Biosafety Preparedness for Viral Hemorrhagic Fevers

Guidance for Clinical Laboratories Handling Specimens from Patients Under Investigation

Please note that this document reflects information as of August 2026. The response to an outbreak of Ebola disease caused by Bundibugyo virus in remote areas of the Democratic Republic of the Congo and Uganda is an evolving situation. Contact your local public health authorities and consult the US Centers for Disease Control and Prevention (CDC) website for the most up-to-date information or with questions.

Introduction

This document provides guidance for clinical laboratories on biosafety considerations when preparing for and when handling specimens from patients under investigation (PUI) for Viral Hemorrhagic Fevers (VHFs) such as Ebola disease. The current Ebola outbreak has ongoing transmission in the Democratic Republic of the Congo and Uganda. While the risk of an individual infected with Ebola disease coming to the United States remains low, recent outbreaks and ongoing transmission demonstrate the importance of maintaining laboratory readiness for the possibility of testing specimens from a PUI.

Following CDC's Standard Precautions and OSHA's Bloodborne Pathogens Standard has been shown to effectively prevent laboratory acquired illnesses from VHFs and other high-consequence pathogens. While laboratory specimens suspected or confirmed to contain VHFs can be handled safely in the clinical laboratory setting, it is essential to follow your site-specific risk assessment prior to testing to identify any potential exposure risks. Appropriate mitigation measures including engineering controls, administrative controls and personal protective equipment (PPE) should be implemented to reduce any identified risks. This document is intended to help laboratories to evaluate their current level of preparedness, identify gaps and strengthen their ability to safely respond to a PUI.

Preparedness Assessment

- Is your laboratory prepared to safely receive, process and test clinical specimens from a PUI for VHFs such as Ebola? Laboratories should be prepared to test specimens from a PUI either on admission or later in their hospitalization. It is essential not to delay any laboratory testing for PUIs. Consider the following preparedness activities:
    a. Perform an audit of your laboratory's biosafety procedures to determine how your laboratory will handle PUI specimens in the laboratory or other areas of the hospital (e.g. within a biocontainment unit) based on institutional and/or jurisdictional expectations and site-specific risk assessments.
        - Review the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th edition- Appendix N- Clinical Laboratories
        - Review the Guidance on Performing Routine Diagnostic Testing for Patients with Suspected VHFs or Other High-Consequence Disease | Viral Hemorrhagic Fevers (VHFs) | CDC
        - Utilize the Handling a Specimen Suspected of Containing a High Consequence Pathogen: A Checklist for Clinical Laboratories to help identify potential gaps in institutional biosafety plans and effective communication when laboratories may handle a specimen suspecting of containing a high consequence pathogen.

b. Perform an audit to determine if staff are consistently following standard precautions, performing handwashing and wearing appropriate PPE including eye protection, surgical mask or face shield [or have access to a certified biological safety cabinet (BSC) and can use it to process and test specimens when the risk assessment indicates it is necessary], gloves and appropriately sized protective gown or lab coat for handling blood and body fluid specimens.
    - For areas of the laboratory that do not routinely incorporate all listed PPE above, please follow your site-specific risk assessment to identify any significant risks to staff, evaluate the barriers and limitations associated with using PPE, and determine opportunities for enhanced precautions to be implemented universally or during PUI specimen testing.
    - Review:
        - OSHA Bloodborne Pathogen Guidance (29 CFR 1910.1030)
        - CDC Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories

c. Minimize the number of staff involved with handling specimens from a PUI and designate low-traffic pathways for transporting specimens throughout the laboratory. Secondary containment should be considered when transporting specimens, especially in high-traffic areas.
    - If transporting specimens within the laboratory, it is recommended the specimens be placed in a container or sealable bag to provide primary leak-proof containment. Place the primary container in a clearly labeled, durable secondary container for transport. Disinfect the exterior of the secondary container as appropriate.

d. If possible, consider avoiding the use of pneumatic tube systems for transporting specimens when VHFs are part of the differential diagnosis to reduce the risk of breakage and/or leaks.

e. Confirm staff have received training and demonstrate competency on procedures related to handling specimens from patients following OSHA's Bloodborne Pathogens Standard and standard precautions.

Risk Assessment, Instrumentation and Engineering Controls

- Has your laboratory performed risk assessments for VHF disease testing? It is essential to perform a risk assessment on all instruments in all sections of the laboratory where blood and body fluids are tested. Consider common routes of infection and transmission of Ebola disease.
    a. APHL has developed the Laboratory Instrument Pre-purchase Risk Assessment Checklist to identify and mitigate risks related to instrument operation.
- Laboratories should consult with instrument manufacturers to determine acceptable decontamination procedures. CDC can help laboratories speak directly to instrument manufacturers about decontamination or warranty coverage by contacting DLSInquiries@cdc.gov.
    a. Please provide written confirmation that the instrument manufacturer has stated they will not service the instrument before contacting CDC with this request.

Risk Assessment Resources

- Risk Assessment Best Practices | APHL
- Biological Risk Assessment | Safe Labs Portal | CDC
- Public Health Laboratory Risk Assessment Template: Ebola Virus Disease Testing | APHL

- When possible, use a Class II BSC for manipulation of specimens. Avoid handling or manipulation on an open laboratory bench whenever possible. Processes should minimize the production of aerosols and exposure risk to laboratory staff.
    a. Consider splash protection shields or other environmental controls that can be placed between the staff and specimen when work cannot be done in a BSC.
    b. If open specimens are handled outside a BSC (such as when placing samples on an automated instrument), a site-specific risk assessment is recommended.
    c. Ensure that the BSC is in a location that has limited foot traffic.

