

**PENNSYLVANIA DEPARTMENT OF HEALTH**  
**2014-PAHAN-282-05-22-ADV**  
**MERS-CoV Lab Testing & Specimen Submission**



<b>DATE:</b>	5/22/2014
<b>TO:</b>	Health Alert Network
<b>FROM:</b>	Michael Wolf, Secretary of Health
<b>SUBJECT:</b>	MERS-CoV Laboratory Testing and Specimen Submission
<b>DISTRIBUTION:</b>	Statewide
<b>LOCATION:</b>	Statewide
<b>STREET ADDRESS:</b>	Statewide
<b>COUNTY:</b>	Statewide
<b>MUNICIPALITY:</b>	Statewide
<b>ZIP CODE:</b>	Statewide

**This transmission is a “Health Advisory”:** provides important information for a specific incident or situation; may not require immediate action.

**HOSPITALS:** PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING, AND LABORATORY STAFF IN YOUR HOSPITAL

**EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE

**FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE

**LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE

**PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

Please find below the Pennsylvania Department of Health’s (PA-DOH) guidance for clinicians and laboratorians regarding the collection and testing of specimens collected from ill patients with suspected Middle East respiratory syndrome coronavirus (MERS-Co V) infection.

**CLINICIANS MUST OBTAIN APPROVAL FROM THE PENNSYLVANIA DEPARTMENT OF HEALTH (PA-DOH) FOR MERS-CoV TESTING PRIOR TO SENDING PATIENT SPECIMENS TO THE PENNSYLVANIA BUREAU OF LABORATORIES (BOL). TO OBTAIN THIS APPROVAL, CLINICIANS, SHOULD CALL PA-DOH OR THEIR LOCAL PUBLIC HEALTH DEPARTMENT.**

- i. **PA-DOH:** 877-PA-HEALTH (877-724-3258)
- ii. **Allegheny County Health Dept:** 412-687-2243; After Hours: 412-687-2243
- iii. **Allentown Health Bureau:** 610-437-7760; After Hours 610-437-7760
- iv. **Bethlehem Bureau of Health:** 610-865-7087; After Hours 610-865-7187
- v. **Bucks County Dept of Health:** 215-345-3318; After Hours: 888-245-7210
- vi. **Chester County Health Dept:** 610-344-6225; After Hours: 610-733-4919
- vii. **Erie County Dept of Health:** 814-451-6700, 24 Hrs/7 Days
- viii. **Montgomery County Dept of Health:** 610-278-5117; After Hours: 610-275-1222
- ix. **Philadelphia Dept of Public Health, Division of Disease Control:** 215-685-6740, After Hours: 215-686-4514
- x. **Wilkes-Barre City Health Dept:** 570-208-4268; After Hours: 570-208-4268
- xi. **York City Bureau of Health:** 717-849-2299; After Hours: 717-324-6591

At this time the risk of illness from MERS is thought to be low to the general population, however, health care providers need to be vigilant in their assessment of patients with acute respiratory symptoms.

On May 2, 2014, the first imported case of MERS was confirmed in the United States. A second, imported, unlinked U.S. case was confirmed on May 11, 2014. In both cases, residents of Saudi Arabia traveled to the U.S. with a history of occupational healthcare exposures in Saudi Arabia.

**Most MERS case-patients have developed a severe, acute respiratory illness, characterized by fever, cough, and shortness of breath.** At hospital admission, common signs and symptoms for these critically patients include: fever, chills/rigors, headache, non-productive cough, dyspnea, and myalgia. Other reported symptoms have included: sore throat, coryza, nausea/vomiting, dizziness, sputum production, diarrhea, vomiting, and abdominal pain. Atypical presentations including mild respiratory illness without fever and diarrheal illness preceding development of pneumonia have been reported. While the majority of case-patients have presented with severe, acute lower respiratory infections, there have been reports of mild and asymptomatic infections. There have been reported cases with respiratory virus or community-acquired bacteria co-infection at admission.

