). Do not use the first drop of blood.
6. Massage the fingertip without touching the puncture site to cause a drop of blood to form. (Fig.3)
7. Touch the drop of blood with the end of the pipette without pressing the pipette (Fig. 4). Capillary forces will now automatically fill the pipette with blood up to the mark. If the mark is not reached, massage the finger again to obtain a new drop of blood. Avoid air bubbles, if possible.
8. Hold the pipette vertically and add 1 drop of whole blood (approx. 10µl) by pressing the pipette into the sample well (S) of the test device (Fig. 5), then immediately add 2 drops (approx. 80µl) of sample buffer into the buffer well (B) (Fig. 6). Avoid air bubbles. Then start the timing! See figure below.
9. Wait until the colored line(s) appear. Read the result after 10 minutes! A Positive result may be visible after 2 minutes. Do not read the result after 15 minutes or later.
10. Dispose of the tests according to local regulations!

**1 drop of whole blood**

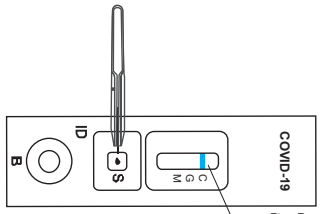


Fig. 5

blue

**2 drops of buffer**

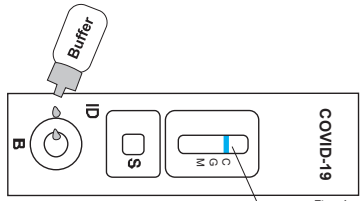
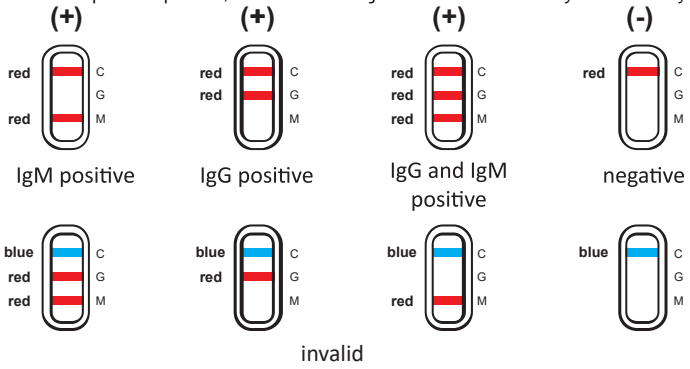


Fig. 6

blue

**Wait 10 minutes**

**Interpretation of Results (see illustration on back)**
**NEGATIVE:** The blue line in the control line region (C) changes to red. No line appears in the test line regions M or G. The result is negative.
**What does this mean?**
You probably haven't been infected with SARS-CoV-2. However, if symptoms persist or worsen, contact a physician for further diagnostic measures! (see restrictions)
**IgM POSITIVE:** The blue line in the control line region (C) changes to red and a red line appears in the test line region M. The result is anti-SARS-CoV-2 IgM positive.
**What does this mean?**
IgM antibodies are formed in the body very shortly after an infection. This means that you have probably recently been infected with SARS-CoV-2 (approx. last 2-3 weeks) if the result is exclusively IgM positive. Contact a doctor and have the result confirmed by further diagnostic measures!
**IgG-POSITIVE:** The blue line in the control line region (C) changes to red and a red line appears in the test line region G. The result is anti-SARS-CoV-2 IgG positive.
**What does this mean?**
IgG antibodies are not formed in the body until about 1-2 weeks after the onset of symptoms and are still detectable in the blood for a long time after infection. If your result is EXCLUSIVELY IgG positive, you have probably been infected with SARS-CoV-2 for some time without symptoms or you have already recovered from the disease. In the case of a viral infection, no IgM antibodies and only IgG antibodies are usually detectable after about 5 weeks. According to the current state of knowledge, you are now probably no longer infectious and therefore immune to SARS-CoV-2. Contact a doctor and have the result confirmed by further diagnostic measures!
**IgG- und IgM-POSITIVE:** The blue line in the control line region (C) changes to red and two red lines appear in the test line regions M and G. The result is anti-SARS-CoV-2 IgM and IgG positive.
**What does this mean?**
Both IgM and IgG antibodies are detectable in your body. You were probably infected with SARS-CoV-2 about 3-5 weeks ago. Contact a doctor and have the result confirmed by further diagnostic measures!
**INVALID:** The control line is still completely or partially blue and does not change completely from blue to red. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.