Biosafety Resources

- Handling VHF - Associated Waste | CDC
- Select Agents and Toxins Biosafety/Biocontainment Plan Guidance | CDC & USDA
- Safe Handling, Treatment, Transport and Disposal of Ebola-Contaminated Waste | OSHA

- Use a puncture-resistant/leakproof and color-coded/labeled container for discarding any sharps materials.

Personal Protective Equipment

- Has your laboratory identified PPE needs? Based on your site-specific risk assessment, ensure that PPE supplies are adequate and available. At minimum, staff working with suspected VHF specimens should wear the following PPE:
    a. Fluid resistant or impermeable gowns; at minimum, follow ANSI/AAMI PB70 - Level 3 Requirements
    b. Disposable gloves
    c. Protective eyewear such as full-face shield or safety goggles
    d. Surgical mask to cover all of the nose and mouth
    e. Laboratories should discuss how to secure supply lines of disposable PPE

PPE Resources

- PPE: Clinically Stable Patients Suspected to have VHF | CDC
- PPE Selection Matrix for Occupational Exposure to Ebola Virus | OSHA

Decontamination

- Does your laboratory have the appropriate supplies and trained personnel to decontaminate surfaces, instruments (if possible) and spills when testing suspected samples?
- For surface decontamination (e.g., BSC, exterior of primary specimen containers, outside of secondary containment including biohazard bags and transport containers), use 0.5% sodium hypochlorite from a product within one year of manufacture. Follow the manufacturer's guidelines for preparation instructions and appropriate contact time.

Decontamination Resources

- List L: Disinfectants for Use Against Ebola Virus | EPA
- List Q: Disinfectants for Emerging Viral Pathogens | EPA

Waste Management

- How is your facility addressing waste management?
    a. Follow applicable federal, state, and local regulations for waste associated with VHF testing.
    b. Review the medical waste management plan and determine if any changes need to be made.
    c. Determine whether VHF-associated waste will be inactivated onsite or transported offsite for inactivation.
- Solid waste generated from a patient confirmed to be infected with VHFs are classified as Category A waste.
    a. This can include medical equipment, sharps, linens, used healthcare products such as soiled absorbent pads/dressings, emesis pans, portable toilets, used PPE, or cleaning byproducts.

Shipping and Regulatory Compliance

- Does your facility have personnel training in packaging and shipping?
    a. Ensure that personnel trained in packaging and shipping of Division 6.2 Category A infectious substances are readily available. Laboratories should also have a defined process for accessing trained personnel when needed outside of standard working hours.
    b. Contact your state, tribal, local, or territorial public health laboratory for additional information and training schedules for shipping Category A infectious substances. For 24/7 public health laboratory contact information please visit APHL's Emergency Response webpage.

Shipping Resources

- VHF Clinical Specimen Packaging and Shipping | CDC
- Packing and Shipping Dangerous Goods – Sample Training Materials | CDC
  Note: free CDC OneLab REACH account is required to access)

- Determine the method of transporting or shipping specimens to the public health laboratory for VHF testing. Align Category A trained staffing availability with the expected shipping schedule to ensure prompt transport and diagnosis/rule-out.
- Ensure that you have a Category A shipping container on hand.
- Refer to the CDC Ebola Hemorrhagic Fever Test Order site for specimen shipping guidance.

Training and Competency

- Are training and competency assessments current?
    a. Ensure all staff who will be working with suspect specimens are properly trained in BSC usage (as applicable) and PPE Doffing/Donning; and certified in packaging and shipping of Class 6.2 Category A infectious substances (as applicable).
- Consider having a drill or exercise with staff to ensure competency.

Viral Hemorrhagic Fever Testing Considerations

- Has your state, tribal, local, or territorial public health laboratory, state epidemiologist and/or CDC been contacted prior to testing? Are other pathogens including malaria part of the testing plan?
- Has your facility addressed notification and reporting of results?
    a. Keep in mind that current tests for Ebolavirus that show a positive result are **presumptive until confirmed by CDC**. Presumptive positive results should be reported to public health authorities in your jurisdiction in addition to the ordering clinician. Consultation with the CDC is strongly recommended for presumptive positive results for select agent viral hemorrhagic fevers.
    b. A negative test result for VHF blood specimens collected less than 72 hours after the onset of symptoms does not necessarily rule out VHF. **The test should be repeated if the patient is still symptomatic after 72 hours.**
- Does the laboratory have a system in place to communicate testing results to appropriate partners and referring specimens to the state, tribal, local, or territorial public health laboratory for confirmatory testing?
    a. Laboratories should follow their health department procedures for notification and consultation for VHF testing requests. Consultation with the CDC is strongly recommended for presumptive positive results for select agent viral hemorrhagic fevers.
    b. Maintenance on an instrument after testing a specimen containing a high-consequence pathogen should be discussed with the instrument manufacturer regarding potential risks (1).
    c. Specimens from a patient confirmed to be infected with VHFs are select agents and must be handled according to Federal Select Agent Program regulations.

Related Resources

- Considerations for Discharging People under Evaluation for Selected VHFs | CDC
- Decontamination of Select Agents Isolated in the Clinical Laboratory | APHL

References

1. Bryan, A, Cook, L, Atienza, EE, Kuypers, J, Cent, A, Baird, GS, Coombs, RW, Jerome, KR, Wener, MH, & Butler-Wu, SM (2016). Bloodborne viral pathogen contamination in the era of laboratory automation. Clinical Chemistry, 62(7), 973–981.

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For biosafety questions, please contact APHL at biosafety@aphl.org.