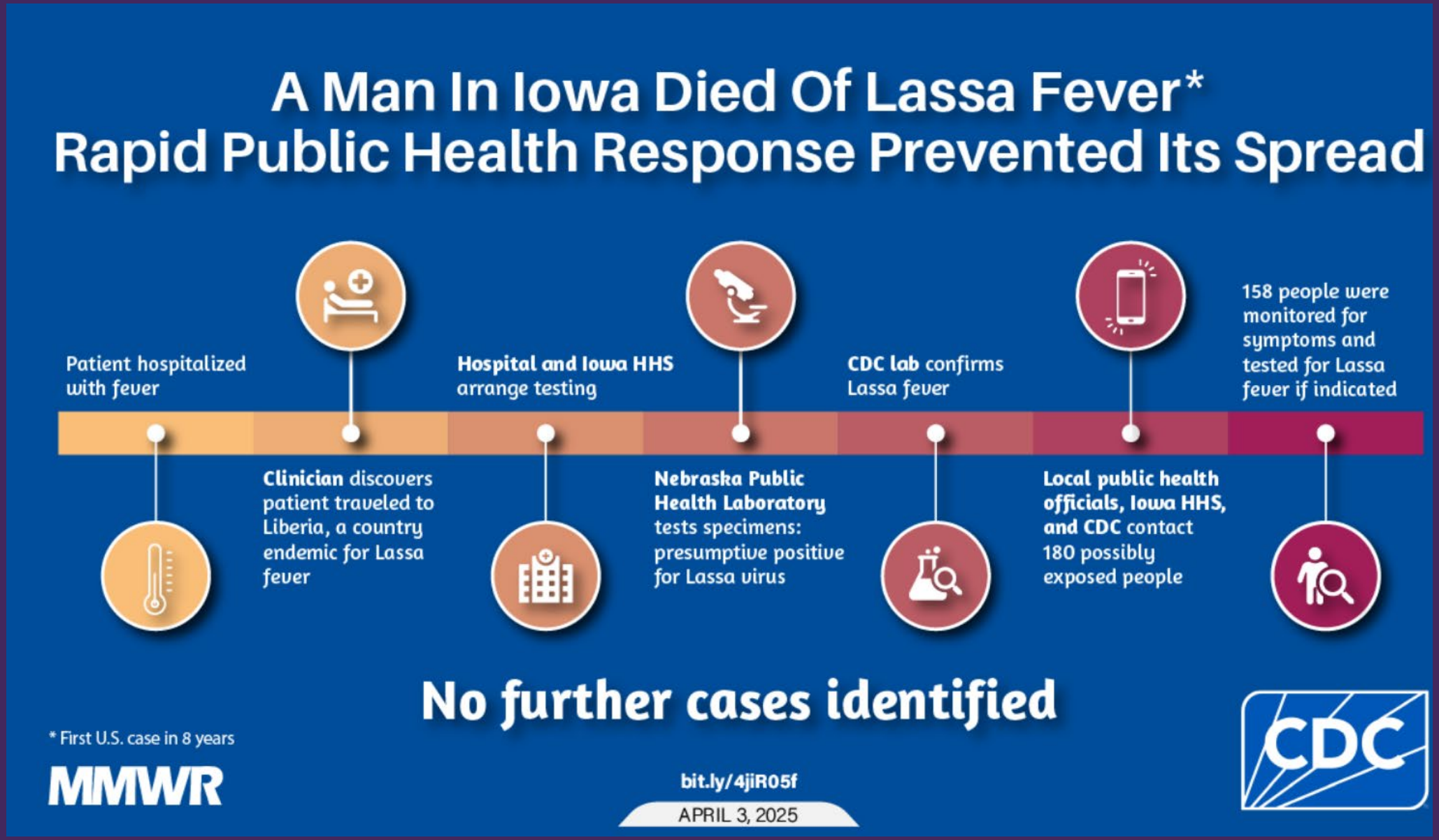


Department of Health
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PREPAREDNESS FOR LABORATORY TESTING FOR HIGH CONSEQUENCE PATHOGENS: BEYOND SAFETY TO OPERATIONAL READINESS