**Limitations**
1. Optimum test performance requires strict adherence to the test procedure described in this manual. Deviations can lead to deviating results.
2. A negative result for an individual indicates the absence of detectable anti-SARS CoV-2 antibodies. However, a negative test result does not exclude the possibility of exposure or infection with SARS-CoV-2.
3. A negative result may occur if the amount of anti-SARS-CoV-2 antibodies present in the sample is below the detection limits of the test or the detected antibodies are not present at the disease stage at which a sample is collected.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made after evaluation of all clinical and laboratory findings by the physician.

Store between 2 °C and 30 °C
Keep dry
Do not reuse
Content sufficient for 1 test
Do not use if the packaging is opened or damaged.
Follow the instructions

Manufacturer
IVD In Vitro Diagnostic
LOT Lot number
Use by
CE 0483 This test complies with Council Directive 98/79/EC of 1998 on in vitro diagnostic medical devices and bears the mark CE 0483 (mdc Medical Device Certification GmbH).

**Questions and Answers**
**1. My result is SARS-CoV-2 negative Does this mean that I am not infected with COVID-19?**
A negative result means that your immune system has not produced antibodies against SARS-CoV-2. This can have two possible causes. Either you are not infected with SARS-CoV-2 or you are already infected but your body has not yet developed an appropriate immune response. If you still suspect that you are infected with SARS-CoV-2, repeat the test after a few days and/or contact a doctor or the relevant health authority.
**2. My result is SARS-CoV-2 IgG and/or IgM positive What should I do now?**
The Robert Koch Institute recommends that people who have symptoms and who have been in an area where Covid-19 cases have occurred should REQUEST a doctor. It is recommended that you contact the medical on-call service. In cases where infection with the new coronavirus is suspected, the doctor will isolate the patient. Anyone who has had contact with a person who is demonstrably infected should call the relevant health office.
**3. When should I test with the YES or NO Corona-Test COVID-19 IgG/IgM COVID-19 IgG/IgM?**
This antibody test is not used for the detection of the actual virus, but to determine the reaction of the immune system to the virus! It cannot therefore be used sensibly on day 1 of a possible infection, but only from the time when the first symptoms of the disease appear (cough, neck scratching, fever). Symptoms can occur between 2 and 14 days (according to WHO average 5-6 days) after infection.
**4. Can the test give a false result?**
If performed correctly, the test results are reliable. However, an incorrect test result may be obtained if the YES or NO Corona-Test COVID-19 IgG/IgM COVID-19 IgG/IgM has become wet before the test is performed or if the amount of blood sample in the sample well was insufficient. Use the provided pipette to ensure the correct amount of blood sample. Please also observe the points „Test procedure" and „Interpretation of the results"!
**5. Is the result reliable if I read it after 15 minutes?**
No. The test should be read after 10 minutes.
**6. What is the meaning of the line that appears in the control line region (C)?**
If this line changes colour from blue to red, it means that the test has been performed correctly.

**Storage and Stability**
The test kit can be stored at temperatures between 2 °C and 30 °C. The test is stable until the expiry date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE! Do not use beyond the expiration date!

**Test Performance**

**Sensitivity and Specificity**

The YES or NO Corona-Test COVID-19 IgG/IgM rapid test cassette was compared with a leading commercial PCR; the results show that the YES or NO Corona-Test COVID-19 IgG/IgM rapid test cassette has high sensitivity and specificity:

The sensitivity of the IgM test is 87.9% (87/99) and the specificity 99% (14/14) compared to RT-PCR.

The sensitivity of the IgG test is 97.2% (35/36) during convalescence time and the specificity is 99% (14/14).

**Bibliography**

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3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24: 490-502.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.



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