### **Who should be considered for MERS-CoV testing**

Healthcare providers should request MERS-CoV testing for the following individuals:

1. “Patients Under Investigation (PUI),” as defined by CDC

A. Definition

- i. An individual with fever ( $\geq 38^{\circ}\text{C}$ ,  $100.4^{\circ}\text{F}$ ) 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<sup>1</sup> within 14 days before symptom onset, OR
  - close contact<sup>2</sup> 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<sup>1</sup> OR
  - a member of a cluster<sup>3</sup> 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
- ii. An individual with close contact<sup>3</sup> to a confirmed or probable case of MERS while the case was ill AND
  - Fever ( $>100^{\circ}\text{F}$ ) or symptoms of respiratory illness within 14 days following the close contact. (This is a lower threshold than category A.)
  - NOTE, as defined by CDC:
    1. Confirmed MERS Case: A person with laboratory confirmation<sup>4</sup> of MERS-CoV infection

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<sup>1</sup> Countries considered in or near the Arabian Peninsula: Bahrain, Iraq, Iran, Israel, Jordan, Kuwait, Lebanon, Oman, Palestinian territories, Qatar, Saudi Arabia, Syria, the United Arab Emirates (UAE), and Yemen.

<sup>2</sup> Close contact is defined as a) any person who provided care for the patient, including a healthcare worker or family member, or had similarly close physical contact; or b) any person who stayed at the same place (e.g. lived with, visited) as the patient while the patient was ill.

<sup>3</sup> In accordance with the World Health Organization’s guidance for MERS-CoV, a cluster is defined as two or more persons with onset of symptoms within the same 14 days period, and who are associated with a specific setting such as a classroom, workplace, household, extended family, hospital, other residential institution, military barracks, or recreational camp. See WHO’s [Interim Surveillance Recommendations for Human Infection with Middle East Respiratory Syndrome Coronavirus](#)

<sup>4</sup> Confirmatory laboratory testing requires a positive PCR on at least two specific genomic targets or a single positive target with sequencing on a second.

2. Probable MERS Case: A PUI with absent or inconclusive laboratory results for MERS-CoV infection who is a close contact<sup>2</sup> of a laboratory –confirmed<sup>4</sup> MERS-CoV case

B. Testing Recommendations (per CDC)

- i. Collect a lower respiratory specimen (e.g., sputum or bronchoalveolar lavage), a nasopharyngeal/oropharyngeal swab, serum, and stool/rectal swab for testing via the CDC's rRT-PCR assay
- ii. If symptom onset was  $\geq 14$  days prior, consider additional serum specimen testing via the CDC MERS-CoV serologic assay.
- iii. Concurrent with MERS-CoV testing, healthcare providers should also evaluate patients with lower respiratory illness for common causes of community-acquired pneumonia<sup>5</sup>, guided by clinical presentation and epidemiologic and surveillance information. Positive results for another respiratory pathogen (e.g., influenza) should not necessarily preclude testing for MERS-CoV because co-infection can occur.

2. Close Contacts of CONFIRMED or PROBABLE Cases

A. Definitions, as defined by CDC

- i. Close contact: a) any person who provided care for the patient, including a healthcare worker or family member, or had similarly close physical contact; or b) any person who stayed at the same place (e.g. lived with, visited) as the patient while the patient was ill.
- ii. Confirmed MERS Case: A person with laboratory confirmation<sup>6</sup> of MERS-CoV infection
- iii. Probable MERS Case: A PUI with absent or inconclusive laboratory results for MERS-CoV infection who is a close contact<sup>2</sup> of a laboratory –confirmed<sup>4</sup> MERS-CoV case

B. Testing Recommendations (per CDC)

- i. Close contacts, if not using the recommended infection control precautions, should be, upon initial evaluation, considered for nasopharyngeal and oropharyngeal swabs collection for MERS-CoV detection via rRT-PCR, regardless of the presence or nature of symptoms.
- ii. *Symptomatic* close contacts should be, depending on their clinical history and presentation, considered for more extensive MERS-CoV testing, including rRT-PCR of lower respiratory and serum specimens and MERS-CoV serology, especially if their symptom onset was  $\geq 14$  days prior.