DR. CHRISTINA EGAN
DIRECTOR, DIVISION OF INFECTIOUS DISEASES
WADSWORTH CENTER

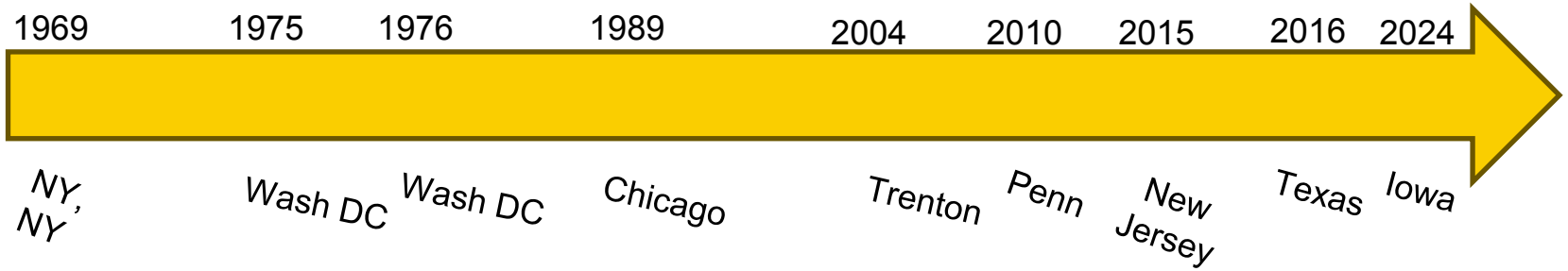
Why is it important to prepare for the possibility of high consequence pathogens in your laboratory?



https://www.cdc.gov/mmwr/volumes/74/wr/mm7411a3.htm

LASSA FEVER IN THE UNITED STATES (US)

9 cases- all travel associated in the US in the last 57 years



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Courtesy of Dr. Michael Pentella, Iowa State Hygienic Laboratory

OCTOBER 24, 2024- IOWA

- The patient returned from Liberia to Iowa on October 7th.
- Developed fevers, myalgias, and headache on October 15th.
- Presented to an emergency department on October 22nd.
- Transferred by emergency medical services (EMS) to Hospital A on October 22nd. Malaria negative.
- EMS transferred to Hospital B on October 26th.
- Patient died on October 28th and was cremated.





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Courtesy of Dr. Michael Pentella, Iowa State Hygienic Laboratory

LASSA FEVER HEALTHCARE EXPOSURES

In Iowa, the detection of Lassa fever resulted in 177 risk assessments

- Five symptomatic individuals were subsequently tested (all negative)
- 173 healthcare workers were monitored



Photo courtesy of the Wadsworth Center

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Wadsworth Center

Courtesy of Dr. Michael Pentella, Iowa State Hygienic Laboratory

TABLE. Exposure group and risk classifications* of contacts of a patient with travel-associated Lassa fever (N = 180) — Iowa, October–November 2024

Exposure location (no.)	Contact risk level (no.)					
	High exposure, nature of risk			Low exposure, nature of risk	No exposure	
	Household† (4)	Health care setting with ≥1 PPE omission†,§,¶ (95)	Health care setting with ≥1 PPE omission§,¶ and skin-to-skin contact or cleaning of body fluids† (6)	No PPE omission§,¶ (health care setting) or risk for exposure was possible (community-associated)† (50)	None (25)	Total contacts (180)
Household (4)	4**	—	—	—	—	**4**
Community (4)	—	3**	—	1	—	**4**
Health care (172)						
Hospital A (ED)	—	6	2††	1	—	**9**
EMS unit A	—	2	—	—	—	**2**
EMS unit B	—	2	—	—	—	**2**
EMS unit C	—	—	—	—	3	**3**
Hospital B	—	35	3††	7	6	**51**
Hospital C§§	—	24††	1††	36	7	**68**
Postmortem care	—	—	—	—	3	**3**
Laboratory						
A (ED)	—	2††	—	—	—	**2**
B	—	13††	—	1	1	**15**
C	—	4††	—	—	—	**4**
D	—	1††	—	1	—	**2**
E	—	3††	—	3	2	**8**
F	—	—	—	—	3†	**3**

Abbreviations: ED = emergency department; EMS = emergency medical services; PPE = personal protective equipment.

* https://www.cdc.gov/viral-hemorrhagic-fevers/php/public-health-strategy/people-with-suspected-or-confirmed-vhf-or-high-risk.html

† Actively monitored for signs and symptoms, including weakness or fatigue, fever, headache, chills, muscles aches, diarrhea, vomiting, unexplained bleeding or bruising, rash, chest pain, sore throat, cough, or dark urine.

