

# THE CLINICAL LABORATORY EBOLA RESPONSE

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Back to the Basics: A Review of Biosafety Practices



# Outline

- Ebola Overview
- Standard (Universal) Precautions
- Primary Barriers
- Secondary Barriers
- Waste Disposal
- Packaging and Shipping
- Risk Assessment

# Ebola Overview

- Ebola, previously known as Ebola hemorrhagic fever.
- Ebola is caused by infection with a virus of the family *Filoviridae*, genus *Ebolavirus*.
- There are five identified Ebola virus species, four of which are known to cause disease in humans.
  - Currently circulating strain in West Africa = *Zaire ebolavirus*
- Ebola is not a new virus. Ebola viruses are found in several African countries. Ebola was first discovered in 1976 near the Ebola River in what is now the Democratic Republic of the Congo. Since then, outbreaks have appeared sporadically in Africa.

# Transmission of Ebola

- Ebola is spread through direct contact (through broken skin or mucous membranes) with:
  - Blood or body fluids (including but not limited to urine, saliva, sweat, feces, vomit, breast milk, and semen) of a person who is sick with Ebola
  - Objects (like needles and syringes) that have been contaminated with the virus
- Ebola is not spread through the air or by water.
- Exposure to Ebola can occur in healthcare settings where staff are not wearing appropriate protective equipment, including, but not limited to, masks, gowns, gloves and eye protection.

# Standard (Universal) Precautions

- All laboratorians and other healthcare personnel collecting or handling specimens must follow established standards compliant with OSHA bloodborne pathogens standard, which includes blood and other potentially infectious materials.
- These standards include wearing appropriate personal protective equipment and following all safety rules for all specimens **regardless of whether they are identified as being infectious.**

# Contact Precautions

- Contact Precautions are intended to prevent transmission of infectious agents which are spread by direct or indirect contact with the patient or the patient's environment.
- Contact Precautions also apply where the presence of excessive wound drainage, fecal incontinence, or other discharges from the body suggest an increased potential for extensive environmental contamination and risk of transmission.
- Wear gloves and gown for all interactions with the patient or the patient's environment.
- Discard Gown and Gloves before exiting the patient's room
- **Wash hands after removing gloves and before exiting the room.**

# Splash (Droplet) Precautions

- Splash (Droplet) Precautions are intended to prevent transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.
- Splash precautions are used anytime blood or body fluids could splash into eyes, nose, or mouth.
- Wear gloves and gown to protect hands and clothing.
- Wear face shield/goggles to protect eyes.
- Wear mask to protect nose and mouth (respiratory mask not necessary)
- Discard Gown, Gloves, Mask, & Goggles before exiting the patient's room
- **Wash hands after removing gloves and before exiting the room.**

# Airborne or (Respiratory) Precautions

- Airborne Precautions prevent transmission of infectious agents that remain infectious over long distances when suspended in the air.
- Wear gloves and gown.
- Wear a N95 mask or respirator that has been fit tested.
- Discard Gown and Gloves before exiting the patient's room.
- Remove N95 respirator after exiting patient room.
- **Wash hands after removing gloves**



# What Standard Precautions are Specific for Ebola?

- Follow Contact and Splash (Droplet) Precautions
- Specimen Collection
  - Full face shield or goggles
  - Barrier Mask to cover all of nose and mouth
  - Gloves (double gloving as needed)
  - Fluid Resistant or impermeable gown (not routine lab coat)
  - Disposable shoe covers or leg coverings
- Transporting samples within the institution
  - Use Plastic tubes
  - Place specimens in a durable, leak-proof transport container
  - **DO NOT USE PNEUMATIC TUBE SYSTEM**
    - Reduce risk of breakage and leaks

# Primary Barriers (PPE)

- PPE = “specialized clothing or equipment worn by an employee for protection against infectious materials” (OSHA)
- OSHA issues workplace health and safety regulations. Regarding PPE, employers must:
  - Provide appropriate PPE for employees
  - Ensure that PPE is disposed or reusable PPE is cleaned, laundered, repaired and stored after use

# Proper Use of PPE

- Lab Coat
  - Fully buttoned from neck to knees
  - Cuffs should be fitted at wrist for maximum protection
- Gowns
  - Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
  - Fasten in back of neck and waist
- Goggles
  - Should fit snugly over and around eyes
  - Personal glasses not a substitute for goggles
  - Anti-fog feature improves clarity

# Proper Use of PPE

- Masks

- Should fully cover nose and mouth
- N95 particulate respirator: should fit snug to the face to cover nose and mouth – protection against airborne infection
  - Seal checked before each use
  - Requires annual medical evaluation
  - Requires annual Fit testing and refresher training
  - How many employees in your facility are currently fit tested for N95 respirator use?

