IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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TO: Local Health Departments, Regional Offices of the Illinois Department of Public Health (IDPH), Infection Control Professionals, Infectious Disease Physicians, Hospital Laboratories, Laboratory Directors

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SUBJECT: New Guidance for Clinical Labs Managing Specimens from Patients Under Investigation (PUI) for Ebola Virus Disease (EVD)

CDC has issued updated guidance to clinical laboratories for the safe handling of specimens from patients under investigation for Ebola Virus Disease. (See reference section). This guidance supplants previous IDPH guidance.

KEY POINTS

- US clinical laboratories can safely handle specimens from Persons Under Investigation (PUIs) for EVD by following all required laboratory precautions and practices specifically designed for pathogens spread by blood, including manufacturer installed safety features for instruments and the laboratory environment, as well as Personal Protective Equipment (PPE) specified below.
- Specimens for patients with NO known exposures to EVD should be received, processed, and tested in accordance with usual and standard procedures for laboratory testing.
- Risk assessment should be conducted by each laboratory director, biosafety officer, or other responsible person to determine the potential for sprays, splashes, or aerosols generated during laboratory procedures.
- Any person collecting specimens from a PUI for EVD, transporting specimens through the healthcare facility or cleaning up specimens after a spill should wear the following PPE:
    - Gloves
    - Fluid-resistant/impermeable gown
    - Full face shield
    - Goggles and mask to cover all of nose and mouth
    - **NOTE: Additional PPE (e.g. shoe and leg covers) would be appropriate if specimen collection is taking place in a room that is heavily contaminated with blood or body fluids (urine, feces, vomit).**

- Do not use a pneumatic tube system for transporting specimens from PUIs.
- Laboratory personnel who process and perform laboratory testing on specimens from a PUI for EVD should wear the same PPE as listed above AND work in a certified Class II biological safety cabinet (BSC) or use a Plexiglass splash guard. If BSC or Plexiglass is not available, **a full face shield should be worn instead of goggles.**
- Personnel should use manufacturer-installed safety features for instruments in order to reduce the likelihood of exposure and to ensure additional protection.

- If procedures (e.g. centrifugation) that have the potential to generate aerosols or small droplets must be performed, physical containment devices such as sealed centrifuge rotors or safety cups should be used in addition to the PPE describe above. Training and practice should be provided to all staff if laboratory administration decides to add additional PPE and safety procedures in advance.
- **NOTE: Using unfamiliar equipment and PPE without sufficient training/practice may lead to breaches in safe practices and increase the risk of contamination (clothes, mouth, eyes), especially when removing PPE.**

FREQUENTLY ASKED QUESTIONS (FAQ)

1. **How should specimen containers that may have been contaminated during collection from the patient be decontaminated before transportation?**
   The outside of blood collection tubes can be wiped off with an appropriate disinfectant as described in CDC's Interim Guidance for Environment Infection Control in Hospitals for Ebola Virus.

2. **Can clinical laboratories safely manage routine testing of specimens from a PUI for EVD?**
   Yes. Clinical laboratories can safely do routine testing such as traditional chemistry, hematology or other laboratory testing used to support and treat patients by following and strictly adhering to CDC's recommendations and proper use of PPE. For automated systems, the manufacturer-installed safety features and decontamination protocols appropriate for enveloped viruses such as HIV, influenza or hepatitis C, should be used to ensure additional protection and safety. Diagnostic testing for Ebola diagnosis (PCR) will be conducted at CDC.

3. **If Ebola Virus Disease is confirmed in a patient, what does CDC recommend for routine laboratory diagnostic testing?**
   Once a patient is confirmed to have EVD, CDC will consult with healthcare personnel to answer questions on specimen handling and testing specific to the patient's needs and facility's capabilities.

4. **What guidance can be given regarding point-of-care (POC) testing devices?**
   POC instrumentation can be utilized. However, the following points should be considered as they relate to CLIA implications with regards to POC testing devices:

   - Ensure POC instruments have FDA clearance for intended use in critical care patients.
   - If the intended use of the instrument does not include testing critical care patients, then the use is considered "off label", and the laboratory must establish performance specifications (accuracy, precision, sensitivity, specificity, reportable range of test results, reference intervals, etc) before results can be reported. In addition, the laboratory must also document performance of quality control and proficiency testing, and that high complexity laboratory education/experience qualifications are met by laboratory directors, other employees and testing personnel.
   - 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 testing.

5. **Why does CDC work with Ebola virus in Biosafety Level 4 (BSL-4) laboratory facility and recommends that clinical laboratories work in a Biosafety Level 2 (BSL-2) laboratory facility?**
   The activities conducted in a BSL-4 laboratory on Ebola virus are different from activities that would be conducted in a US clinical laboratory. CDC BSL-4 laboratorians grow large volumes of virus stocks and use them for a variety of scientific purposes (e.g. testing possible vaccines, antiviral therapeutics). Proper containment of these large volume virus stocks is critical to the safety of laboratory personnel. CDC's recommendations to US clinical laboratories for safe management of diagnostic specimens from PUI for Ebola Virus Disease are consistent with recommendations for other known infectious diseases that are transmitted through blood or body fluids, such as HIV and hepatitis viruses.

