

Dear Testee,

Kelen Hospital uses a "CE" device approved by the European Union to identify the presence of the two immune proteins produced by the human body to fight the new coronavirus (SARS-CoV-2¹).

Symptoms of the viral disease only show in some people infected by the SARS-CoV-2 virus. They are the ones developing the disease called COVID-19². In others, the infection may take place without the patients experiencing any symptoms at all. Yet, antibodies, i.e. the two immune proteins identified by us (IgM³ and IgG⁴) are produced by the bodies of all infected people, whichever group they may belong to. The virus can be detected in their bodies as late as two weeks after the disappearance of their last symptoms of COVID-19.⁵

A. Who should NOT apply for screening/testing?

1. Anyone with a clear record of having contracted this virus based on either viral testing or an analysis of the typical and specific antibodies.
2. Anyone with a recorded immune deficiency disease or those taking immune suppressive medication for a pre-existing medical condition.

B. Why is it important to know if you have had a SARS-CoV-2 infection?

1. If the test does not identify an elevated level of antibodies, you either have not been infected by SARS-CoV-2, or you are at such an early stage of the infection that it has not yet induced the production of antibodies. You should therefore take extra measures to protect yourself, and may wish to repeat the test in 4 weeks' time, depending on your circumstances.
2. If the test identifies an elevated level of the IgM antibody, you will know that the coronavirus infection is currently underway in your body – whether you show symptoms or not.
3. If the test identifies elevated levels of both IgM and IgG antibodies, you have either combatted coronavirus or you are toward the end of the infection, with the possibility of still spreading the infection.
4. If the test identifies an elevated level of the IgG antibody, you have most likely combatted coronavirus already, but to prove that beyond doubt, viral testing should be applied.
5. In the cases outlined under items 2-4, viral testing must be performed under the disease control procedure⁶ of April 1, 2020. If the test has produced these results, you must stay in isolation in a room of Kelen Hospital designated for this specific purpose until adequate sample has been collected from you for testing. We will proceed to notify the National Rescue Services and the district Disease Control Agency, who will decide on the procedure to follow in your case.

C. Steps of the screening:

1. Our security guard meets you at the entrance and checks if you have arrived at the right time slot.

¹ **S**evere **A**cute **R**espiratory **S**yndrome **C**orona**V**irus-**2**

² **C**orona **V**irus **D**isease-**19**

³ **I**mmunoglobulin **M**: an antibody consisting of 5 molecules and showing a high affinity against viruses in the first place, only detectable in the circulation for a relatively short period of time

⁴ **I**mmunoglobulin **G**: an antibody produced by plasma cells and memory cells (cells formed from B-lymphocytes), permanently detectable in the blood

⁵ <https://jamanetwork.com/journals/jama/fullarticle/2762452>

⁶ The disease control procedure of the National Health Service Center effective as of April 1, 2020

<https://www.nnk.gov.hu/attachments/article/567/NNK%20elj%C3%A1r%C3%A1srend%202020.04.01.pdf>

2. You are given protective gear, sanitizer to disinfect your hands, and your temperature is taken. You are only allowed to enter the reception area in protective gear on condition your body temperature proved normal.
3. We check your personal data at the reception desk, print the questionnaire (sent to you and filled out earlier) as well as the Statement of Consent and the Privacy Notice, which you then sign. You are to pay the costs of the testing - by card solely.
4. Should your oral report of past events classify you as a suspected COVID-19 patient (despite the questionnaire suggesting the opposite), you will not be screened. Instead, you will be reported to the Disease Control Agency as a suspected case. They will then proceed to take action in your case.
5. Should you have any further questions regarding the read and signed Statement of Consent, our patient coordinator will be happy to answer them for you.
6. Our coordinator will accompany you to the examination room, where you can get seated after washing your hands.
7. After alcohol-based disinfection of your hands, you will be pricked on one finger. The first drop of blood will be wiped off, and the second one will be dropped into the testing device by means of a pipette. After having the spot of the prick bandaged, you may leave the examination room. You may take a seat in the waiting room while still keeping all protective gear on you. Please keep a minimum distance of 1,5 meters from any other people in the waiting room.
8. The coordinator will walk you to the reception desk in about 20 minutes, where you receive your test results. If you tested negative for coronavirus, you may leave. Please dispose of your protective gear, with the exception of your mask, leaving it in the container beside the exit. You may exit the building through the designated door, which you will be shown by the coordinator.
9. If you tested positive for coronavirus, however, this fact, along with your personal data, must be reported to the competent Disease Control Agency. That done, our coordinator will inform you both orally and in writing of the effective procedure to follow.

D. Is there any other testing to verify you have successfully recovered from SARS-CoV-2 infection?

1. At the early stage of infection, at the stage of apparent symptoms, and no later than two weeks after the disappearance of symptoms, the virus can be detected by means of a PCR⁷ method. PCR testings are usually carried out on patients who qualify for suspected cases based on their medical history and/or symptoms, but it can also be done for screening purposes. As the virus is no longer present in the body after a total immune response, there is no way of detecting it either. Currently, there is no other testing method available, especially with regard to the detection of a possible prior infection without symptoms.

E. How accurate are the test results?

1. There is no such thing as flawless medical testing, and accordingly, the sensitivity and specificity of this test do not reach a 100% accuracy, either - yet, it can be regarded as a highly accurate one by all standards. With regard to the identification of IgM, clinical sensitivity is 87.01%, clinical specificity is 98.89%, while accuracy is 93.41%. With regard to the identification of IgG, however, clinical sensitivity is as high as 99.42%.
2. If you have shown up for testing on the grounds that you have recently been in close contact (within 1,5 meters, for longer than 15 minutes, without wearing a mask) with someone suspected to have been infected with coronavirus, yet possibly not confirmed, and the encounter with this person took place within less than the past two weeks, it could be the case that your body has not started producing antibodies just yet. This may cause a false negative test result. Should you develop a fever

⁷ Polymerase Chain Reaction

or start coughing within two weeks from the date of the testing, please contact your general practitioner immediately.

F. What adverse reactions are to be expected?

1. The spot of the prick might hurt for a while.
2. In extremely rare cases, the spot of the prick might get inflamed. This is possible even despite the most thorough handwashing and disinfecting, as the skin can never be made completely free from bacteria, thus allowing for a mild chance of pathogenic germs getting into the deeper layers, much like when you accidentally prick your finger with a needle at home. The likelihood of this happening, though, is so little that the protocol issued by the World Health Organization makes no mention of it.⁸

I hereby confirm having read, understood and accepted the Privacy Notice handed to me on a separate sheet.

I have read and understood this information sheet, was granted an opportunity to ask questions and received comprehensible, in-depth answers to them.

Accordingly, I request that an IgM/IgG testing be carried out on me and the results be communicated to me.

Budapest, _____

name

social security number

signature

⁸ <https://www.ncbi.nlm.nih.gov/books/NBK138654/#ch7.s1/>