FACT SHEET FOR PATIENTS

Mayo Clinic SARS-CoV-2 Molecular Detection Assay

PATIENTS

COVID-19 (Coronavirus)

You are being provided this fact sheet since your specimen(s) was tested for Coronavirus Disease 2019 (COVID-19) using the Mayo Clinic SARS-CoV-2 Molecular Detection Assay.

This fact sheet contains information to help you understand the benefits and risks of using this test for COVID-19 diagnosis. Should you have questions after reading through the information, please reach out to your healthcare provider.

- For the most current COVID-19 information, visit the CDC Coronavirus Diseases 2019 (COVID-19) website: CDC COVID-19 Webpage.

COVID-19 explained:

COVID-19 is caused by the SARS-CoV-2 virus, which can cause mild to severe respiratory disease. The virus was first identified in Wuhan, China and has now been identified in the United States (all 50 states) and 115 international locations. There is still limited information available to characterize the spectrum of clinical illness associated with COVID-19, but the virus is likely spread to others when an individual has symptoms of the disease (e.g. fever, coughing, sneezing, difficulty breathing).

What is the Mayo Clinic SARS-CoV-2 Molecular Detection Assay?

The test is a laboratory-developed test using a real-time PCR method, designed to detect the SARS-CoV-2 virus in respiratory specimens. Respiratory specimens include: nasopharyngeal, throat, and nares/nasal swabs, as well as tracheal aspirate/secretion, and bronchial specimens.

Why am I being tested?

You are being tested because your healthcare provider believes that your signs and symptoms (e.g. fever, cough, difficulty breathing) mean that you could have had exposure to the virus that causes COVID-19. Other reasons include:

- You live in or have recently been a traveler to a location where COVID-19 transmission is known to occur.
- You are or have been in close contact with a person who has been suspected to have or diagnosed with COVID-19.

Testing your specimen will help your healthcare provider determine if you might have COVID-19.

Potential benefits and risks of the test:

Potential benefits include:

- Your healthcare provider can make informed recommendations about your care using the results from this test along with other pertinent information.
- Test results may assist with limiting the spread of COVID-19 to your family, friends and others in the community.

Potential risks include:

- Potential sample collection discomfort or other complications
- Possible incorrect test result (see next section for additional details).

Where to go for updates and more information: The most current information on COVID-19 is available on the CDC general website CDC COVID-19 Webpage. Always contact your healthcare provider with any questions or concerns.

Created on March, 20, 2020

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Positive test results explained:

It is likely that you have COVID-19 if you test positive using the SARS-CoV-2 Molecular Detection Assay. After testing positive, it is likely you will be placed in isolation to prevent the spread of the disease to others. There is a small likelihood that the test can give an incorrect positive result (false positive). Your healthcare provider will determine with your input how to care for you based on test results and other pertinent information such as:

- Medical history
- Signs and symptoms
- Possible exposure(s)
- Geographic locations
- Travel history

Negative test results explained:

A negative result indicates that SARS-CoV-2 virus was not detected in your sample. In relation to COVID-19, a negative result for specimens collected while a person has symptoms likely means that the COVID-19 virus did not cause your recent illness.

It is possible for the SARS-CoV-2 Molecular Detection Assay to give an incorrect negative result (false negative) in those with COVID-19, which means you could still have COVID-19. Your healthcare provider will decide how to care for you while considering your tests results along with other pertinent information such as:

- Medical history
- Signs and symptoms
- Possible exposure(s)
- Geographic locations
- Travel history

FDA Status of the SARS-CoV-2 Molecular Detection Assay

This SARS-CoV-2 Molecular Detection Assay is not approved or cleared by the United States Food and Drug Administration (FDA).

The FDA is making this test available to the public under an emergency access mechanism defined as an Emergency Use Authorization (EUA).

The Secretary of Health and Human Services (HHS) supports the EUA process and has declared that circumstances exist to justify emergency use of lab developed tests (LDT) for detection of the virus that causes COVID-19.

The EUA is in effect for the duration of the FDA COVID-19 declaration, which justifies emergency use of lab developed tests unless terminated or revoked by the FDA. Should it be terminated or revoked, this test would no longer be used to detect SARS-CoV-2 virus.

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