

Fact Sheet for Patients: Understanding Results from the RealStar[®] MERS-CoV RT-PCR Kit U.S.

February 12, 2016

Dear Patient:

If you have received this Fact Sheet, your lower respiratory tract specimen(s) were tested to help determine whether you may be infected with Middle East Respiratory Syndrome Coronavirus, also called “MERS-CoV” for short. The test that was used on your respiratory specimen(s) is called the RealStar[®] MERS-CoV RT-PCR Kit U.S.

This Fact Sheet contains the minimum information necessary to help you understand the significant known and potential risks and benefits of the emergency use of the RealStar[®] MERS-CoV RT-PCR Kit U.S. If possible, you may want to discuss with your health care professional the benefits and risks described in this Fact Sheet.

What is Middle East Respiratory Syndrome (MERS)?

MERS is a respiratory illness caused by a novel (new) coronavirus called Middle East Respiratory Syndrome Coronavirus, or "MERS-CoV" for short. From April 2012 to January 2016, all cases of MERS-CoV have been directly or indirectly linked through travel to or residence in the Arabian Peninsula and surrounding countries, particularly the Kingdom of Saudi Arabia and the United Arab Emirates. Starting in May 2015 there have been additional cases linked to an outbreak in South Korea. This outbreak stems from a single traveler from the Arabian Peninsula. In May 2014, two individuals in the United States were diagnosed with MERS by public health officials using this test after they had traveled from a country which reported MERS cases. This virus can spread from person-to-person.

Most people diagnosed with MERS developed severe respiratory illness with symptoms of fever, cough, and shortness of breath. As of December 2015, about 35 percent of MERS-CoV patients have died. Some people confirmed to have MERS-CoV infection experienced mild respiratory illness or no symptoms at all. Public health officials have determined that MERS-CoV has a potential to spread to the United States and pose risks for the public health.

What is the RealStar[®] MERS-CoV RT-PCR Kit U.S.?

The RealStar[®] MERS-CoV RT-PCR Kit U.S. is a laboratory test designed to detect MERS-CoV. The FDA has not cleared or approved this test. No FDA-cleared or FDA-approved test exists that can detect MERS-CoV. However, based on data submitted to FDA by altona Diagnostics GmbH, FDA has authorized the use of this test, given the significant potential for a public health emergency, under an Emergency Use Authorization (EUA).

Why is my specimen being tested using the RealStar[®] MERS-CoV RT-PCR Kit U.S.?

The specimen collected from you was tested using the RealStar[®] MERS-CoV RT-PCR Kit U.S. to help determine whether you are infected with MERS-CoV. It may help your health care provider take better care of you. The test results could also help public health officials to identify and limit the spread of this virus in your community.

What are the known risks and benefits of the RealStar[®] MERS-CoV RT-PCR Kit U.S.?

Besides minimal potential discomfort during specimen collection, a risk of incorrect test results exists. However, this risk is believed to be very small (see next paragraphs for more information). The benefit of having this test is that the results of this test, along with other information, can help your health care provider take better care of you. Also, knowing your test results may help you to take precautions to prevent the spread of the virus to your family or others.

If this test is positive, does it mean that I have MERS-CoV infection?

If you have a positive test, it is very likely that you have MERS-CoV infection. Although unlikely, there is a very small chance that this test can give a positive result that is wrong; this is called a “false positive.” A false positive has the potential to delay a correct diagnosis. If your result from this test is positive, your health care provider can determine how to care for you.

If this test is negative, does it mean that I do not have MERS-CoV infection?

If you have a negative test, you probably are not infected with MERS-CoV and are most likely sick with something else. There is a small chance that this test can give a negative result that is wrong (called a “false negative”), meaning you could possibly still be infected with MERS-CoV even though the test is negative. It is possible to test a person too early or too late for MERS-CoV infection using this test. A false negative has the potential to delay a correct diagnosis. A false negative result might cause any or all of the following: delayed treatment, potential lack of treatment, or stopping treatment too soon. To avoid a false negative result affecting your care, your health care provider should not change your medical care solely based on a negative result. Instead, your health care provider should consider all other aspects of your illness along with your test result in deciding how to treat you.

What is an Emergency Use Authorization (EUA)?

The Secretary of Health and Human Services (HHS) has declared circumstances exist to justify the authorization of the emergency use of *in vitro* diagnostic tests for detection of MERS-CoV because of the significant potential for a public health emergency involving this virus.

Therefore, FDA has authorized the emergency use of the RealStar[®] MERS-CoV RT-PCR Kit U.S. to test for the presence of MERS-CoV in respiratory specimens. Use of this test is authorized under an EUA only for the duration of the threat of emergency, unless it is revoked sooner.

How can I learn more?

Information about MERS will be made available at www.cdc.gov/coronavirus/mers/index.html and any significant new findings observed during the course of the emergency use of the RealStar[®] MERS-CoV RT-PCR Kit U.S. will be made available at www.altona-diagnostics.com.

Please also contact your health care provider if you have any questions.