6. **What other diseases should clinical laboratories consider when evaluating ill travelers from West Africa other than Ebola Virus Disease?**
   Patients from countries currently affected by the Ebola outbreak who present with fever could have other potentially fatal infectious diseases that should be considered in the differential diagnosis, including but not limited to malaria, typhoid fever, Lassa fever, Dengue Fever, Chikungunya, and bacterial infections. Evaluation of febrile illness in a recent traveler should include a thorough travel and exposure history. Travel and exposure history should be gathered and assessed in consultation with the State and Local health department.

7. **Can a PUI for EVD have more than one infection?**
   Yes. It is possible for a patient to suffer from more than one illness at the same time. Differential testing and PPE requirements should be based on clinical and travel history and symptom information.

ASM GUIDANCE

- Interim Laboratory Guidelines for Handling/Testing Specimens from Cases or Suspected Cases of Hemorrhagic Fever Virus (HFV), September 10, 2014 (2nd version): https://www.asm.org/images/PSAB/Ebola9-10-14.pdf

PCR Testing for Ebola Virus at CDC

- PCR testing for Ebola virus is available at CDC once testing has been approved by IDPH and the CDC Emergency Operation Center. ****NOTE: Testing will not be performed without prior consultation with IDPH and CDC.**
- Ebola virus can be detected in blood only after onset of symptoms, most notably fever; however it may take up to 3 days post-onset of symptoms for the virus to reach detectable levels.
- If EVD is suspected, and a blood specimen is collected **≤ 3** days post-onset of symptoms, a subsequent specimen will be required for testing to completely rule-out Ebola virus infection.

Requesting PCR Testing for Ebola Virus at CDC

- Hospitals and health care providers should contact their local health department to discuss testing. If the local health department can not be reached, contact the IDPH Division of Infectious Diseases.
- Local health departments should contact the Division of Infectious Diseases for a consultation. Contact the after-hours duty officer through the Illinois Emergency Management Agency, if necessary.
- If the consultation warrants additional follow-up, Infectious Diseases will contact the CDC Emergency Operations Center to discuss specimen submission.
- If testing at CDC is authorized, IDPH Division of Infectious Diseases and Division of Laboratories will work with the submitter on submission of specimens.

Specimen Collection

- Collect **2 lavender top** blood tubes containing **whole blood** preserved with EDTA (**minimum volume of 4mL each**).
- Collect blood in **plastic** tubes only. **Do not collect in glass tubes. Do not centrifuge specimens**.
- Specimens should be stored at 4C.

Submission Forms

- Complete and submit the IDPH Laboratory Request Form. http://www.idph.state.il.us/about/laboratories/CDform082002a.pdf
- Provide all patient information, including full address and medical history.
- Complete and submit the CDC Laboratory Request Form. ****NOTE: Contact the IDPH Division of Laboratories for the CDC form and completion assistance. Additional forms and information may be requested.**

Specimen Packaging and Transport

- **Prior to shipping specimens, please contact the nearest IDPH laboratory and ask to speak about Ebola testing.**
- If shipment is via commercial transportation, adhere to Category A Substances shipping requirements, unless otherwise specified. (There may be some occasions when Category B is appropriate depending on available clinical data and if Ebola virus infection is not the likely cause of disease.)
- All specimens should be transported at 4 degrees C on cold packs.

Contact Information for IDPH

The IDPH Division of Laboratories can be contacted during business hours at the following numbers:

- Chicago: 312-793-4760
- Springfield: 217-782-6562
- Carbondale: 618-457-5131

The IDPH Division of Infectious Diseases can be contacted during business hours at 1-217-782-2016.

To reach IDPH personnel during Holidays and non-business hours, please contact the Illinois Emergency Management Agency at 1-800-782-7860 (ask for the IDPH duty officer).

REFERENCE LINKS:

1. Case definitions for Ebola Virus Disease, including PUI definition:
http://www.cdc.gov/vhf/ebola/hcp/case-definition.html

2. CDC's Interim Guidance for Specimen Collection, Transport, Testing and Submission for Persons Under Investigation for Ebola Virus Disease in the United States:
http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html

3. CDC's Interim Guidance for Specimen Management in Clinical Laboratories:
http://www.cdc.gov/vhf/ebola/hcp/safe-specimen-management.html

4. Printable CDC Fact Sheet for Laboratories:
http://www.cdc.gov/vhf/ebola/pdf/ebola-lab-guidance.pdf

5. OSHA 29 CFR 1910.1030:
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS

6. CDC Interim Guidance for Environment Infection Control in Hospitals for Ebola Virus:
http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html

7. Interim Guidance Regarding Compliance with Select Agent Regulations for Laboratories Handling Patient Specimens that are Known or Suspected to Contain Ebola Virus: http://www.cdc.gov/vhf/ebola/hcp/select-agent-regulations.html