### **MERS-CoV Specimen Collection**

1. **CLINICIANS MUST OBTAIN APPROVAL FROM THE PA-DOH FOR MERS-CoV TESTING PRIOR TO SENDING PATIENT SPECIMENS TO THE PA-DOH BUREAU OF LABORATORIES (BOL).**

- A. TO OBTAIN THIS APPROVAL, CLINICIANS, SHOULD CALL PA-DOH OR THEIR LOCAL PUBLIC HEALTH DEPARTMENT (For appropriate telephone numbers, see pg. 1)

2. Specimen Collection

A. Specimen type

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<sup>5</sup> Examples of respiratory pathogens causing community-acquired pneumonia include influenza A and B, respiratory syncytial virus, *Streptococcus pneumoniae*, and *Legionella pneumophila*.

<sup>6</sup> Confirmatory laboratory testing requires a positive PCR on at least two specific genomic targets or a single positive target with sequencing on a second.

- i. To increase the likelihood of detection, multiple specimens from different sites, collected at different times after symptom onset, should be obtained, if possible.
- ii. Lower Respiratory Tract: bronchoalveolar lavage, tracheal aspirate, pleural fluid, sputum
- iii. Upper Respiratory Tract: nasopharyngeal AND oropharyngeal swabs, nasopharyngeal wash/aspirate, nasal aspirate
- iv. Blood Components: serum, EDTA blood (plasma)
- v. Stool/Rectal swab

B. Respiratory specimens should be collected as soon as possible after symptoms begin. Ideally, respiratory specimens should be collected within 7 days of onset and before antiviral medications are administered.

- i. NOTE: If more than a week has passed since onset and the patient is still symptomatic, respiratory samples, especially lower respiratory specimens, should still be collected

C. *FOR ADDITIONAL INFORMATION ON CDC'S RECOMMENDATIONS FOR MERS-CoV SPECIMEN COLLECTION, STORAGE, AND SHIPPING* please refer to the "Interim Guidelines for Collection, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for Middle East Respiratory Syndrome Coronavirus (MERS-CoV)—*Version 2*," which is located at: <http://www.cdc.gov/coronavirus/mers/downloads/guidelines-clinical-specimens.pdf>

### 3. Viral Specimen Collection Instructions for PA-DOH BOL

#### A. BOL-specific Viral Specimen Collection

- i. All respiratory swabs collected from the same patient should be inserted into the same tube of viral transport medium, one tube per patient
- ii. Refrigerate specimens until ready for packaging and shipping (or if not shipping immediately). If the specimen will not arrive at the BOL within 24-48 hours of collection, freeze the specimens and package to maintain as frozen
  - 1. *FOR GUIDANCE ON REFRIGERATING AND FREEZING SPECIMENS, PLEASE SEE CDC'S "Interim Guidelines for Collection, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for Middle East Respiratory Syndrome Coronavirus (MERS-CoV)—Version 2"* <http://www.cdc.gov/coronavirus/mers/downloads/guidelines-clinical-specimens.pdf>

### 4. Infection Control and Personal Protective Equipment (PPE) for Specimen Collection

A. Infection control measures should include standard, contact, and airborne precautions

B. When performing aerosol generating procedures, including specimen collection, the following steps should be taken:

- i. Limit the number of healthcare personnel (HCP) present during the procedure
- ii. Conduct the procedure in a private room, ideally an airborne infection isolation room, with the doors closed. Minimize entry and exit during and shortly after the procedures
- iii. HCP should follow PPE precautions during the procedure, and perform hand hygiene before and after (1) patient contact, (2) contacting potentially infectious material, (3) putting on and removing PPE, including gloves
- iv. Conduct environmental surface cleaning after the procedure using standard procedures, per hospital policy

#### C. PPE

- i. Gloves, gowns, eye protection (goggles or face shield), respiratory protection (N95 respirator or better). NOTE: If a respirator is unavailable, a facemask should be worn, but respirators should be made available as quickly as possible.

