NOVEL CORONAVIRUS 2012 REAL-TIME RT-PCR ASSAY

Centers for Disease Control and Prevention (CDC)

All individuals whose specimens are tested with this product will receive the Fact Sheet for Patients and Contacts for the product.

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This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Novel Coronavirus 2012 Real-time RT-PCR Assay.

WHERE CAN I GO FOR GENERAL INFORMATION ON MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS (MERS-COV)?

For general information on MERS-CoV, the virus which causes Middle East Respiratory Syndrome (MERS), including the symptoms of MERS, infection control precautions, and other information please check the CDC MERS webpage (see links provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdiction's website for the most up to date information.

WHAT DO I NEED TO KNOW ABOUT MERS-COV TESTING WITH THIS DEVICE?

- The Novel Coronavirus 2012 Real-time RT-PCR Assay can be used to test nasopharyngeal or oropharyngeal swabs, sputa, and lower respiratory aspirates/washes.
- The Novel Coronavirus 2012 Real-time RT-PCR Assay should be ordered for the detection of MERS-CoV in individuals meeting MERS clinical and/or epidemiological criteria, for example, clinical signs and symptoms associated with MERS-CoV infection, contact with a presumptive or confirmed MERS case, or history of travel to geographic locations where MERS cases were detected.
- The Novel Coronavirus 2012 Real-time RT-PCR Assay is only authorized for use at Centers for Disease Control and Prevention designated laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions. When collecting and handling specimens from individuals suspected of being infected with Middle East Respiratory Syndrome Coronavirus (MERS-CoV), appropriate personal protective equipment should be used as outlined on the CDC *Prevention and Control for Hospitalized MERS Patients* webpage. For additional information, refer to the CDC's *Diagnostic Testing for MERS* and *Laboratory Testing for MERS* webpages (see links provided in "*Where can I go for updates and more information?*" section at the end of this document).

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR MERS-COV?

A positive test result indicates that RNA from MERS-CoV was detected, and therefore the patient is presumptively infected with the virus and presumed to be contagious. A positive test result for MERS does not preclude the possibility of another infectious pathogen (e.g., a bacterial infection or co-infection with other viruses) contributing to the patient's symptoms. Healthcare providers should always consider laboratory test results in the context of clinical observations and

epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in determining individual diagnosis and patient management decisions and should follow current CDC guidelines.

The Novel Coronavirus 2012 Real-time RT-PCR Assay has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result. In the event of a false positive result, risks to patients could include the following: a recommendation for quarantine of household or other close contacts and monitoring for symptoms, a recommendation for isolation of the patient that might limit contact with family or friends and may increase contact with other potential patients with MERS, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, negative impact on mental health and/or interpersonal relationships, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

WHAT DOES IT MEAN IF THE SPECIMEN TESTS NEGATIVE FOR MERS-COV?

A negative test result means that MERS-CoV RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out MERS and should not be used as the sole basis for treatment or patient management decisions. It is possible for a test to miss infection with the MERS-CoV if testing occurs too early or too late during the illness and/or because of improper specimen collection and handling.

Some individuals may meet CDC's testing criteria due to certain epidemiological risk factors (for example, close contact with a confirmed MERS case), but may not demonstrate clinical signs and symptoms associated with MERS. Negative results for these individuals do not rule out future illness and do not demonstrate that an individual is not infectious.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with MERS. The possibility of a false negative result should especially be considered if the individual's recent exposures or clinical presentation indicate that MERS is likely, and diagnostic tests for other causes of illness (e.g., other illnesses with similar symptoms) are negative. Special consideration should be given to patients who are immunocompromised, pregnant, very young, or otherwise at increased risk of severe or complicated disease.

If MERS is still suspected based on exposure history together with other clinical findings, re-testing with this test or an alternative method should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test result include delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of MERS within the community, or other unintended adverse events.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. New epidemiological, microbiological, and clinical information may emerge over time requiring updates to best practices in testing, prevention, and treatment of this virus.

WHAT IS AN EUA?

The U.S. FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA 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 (IVDs) for the detection and/or diagnosis of the virus that causes MERS.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing MERS.

The EUA for this test is in effect for the duration of the MERS declaration justifying emergency use of IVDs, unless the declaration is terminated or authorization is revoked sooner.

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. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

WHERE DO I REPORT ADVERSE EVENTS?

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

WHERE CAN I GO FOR UPDATES AND MORE INFORMATION?

CDC WEBPAGES:

MERS Home Page: https://www.cdc.gov/mers/about/index.html

Symptoms: https://www.cdc.gov/mers/about/index.html

Healthcare Professionals: https://www.cdc.gov/mers/site.html#hcp

Information for Laboratories: https://www.cdc.gov/mers/site.html#php

Laboratory Biosafety: https://www.cdc.gov/mers/php/laboratories/index.html

[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.

Isolation Precautions in Healthcare Settings: https://www.cdc.gov/mers/hcp/infection-control/index.html

Specimen Collection and Infection Control: https://www.cdc.gov/mers/php/laboratories/index.html

FDA WEBPAGES:

General: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#othercurrenteuas

EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#coronavirus2013

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC):

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