§ https://www.cdc.gov/viral-hemorrhagic-fevers/hcp/guidance/ppe-clinically-stable-puis.html

¶ https://www.cdc.gov/viral-hemorrhagic-fevers/hcp/guidance/ppe-clinically-unstable.html

** Quarantined until 21 days after the last exposure.

†† Excluded from work until 21 days after last exposure.

§§ The patient was clinically stable until arrival at hospital C.

https://www.cdc.gov/mmwr/volumes/74/wr/mm7411a3.htm

EXPOSURE RISK

Exposure determined by risk assessment

•Personal protective equipment (PPE) for all healthcare providers entering the room of a patient confirmed to have a selected viral hemorrhagic fever (VHF) or a patient suspected to have a selected VHF who is clinically unstable or has bleeding, vomiting, or diarrhea.
From https://www.cdc.gov/viral-hemorrhagic-fevers/hcp/guidance/
PPE includes disposable fluid resistant gown, gloves, respirator, eye protection, boot covers

•Laboratorians handling specimens required to have lab coat, gloves, eye protection and a facemask

Courtesy of Dr. Michael Pentella, Iowa State Hygienic Laboratory

EXPOSURE INVESTIGATION BY PUBLIC HEALTH

Number of Contacts	Risks Identified
Total= 173	PPE omissions
155 Contacts Monitored	5 tested for possible infection, all negative
31 laboratorians in 6 labs	Specimens were processed with one or more PPE omissions while the specimen was uncapped outside of a contained system
4 laboratorians were low risk	Specimen transfer in absence of a facemask

Courtesy of Dr. Michael Pentella, Iowa State Hygienic Laboratory

VIRAL HEMORRHAGIC FEVER LABORATORY TESTING IN A HOSPITAL SETTING

- Laboratory professionals can **safely** and **effectively** perform routine diagnostic testing on clinical specimens from these patients for both general clinical assessment (basic hematology and chemistry) and additional pathogens as indicated, by following Standard Precautions for All Patient Care and the Bloodborne Pathogen Standard (29 CFR 1910.1030).
- Experience with patients with Ebola Virus Disease and other Hemorrhagic Fever Viruses in the United States and multiple other countries, has demonstrated that laboratory testing can be performed safely in clinical Biosafety Level (BSL) 2 laboratories with appropriate safety measures in place.
- The laboratory risk assessment should include the use of all instrumentation and associated procedures that could generate aerosols. Labs should have decontamination protocols with information from manufacturers.

How do you begin to prepare your laboratory?

RESOURCES

COLLEGE of AMERICAN PATHOLOGISTS

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

ASM

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.

https://aphl.org/docs/default-source/phpr/aphl_cap_asm-ebola-biosafety-preparedness-guidance.pdf

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RESOURCES

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

https://aphl.org/docs/default-source/phpr/aphl_cap_asm-ebola-biosafety-preparedness-guidance.pdf

RESOURCES

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

https://aphl.org/docs/default-source/phpr/aphl_cap_asm-ebola-biosafety-preparedness-guidance.pdf

RESOURCES

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.

https://aphl.org/docs/default-source/phpr/aphl_cap_asm-ebola-biosafety-preparedness-guidance.pdf

RESOURCES

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.

https://aphl.org/docs/default-source/phpr/aphl_cap_asm-ebola-biosafety-preparedness-guidance.pdf

ASSOCIATION OF PUBLIC HEALTH LABORATORIES (APHL) HIGH CONSEQUENCE PATHOGEN CHECKLIST

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

APRIL 2026

Handling a Specimen Suspected of Containing a High Consequence Pathogen

A Checklist for Clinical Laboratories

This checklist is intended for any laboratory that might handle a specimen containing a suspected high consequence pathogen (HCP) and is designed to help identify potential gaps in institutional biosafety plans. This will allow the laboratory to prepare for and respond to an HCP and provide the necessary training to mitigate any enhanced exposure risks.

High consequence pathogen (HCP): HCPs, which can include select agents, are characterized as causing an acute infectious disease with a high mortality rate in otherwise healthy people, where the pathogen is easily transmitted from person-to-person with epidemic or pandemic potential. In addition, there may not be effective prophylaxis or treatment, or the pathogen may be difficult to recognize rapidly. There is a heightened risk in a laboratory handling a potential HCP.

Biorisk management (BRM): The process by which laboratories and facilities combine safety and security measures to control or minimize risks associated with the handling, storage and disposal of biological agents and toxins. Strong BRM practices are essential for laboratories working with potential HCPs to ensure the protection of laboratory personnel, the public and the environment.

