KAI MEDICAL LABORATORY

FACT SHEET FOR PATIENTS

SARS-CoV-2 RT-PCR

Updated: May 27, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (SARS-CoV-2 rRT-PCR) test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**

- **https://www.cdc.gov/COVID19**

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness has spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

What is the SARS-CoV-2 rRT-PCR?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.

give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

What does it mean if I have a negative test result?
A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.

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COVID-19 Rapid Antibody Test

Coronavirus Disease 2019 (COVID-19)

Today, you have had *antibody testing* for the SARS-CoV-2, COVID-19. *Antibodies* are produced by your body in response to infection. Serology tests should not be used to diagnose an active infection, as they only detect antibodies the immune system develops in response to the virus – NOT the virus itself. There are two main types of antibody produced by your body.

- *IgM* is produced immediately when you are first exposed to infection, and then goes away with time
- *IgG* is produced later after your body has begun to fight off the infection and remains after you have recovered
- You may test positive for IgG, IgM or both IgG and IgM

- What do your results mean?
  - **If you have tested positive for IgM, it indicates that you may have recently been exposed to COVID and are likely still sick and able to infect others.**
    - In this case, you should monitor symptoms closely. If you do not feel very sick, you do not need additional medical care. We recommend you follow CDC Guidelines https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html. Others in your home, or who you have had close contact with, should have COVID-19 testing.
  - **If you have tested positive for IgG, it indicates that you have been infected with COVID in the past and have already recovered.**
    - You do not need to self-quarantine. Others in your home, or who you have had close contact with, should have COVID testing.
    - It is unknown how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Due to these unknowns, the FDA cautions patients against using serology results as an indication that they have any level of immunity.
  - **If you have tested positive for both IgM and IgG, it indicates that you may be infected with COVID but beginning to recover; you are still able to infect others.**
    - In this case, you should monitor symptoms closely. If you do not feel very sick, you do not need additional medical care. We recommend you follow CDC Guidelines https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html. Others in your home, or who you have had close contact with, should have COVID testing.
  - **If you have neither IgM or IgG, it is likely that you have never been exposed to COVID.**
    - You should repeat testing if your symptoms worsen or if you have other known exposures.
    - It is possible that you were recently exposed to COVID and your body has not yet had time to develop antibodies. *In this case, even though the test is negative, you may still be infected with COVID.* To be totally certain you are not infected with COVID, you should repeat testing in 7 days. Your medical provider will indicate if this is necessary.