

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
- Tai Forest virus (species *Orthoebolavirus taiense*) causes Tai 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.



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Assessment Information

Laboratory Unit/Section	
Date of Assessment	
Name of Assessor	
Name of Organism/Agent	Orthoebolaviruses e.g., <i>Orthoebolavirus zairensis</i>

Ebola Disease Testing Overview

#	Procedure	Potential Hazard(s)	Control/Protection	Additional Information
1	Package receipt and transfer to testing area	Leaking package	<ul style="list-style-type: none"> Transfer and open inside a Biological Safety Cabinet (BSC) PPE: nitrile/latex gloves, lab coat, safety glasses 	<ul style="list-style-type: none"> Immediately contact safety officer or other appropriate staff as designated by your facility Disinfect exterior of sealed plastic bag prior to transfer to testing area
		Unexpected delivery	<ul style="list-style-type: none"> Immediately transfer to BSC and contact clinical lab staff/supervisor of unexpected delivery If transporting specimen to another facility, use Category A packaging 	<ul style="list-style-type: none"> Notify key staff of expected package delivery All Category A packages should be opened in certified class II BSC using safety blades Select agents and toxins should be classified as outlined by the US Department of Transportation (DOT) and packaged in accordance with the DOT's Hazardous Materials Regulations
2	Transport of specimens between testing areas	Breakage of the specimen container	<ul style="list-style-type: none"> Inside the facility: <ul style="list-style-type: none"> Specimens should be transported in a clearly labeled, durable, leak-proof transport container, lined with absorbent material Wipe the outside of the container with an approved disinfectant before leaving the patient bedside Bring container directly to the specimen handling area of the laboratory and disinfect again prior to testing Outside of the facility: Use a Category A shipping container and IATA and DOT requirements 	<ul style="list-style-type: none"> Decontaminate all surfaces of transport container prior to reuse If transporting in biohazard bags, dispose of in biohazard waste: do not use pneumatic tube transport system

#	Procedure	Potential Hazard(s)	Control/Protection	Additional Information
3	Preparation of specimens for testing	Aerosolization, splash or splatter	<ul style="list-style-type: none"> • Minimize the number of workers handling the specimens • Use BSL-3 PPE: <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ 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 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Perform in BSC • Use BSL-3 practices that include the following PPE: <ul style="list-style-type: none"> ○ 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 	<ul style="list-style-type: none"> • 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.

#	Procedure	Potential Hazard(s)	Control/Protection	Additional Information
		Trizol reactivity	<ul style="list-style-type: none"> Do not mix Trizol or Trizol waste with bleach or acids Do not use bleach or acids in BSC while Trizol in use 	<p>If accidental mixture of Trizol and bleach/acid occurs:</p> <ul style="list-style-type: none"> Remove PPE Exit BSL-3 as soon as possible and notify safety officer and supervisor Post “Do Not Enter” sign on BSL-3 suite and do not enter for at least one (1) hour (this time frame will be based on your institutional specific risk assessment)
5	Vortexing and Centrifuging	Aerosolizing	<ul style="list-style-type: none"> Vortex inside BSC; ensure microcentrifuge tube is tightly sealed Use sealed head rotor inside the BSC Place specimens in centrifuge cups inside the BSC and cap. Bring bucket to centrifuge to spin, then return to BSC to open Wipe down tube with appropriate disinfectant 	Specimens, equipment and all materials must be decontaminated with approved disinfectant before removing from BSC
6	After specimen inactivation and before removal of submitted specimen from BSC	Accidental transfer of contaminated material from the BSC	<ul style="list-style-type: none"> Wipe all tubes with disinfectant before removing from BSC Place remaining specimen in Ziploc plastic bag; disinfect exterior of bag before removing from BSC. Change gloves 	A dedicated waste bag for gloves and other waste is recommended.
7	Post extraction BSC decontamination	Contamination of BSC surfaces	<ul style="list-style-type: none"> Wipe the inside of the BSC with approved disinfectant Remove all PPE and discard into biohazard waste stream 	<ul style="list-style-type: none"> Use 10% bleach disinfectant followed by appropriate contact time. Follow manufacturer’s guidelines for proper disinfection and maintenance. Wipe down all surfaces in the BSC with 70% alcohol and allow to air dry.
8	Waste	External contamination of waste containers	Disinfect outside of waste containers with approved disinfectant before removal from BSC and BSL-3	<ul style="list-style-type: none"> Use 10% bleach disinfectant followed by appropriate contact time Autoclave all PPE used in specimen handling and testing If autoclaving is not possible, review the waste handling protocols with facility management to determine what is required