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https://aphl.org/docs/default-source/technical/phpr-hcp-checklist.pdf?sfvrsn=ac77edd7_5

APHL HIGH CONSEQUENCE PATHOGEN CHECKLIST

HCP Preparedness and General Laboratory Safety

Preparedness and Safety Questions	Answer	Comments
Has your facility developed a BRM program?	☐ Yes ☐ No ☐ N/A	
Is there supporting documentation that outlines biosafety and biosecurity training and competency requirements? e.g., biosafety plan or training records	☐ Yes ☐ No ☐ N/A	
Are staff competencies in biosafety and biosecurity assessed and documented?	☐ Yes ☐ No ☐ N/A	
Is biosafety and biosecurity training provided at regular intervals?	☐ Yes ☐ No ☐ N/A	
Is there guidance on how to conduct a biological risk assessment?	☐ Yes ☐ No ☐ N/A	
Has a biological risk assessment been conducted for all procedures to include equipment where a potential HCP specimen may be handled?	☐ Yes ☐ No ☐ N/A	
Are protocols in place to identify and respond to an HCP?	☐ Yes ☐ No ☐ N/A	
Is there a current biosafety manual or plan available, including any enhanced HCP-specific controls?	☐ Yes ☐ No ☐ N/A	

https://aphl.org/docs/default-source/technical/phpr-hcp-checklist.pdf?sfvrsn=ac77edd7_5

APHL HIGH CONSEQUENCE PATHOGEN CHECKLIST

Closed Systems

Closed systems protect laboratory personnel from the specimen from the time the specimen (without prior handling or manipulation) is placed in the instrument until the results are generated.

☐ **A close instrument system is in use. Describe:**

Closed System Questions	Answer	Comments
Is the specimen aliquoted or otherwise manipulated prior to placing on the instrument? Manipulation may include (but is not limited to): centrifugation, making smears, slide agglutination, needles, syringes and sharps. See Routes of Exposure (page 8) and Aerosols (page 9).	☐ Yes ☐ No	
Does disposal of the leftover specimen or other waste from testing require direct handling by personnel?	☐ Yes ☐ No	

Routes of Exposure

Evaluate potential routes of transmission of the infectious agent:

- ☐ **Sharps injury (e.g., needles, scalpel, scissors)**
- ☐ **Spills, splashes and droplet contamination**
- ☐ **Blood and body fluid contamination of non-intact skin**
- ☐ **Inhalation of aerosols/droplets (including potential sources from automated equipment)**
- ☐ **Direct mucous membrane contact to mouth, nose and eyes**

If yes to any exposure routes, describe:

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https://aphl.org/docs/default-source/technical/phpr-hcp-checklist.pdf?sfvrsn=ac77edd7_5

APHL HIGH CONSEQUENCE PATHOGEN CHECKLIST

Compliance with Select Agent Regulations When a Select Agent is Confirmed

Select Agent Compliance Questions	Answer	Comments
Upon identification of a select agent, are procedures available to comply with the Federal Select Agent Program regulations to include destruction (using acceptable decontamination method) or transfer of any materials that might contain a select agent, and the reporting of a potential exposure event?	☐ Yes ☐ No ☐ N/A	If yes, describe the method:
Is the laboratory, in consultation with the Federal Select Agent Program, prepared to complete Sections C and D of the CDC Form 4A and submit to the Division of Regulatory Science and Compliance's Federal Select Agent Program within the stipulated regulatory timeframe following HCP confirmation?	☐ Yes ☐ No ☐ N/A	

Laboratory personnel need to be interviewed to determine what procedures/activities were performed, where they were performed, what types of instruments were used and whether personnel exposure to blood and body fluids could have occurred.

From the above information, determine the level of risk based on activities performed and characteristics of pathogen detected:

If high risk:

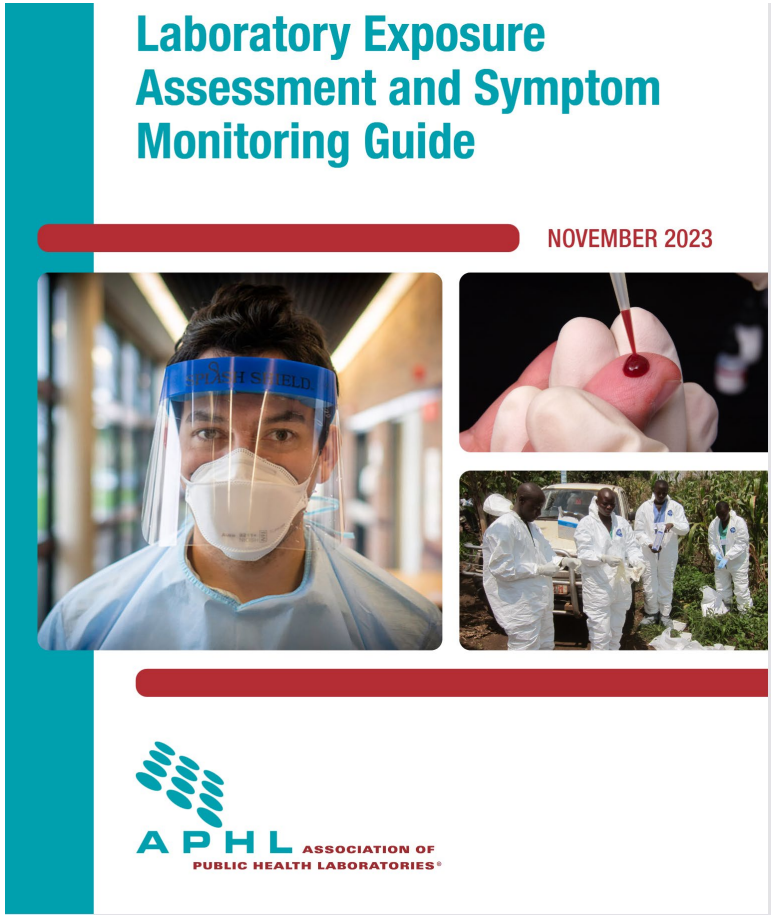
- Exclude from work and medical surveillance/symptom monitoring provided for appropriate length of days based on pathogen present.
- Offer post exposure prophylaxis, if available.
- If signs and symptoms consistent with illness detected/reported transport to assessment or treatment hospital and evaluate patient and perform testing if indicated.

If low risk:

- Medical surveillance/Symptom monitoring provided for appropriate length of days based on pathogen present.
- Offer Post Exposure Prophylaxis, if available.

https://aphl.org/docs/default-source/technical/phpr-hcp-checklist.pdf?sfvrsn=ac77edd7_5

APHL LABORATORY EXPOSURE GUIDE



https://aphl.org/docs/default-source/technical/phpr-lab-exposure-guide.pdf?sfvrsn=b8fcc6c_1

APHL LABORATORY EXPOSURE GUIDE

Ebola Virus Disease

Learn more at
cdc.gov/vhf/ebola

About Ebola Infection

Common Route/Mode of Transmission

Natural Environment

It is hypothesized that people are initially infected with Ebola virus through contact with an infected animal, such as a fruit bat or nonhuman primate; this is called a spillover event. After that, the virus spreads from person to person, potentially affecting a large number of people.

The virus spreads through direct contact (such as through broken skin or mucous membranes in the eyes, nose or mouth) with:

- Blood or body fluids (urine, saliva, sweat, feces, vomit, breast milk, and semen) of a person who is sick with or has died from Ebola virus disease (EVD)
- Objects (such as needles and syringes) contaminated with body fluids from a person sick with EVD or the body of a person who died from EVD
- Infected fruit bats or nonhuman primates (such as apes and monkeys)
- Semen from a man who recovered from EVD (through oral, vaginal or anal sex).

The Ebola virus cannot spread to others when a person shows no signs or symptoms of EVD. Additionally, Ebola virus is not usually transmitted by food. However, in certain parts of the world, Ebola virus may spread through the handling and consumption of bushmeat (wild animals hunted for food). There is also no evidence that mosquitoes or other insects can transmit Ebola virus.

Laboratory Setting

Direct contact with infectious material with mucous membranes, accidental parenteral inoculation.

Typical Incubation Period

Two to 21 days.

Prevention & Treatment

Vaccine

Not available in the United States.

Treatment

Supportive therapy, including oxygen and fluids.