D. *FOR ADDITIONAL GUIDANCE ON INFECTION CONTROL RECOMMENDATIONS FOR HOSPITALIZED PATIENTS WITH MERS-CoV, SEE CDC'S "Interim Infection Prevention and*

## Transporting MERS-CoV Specimens to the PA-DOH BOL

### 1. Specimen Collection Supplies

- A. Specimen Tube
  - i. Screw-capped 15mL tube with 3mL of viral transport medium (VTM)
  - ii. Store tubes at room temperature before use
- B. Two sterile flock-tipped plastic-shaft swabs
  - i. 1 minitip (NP) swab
  - ii. 1 standard swab
  - iii. **NOTE:** Cotton-tipped swabs with wooden shafts are not acceptable and will be rejected
- C. Sealable, multi-compartment, plastic biohazard bag, with absorbent sheets
- D. Specimen submission form (SSF), with clear plastic bag
- E. Foam packing insert, with cardboard mailer
- F. Cold pack
  - i. Upon kit receipt, freeze cold pack. Maintain as frozen until packaging is complete.
- G. Address labels for shipping

### 2. Specimen Packaging Instructions

- A. Label the container with patient's name and the collection date
  - i. This information must appear on BOTH the specimen and the specimen submission form. If this information is missing or mismatched, testing will not be performed
- B. Place transport tube in one of the compartments of the biohazard bag (provided)
  - i. Place only one tube per compartment
  - ii. Up to 5 tubes may be transported per multi-component biohazard bag
- C. Seal bag and refrigerate specimen until shipping
- D. Place biohazard bag containing specimen into foam box (provided)
- E. Add frozen cold pack and close foam box
- F. Place foam box into cardboard mailer (provided)
- G. Put completed SSF (see below) in clear plastic bag (provided)
- H. Seal plastic bag containing SSF and place bag between the foam box and cardboard mailer
- I. Close outer mailer and seal with tape

### 3. Specimen Submission Form Completion Instructions

- A. Enter the following patient/submitter information and FI number (if applicable):
  - Patient Name (Last, First, Middle)
  - Address
  - City, including zip code
  - Date of birth
  - Sex
  - Onset date
  - Suspected agent
  - Specimen source
    - Example: NP Swab (or other appropriate description)
  - Collection date
  - Requested laboratory examination/test

- Submitter: Name, address, phone number

- B. Specimen submission form is provided in specimen collection kit. *TO ACCESS THE FORM ONLINE, REFER TO*

<http://www.portal.state.pa.us/portal/server.pt?open=18&objID=769264&mode=2>

under "Use the following forms when submitting specimens to the Bureau of Laboratories"

4. Specimen Shipping Instructions

- A. Ensure that the specimen will remain cold until it reaches the BOL

**All specimens (respiratory, serum and stool (if collected)) are to be submitted to the BOL. Some specimens may be forwarded to other laboratories as appropriate.**

- B. Address package: Address labels provided with specimen collection kit and is provided on SSF

**Bureau of Laboratories  
Pennsylvania Department of Health  
110 Pickering Way  
Exton, PA 19341**

*FOR ADDITIONAL INFORMATION ON SUBMITTING VIRAL SPECIMENS TO THE BOL PLEASE REFER TO THE "Viral Respiratory Specimen Collection Instructions" Document located under the "Collection Guidelines:"*

<http://www.portal.state.pa.us/portal/server.pt?open=18&objID=1286461&mode=2>

Categories of Health Alert messages:

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; no immediate action necessary.

This information is current as of May 22, 2014, but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.

