Centers for Disease Control and Prevention

How U.S. Clinical Laboratories Can Safely Manage Specimens from Persons Under Investigation for Ebola Virus Disease

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Who this is for: Laboratorians and other healthcare personnel handling specimens from patients under investigation (PUI) for Ebola virus disease (EVD)

What: CDC provides answers to frequently asked questions regarding the safe handling of specimens from PUI for EVD

How to use: This document should be used as a supplement to CDC's document, Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Persons Under Investigation for Ebola Virus Disease in the United States.

Key Points

- U.S. clinical laboratories can safely handle specimens from PUI for EVD by following all required laboratory precautions and practices as specified in 29 CFR 1910.1030 (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) for bloodborne pathogens
- Any person collecting specimens from a PUI for EVD should wear recommended personal protective equipment (PPE).
- Personnel who process and perform laboratory testing on specimens from a PUI for EVD should wear gloves, fluid-resistant or impermeable gowns, full face shield or goggles, and masks to cover all of nose and mouth AND use a certified Class II biosafety cabinet or Plexiglass splash guard. If a certified Class II biosafety cabinet or Plexiglass splash guard is not available, a full face shield should be worn instead of goggles.
- Anyone collecting specimens from a patient should follow the procedures included in this document for transporting specimens through the healthcare facility and clean-up of spills.

Background

The recent outbreak of Ebola virus disease (EVD) in West Africa raises the possibility that a patient with EVD could travel to the United States. U.S. clinical laboratories may have many questions about how to safely manage laboratory specimens from PUI for EVD. CDC recognizes that Ebola can cause a great deal of fear, but U.S. clinical laboratories have safety measures in place for other known (and more importantly, unknown) infectious diseases; these measures are critical to ensuring the safety of laboratory personnel when evaluating PUI for EVD.

Ebola virus is transmitted through contact with blood or body fluids (e.g., urine, feces, and vomit) or objects such as needles that have been contaminated with infected body fluids, or contact with infected animals. Persons known to have EVD or under investigation for EVD presenting to healthcare settings should be managed with appropriate isolation and other precautions as soon as possible to prevent transmission of Ebola virus to others. CDC infection control guidance is available here.

Potentially infectious diagnostic specimens are routinely handled and tested in U.S. laboratories in a safe manner, through adherence to safety precautions as specified in the OSHA bloodborne pathogens safety standard (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) and outlined in CDC's clinical laboratory guidance. The frequently asked questions below are meant to help clarify the guidance.

U.S. hospitals or clinical laboratories that are concerned about a PUI for EVD should contact their relevant state public health authorities and CDC (770-488-7100) for consultation.

PPE

How does personal protective equipment (PPE) protect lab personnel?

Laboratorians may use a variety of PPE to prevent transmission of infectious pathogens to laboratory staff during the collection, processing, and laboratory testing of patient specimens. Risk assessments should be conducted to identify potential occupational exposures, and employers of laboratorians must provide appropriate PPE to their employees as detailed by the OSHA bloodborne pathogens standard (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS). PPE is considered "appropriate" only if it prevents blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes. The proper donning and removing of PPE is essential for worker safety, and strict adherence to protocols is expected. Some recommendations are given below, but each laboratory should work with its institution's infection control and laboratory safety departments to ensure laboratory personnel safety.

What PPE should health professionals (phlebotomists, nurses, etc.) wear when collecting specimens from a PUI for EVD?

Health professionals may collect specimens, such as blood, from a PUI for EVD to confirm or rule out other possible infections or to conduct other patient care testing (e.g., hematology and clinical chemistry). Specimen collection should be conducted by personnel as described by the institution's isolation protocols and/or risk assessment. For this activity, health professionals should refer to 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).

What PPE should clinical laboratorians wear and what equipment safety features should be used when processing and performing laboratory testing on specimens from a PUI for EVD?

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. OSHA's Hierarchy of Controls [PDF - 1 page] (https://www.osha.gov/dte/grant_materials/fy10/sh-20839-10/hierarchy_of_controls.pdf) should be followed for adjusting work practices, safety equipment controls and PPE requirements as needed to protect the laboratorian's skin, eyes, and mucous membranes. Laboratory personnel should keep in mind that a patient may have an infectious disease other than EVD which may require additional PPE.