Prophylaxis/Monitoring

Follow CDC's treatment and medical care guidelines.

https://aphl.org/docs/default-source/technical/phpr-lab-exposure-guide.pdf?sfvrsn=b8fcc6c_1

APHL LABORATORY EXPOSURE GUIDE

Exposure Event Evaluations

Unknown Pathogen Exposure Event Form

Exposure Event Summary

Date of Exposure: _____ Exposure Location(s): _____

Multiple people exposed? ☐ No ☐ Yes. *Complete this form for each person to determine individual exposure risk.*

Name/Identifier of Person Exposed: _____

Individual's Predispositions: ☐ Pregnant ☐ Immunocompromised ☐ Other: _____

Interactions with Pathogen

Individual worked with organism: ☐ Within BSC ☐ Outside BSC ☐ Did not work directly with organism

Individual did not work with organism, but was: ☐ Within five feet ☐ More than five feet away ☐ Unsure

Individual wore: ☐ Gloves ☐ Lab coat/gown ☐ Safety glasses ☐ Face shield ☐ Respirator (e.g., N95, PAPR)

Individual performed the following activities or types of manipulation with the organism:

- ☐ Removed caps or swabs from culture containers, opened lyophilized cultures or cryotubes
- ☐ Manipulated needles, syringes or sharps (scratch, puncture, cuts)
- ☐ Aspirated/transferred body fluids
- ☐ **Vortex** ††
- ☐ Centrifuge setup or run
- ☐ **Sonication** ††
- ☐ Harvested tissue
- ☐ Handled broken/leaky specimen or container
- ☐ Blood culture bottle inoculation
- ☐ Inoculation of media
- ☐ Mixed, blended, ground or shook
- ☐ Spilled infectious material
- ☐ Cleaned up spill
- ☐ Flamed a loop
- ☐ Wet preps
- ☐ Rapid antigen testing
- ☐ Blood culture bottle subculture
- ☐ Withdrew needles from stopper
- ☐ Expelled air from tubes or bottles
- ☐ Expelled last drop from a pipette
- ☐ Separated needles from syringes
- ☐ Prepared smears
- ☐ Heat fixation
- ☐ Stained slides
- ☐ Gram stain
- ☐ **Opened a culture plate (even without manipulating culture)** ‡‡
- ☐ Examined growth on media
- ☐ Sniffed plate
- ☐ **Catalase test** ††
- ☐ Oxidase test
- ☐ Slide agglutination
- ☐ Urease test
- ☐ Subculture isolate
- ☐ Cooled loop in culture media
- ☐ Liquid suspension preparation (e.g., pouring, splitting, decanting)
- ☐ **Spilled media with culture** ††
- ☐ **Splashed media with culture** ††
- ☐ Filtered specimens under vacuum
- ☐ Used automated system
- ☐ Prepared isolate(s) for automated identification or susceptibility testing
- ☐ Spotted for MALDI-TOF
- ☐ Applied matrix for MALDI-TOF
- ☐ Loaded plate in MALDI-TOF
- ☐ Antimocrobial resistance testing
- ☐ Threw contaminated items into biohazrdous waste
- ☐ Serology testing
- ☐ Improper PPE doffing
- ☐ Other: _____
- ☐ Other: _____

Describe any additional precautions or engineering equipment used (e.g., splash guard):

†† **Classified as an aerosol generating procedure** (Note: centrifuging is considered an aerosol-generating event when performed without a sealed carrier).

‡‡ May require further investigation or case by case evaluation. Aerosols can be generated from most routine laboratory procedures but often are undetectable. The above procedures have previously been associated with the generation of infectious aerosols, however, your facility may have additional procedures to consider. Any procedure that imparts energy to a microbial suspension can produce infectious aerosols. Organism risk group information may be obtained by searching the ABSA International Risk Group database. Organism risk group information can help a laboratory assess the consequences (e.g., low vs. moderate vs. high risks) if an exposure occurs to it.

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https://aphl.org/docs/default-source/technical/phpr-lab-exposure-guide.pdf?sfvrsn=b8fcc6c_1

APHL LABORATORY EXPOSURE GUIDE

Exposure Event Follow-up

Treatment and Monitoring

Post Exposure Prophylaxsis (PEP):	☐ Will begin	☐ Declined	☐ N/A
Serological Monitoring:	☐ Will begin	☐ Declined	☐ N/A
Fever Watch:	☐ Yes	☐ No	☐ N/A

Other Notes:

Corrective Actions and Mitigations

Use the risk assessment determinations above to evaluate the overall risk of exposure according to the likelihood of occurrence and severity of consequences.

What needed correction/improvement?

What was done?