#	Procedure	Potential Hazard(s)	Control/Protection	Additional Information
9	Doff PPE with trained observer	Improper PPE removal can result in exposure	<ul style="list-style-type: none"> • Doff BSL3+ PPE accompanied by a trained observer • Use a PPE doffing checklist to ensure PPE was properly removed to prevent exposure. • Follow your institutional hand washing policy <p>Have the trained observer confirm that the individual doffing PPE has successfully avoided direct contact with contaminated areas and has no observable contamination on their skin or clothing</p>	<ul style="list-style-type: none"> • CDC’s Clinical Safety: Hand Hygiene for Healthcare Workers • CDC’s Clean Hands in Healthcare Training • PPE doffing should be practiced and competency assessed prior to conducting the procedure in a real-world situation

Biological Safety

There are examples included in italics of what information might go in the response column, but this should be tailored to the laboratory’s procedures and inventory.

#	Item	Response	Comments
1	Biosafety level (BSL) established in this unit	<input type="checkbox"/> N/A, no BSL	
		<input type="checkbox"/> BSL-3+	<i>List BSL-3+ processes e.g., Sample processing including inactivation and extraction steps; Sample storage</i>
		<input type="checkbox"/> BSL-2	List BSL-2 processes: <i>e.g., PCR (after inactivation) and associated reagent preparation</i>
		<input type="checkbox"/> BSL-1	List BSL-1 processes:
2	List parts of testing process that pose a risk of aerosol generation	<input type="checkbox"/> Vortexing	
		<input type="checkbox"/> Specimen loading	<i>e.g., Loading into cartridge by syringe</i>
		<input type="checkbox"/> Pipetting	
		<input type="checkbox"/> Centrifuging	
		<input type="checkbox"/> Opening and closing collection and microcentrifuge tubes	
3	List all equipment involved in the use and storage of infectious materials Note: All must have biosafety labels affixed	<input type="checkbox"/> BSC	<input type="checkbox"/> has biosafety label
		<input type="checkbox"/> Centrifuge	<input type="checkbox"/> has biosafety label
		<input type="checkbox"/> Freezers/refrigerators	<input type="checkbox"/> has biosafety label <i>e.g., Have 2 of each - 1 for specimen, 1 for reagents</i>
		<input type="checkbox"/> Pipettes	<input type="checkbox"/> has biosafety label <i>e.g., Set is dedicated to Ebola testing</i>

#	Item	Response	Comments
		<input type="checkbox"/> Heat block	<input type="checkbox"/> has biosafety label
4	Are buckets with safety caps/cups or aerosol tight rotor lids used when centrifuging infectious materials?	<input type="checkbox"/> No <input type="checkbox"/> Yes	
5	Is health monitoring performed in this Unit?	<input type="checkbox"/> No <input type="checkbox"/> Yes	If yes, please indicate frequency and the process:
6	Are vaccines recommended for work in this Unit?	<input type="checkbox"/> No <input type="checkbox"/> Yes	If yes, please indicate how employees are informed of the vaccines, what vaccines are recommended, etc.:
7	List all sharps used and whether they include any safety features	<input type="checkbox"/> Safety blades	<input type="checkbox"/> includes safety device feature
		<input type="checkbox"/> Syringe	<input type="checkbox"/> includes safety device feature
		<input type="checkbox"/> Pipette tips	<input type="checkbox"/> includes safety device feature
		<input type="checkbox"/> Reagent needles	<input type="checkbox"/> includes safety device feature
		<input type="checkbox"/> No sharps used	
8	Is a BSC in use?	<input type="checkbox"/> No <input type="checkbox"/> Yes	Please indicate if the BSC has been certified within the past year, whether the air vents are not blocked and the sash is in place and operable:

Comments

Suggest using a buddy system in BSL-3 Ebola Testing Processing and Extraction.

Laboratory instruments should be maintained as they normally would with any other bloodborne pathogen. A risk assessment should be done before testing specimens from a suspect case on specific automated instruments. Laboratories should consult the manufacturers' instructions, or the manufacturer directly, on whether there is a need to, and how to, decontaminate the interior surfaces or areas of laboratory instruments.

