Alabama Department of Public Health Interim Laboratory Guidance for

Handling Specimens from Persons Under Investigation (PUI) for Ebola Virus Disease (EVD)

Notification and Consultation:

- For SUSPECTED EBOLA cases immediately contact Alabama Department of Public Health (ADPH) Epidemiology Division (EPI) at 1-800-338-8374.
- After approval for contact ADPH Bureau of Clinical Laboratories (BCL) Emerging Infectious Disease (EID) Department at 334-260-3400.
- Approved specimens will be forwarded by ADPH BCL to Centers for Disease Control and Prevention (CDC).
- **DO NOT SHIP SPECIMENS DIRECTLY TO CDC.** CDC **WILL NOT** accept them.

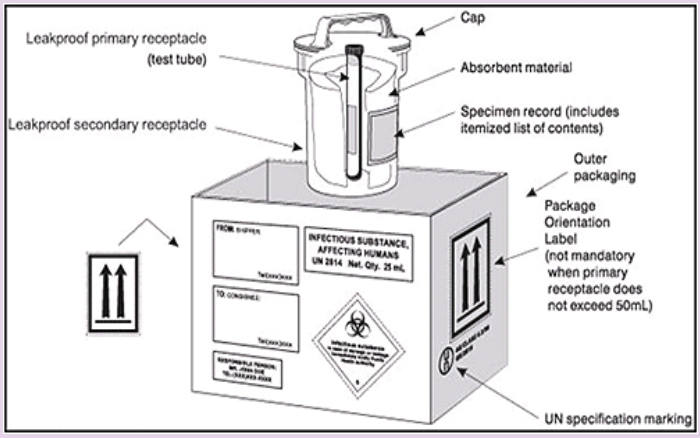
Specimen Collection and Transporting:

Follow 29 CFR 1910.1030 (d) (3) for compliance with the OSHA bloodborne pathogens regulations .

- **Specimen collection:**
  - ⇒ Collect as described by the institution's isolation protocols and/or risk assessment. Refer to CDC's Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing).
- **Collection amount:**
  - ⇒ Collect a minimum 4mL of whole blood in a plastic (purple top) tube with EDTA.
- **Collection period:**
  - ⇒ Ebola is detected in blood only after onset of symptoms, most notably fever.
  - ⇒ Specimens ideally should be collected when a symptomatic patient seeks care; however, if the onset of symptoms is <3 days a subsequent specimen will be required to completely rule-out EVD.
- **Collection container:**
  - ⇒ Do not use glass containers.
  - ⇒ Label with standard identifiers (patient's name, hospital identification code, patient's date of birth and date of collection).
  - ⇒ Specimens should be placed in a durable, leak-proof secondary container for transport within the facility. Do not use automated delivery (pneumatic tube) systems.
- **Specimen Storage:**
  - ⇒ Alert laboratory staff to the nature of the specimen.
  - ⇒ Specimen should remain in the custody of a designated person until delivered to the laboratory.
  - ⇒ Store specimen at 2-8°C or freeze until packaged for shipment.

Refer to CDC's Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Persons Under Investigation for Ebola Virus Disease in the United States **for further guidance.**

Specimen Packaging and Shipping:



- Do Not open or aliquot specimens.
- **Contact ADPH BCL EID prior to shipping.**
- **Package and ship specimens with frozen cold packs as a Category A infectious substance.**
- Note: The person preparing the package must be trained and certified to package and ship in accordance with International Air Transport Association (IATA) and Federal Department of Transportation (DOT) regulations.
- Ship Specimens to:
  Bureau of Clinical Laboratories
  Att: Microbiology EID
  8140 AUM Drive
  Montgomery, AL 36117

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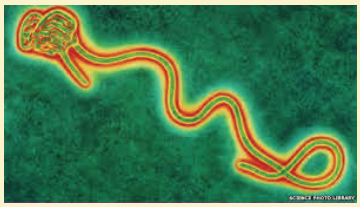
Testing Information:

Routine Laboratory Testing:

- Risk assessments should be conducted by each laboratory director, biosafety officer, and other responsible personnel to determine the potential for sprays, splashes, or aerosols generated from laboratory procedures.
- When laboratorians are manipulating primary patient specimens in the laboratory, staff should use an appropriate combination of PPE and physical containment devices such as a certified class II Biosafety cabinet or Plexiglass splash guard to protect their skin and mucus membranes.
- For laboratory instruments, the manufacturer-installed safety features and decontamination protocols should be used.
- If laboratories decide to add additional precautions, they should provide training and have staff practice these procedures and use the PPE in advance.



Point-Of-Care (POC) testing:

- POC instrumentation may be utilized on a patient with a suspected case of Ebola virus. The following points should be considered related to CLIA implications:
  - ⇒ Ensure POC instruments used have Food and Drug Administration clearance for intended use in critical care patients.
  - ⇒ An alternative plan for specimen transport to the clinical laboratory should be in place should a POC instrument fail or critical testing be required that cannot be performed by POC.
- If clinical laboratories decide to add POC instruments specifically for testing PUI, they should provide training and have staff practice these procedures while wearing the appropriate PPE.

Ebola Virus Testing:

- If laboratories are considering implementation of Ebola Virus Testing, they should review the Guidance for Clinical Laboratories Using FDA Authorized Diagnostic Assay for Ebola Virus Detection. All Ebola cases must be reported to ADPH and **confirmed** by an assay approved by the CDC.

Select Agent:

- As outlined in CDC's Interim Guidance Regarding Compliance with Select Agent Regulations for Laboratories Handling Patient Specimens that are Known or Suspected to Contain Ebola Virus, specimens from PUI for EVD are not select agents.
- If a PUI is confirmed for EVD, the specimen's classification as select agents is dependent upon additional testing and consultation from CDC.

Waste Management:

- Any item that is contaminated or suspected of being contaminated with Ebola virus, when transported in commerce, is regulated by DOT's Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180).
- Waste generated during laboratory testing, including PPE, should be placed in leak-proof containment. To minimize contamination of the exterior of the waste bag, place this bag in a rigid waste container designed for this use.
- If available, steam sterilization (autoclave) or incineration as a waste treatment process will inactivate the virus and reduces waste volume.

What's Next?

- Once a patient is confirmed to have EVD, CDC will consult with ADPH and healthcare personnel to answer questions on specimen handling and testing specific to the patient's needs and facility capabilities.

Direct questions to the ADPH BCL Emerging Infectious Disease (EID) Department at 334-260-3400.

It is imperative that healthcare facilities obtain the most current guidance at www.cdc.gov/vhf/ebola