Date Completed:

Other Notes

Overall Risk Assessment

Evaluation Date: **Evaluated By:**

Determined Exposure Risk Level: ☐ High ☐ Low ☐ No or Minimal Risk

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APHL RISK ASSESSMENT TEMPLATES



Ebola Risk Assessments

Ebola Testing Risk Assessment Template for Public Health Laboratories

Tool / Work Aid | JUN '26

+ Show Summary

Ebola Testing Risk Assessment Template for Clinical Laboratories

Tool / Work Aid | JUN '26

+ Show Summary

https://aphl.org/resources/emergency-response/resources

APHL RISK ASSESSMENT TEMPLATE

Clinical Laboratory Risk Assessment Template: Ebola Disease Testing

Introduction

This template is designed to assist laboratories in the development of their risk assessment for Ebola disease**. It may not be an all-encompassing plan, as each facility will have their laboratory-specific risk assessment procedures.**

Ebola disease is caused by a group of viruses, known as orthoebolaviruses (formerly ebolavirus) which can cause serious illness and without treatment, can result in death. There are four types of orthoebolaviruses that cause illness in people:

- Ebola virus (species *Orthoebolavirus zairense*) causes Ebola virus disease
- Sudan virus (species *Orthoebolavirus sudanense*) causes Sudan virus disease
- Taï Forest virus (species *Orthoebolavirus taiense*) causes Taï Forest virus disease
- Bundibugyo virus (species *Orthoebolavirus bundibugyoense*) causes Bundibugyo virus disease

Two other types of orthoebolaviruses have not affected people, to date:

- Reston virus (species *Orthoebolavirus restonense*) causes disease in non-human primates, like macaques
- Bombali virus (species *Orthoebolavirus bombaliense*) was recently identified in bats

Standard precautions have been highly effective in preventing transmission of bloodborne infection while handling blood and other potentially infectious material in the clinical laboratory. Standard precautions should be effective in preventing the transmission of orthoebolaviruses and other viral hemorrhagic fever agents in the clinical laboratory. However, orthoebolaviruses are high-consequence pathogens, and there has been limited experience handling specimens potentially contaminated with such a high-consequence pathogen in a clinical laboratory using current specimen handling procedures and automated instrumentation. Therefore, **this risk assessment can help enhance precautions and personal protective equipment (PPE) when handling specimens from patients who may be at risk of having Ebola disease.**

Laboratories are encouraged to use this risk assessment in conjunction with the APHL Handling a Specimen Suspected of Containing a High Consequence Pathogen Checklist for Clinical Laboratories. The checklist helps laboratories evaluate institutional preparedness, identify potential gaps in biosafety plans, assess training needs and strengthen procedures for safely handling specimens that may contain a suspected high-consequence pathogen. Together, these tools support a proactive approach to risk identification, mitigation and response.

Hospitals or clinical laboratories in the United States concerned about a patient with potential exposure to orthoebolaviruses should contact their local and/or state health departments and follow their jurisdiction's procedures for consultation on patient assessments and testing.

APHL recommends that facilities refer to the US Centers for Disease Control and Prevention (CDC) Clinical Guidance for Ebola Disease for additional information.

Visit the APHL Preparedness Planning and Training Resources for additional preparedness resources, including a Public Health Laboratory version of this template.

Prepared by the Association of Public Health Laboratories (APHL), last updated June 2026.

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https://aphl.org/resources/emergency-response/resources

APHL RISK ASSESSMENT TEMPLATE

#	Procedure	Potential Hazard(s)	Control/Protection	Additional Information

3	Preparation of specimens for testing	Aerosolization, splash or splatter	• Minimize the number of workers handling the specimens
			• Use BSL-3 PPE:
			  ○ Liquid-impermeable closed front gown OR full body jumpsuit
			  ○ double gloves
			  ○ N95 respirator and goggles or full-face shield (ensure eyes and mucous membranes covered)
			  ○ Don PPE with a trained observer
			• Work should be performed inside a certified class II BSC, following CDC's acceptable BSC practices:
			  ○ Keep sash at the appropriate level
			  ○ Adjust chair to appropriate height for user
			  ○ Minimize unnecessary movements while working in the BSC
			  ○ Limit the traffic around the BSC
			  ○ Work over a moistened, plastic-backed absorbent pad with appropriate disinfectant
			  ○ Only use pipette tips with barrier filters
			  ○ Have a dedicated rigid waste container and sharps container in the BSC
				• Prepare disinfectant according to manufacturer's instructions (e.g., EPA List L: Disinfectants for Use Against Ebola Virus) and wipe all materials down with the disinfectant before bringing into BSC
				• No exposed skin inside the BSC
				• Bring all necessary materials into the BSC before starting to work.
				• Verify BSC is operating at acceptable flow rate
				• Minimize use of sharps; dispose of all pipette tips and sharps in the dedicated containers in the BSC
				• Specimens, equipment and all materials must be decontaminated before removing from BSC
				• DO NOT set up any viral cultures
				• Put still-sealed transfer pipets in the BSC, as contamination with bleach or nucleic acids can equate to false negatives or positives

