Annex F. Specimen Management and Laboratory Testing

**Purpose**
The purpose of this annex is to describe the process for specimen management and laboratory testing relating to Ebola Virus Disease (EVD).

**Situation**
Patients with travel and exposure history for EVD must be evaluated by the Section of Epidemiology to determine their exposure risk and whether specimens should be collected and tested. Molecular diagnostic testing for the virus can be performed at the Alaska Public Health Laboratory, with confirmation testing at the Center for Disease and Prevention (CDC). Rapid testing for EVD will allow appropriate patient care and public health measures.

**Assumptions**
The Section of Epidemiology is the lead for determining if specimens should be tested for EVD. The Alaska Public Health Laboratory (ASPHL) is the lead agency for specimen testing and transport to the Centers for Disease Control and Prevention (CDC; see: [http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen_collection-submission-patients-suspected-infection-ebola.html](http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen_collection-submission-patients-suspected-infection-ebola.html)).

**Procedures**
- All EVD testing must be approved by the Alaska Section of Epidemiology (907-269-8000) prior to specimen submission.
- Testing for EVD is currently available at the ASPHL (located in Anchorage) via a Polymerase Chain Reaction (PCR) test, which only provides a presumptive (positive or negative) result. The test takes approximately 6 hours to complete after specimen receipt.
- Confirmatory testing is required through additional testing at the CDC.
- ASPHL must be called prior to sending in a specimen for EVD testing (907-334-2100).
- If Ebola RNA is not detected and the suspect EVD patient’s fever or symptoms have been present for <72 hours, a repeat test may be required to rule out Ebola virus infection (it can take 72 hours after symptom onset for detectable levels of virus to be present in blood).

**Specimen collection, packaging and shipping**
- Contact the Section of Epidemiology before shipping any diagnostic specimens for EVD testing.
- The appropriate clinical specimen for EVD testing is whole blood collected in plastic tubes with EDTA or SPS (i.e., a purple, yellow, or blue topped tube). Tubes must be labeled with patient’s name and date of birth.
- Fill in the Test Request Form. Fill in the Suspect agent requested for testing in the lower right hand corner for Special Pathogens/Biological/Chemical Terrorism.
Specimens for EVD should be packaged following the triple packaging system, which consists of a primary receptacle (a sealable specimen bag) wrapped with absorbent material, secondary receptacle (watertight, leak-proof), and an outer shipping package.

- Keep and ship specimens cool using wet ice packs; it is okay to freeze specimens, if necessary.
- ASPHL recommends shipping the specimen as “Category B Diagnostic Specimens”.
  - ASPHL can provide Category B shippers upon request from the Supply Request form on the ASPHL website.
- Additional information for EVD specimen collection, packaging, and shipping is available at http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen_collection-submission-patients-suspected-infection-ebola.html

Alternative Testing after EVD is Ruled Out

- If malaria is in the differential diagnosis for a suspected EVD case, request malaria testing as well on the Test Request Form. Malaria testing will be performed as soon as possible following EVD rule-out.
- If influenza is on the differential diagnosis for a suspected EVD case, please collect a respiratory specimen and submit to the State of Alaska Virology Laboratory in Fairbanks AFTER EVD has been ruled out.

EVD Testing at Other Facilities

- The Section of Epidemiology should be immediately notified of any person suspected of having EVD (907-269-8000).
- In the event that a clinical laboratory gains EVD testing capacity in Alaska with an FDA-authorized assay (e.g., the BioFire Defense “FilmArray Biothreat-E test”), any patient suspected of having EVD in Alaska should also be tested for EVD at ASPHL, the National Laboratory Response Network Reference Laboratory for the State of Alaska.
  - Inactivation of specimens for EVD testing should be performed under Biosafety Level 3 conditions.
- The Section of Epidemiology must determine if a patient in Alaska should be tested for EVD prior to specimen shipment to ASPHL.
- At this time, all presumptive-positive PCR tests performed at ASPHL or other facilities must be confirmed by additional testing at CDC.