

Information Sheet – Diagnostic Testing for MERS-CoV by DoD Laboratories

using the

CDC Novel Coronavirus 2012 Real-Time RT-PCR Assay (MERS-CoV)

**(For Emergency Use Only IAW Conditions of Authorization as specified in the FDA’s
Emergency Use Authorization)**

On 29 May 2013, Secretary Sebelius, Department of Health and Human Services, determined there is a significant potential for a public health emergency involving the Middle East respiratory syndrome coronavirus (MERS-CoV) that has a significant potential to affect national security or the health and security of United States citizens living abroad. On the basis of the determination, she declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the MERS-CoV.

(<http://www.phe.gov/emergency/news/healthactions/phe/Pages/MERS-CoV.aspx>)

On 5 June 2013, the Food and Drug Administration (FDA) Commissioner, Dr. Hamburg, authorized emergency use of the CDC Novel Coronavirus 2012 Real-Time RT-PCR Assay for the **presumptive** detection of MERS-CoV.

(<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>)

Conditions of Authorization as specified in the 5 June 2013 Emergency Use Authorization (EUA) (**NOTE:** this is not a complete listing of the Conditions – see the EUA

(<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm355529.htm>: also included as a pdf on this DoD PI/ID Watchboard site) for the full listing of Conditions):

- CDC will distribute the assay only to qualified laboratories. Questions regarding the designation of “qualified laboratories” within DoD can be referred to the appropriate point-of-contact via e-mail inquiry submitted at FHPR.Communications@tma.osd.mil. **NOTE:** Use of this kit is for **diagnostic use only** in accordance with the conditions of authorization as specified in the EUA and the assay’s instructions for use as distributed with the assay.
- The CDC will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which CDC becomes aware.
- Qualified laboratories will include with reports of the results the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. Fact sheets may be provided as electronic attachments to the test results, as a hard copy document, or via provision of an internet link to a web site that has posted the documents. Both Fact sheets are included as a pdf on this DoD PI/ID Watchboard site.)
- Qualified laboratories will have a process in place for reporting test results to healthcare providers and federal, state, and/or local public health authorities, as appropriate. **Laboratory management personnel shall coordinate with the installation’s Public Health Emergency Officer regarding such reporting.**

- Qualified laboratories will collect information on the performance of the assay, and report to CDC any suspected occurrence of false positive or false negative results of which they become aware.
- Qualified laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The CDC Novel Coronavirus 2012 Real-Time RT-PCR Assay is for use in patients with signs and symptoms of MERS-CoV in conjunction with clinical and epidemiological risk factors.

The Armed Forces Health Surveillance Center (AFHSC) recommends screening criteria for use within the DoD that differs slightly from that of the CDC. Due to frequent deployments with geographic exposure potential, questions surrounding transmission, and an unknown spectrum of illness presentation in DoD populations, AFHSC recommends screening criteria as follows:

Category A: A person with fever ($\geq 38^{\circ}\text{C}$, 100.4°F) and cough or respiratory illness;

AND EITHER

- a history of travel to the Arabian Peninsula or neighboring countries within 14 days before onset of illness;

OR

- close contact with a symptomatic person who developed fever and acute respiratory illness within 14 days after traveling from the Arabian Peninsula or neighboring countries;

OR

- is a member of a cluster of patients with severe acute respiratory illness of unknown etiology in which MERS-CoV infection is being evaluated.

OR

Category B: Close contact (or health care provider) of a confirmed or probable case of MERS-CoV infection.

For further AFHSC information/guidance, see the MERS-CoV tab in the 'Featured Items' section at <http://afhsc.mil/home>.

NOTE:

The current CDC definition for a “Patient Under Investigation (PUI)” (<http://www.cdc.gov/coronavirus/mers/case-def.html>) is:

A PUI is a person with the following characteristics -

CDC Category A:

- fever ($\geq 38^{\circ}\text{C}$, 100.4°F) and pneumonia or acute respiratory distress syndrome (based on clinical or radiological evidence);

AND EITHER

- a history of travel from countries in or near the Arabian Peninsula within 14 days before symptom onset;

OR

- close contact with a symptomatic traveler who developed fever and acute respiratory illness (not necessarily pneumonia) within 14 days after traveling from countries in or near the Arabian Peninsula;

OR

- is a member of a cluster of patients with severe acute respiratory illness (e.g., fever and pneumonia requiring hospitalization) of unknown etiology in which MERS-CoV is being evaluated, in consultation with State and local health departments.