When clinical laboratorians are manipulating primary patient specimens in the laboratory, staff should use an appropriate combination of PPE and physical containment devices to protect their mouth, nose, eyes and bare skin from coming into contact with patient specimens. This could include:

Use of a certified Class II biosafety cabinet or Plexiglass splash guard, if a biosafety cabinet is not available, and

- Gloves
- Gowns that are fluid resistant or impermeable
- Mask to cover all of nose and mouth
- Eye protection such as full face shield or goggles

If a certified class II biosafety cabinet or Plexiglass splash guard is not available, clinical laboratorians should wear:

- Gloves
- Gowns that are fluid resistant or impermeable
- Mask to cover all of nose and mouth
- Full face shield

Additionally, clinical laboratorians should use manufacturer-installed safety features for instruments that reduce the likelihood of exposure and to ensure additional protection.

Some laboratory procedures (e.g., centrifugation) have the potential to produce aerosols or small droplets. If such procedures must be performed, physical containment devices such as sealed centrifuge rotors or centrifuge safety cups should be used, along with PPE as indicated above.

What if clinical laboratories choose to use additional PPE or a higher Biosafety Level laboratory when evaluating patients with EVD?

CDC's recommendations to U.S. clinical laboratories for safe management of diagnostic specimens from PUI for EVD are consistent with recommendations for other known infectious diseases that are transmitted through blood or body fluids, such as HIV and hepatitis. If clinical laboratories decide to add additional precautions, they should provide training and have staff practice these procedures and use the PPE in advance. Changing to unfamiliar equipment or PPE without sufficient training and practice may lead to breaches in safe practices and may increase a person's risk of contaminating their clothes, mouth, or eyes, especially when removing PPE. Consistency of these planned procedures is important to protect personnel. Using available PPE and procedures that meet CDC guidelines and are familiar to clinical laboratorians will allow them to safely manage specimens from a PUI for EVD.

Decontamination

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 Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus.

How should spills of blood or body substances be handled?

As outlined in the Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus, the basic principles for blood or body substance spill management are outlined in the United States Occupational Safety and Health Administration (OSHA) bloodborne pathogens standard (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) (29 CFR 1910.1030).4 Before any spill clean up is initiated, ensure that staff are trained and wear recommended PPE including, at a minimum, disposable gloves, gown (fluid resistant/ impermeable), eye protection (goggles or face shield), and facemask to protect against direct skin and mucous membrane exposure of cleaning chemicals, contamination, and splashes or spatters during environmental cleaning and disinfection activities. CDC guidelines recommend removal of bulk spill matter, cleaning the site, and then disinfecting the site with a disinfectant effective against the potential agent.3 For large spills, a chemical disinfectant with sufficient potency is needed to overcome the tendency of proteins in blood and other body substances to neutralize the disinfectant's active ingredient. An EPA-registered hospital disinfectant with label claims for non-enveloped viruses (e.g., norovirus, rotavirus, adenovirus, poliovirus) and instructions for cleaning and decontaminating surfaces or objects soiled with blood or body fluids should be used according to those instructions.

Transportation

How should specimens from PUI for EVD be transported within the hospital/institution?

In compliance with 29 CFR 1910.1030, specimens should be placed in a durable, leak-proof secondary container for transport within a facility. To reduce the risk of breakage or leaks, do not use any pneumatic tube system (automated or vacuum specimen delivery system) for transporting specimens from PUI for EVD. If the pneumatic tube system was inadvertently used for transport and the specimen collection tube was damaged, follow the manufacturer's instructions for decontamination or contact the CDC EOC for consultation at 770-488-7100.

Routine Testing

Can clinical laboratories safely manage routine testing of specimens from a PUI for EVD?

Yes. Clinical laboratories can safely do routine laboratory 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.

Ebola virus is spread by direct contact with blood or body fluids from an infected individual. OSHA's bloodborne pathogens standard (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) was put in place many years ago to protect laboratory personnel from any known and unknown infectious specimens that are present in blood or body fluids. By wearing appropriate PPE during specimen collection and utilizing PPE plus a certified Class II biosafety cabinet or Plexiglass splash guard when processing and testing specimens, laboratory personnel can safely conduct routine diagnostic tests on PUI for EVD or other potential infectious diseases.

