NOVEL CORONAVIRUS 2012 REAL-TIME RT-PCR ASSAY

Centers for Disease Control and Prevention (CDC)

For the most up to date Middle East Respiratory Syndrome Coronavirus (MERS-CoV) information, including symptoms, please visit: https://www.cdc.gov/mers/about/index.html

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Your sample(s) was tested for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) using the Novel Coronavirus 2012 Real-time RT-PCR Assay.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of Middle East Respiratory Syndrome (MERS). After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

WHAT IS MIDDLE EAST RESPIRATORY SYNDROME (MERS)?

Middle East Respiratory Syndrome (MERS) is a disease caused by the Middle East Respiratory Syndrome Coronavirus (MERS-CoV). Most MERS patients developed severe respiratory illness with symptoms of fever, cough and shortness of breath. So far, all cases of MERS have been linked through travel to, or residence in, countries in and near the Arabian Peninsula.

WHAT IS THE NOVEL CORONAVIRUS 2012 REAL-TIME RT-PCR ASSAY?

The test is designed to help diagnose if you have MERS, by detecting the virus that causes MERS (MERS-CoV) in the following clinical specimens: nasopharyngeal or oropharyngeal swabs, sputa, and lower respiratory aspirates/washes.

WHY WAS MY SPECIMEN TESTED?

Testing of your specimen(s) will help find out if you have MERS. In some cases, you may not feel sick, but you were tested because you may have been exposed to MERS-CoV; for example, through contact with a person who has MERS-CoV infection or because you traveled from countries where this infection is relatively frequent. The test results could also help public health officials identify and limit the spread of this virus in your community.

WHAT ARE THE KNOWN AND POTENTIAL RISK AND BENEFITS OF THE TEST?

Potential risks include:

- Possible discomfort or other complications that can happen during specimen 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 MERS to your family, intimate partners, and others you come into close contact with.

WHAT DOES A POSITIVE TEST RESULT MEAN?

If you have a positive test result, it is very likely that you have MERS. Although there is a very small chance that this test can give a positive result that is wrong (false positive), it is unlikely. If your result from this test is positive, your doctor will work with you to determine how best to care for you based on the test results, along with other factors. Your doctor or health department will help you understand the steps you should take to keep from spreading the virus to others.

WHAT DOES A NEGATIVE TEST RESULT MEAN?

A negative test result means that the virus that causes MERS was not found in your specimen. This means you probably do not have MERS and are most likely sick with something else. Because this test cannot be used to rule out MERS-CoV infection in people without symptoms of illness, you should continue to monitor your health for the full period of time recommended by CDC. If you develop symptoms during this time, please be sure to let your healthcare provider know so they can take care of you.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with MERS. You might test negative if the specimen was collected too early or too late during your infection and/or because of improper specimen collection and handling. This means that you could possibly still have MERS even though the test result is negative. A false negative result might cause any or all of the following: delayed treatment, potential lack of treatment, or stopping treatment too soon. However, to avoid a false negative result affecting your care, your healthcare provider should not change your medical care solely based on a negative result. Instead, your healthcare provider should consider all other aspects of your illness along with your test result in deciding how to treat you.

WHAT IS AN EUA?

This test has been issued an Emergency Use Authorization (EUA) by the U.S. FDA. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternative tests. 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 laboratory tests for the diagnosis of infection with the MERS-CoV. This EUA will remain in effect (meaning this test can be used) for the duration of the MERS declaration justifying the emergency use of in vitro diagnostics, unless the declaration is terminated or authorization is revoked sooner. An EUA is NOT an FDA-approval or clearance.

WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. As of the date of this fact sheet, there is only one cleared test.[1] A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. Any tests that are issued an EUA by FDA can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization].

[1] The FilmArray Respiratory Panel 2 Plus was granted De Novo by FDA (Product Code: PZF; DEN170017) and the FilmArray Pneumonia Panel plus received marketing clearances from FDA under section 510(k) of the Act (Product Code: QDS; K181324 and K222601), both products include the detection of MERS-CoV.