Since April 2012, MERS-CoV has caused severe respiratory illnesses. As of July 2017, 2040 laboratory-confirmed cases of MERS including at least 710 deaths have been reported to the World Health Organization (WHO) by 27 countries. Most cases (82%) have occurred in Saudi Arabia. In the US, there have been only 2 imported cases, both diagnosed in May 2014. The virus can spread from person to person and has caused outbreaks in healthcare settings. Approximately 35% of cases have been fatal, and 30% of cases have been associated with transmission in a healthcare facility. The information below addresses laboratory testing.

Testing at Washington State Public Health Laboratories (PHL)
All testing must be discussed with and approved by local health before submission to PHL. SPHL will test specimens from patients who meet the criteria for Patient Under Investigation (PUI). The criteria are:

- Fever AND pneumonia or acute respiratory distress syndrome (based on clinical or radiologic 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
  - 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 in the US.
- Fever AND symptoms of respiratory illness (not necessarily pneumonia; e.g., cough, shortness of breath) AND
  - A history of being in a healthcare facility (as a patient, worker, or visitor) within 14 days before symptom onset in a country or territory in or near the Arabian Peninsula in which recent healthcare-associated cases of MERS have been identified, or
  - Close contact with a confirmed MERS case while the case was ill.

Countries considered in the Arabian Peninsula and neighboring include: Bahrain; Iraq; Iran; Israel, the West Bank and Gaza; Jordan; Kuwait; Lebanon; Oman; Qatar; Saudi Arabia; Syria; the United Arab Emirates (UAE); and Yemen.

Close contact is defined as: a) being within approximately 6 feet (2 meters) or within the room or care area, of a confirmed MERS case for a prolonged period of time (such as caring for, living with, visiting, or sharing a healthcare waiting area or room with a confirmed MERS case) while not wearing recommended personal protective equipment (i.e., gowns, gloves, NIOSH-certified
disposable N95 respirator, eye protection or, b) having direct contact with infectious secretions (e.g., being coughed on) while not wearing recommended personal protective equipment. See CDC’s Infection Prevention and Control Recommendations for more detail. Data to inform the definition of close contact are limited. Transient interactions, such as walking by a person with MERS, are not thought to constitute and exposure; however, final determination should be make in consultation with public health authorities.

**Laboratory Testing**

PHL use a PCR assay from Centers for Disease Control and Prevention (CDC) to detect MERS-CoV in respiratory and serum or plasma specimens with confirmatory testing performed at CDC.

**Use appropriate infection control precautions when collecting respiratory tract and serum specimens.** Collect and submit specimens from at least two sites, including respiratory tract and serum. Lower respiratory samples may include bronchoalveolar lavage, tracheal aspirate, pleural fluid, and sputum; upper respiratory samples include nasopharyngeal and oropharyngeal swabs. In ventilated patients, lower respiratory tract specimens, such as BAL or tracheal aspirate, are preferred over upper. However, in non-ventilated patients, upper respiratory specimens are preferable. CDC provides testing guidance at: [http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html](http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html)

**Holding and Shipping Temperatures:**

Refrigerate all specimens at 2-8°C up to 72 hours and ship cold; if exceeding 72 hours holding time, freeze at -70°C and ship on dry ice. **Do not freeze EDTA blood.**

**Lower Respiratory Tract:**

- **Bronchoalveolar lavage, tracheal aspirate, pleural fluid**
  Collect 2-3 mL in a sterile, leak-proof, screw-cap sputum cup or sterile dry container.

- **Sputum**
  Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

**Upper Respiratory Tract:**

- **Nasopharyngeal and oropharyngeal swabs (NP/OP swabs)**
  Use only synthetic fiber swabs with plastic shafts. Calcium alginate swabs or wooden shafted swabs may inhibit PCR tests. Place swabs immediately into sterile tube containing 2-3 mL viral transport media. NP/OP specimens should be combined, placing both swabs in the same vial.
  - **Nasopharyngeal swabs** -- Insert a swab in the nostril parallel to the palate. Leave in place for a few seconds to absorb secretions. Swab both nasal areas.
  - **Oropharyngeal swab** -- Swab the posterior pharynx, avoiding the tongue.

- **Nasal aspirate**
  Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum cup or sterile dry container.
Serum:

- **PHL can perform PCR for detection of the virus on serum.** Serum for PCR testing should be collected during the first week after symptom onset, preferably within 3-4 days after symptom onset.
  - **Adults and children:** Collect 1 tube (5-10 mL) 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.
  - **Infants:** A minimum of 1 mL of whole blood is needed for testing of pediatric 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.

- **Serologic testing for MERS antibodies is currently available only at CDC upon request and approval.** Please consult with DOH Office of Communicable Disease Epidemiology for ideal timing of specimen collection for serologic testing. In general, for serologic testing, collect serum during acute symptoms, preferably the first week after onset of illness, and again ≥ 3 weeks later.
  - **Adults, children and infants:** Collect and process as above. Note, if both MERSCoV serology and rRT-PCR tests are planned, the minimum amount of serum required is 400 μL (200 μL for each test).

Shipping:

Specimens from suspected MERS-CoV cases shipped within the United States must be packaged, shipped, and transported in accordance with the shipping regulations from the US Department of Transformation (USDOT). Packaging procedures can be found in the USDOT document entitled, *Transporting Infectious Substances Safely* at: [http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_54AC1BCBF0DFBE298024C4C700569893C2582700/filename/Transporting_Infectious_Substances_brochure.pdf](http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_54AC1BCBF0DFBE298024C4C700569893C2582700/filename/Transporting_Infectious_Substances_brochure.pdf)

- Specimens should be stored and shipped at the temperatures indicated above.
- Package all specimens to prevent breakage and spillage.
  - The primary container (containing specimen) must be leak-proof and sealed securely with either tape or Parafilm® and placed in a zip-sealing, leak-proof bag with enough absorbent material to capture the contents of the primary container. Each requisition form should be attached to the outside of the zip-sealing bag containing the primary container.
  - Multiple primary containers (each in a zip-sealing bag with requisition slip attached) may be placed in a secondary leak-proof container.
  - The secondary container is then placed in an outer certified box. The outer box must be labeled with the bioterrorism agent category level of the specimen. Clinical specimens for MERS-CoV testing are category B.
- When shipping frozen specimens use a combination of dry ice and frozen gel ice-packs, not wet ice, to maintain temperatures over several days.
Avoid Shipping Problems:
- Do not place any dry ice in the primary container or secondary container, foam envelopes, ziplock bags, cryovial boxes, or hermetically sealed containers.
- Do not place primary containers sideways or upside down in zip-sealing bags.
- Do not place any paperwork in the zip-sealing bags, so as not to damage the paperwork.
- Do not use biohazard autoclave bags to prepack materials due their inadequate sealing.

Note that PHL require that all clinical specimens have two patient identifiers, a name and a second identifier (e.g., date of birth) both on the specimen label and on the submission form. Due to laboratory accreditation standards, specimens will be rejected for testing if not properly identified. Also include specimen source and collection date. Each specimen sent to PHL must be accompanied by a separate completed PHL requisition form: http://www.doh.wa.gov/Portals/1/Documents/5230/302-018-BioterrorismSpecimen.pdf. Along with the patient and submitter names, be sure to include the date of collection and date of illness onset on the form.