Fact Sheet for Patients: Understanding Results from the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay

June 10, 2014

Dear Patient:

If you have received this Fact Sheet, samples from your nose, throat, lower respiratory tract, stool, or blood were taken to test whether you may be infected with Middle East Respiratory Syndrome Coronavirus, also called "MERS-CoV" for short.

Because there is a significant potential for a public health emergency involving MERS-CoV, the Food and Drug Administration (FDA) has authorized the use of the Centers for Disease Control and Prevention (CDC) Novel Coronavirus 2012 Real-time RT-PCR Assay (NCV-2012 rRT-PCR Assay) to test for the presence of MERS-CoV in clinical respiratory, blood, and stool samples.

This Fact Sheet contains information to help you understand the significant known and potential risks and benefits of the emergency use of the CDC NCV-2012 rRT-PCR Assay, the lab test used to check for MERS-CoV infection. 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 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 May 2014, all cases of MERS 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. 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 May 2014, 30 percent of MERS 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 CDC NCV-2012 rRT-PCR Assay?

The CDC NCV-2012 rRT-PCR Assay is a laboratory test designed to detect MERS-CoV. The FDA has not cleared or approved this test. No FDA-cleared or FDA-approved tests exist that can identify MERS-CoV. However, based on data submitted to FDA by CDC, FDA has authorized the use of this test for this potential emergency under an Emergency Use Authorization (EUA).

What is an Emergency Use Authorization (EUA)?

The Secretary of Health and Human Services (HHS) has declared circumstances exist to allow emergency use of 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 CDC NCV-2012 rRT-PCR Assay to test for the presence of MERS-CoV in respiratory, stool, and blood samples. Use of this test is authorized under an EUA only for the duration of the threat of emergency, unless it is revoked sooner.

Why was my sample tested using the CDC NCV-2012 rRT-PCR Assay?

The sample collected from you was tested using the CDC NCV-2012 rRT-PCR Assay to help determine whether you are infected with MERS-CoV. The test results may help your health care provider take better care of you. The test results could also help public health officials identify and limit the spread of this virus in your community.

What are the known risks and benefits of the CDC NCV-2012 rRT-PCR Assay?

Besides minimal potential discomfort during sample 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?

If you have a positive test, 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 health care provider can determine how to care for you based on the test results, along with other factors.

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

If you have a negative test, you probably do not have MERS and are most likely sick with something else. A small chance exists that this test can give a negative result that is wrong (false negative), meaning you could possibly still have MERS even though the test 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 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.

How can I learn more?

Information about MERS and any significant new findings observed during the course of the emergency use of the CDC NCV-2012 rRT-PCR Assay will be made available at http://www.cdc.gov/coronavirus/mers/index.html.

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