OR

CDC Category B:

- close contact with a confirmed or probable case of MERS while the case was ill **AND** has a fever ($> 100^{\circ}\text{F}$) or symptoms of respiratory illness within 14 days following the close contact. **NOTE:** This is a lower threshold than Category A.

Close contact is defined as:

- Any person who provided care for the patient, including a healthcare worker or family member, or had similarly close physical contact.
- Any person who stayed at the same place (e.g., lived with, visited) as the patient while the patient was ill.

Probable case: A probable case is a PUI with absent or inconclusive laboratory results for MERS-CoV infection who is a close contact of a laboratory-confirmed MERS-CoV case.

Additional Considerations Regarding Testing:

- Clusters of cases with severe acute respiratory illness (e.g., fever and pneumonia requiring hospitalization) without recognized links to a case of MERS-CoV infection or to travelers from countries in or near the Arabian Peninsula should be evaluated for common respiratory pathogens. If the illnesses remain unexplained, providers should consider testing for MERS-CoV, in consultation with DoD/State/local public health points-of-contact.
- Patients with lower respiratory illness should also be evaluated for common causes of community-acquired pneumonia. This evaluation should be guided by clinical presentation and epidemiologic and surveillance information. Testing for MERS-CoV and other respiratory pathogens can be done simultaneously. Positive results for another respiratory pathogen should **not** necessarily preclude testing for MERS-CoV because co-infection can occur.

Test results from the Novel Coronavirus 2012 Real-Time RT-PCR Assay **are considered to be PRESUMPTIVE at the current time. At present, CASES CAN ONLY BE CONFIRMED AFTER laboratory testing at CDC.**

Reporting PUIs – DoD healthcare professionals (in coordination with the designated Public Health Emergency Officer) should immediately report to their respective Service and DoD public health activities and the State or local health department any person being evaluated for MERS-CoV infection as a PUI. PUIs should subsequently be reported to CDC using the **MERS PUI Short Form** (<http://www.cdc.gov/coronavirus/mers/interim-guidance.html>). Probable cases should also be reported to CDC.

Viral culture in laboratories – **Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of MERS-CoV specimens are NOT recommended at this time.** However, if done, these activities must be performed in a BSL-3 facility using BSL-3 work practices.

Current CDC guidance for health professionals, clinicians, and laboratorians (including case definitions and diagnosis and laboratory testing guidance) can be found at <http://www.cdc.gov/coronavirus/mers/interim-guidance.html>. Laboratories should follow the **Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation for MERS – Version 2** and the **Interim Laboratory Biosafety**

NOTE:

The Clinical Specimens Version 2 guidance expanded the “Specimen Type and Priority” section to better describe what specimens are preferred for testing (i.e., **Lower respiratory specimens are preferred, but collecting nasopharyngeal and oropharyngeal (NP/OP) specimens, as well as stool and serum, are strongly recommended depending upon the length of time between symptom onset and specimen collection.**); expanded the “Blood Components – Serum” section; and revised the “Summary of MERS-CoV rRT-PCR Testing Guidelines for Respiratory Specimens” section that describes reporting MERS-CoV test results and testing for other respiratory pathogens.

The Laboratory Biosafety Version 2 guidance added a section titled “Clinical Laboratory Testing” to describe recommendations when handling potential MERS-CoV specimens in the clinical laboratory setting and expanded the “Packing, Shipping and Transport” section to include updated and useful documents.

DoD Qualified Laboratories - CONUS:

Walter Reed National Military Medical Center (WRNMMC)

Naval Infectious Diseases Diagnostic Laboratory (NIDDL)

U.S. Air Force School of Aerospace Medicine (USAFSAM)

Brooke Army Medical Center (BAMC)

Naval Health Research Center (NHRC)

DoD Qualified Laboratories – OCONUS:

Naval Medical Research Unit 3 (NAMRU 3)

Landstuhl Regional Medical Center (LRMC)

Tripler Army Medical Center (TAMC)