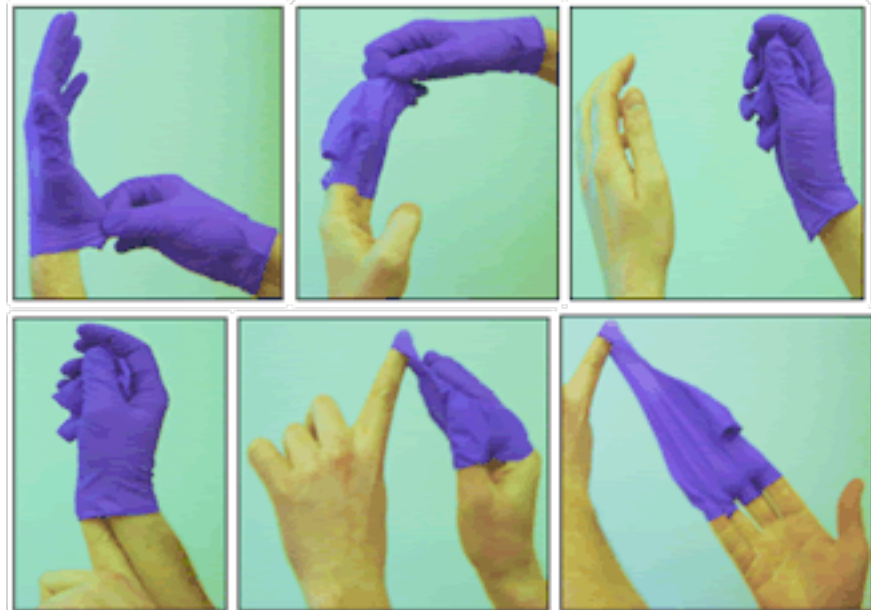
- Face Shields

- Should cover forehead, extend below chin and wrap around side of face
- Accommodates mask or respirator underneath

# Proper Use of PPE

- Gloves

- Single use only – gloves should **never** be reused
- Double glove when warranted by risk assessment
- Wash hands after glove removal
- If collecting patient specimens, hands should be washed prior to and after glove usage.



# Donning PPE

What is Donning?  
To put on or dress in

## SEQUENCE FOR PUTTING ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE should be tailored to the specific type of PPE.

### 1. GOWN

- Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
- Fasten in back of neck and waist



### 2. MASK OR RESPIRATOR

- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator



### 3. GOGGLES OR FACE SHIELD

- Place over face and eyes and adjust to fit



### 4. GLOVES

- Extend to cover wrist of isolation gown



## USE SAFE WORK PRACTICES TO PROTECT YOURSELF AND LIMIT THE SPREAD OF CONTAMINATION

- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform hand hygiene

# Doffing PPE

- What is Doffing?
- To remove or take off

## HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. Remove all PPE before exiting the patient room except a respirator, if worn. Remove the respirator after leaving the patient room and closing the door. Remove PPE in the following sequence:

### 1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in an infectious\* waste container



### 2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in an infectious\* waste container



### 3. GOWN

- Gown front and sleeves are contaminated!
- If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- Fold or roll into a bundle and discard in an infectious\* waste container



### 4. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in an infectious\* waste container



### 5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE

\*An infectious waste container is used to dispose of PPE that is potentially contaminated with Ebola virus.



PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS  
BECOME CONTAMINATED AND IMMEDIATELY AFTER  
REMOVING ALL PPE





# Doffing PPE

## HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 2

Here is another way to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Remove all PPE before exiting the patient room except a respirator, if worn. Remove the respirator after leaving the patient room and closing the door. Remove PPE in the following sequence:

### 1. GOWN AND GLOVES

- Gown front and sleeves and the outside of gloves are contaminated!
- If your hands get contaminated during gown or glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp the gown in the front and pull away from your body so that the ties break, touching outside of gown only with gloved hands
- While removing the gown, fold or roll the gown inside-out into a bundle
- As you are removing the gown, peel off your gloves at the same time, only touching the inside of the gloves and gown with your bare hands. Place the gown and gloves into an infectious\* waste container



### 2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in an infectious\* waste container



### 3. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in an infectious\* waste container



### 4. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



\* An infectious waste container is used to dispose of PPE that is potentially contaminated with Ebola virus.

PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS  
BECOME CONTAMINATED AND IMMEDIATELY AFTER  
REMOVING ALL PPE



# What PPE is Specific for Ebola?

- Follow Contact and Splash (Droplet) Precautions
- PPE Recommendations for Laboratory Testing
  - Full face shield or goggles
  - Barrier Mask to cover all of nose and mouth
  - Gloves (double glove as indicated per risk assessment)
  - Fluid Resistant or impermeable gown (not routine lab coat)
- Ensure adequate supply of PPE for Ebola Emergency Preparedness
  - Masks
  - Gowns, gloves, face shields, goggles
  - Shoe Covers

# Primary Barriers: Engineering Controls

- Biological Safety Cabinets
- Safety Centrifuges – automatic locking mechanisms, hermetically sealed rotors cups
- Splash Shields
- Transport Containers



# Proper Use of a Biosafety Cabinet (BSC)

- **To ensure proper airflow, only equipment needed should be inside the BSC**
- To ensure BSC is working properly, check the airflow gauge readings.
- Check sash height for safe operation
- Always move hands and arms straight in and out of the BSC and sit in the center
- Use no sweeping motions when working
- Remember 10 cm rule & place no objects on BSC grill
- Minimize traffic in the area
- Decontaminate interior of BSC with an appropriate disinfectant

# What Engineering Controls are Specific for Ebola?

- Certified Class II BSC
- Splash shields when a BSC is not available to place between the worker and specimen (ex: uncapping of tubes of blood)
- Manufacturer installed safety features for instruments
- Follow the equipment manufacturer's proper use and decontamination guidelines
- Specimen transport containers for movement of all specimens suspicious of Ebola within the facility

# Laboratory Secondary Barriers

- The design and construction of the facility contributes to the laboratory workers' protection, provides a barrier to protect persons outside the laboratory, and protects the community from infectious agents that may be accidentally released from the laboratory.
- Design features include specialized ventilation systems to ensure directional airflow, air treatment systems to decontaminate or remove agents from exhaust air, controlled access zones, airlocks at laboratory entrances, or separate buildings or modules to isolate the laboratory.

# Possible Secondary Barriers for EVD

- A laboratory space near or adjacent to the suspected or confirmed EVD patient room equipped with Point of Care (POC) testing systems.
- This “satellite” lab is dedicated for EVD patient care in close proximity to patient room.
- Decreases transport distance of infectious EVD blood and body fluid; therefore, increasing biosafety.
- Dedicated POC instruments eliminates contamination of main laboratory analyzers with EVD.

# Waste Disposal

- Preferred: Biohazardous waste should be sterilized by autoclaving on-site
  - pressurized steam
  - neutralizes infectious agents during autoclaving process
- Alternately: Biohazardous Waste Management Company used for disposal
  - Place waste into leak proof container labeled as “Biohazardous Waste”
  - Pretreat waste by dousing with freshly made 1:10 bleach solution for 24 hours prior to pick up



# Spill Decontamination and Clean Up

- Accidental spills of blood or body fluids
  - Wear PPE and respirator protection during clean up
  - Cover with absorbent paper and douse with 1:10 fresh bleach
  - Let soak for at least 15 min
  - Place absorbent material into leak proof container
  - If needed, use broom and dust-pan to remove broken glass or plastic – place in appropriate sharps container
  - Repeat disinfection process



# Sharps

- All sharp objects should be discarded into a sharps container to avoid injury
  - Glass
  - Syringes with needles
  - Scalpels
- Never pick up broken glass by hand
- Never Recap Needles



