FACT SHEET FOR PATIENTS

Alimetrix® SARS-CoV-2 RT-PCR Assay

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was/were tested for the virus that causes Coronavirus Disease 2019 (COVID-19) using the Alimetrix® Corporation SARS-CoV-2 RT-PCR Assay.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. If you have questions or would like to discuss the information provided after you have read this Fact Sheet, please speak with 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 can cause a mild to potentially severe respiratory illness and has spread globally, including throughout the United States. The current information available characterizing the spectrum of clinical illness associated with COVID-19 suggests that symptoms include fever, cough, shortness of breath or difficulty breathing, chills, muscle pain, headache, sore throat, or new loss of taste or smell.

Why was my sample tested?

Your doctor has ordered the Alimetrix test to check if virus is detected in the respiratory sample (nasopharyngeal (NP), oropharyngeal (OP), throat, nasal, mid turbinate nasal, nasopharyngeal washes/aspirates or nasal aspirates) collected from you using a swab. Your doctor will decide which sample should be collected.

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 your samples will help find out if you 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 more informed recommendations about your medical care.

- The results of this test may help limit the spread of COVID-19 to your family and to 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 will be placed in isolation to avoid spreading the virus to others as directed by guidance from the CDC and public health authorities. There is a very small chance that this test can 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, 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 result is negative. If this is the case, your healthcare provider will consider the test result together with your 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 COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency use 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 2019-nCoV is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.