4	Trizol inactivation	Accidental exposure	• Perform in BSC
			• Use BSL-3 practices that include the following PPE:
			  ○ Fluid resistant back-closing gown
			  ○ Double gloves
			  ○ N95 respirator
			  ○ Goggles or full-face shield (eyes and mucous membranes covered)
			• Vortex inside BSC; ensure microcentrifuge tube is tightly sealed
				• Prevent contact with skin, eyes and clothing
				• Wash exposed skin with soap and water immediately. Remove all contaminated clothing or shoes.
				• After Trizol inactivation, specimen is no longer infectious and may be handled using BSL-2 practices.

https://aphl.org/resources/emergency-response/resources

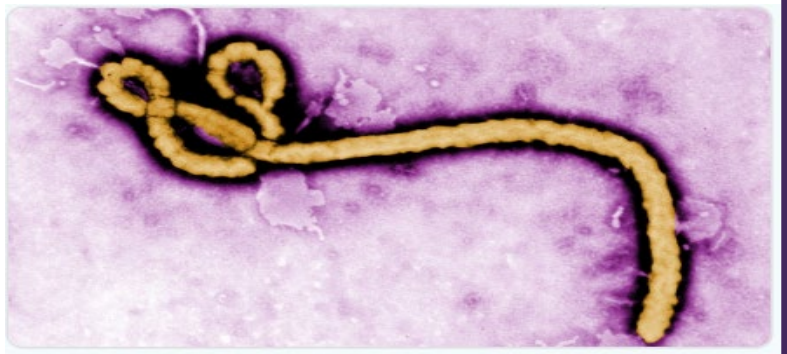
SPECIAL REQUIREMENTS FOR VHF REGULATED MEDICAL WASTE

- Management and handling of Ebola Virus Disease (EVD) regulated medical waste (RMW) generated during patient care and testing – talk to New York State Department of Health (DOH) / Department of Environmental Conservation (DEC).
- Packaging of EVD RMW – talk to your waste hauler now!
- Transport of EVD RMW – talk to your waste hauler now!
- Treatment of EVD RMW – talk to DOH / DEC.
- Disposal of EVD RMW.

Hospitals should review waste management plans to ensure protocols are in place for the management of EVD RMW in the event they have *suspected* or *confirmed* case of EVD.

WHAT CAN YOUR LABORATORY DO NOW?

- Review and update your biohazard risk assessment, laboratory protocols, and notification/reporting pathways.
- Ensure your laboratory has sufficient personal protective equipment (PPE).
- Verify that Biosafety cabinets are certified and in-date.
- Verify that staff have their certifications for packaging and shipping specimens that may contain infectious substances to comply with DOT and IATA regulations.
- Obtain Category A Infectious Substance shippers for transport of specimens to the public health laboratory.
- Ensure a site-specific waste management plan is in place for specimens, PPE, and associated waste from patients with confirmed Viral Hemorrhagic Fever (VHF).



https://www.cdc.gov/ebola/situation-summary/index.html

DOT = Department of Transportation
IATA = International Air Transport Association

APPROPRIATE SPECIMENS FOR BUNDIBUGYO EBOLAVIRUS TESTING

- Two lavender top whole blood specimens with EDTA anticoagulant (4 mL per tube for adults and 1 mL per tube for pediatric samples).
  - One specimen will be tested and the other held for testing at the Centers for Disease Control and Prevention.
- The outside of all tubes containing specimens should be decontaminated before packaging.
- Must use Category A Infectious substances packaging.
- If the initial specimen is collected less than <72 hours after symptom onset and is negative, collect a second specimen >72 hours after symptom onset in consultation with public health officials.
- Specimens should be refrigerated immediately after collection and transported on cold packs to Wadsworth Center or the New York City Public Health Laboratory. Transportation of specimens will be arranged in conjunction with the New York State Department of Health or New York City Department of Health and Mental Hygiene.

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  - Public Health Preparedness and Response Committee
  - Biosafety and Biosecurity Committee

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