Guidelines for MERS-CoV sampling, packaging, and shipment

(Updated as of June 2015)

- Before collecting and handling specimens for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) testing, determine whether the person meets the current case definition for a Suspect, Probable or Confirmed case.
- All specimens should be regarded as potentially infectious, and HCWs who collect or transport clinical specimens should adhere rigorously to standard precautions to minimize the possibility of exposure to pathogens.
- Ensure that HCWs who collect specimens should be properly trained on the technique and wear PPE appropriate for aerosol generating procedures. Institutions will be responsible in assigning and training personnel to perform nasopharyngeal swabbing.
- Ensure that personnel who transport specimens are trained in safe handling practices and spill decontamination procedures.
- Place specimens for transport in leak-proof specimen bags (secondary container) that have a separate sealable pocket for the specimen (i.e. a plastic biohazard specimen bag), with the patient's label on the specimen container (primary container), and a clearly written request form.
- Ensure that health-care facility laboratories adhere to appropriate biosafety practices and transport requirements according to the type of organism being handled.
- Deliver all specimens by hand whenever possible. Do not use pneumatic- tube systems to transport specimens.
- State the name of the suspected ARI of potential concern clearly on the accompanying request form. Notify the laboratory as soon as possible that the specimen is being transported.
- For further information on specimen handling in the laboratory and laboratory testing for MERS-CoV, see CDC and WHO Laboratory bio-risk management [12,13], and the Laboratory testing for MERS-CoV [14,15], and CDC and WHO laboratory biosafety manuals [16,17].

Specimen type and priority

To increase the likelihood of detecting infection, lower respiratory specimens (sputum, endotracheal secretions, or bronchoalveolar lavage) are preferred such as blood, and serum should be collected on presentation and when convalescent. Collection of stool and urine is also recommended.

Points to consider when collecting specimens from a patient under investigation for MERS include:

- Maintain proper infection control when collecting specimens
- Use approved collection methods and equipment when collecting specimens
- Handle, store, and ship specimens following appropriate protocols

Respiratory specimens should be collected as soon as possible after symptoms begin – ideally within 7 days and before antiviral medications are administered. However, if more than a week has passed since onset of illness and the patient is still symptomatic, respiratory samples should still be collected, especially lower respiratory specimens since respiratory viruses can still be detected by rRT-PCR.

General guidelines

Samples should be stored in hospital for less than 4 hours before collection by SAMSA. **ONLY** SAMSA delivery is allowed for MERS-CoV samples. Pick up **MUST** be requested at the following number:

(800-6149999).

Label each specimen container with the unique MERS number, patient's hospital

ID number, specimen type and the date the sample was collected.

1. Diagnostic samples

A. Upper respiratory tract

Nasopharyngeal AND oropharyngeal swabs (NP/OP swabs) MUST BE TAKEN TOGETHER. Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media. NP/OP specimens MUST BE combined, placing both swabs in the same vial. Refrigerate specimen at 2-8°C up to 72 hours; if exceeding 72 hours, freeze at -70°C and ship on dry ice.

- Nasopharyngeal swabs: Insert a swab into the nostril parallel to the hard palate. Leave the swab in place for a few seconds to absorb secretions. Swab both nasopharyngeal areas.

Figure 1: Correct technique for taking a nasopharyngeal swab

For more information see NEJM Procedure: Collection of Nasopharyngeal Specimens with the Swab Technique: http://www.youtube.com/watch?v=DVJNWefmHjE

- Oropharyngeal swabs: Swab the posterior pharynx, avoiding the tongue.

- Nasopharyngeal wash/aspirate or nasal aspirates: Collect 2-3 ml into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C up to 72 hours; if exceeding 72 hours, freeze at -70°C and ship on dry ice.

B. Blood samples

a. Serum for serologic testing

For serum antibody testing: Serum specimens should be collected during the acute stage of the disease, preferably during the first week after onset of illness, and again during convalescence, ≥ 3 weeks after the acute sample was collected. However, since we do not want to delay detection at this time, a single serum sample collected 14 or more days after symptom onset may be beneficial. Serologic testing is NOT currently available but will be implemented within the next 2 months at key regional laboratories.

Please be aware that the MERS-CoV serologic test is currently under investigation and is for research/surveillance purposes and not yet for diagnostic purposes - it is a tool developed in response to the MERS-CoV outbreak. Contact Labs@mohfeedback.com for consultation and approval if serologic testing is being considered.

b. Serum for rRT-PCR testing

For rRT-PCR testing (i.e., detection of the virus and not antibodies), a single serum specimen collected optimally during the first week after symptom onset, preferably within 3-4 days, after symptom onset, may be also be beneficial.

Note: These time frames are based on SARS-CoV studies. The kinetics of MERS-CoV infection in humans is not well understood and may differ from SARS-CoV. Once additional data become available, these recommendations will be updated as needed.

- Children and adults. Collect 1 tube (5-10 ml) of whole blood in a serum separator tube. Allow the blood to clot, centrifuge

briefly, and separate sera into sterile tube container. The minimum amount of serum required for testing is 200 µl. Refrigerate the specimen at 2-8°C and ship on ice- pack; freezing and shipment on dry ice is permissible.

- Infants. A minimum of 1 ml of whole blood is needed for testing of paediatric patients. If possible, collect 1 ml in an EDTA tube and in a serum separator tube. If only 1 ml can be obtained, use a serum separator tube.

c. EDTA blood (plasma)

Collect 1 tube (10 ml) of heparinized (green-top) or EDTA (purple-top) blood. Refrigerate specimen at 2-8°C and ship on ice-pack; do not freeze.

