Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing

Important Note: This template is designed to assist laboratories in the development of their risk assessment for Ebola Virus Disease (EVD). It may not be an all-encompassing plan as each facility will have their laboratory specific risk assessment procedures.

Standard precautions have been highly effective in preventing transmission of bloodborne infection in the course of handling blood and other potentially infectious material in the clinical laboratory. Standard precautions should be effective in preventing the transmission of Ebola virus and other viral hemorrhagic fever agents in the clinical laboratory. However, Ebola virus is a high consequence pathogen, 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 is provided for enhanced precautions and personal protective equipment (PPE) in handling specimens from patients who may be at risk of having Ebola virus infection.**

Laboratory Unit/Section	
Date of Assessment	
Name of Assessor	
Name of Organism/Agent	**Ebola Zaire Virus (Ebola Virus)**

Procedure	Potential Hazard(s)	Control/Protection	Additional Information
A. Package receipt and transfer of packages to testing area	Leaking Package	• Place leaking package in plastic bag and transfer to a Biological Safety Cabinet (BSC). • PPE: nitrile/latex gloves, lab coat, safety glasses	• Contact RO/ARO/Safety Officer immediately • Disinfect exterior of sealed plastic bag prior to transfer to testing area.
	Unexpected delivery	• Immediately transfer to BSC and contact RO/ARO/Safety Officer of unexpected delivery. • Deliver specimen in original category A packaging to testing area.	• Notify key staff of expected package delivery. • ARO/RO notifies section/unit • All category A Packages opened in certified class II BSC with safety blades.
B. Transport of Specimens between testing areas	Breakage of the specimen container.	• Specimens should be transported in a clearly labeled, durable, leak-proof transport container directly to the specimen handling area of the laboratory.	• Decontaminate all surfaces of transport container prior to reuse.

C. Preparation of Specimens for testing,	Aerosolization/Splash/Splatter	• Minimize the number of workers handling the specimens • Work inside a certified class II BSC with the sash at the appropriate level. • Minimize unnecessary movements while working in the BSC. Follow acceptable BSC practices. • Use BSL-3 practices that include the following PPE: fluid resistant back-closing gown, double gloves, N95 respirator and goggles or full face shield, (eyes and mucous membranes covered). • Limit the traffic around the BSC. • In the BSC, work over a Wexcide moistened plastic backed absorbent pad. • Use only pipette tips with barrier filters. • Have a dedicated rigid waste container in the BSC. • If making aliquot tubes: Wipe outside of primary and aliquot tubes before removing from BSC – Go to "Step D"	• No exposed skin inside the BSC. • Bring all necessary material into the BSC before starting to work. • Wexcide (1oz/gal) Contact time = 10 minutes • Minimize use of sharps. Dispose of all pipette tips and sharps in the dedicated container in the BSC • Specimens, equipment, and all materials must be decontaminated before removing from BSC • DO NOT set up any viral cultures

D. 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.
	Trizol reactivity	• Do not mix Trizol or Trizol waste with bleach or acids • Do not use bleach or acids in BSC while Trizol in use.	• If accidental mixture of Trizol and bleach/acid occurs, remove PPE, exit BSL-3 as soon as possible and notify Safety Officer and supervisor. Post Do Not Enter sign on BSL-3 suite. Do not enter BSL-3 for at least 1 hour.

E. Vortexing and Centrifuging	Aerosolizing	• Vortex inside the BSC. Ensure microcentrifuge tube is tightly sealed. • Use sealed head rotor inside the BSC. • Load and unload buckets in the BSC.	• Specimens, equipment, and all materials must be decontaminated before removing from BSC
F. After specimen inactivation completed and before removal of specimen from the BSC	Accidental transfer of contaminated material from the BSC.	• 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. • Store specimen(s) in refrigerator inside BSL-3 suite	• Disinfectants for containers and work surfaces: • Wexcide (1oz/gal) Contact time = 10 minutes • Dedicated waste bag for gloves and other waste
G. Post extraction BSC Decontamination	Contamination of BSC surfaces	• Wipe the inside of the BSC with disinfectant. • Remove all PPE and discard into medical waste stream	• 10% bleach disinfectant is used: contact time = 10 minutes followed by wiping down all surfaces in the BSC with 70% alcohol and allow to air dry.
H. Waste autoclaving	External contamination of waste containers	• Disinfect outside of waste containers before removal from BSC and BSL-3.	• 10% bleach disinfectant is used: contact time = 10 minutes • Autoclave all PPE used in specimen handling waste and testing.