Chemical Safety

#	Item	Response	Comments
Proper Labeling			
1	All containers are labeled with chemical name	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
2	Fire Department Permit is posted on laboratory door	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
3	Chemical inventory is updated	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
4	Safety data sheets are accessible to staff	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
Chemical Storage			
5	Incompatible chemicals are segregated	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
6	Flammable liquids are...		
	Stored in rated chemical cabinets	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	Stored in flammable-rated refrigerators/freezers	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
7	Excessive chemicals are stored in a chemical storage room	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
8	Compressed gas cylinders are stored in the laboratory	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
9	Chemicals are stored at eye-level	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
10	Acids and bases are...		
	Stored in a cabinet	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	Stored in a labeled area	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	Stored free from metals	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
Chemical Fume Hoods			
11	Hoods have been certified within the past year	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	Sash is closed when not in use	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	Exhaust air is not blocked by large equipment or containers	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	Hoods are used for hazardous, toxic or flammable procedures	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

Additional Comments

Personal Protective Equipment (PPE)

#	Item	Response	Comments
Education and Training			
1	Laboratory staff are aware of PPE requirements for this laboratory	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2	Staff receive an annual PPE competency assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No	
PPE Care			
3	PPE are appropriately stored in laboratory	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4	PPE are inspected prior to use and are in good condition	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5	PPE are not worn outside the laboratory area	<input type="checkbox"/> Yes <input type="checkbox"/> No	
PPE in Use			
6	Safety glasses/goggles	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7	Facial shields/splash guards	<input type="checkbox"/> Yes <input type="checkbox"/> No	
8	Disposable laboratory coats	<input type="checkbox"/> Yes <input type="checkbox"/> No	
9	Nitrile gloves	<input type="checkbox"/> Yes <input type="checkbox"/> No	
10	Respiratory protection	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	If yes, users are enrolled in a respiratory protection program	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13	Cryo or autoclave gloves	<input type="checkbox"/> Yes <input type="checkbox"/> No	
14	Over sleeves/booties/bonnet	<input type="checkbox"/> Yes <input type="checkbox"/> No	
15	Closed-toe shoes that cover entire foot are worn in laboratory	<input type="checkbox"/> Yes <input type="checkbox"/> No	
16	Proper Handwashing Technique	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Additional Comments

Emergency Preparedness

#	Item	Response	Comments
1	Emergency contact information is posted	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2	First aid kit is maintained	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3	Biological spill kit is maintained	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4	Staff are aware of occupational injury procedures	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Additional Comments

Documentation and Training

#	Item	Response	Comments
1	Employee(s) completed right-to-know training	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2	Employee(s) completed unit-specific training	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3	Employee(s) completed bloodborne pathogens training	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4	Employee(s) read and understand safety and health plans	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5	Door sign is up-to-date and posted	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6	Laboratory microwaves and refrigerators are labeled with "Not for Food or Drink – Biohazard"	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Additional Comments

Waste Management

#	Item	Response	Comments
Chemical Waste			
1	Containers are labeled with chemical name and percent of each chemical	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2	Containers are properly sealed	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3	Containers are in good condition for transport	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Biohazard Waste			
4	Broken glass is placed in the appropriate receptacle	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Additional Comments

Engineering Controls

#	Item	Response	Comments
1	Laminar flow hoods	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2	Transport containers	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3	Sharps container	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Additional Comments

At Risk Employees

Name	Signature	Date

Assessment Approval

This risk assessment should be reviewed annually or after any major changes (e.g., new facility, new employees, new technology, new method, changes in information for organism/agent, etc.). Minor changes should be recorded under Amendments. Major changes require a new risk assessment to be performed.

Reviews have been carried out on the following dates:

Title	Printed Name	Signature	Date
Principal Investigator			
RO/ARO			
Section Manager			
Unit Manager			

Reviewed by:

Testing Personnel	Printed Name	Signature	Date

LABORATORY SPECIMEN(S) HANDLING LOG

Use one form for each patient—multiple specimens per patient may use single log form.

Receiver of Specimen(s): _____

Date Received: _____ Time: _____ Intake #: _____

Delivery Method: FedEx/UPS Storeroom Department of Health Driver Messenger/Name: _____

Laboratory Number Call for Pick-up: _____ Time Picked Up by Laboratory: _____

To be completed by the laboratory:

Picked up from Receiver By: _____

Purpose: Patient Clinical Test QC Training/Validation _____ Proficiency

Number of Specimens in Package: _____ Sample Type(s): _____

Accession #: (1) _____ (2) If Applicable: _____

Patient ID # on Submission Form: _____ Submitter: _____

Consult your state, tribal, local, or territorial public health department and [Laboratory Response Network for Biological Threats](#) (LRN-B) laboratory early and use them as a resource for planning and testing recommendations.