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.

U.S. hospitals or clinical laboratories that are concerned about a PUI for EVD should contact their relevant state public health authorities and CDC (770-488-7100) for consultation.

If EVD 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 the healthcare personnel to answer questions on specimen handling and testing specific to the patient's needs and facility capabilities.

Select Agents

What issues should be considered in relation to Select Agent and Toxins regulations?

As outlined in the 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. For confirmed patients, CDC will work with the facility to determine the proper reporting and handling of these specimens.

Managing Patients

Have any U.S. hospitals ever managed patients infected with hemorrhagic fever viruses in the past?

Following the guidelines outlined in this document, U.S. hospitals and clinical laboratories have safely managed several patients with viral hemorrhagic fevers including patients with Marburg virus (a closely related virus to Ebola) and Lassa virus1-4. The Marburg patient was diagnosed several months after hospitalization. The patient was hospitalized for 10 days and had bloodwork done before and during hospitalization, with no infections to any healthcare personnel. The OSHA bloodborne pathogen standard (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) was developed to protect laboratory personnel from these types of unknown and undiagnosed pathogens.

POC Testing Devices

What guidance can be given regarding point-of-care (POC) testing devices?

Although specimens from PUI for EVD can be safely handled in a clinical laboratory using the guidance provided above, POC instrumentation may also be utilized. However, the following points should be considered as relates to CLIA implications with regards to POC testing devices:

If POC instruments are used in the critical care of isolated patients then the clinical laboratory must:

a. Ensure POC instruments used have Food and Drug Administration clearance for intended use in critical care patients. If the intended use of the instrument does not include testing critical care patients:
    a. Then the use of the POC instrument on these patients is considered off-label use, and before reporting patient results, the laboratory must establish the performance specifications for accuracy, precision, sensitivity, specificity, reportable range of test results, reference intervals and any other performance characteristic required for test performance.
    b. In addition to establishing performance specifications for the specific use of the test, the laboratory must also document performance of quality control and proficiency testing, and that high complexity laboratory education/experience qualifications (42 CFR § 493.1441 – 1495) are met by laboratory directors and other employees, including testing personnel.
b. Additionally 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 for EVD, they should provide training and have staff practice these procedures while wearing the appropriate PPE in advance. Changing to unfamiliar equipment or PPE without sufficient training and practice may lead to breaches in safe practices and may increase a person's risk of contaminating their clothes, mouth, or eyes.

Biosafety Level

Why does CDC work with Ebola virus in a Biosafety Level 4 laboratory facility and recommends that clinical laboratories work in a Biosafety Level 2 laboratory facility?

The activities conducted in the BSL-4 laboratory (BSL-4) on Ebola virus are different from activities that would be conducted in a U.S. clinical laboratory. CDC BSL-4 laboratorians grow large volumes of virus stocks and use them for a variety of scientific purposes such as testing possible vaccines and antiviral therapeutics. Proper containment of these large volume virus stocks is critical to the safety of laboratory personnel.

CDC's recommendations to U.S. clinical laboratories for safe management of diagnostic specimens from PUI for EVD are consistent with recommendations for other known infectious diseases that are transmitted through blood or body fluids, such as HIV and hepatitis viruses. If clinical laboratories are following CDC recommendations and the OSHA bloodborne pathogens standard (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS), they can safely manage specimens from PUI for EVD.

Additionally, CDC and international partners are able to safely manage clinical specimens of patients with known EVD in field laboratories in remote locations without modern facilities or infrastructure such as electricity, running water, or sanitation. These field laboratories are not BSL-4 facilities.

Isolation Facility

Why did Emory work with specimens from confirmed EVD patients in a special isolation facility instead of following CDC guidance?

Emory has a special isolation unit designed to treat patients with an unknown illness with unknown transmission. Emory followed their protocols for specimen handling and patient care specified for their isolation unit. The Emory unit is not run by CDC.

Patients Under Investigation

What other diseases should clinical laboratories consider when evaluating ill travelers from West Africa other than EVD?