C. Stool samples

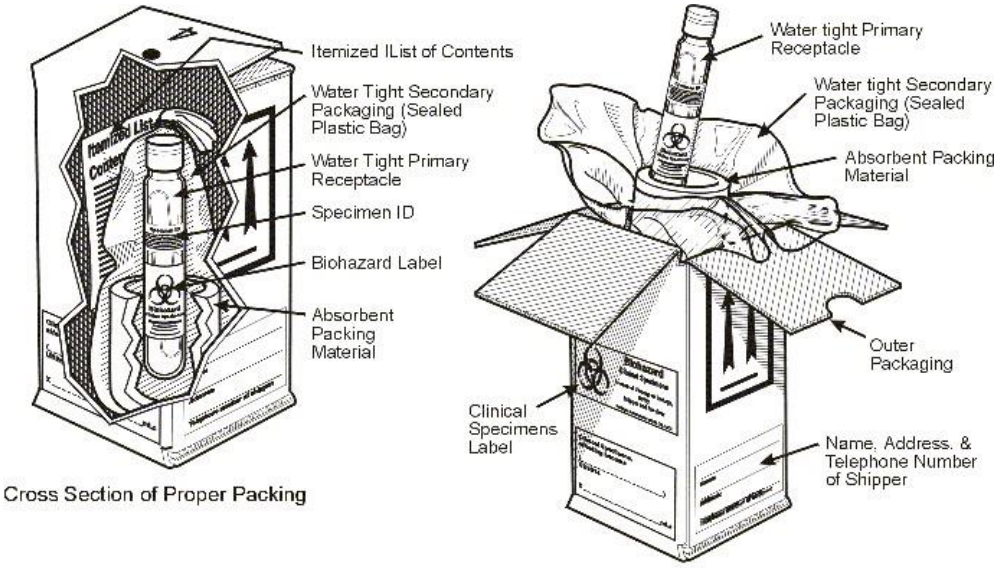
Collect 2-5 grams of stool specimen (formed or liquid) in sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C up to 72 hours; if exceeding 72 hours, freeze at -70°C and ship on dry ice.

2. Packaging

Diagnostic and clinical specimens must be triple-packaged and compliant with IATA

Packing Instructions 650 are detailed in Figure 2. The maximum quantity for a primary receptacle is 500 ml or 500 g and outer packaging must not contain more than 4 L or 4 kg.

Figure 2 Packing instruction 65



Packing containers

1. Packages must be of good quality, strong enough to withstand the rigors of transport

2. Triple packaging consisting of leak proof primary receptacles (for liquid shipments), silt-proof primary receptacles (for solid shipments), leak-proof secondary packaging, outer packaging of sufficient strength to meet the design type test (1.2 meter drop test)

3. For liquid shipments, primary receptacle or secondary packaging capable of withstanding a 95Kpa internal pressure differential

4. Absorbent material sufficient to absorb the entire contents of the shipment

5. An itemized list of contents must be included between the secondary and outer packaging

6. “Biological Substance, Category B” must appear on the package

7. Minimum dimension 100 mm

Samples containing multiple samples will be packaged so that the samples are organized in numerical order of patient hospital ID. Patient Data Sheets and an Itemized List of Contents will accompany the package. The paperwork will be packaged inside the outer package NOT the secondary container.

3. Labeling

The outer container of all diagnostic/clinical specimen packages must display the following on two opposite sides:

- Sender's name and address
- Recipient's name and address
- The words "Biological Substance, Category B"
- UN 3373 label
- Class 9 label, including UN 1845, and net weight if packaged with dry ice

All specimens must be pre-packed to prevent breakage and spillage. Specimen containers should be sealed with Parafilm® and placed in ziplock bags. Place enough absorbent material to absorb the entire contents of the Secondary Container (containing Primary Container) and separate the Primary Containers (containing specimen) to prevent breakage. Send specimens with cold packs or other refrigerant blocks that are self-contained, not actual wet ice. This prevents leaking and the appearance of a spill. When large numbers of specimens are being shipped, they should be organized in a sequential manner in boxes with separate compartments for each specimen.

For additional information, consultation, or the appropriate shipping address, contact the Labs@mohfeedback.com or the Regional MERS Laboratory.

4. Shipping

Any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigational purposed, but excluding live infected animals.

Specimens from suspected MERS-CoV cases must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations. At present MERS-CoV diagnostic specimens must be assigned to UN3373 and must be packaged as Category B infectious substances.

Category B infectious substances should have the proper shipping name

“Biological Substance, Category B” and the identification number UN 3373.

5. Rejection of packages and samples

Samples and packages will be rejected if:

- Samples are not packaged according to packing instruction P650 as UN3373 Diagnostic Specimens.
- An itemized list of samples organized by hospital patient ID number is NOT included inside the outer package.
- The patient data sheets are incomplete, missing or incorrectly filled out.
- If the primary container has leaked
- If dry ice is placed in the "Primary Container" or "Secondary Container", foam envelopes, ziplock bags, cryovial boxes, or hermetically sealed containers.
- If the Primary Containers sideways or upside down in ziplock bags.
- Primary containers must be packaged securely in an upright position and in the numerical order used on the Itemized List of contents
- If red top Secondary Containers for Category A Infectious Substances are used.
- If any paperwork in the Secondary Containers or ziplock bags, so as not to damage the paperwork.
- If biohazard/autoclave bags to prepack your materials due to the inadequate seal of these bags.