Biological Safety	
Item	**Response**
1. Indicate the biosafety level (BSL) established in this unit. (BSL-1, BSL-2, BSL-3, N/A)	BSL-3: Sample processing including inactivation and extraction steps BSL-3: sample storage BSL-2: PCR and associated reagent preparation
2. Is there potential for aerosol generation?	*yes, please indicate the task. (i.e., sonicating, vortexing,etc.)* Vortexing Pipetting Centrifuging Opening and closing collection tubes and microcentrifuge tubes
3. Equipment such as centrifuges, incubators, freezers involved in the use and storage of infectious materials have the biosafety label affixed?	Equipment needed (all to have biosafety label affixed): BSC Eppendorf Centrifuge 2 freezer/refrigerators (1 for specimen, 1 for reagents) Pipettes (dedicated to Ebola testing) Heat block (maybe)
4. Buckets with safety caps/cups or aerosol tight rotor lids used when centrifuging infectious materials?	Yes for the Eppendorf Centrifuge
5. Is health monitoring performed in this Unit?	*If yes, please indicate frequency and the process.* [LAB TO COMPLETE]
6. Are vaccines recommended for work in this Unit?	*If yes, please indicate how employees are informed of the vaccines? What vaccines are recommended?* There is no commercially licensed vaccine available for Ebola virus.
7. Are sharps used?	*If yes, please indicate the sharp (needle, blades, etc.) Does the sharp include safety device feature?* Pipette tips
8. Does work include a Biological Safety Cabinet?	*If yes, indicate if the BSC has been certified within the past year, the air vents are not blocked, and the sash is in place and operable?* [LAB TO COMPLETE]
Comments: Buddy system to be used in BSL-3 Ebola Testing Processing and Extraction	

Chemical Safety		
Item	**Yes**	**No**
1. Proper labeling: All containers labeled with the name of chemical?		
2. Fire Department Permit posted on the laboratory door?		
3. Updated chemical inventory?		
4. Materials safety data sheets accessible to staff?		
5. Incompatible chemicals segregated?		
6. Flammable liquids stored: rated chemical cabinets?		
7. Flammable liquids stored: stored in flammable-rated refrigerators/freezers?		
8. Excessive chemicals stored in chemical storage room?		
9. Compressed gas cylinders stored in laboratory?		
10. Chemicals stored at eye-level?		
11. Acids and bases stored?		
a. Cabinet?		
b. Labeled area?		
c. Free from metals?		
12. Chemical fume hoods:		
a. Certified within past year?		
b. Sash closed when not in use?		
c. Exhaust air not blocked by large equipment or containers?		
d. Used for hazardous/toxic or flammable procedures?		
Comments:		

Personal Protective Equipment		
Item	**Yes**	**No**
1. Laboratory staff aware of personal protective equipment (PPE) requirements for this laboratory		
2. Do staff receive annual PPE competency assessment?		
3. PPE Care:		
a. Appropriately stored in laboratory?		
b. Inspected prior to use and in good condition?		
c. Not worn in laboratory area?		
4. PPE Selected:		
a. Facial shields/splash guards?		
b. Disposable laboratory coats?		
c. Nitrile gloves?		
d. Respiratory protection?		
i. Users are enrolled in a respiratory protection program?		
e. Cryo or autoclave gloves?		
f. Over sleeves/booties/bonnet		
5. Closed-toe shoes that cover entire foot worn in laboratory?		
Comments:		

Emergency Preparedness		
Item	**Yes**	**No**
1. Emergency contact information posted?		
2. First aid kit maintained?		
3. Biological spill kit maintained?		
4. Staff aware of occupational injury procedures?		
Comments:		

Documentation And Training		
Item	**Yes**	**No**
1. Employee(s) completed right-to-know training?		
2. Employee(s) completed unit-specific training?		
3. Employee(s) read and understand safety and health plans?		
4. Door sign up-to-date and posted?		
5. Laboratory microwaves and refrigerators labeled with “Not for Food or Drink – Biohazard”?		
Comments:		

Waste Management		
Item	**Yes**	**No**
1. Chemical waste containers:		
a. Labeled with chemical name and percent of each chemical?		
b. Properly sealed?		
c. In good condition for transport?		
2. Biohazard waste:		
3. Broken glass placed in appropriate receptacle?		
Comments:		

Engineering Controls		
Item	**Yes**	**No**
1. Laminar Flow Hoods		
2. Transport Containers		
3. Sharps Container		
Comments:		

At Risk Employees		
Name	**Signature**	**Date**

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.). Reviews have been carried out on the following dates. Minor changes should be recorded under Amendments. Major changes require a new risk assessment to be performed.

Approved by:

	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

One Form For Each Patient – Multiple Specimens Per Patient May Use Single Log Form

Receiver of Specimen(s):

1) Date Received: _____ Time: _____ Intake #: _____

2) Method of Delivery:

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

3) Laboratory Number Call for Pick-Up: _____ Time Picked Up By Laboratory: _____

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To Be Completed by 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: _____

Function	Name of Responsible Technologist	Time
Delivered to Lab/BSL-3		
Accessioned By		
BSL-3 Processing		
RNA Extraction		
PCR Reaction Setup/Master Mix/Template		
ABI Run		
ABI Analysis		
Storage of Original Sample(s) Unit: Location:		
Storage of RNA Unit: Location:		
LIMS Result Verification and Report Verification of Report Received ☐		
Results Reported To: ☐ CDC ☐ _____ Specimen(s) Shipped To: ☐ CDC ☐ _____		
Other		
Other		