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, and bacterial infections. Evaluation of febrile illness in a recent traveler should include a thorough travel and exposure history.

Additional information about fever in travelers returning from affected countries is available here. (http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-5-post-travel-evaluation/fever-in-returned-travelers)

CDC information regarding malaria diagnosis & treatment in the United States (http://www.cdc.gov/malaria/diagnosis_treatment/index.html)

Healthcare providers needing assistance with diagnosis or management of suspected cases of malaria should call the CDC Malaria Hotline: 770-488-7788 or 855-856-4713 toll-free (M-F, 9am-5pm, eastern time). Emergency consultation after hours, call: 770-488-7100 and request to speak with a CDC Malaria

Branch clinician.

For more details on travel, please see CDC Interim Guidance for Monitoring and Movement of Persons with Ebola Virus Disease Exposure.

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.

Diagnostic Testing for EVD

What viral diagnostic testing would CDC do on a PUI for EVD?

Several diagnostic tests are available at CDC for detection of EVD. Evidence of acute infection will be verified using a real-time RT-PCR assay (CDC test directory code CDC -10309 Ebola Identification) in a CDC CLIA-certified laboratory. The actual presence of infectious Ebola virus in a clinical sample will be confirmed by isolating virus in culture. Viral isolation must be done in a laboratory that meets appropriate biosafety level - 4 guidelines for safely culturing this virus. Serologic testing for IgM and IgG antibodies will be completed for certain specimens and to monitor the immune response in confirmed EVD patients (#CDC-10310 Ebola Serology).

Lassa fever is also endemic in certain areas of West Africa and may show symptoms similar to early EVD. Diagnostic tests including but not limited to RT-PCR, antigen detection, and IgM serology may be utilized to rule out Lassa fever in EVD-negative patients.

Virus Inactivation

Can I use virus inactivation methods on specimens from a PUI for EVD prior to testing?

Any changes to the standard management of specimens for routine clinical laboratory testing would need to be validated either by the testing laboratory or the test manufacturer. The changes would need to be applied to all specimens, since any specimen could contain a potentially infectious pathogen.

Heat inactivation is mentioned in several documents as an optional method to inactivate virus; however, while it has been scientifically shown to reduce the amount of virus in a specimen, it is not 100% effective, and is dependent on several variables (i.e., time, temperature, pressure, organic material pH, etc.). All safety procedures as designated above should still be utilized.

Current Guidance

Why does the current CDC guidance differ from the 2005 MMWR [PDF - 4 pages] (http://www.cdc.gov/HAI/pdfs/bbp/VHFinterimGuidance05_19_05.pdf)?

The current specimen guidance is meant to update the interim guidance in the 2005 MMWR on managing patients with suspected viral hemorrhagic fever in U.S. hospitals. The current guidance takes into consideration the OSHA bloodborne pathogens standards

(https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS), which is meant to protect all laboratorians from known and more importantly unknown pathogens that may be present in a specimen, as well as the impact enhanced precautions would have on all patient care in the U.S. Additionally, since 2005, there have been several imported cases of viral hemorrhagic fever with no nosocomial (hospital acquired) infections[1-4].

Why does the CDC guidance differ from other countries such as Canada and Australia?

CDC's guidance is based on the scientific information about Ebola transmission and the U.S. regulations for the handling of bloodborne pathogens by clinical laboratories, which may differ from other countries' regulations. Both personnel safety and patient care are considered when developing guidance. The OSHA bloodborne pathogens standard (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) is meant to provide all laboratorians with the proper protections from known, suspected, and unknown infectious diseases.

CDC acknowledges the existence of variations in the guidelines provided by different countries.

References:

1. Amorosa V, et al.,. Imported Lassa fever, Pennsylvania, USA, 2010. Emerg Infect Dis. 2010 Oct;16(10):1598-600.
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3. Timen A, et. al., Response to imported case of Marburg hemorrhagic fever, in the Netherlands. Emerg Infect Dis. 2009 Aug;15(8):1171-5.
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5. Centers for Disease Control and Prevention (CDC). Interim guidance for managing patients with suspected viral hemorrhagic fever in U.S. hospitals. MMWR Morb Mortal Wkly Rep. 2005 May 19.

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