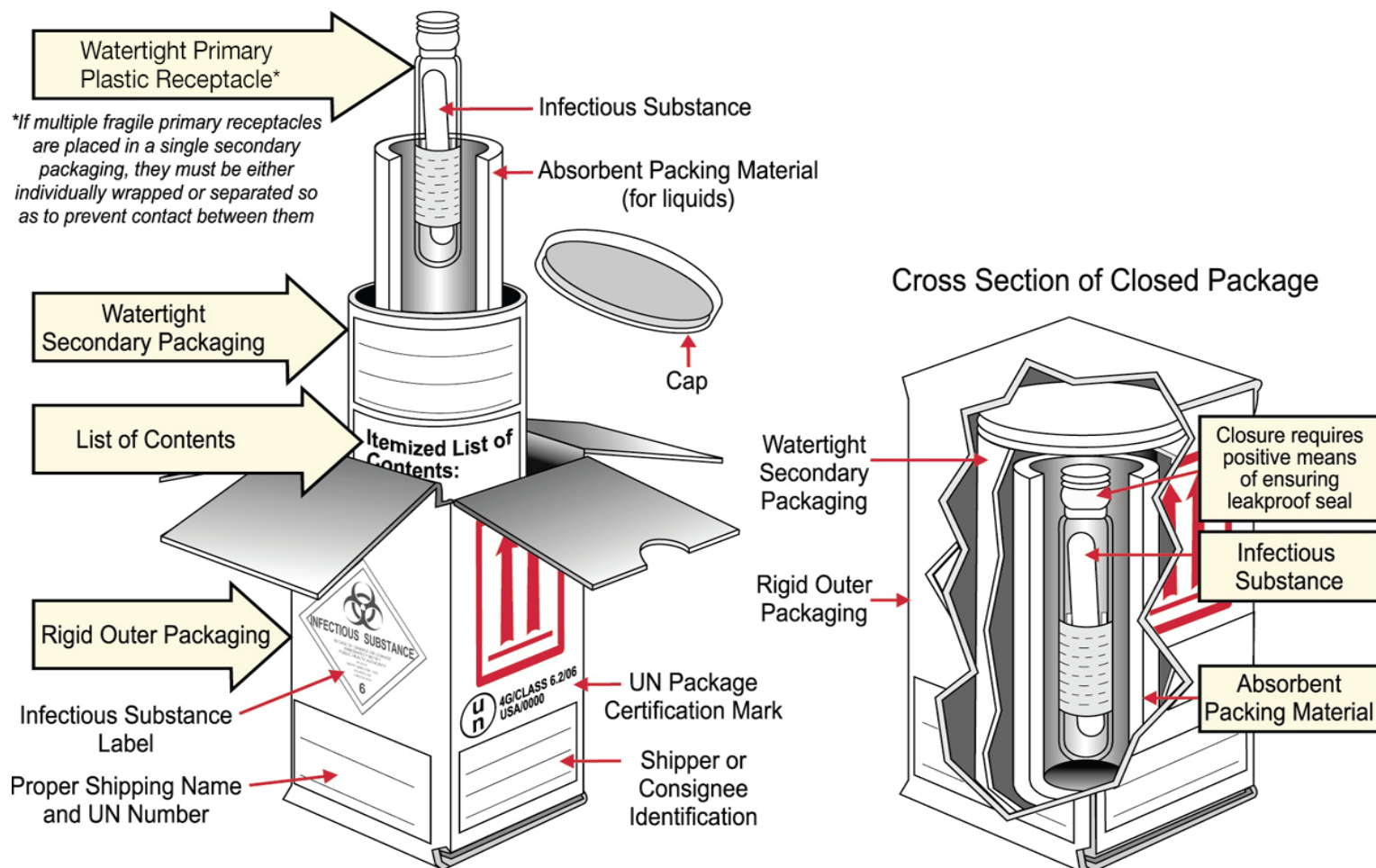
# What Waste Disposal Practices are Specific for Ebola?

- Waste generated during laboratory testing should be placed in leak-proof containment.
- If using a waste bag, place this bag in a rigid waste container designed for this use.
- If available, steam sterilization (autoclave) or incineration as a waste treatment process can inactivate the virus and reduces waste volume.
- For equipment that drains directly into the sewer system, the U.S. sanitary sewer system handling processes (e.g., anaerobic digestion, composting, disinfection) are designed to safely inactivate infectious agents.

# Shipping Requirements for Ebola Testing

- All testing must be approved by CDC and TN Epidemiology prior to shipment to TN Dept. of Health Laboratory Services.
- Submit **Two** plastic tubes of whole blood preserved with **EDTA** (lavender tops). Specimen collection tubes should not be opened prior to packaging and shipping.
- Specimens should be shipped at **2-8°C** (on cool packs). Do not submit specimens in glass containers. Do not submit specimens in any preservative other than EDTA.
- Submit the TDHLS Clinical Submission Requisition form and the CDC DASH form. Specimens should be packaged and shipped according to Category A regulations.

# Shipping Example: Category A



# Risk Assessment

- Risk assessments should be conducted by each laboratory director, biosafety officer, or other responsible personnel to determine the potential for sprays, splashes, or aerosols generated from laboratory procedures.
- Adjustments should be made as needed for PPE requirements, practices, and safety equipment controls to protect the laboratorian's skin, eyes, and mucous membranes.
- Risk assessments should be conducted for each individual laboratory procedure.

Save

Print

E-mail

Reset Form

## Biological Risk Assessment Worksheet

Tracking # \_\_\_\_\_ Building/Lab Room # \_\_\_\_\_ PI Name \_\_\_\_\_

Laboratory protocols consist of one or more procedures. Each procedure in the protocol needs an agent-specific Biological Risk Assessment. Once an agent-specific Biological Risk Assessment has been completed for the procedure, it can be used for multiple protocols by referencing its tracking number. The procedure may be performed with additional precautions, if desired, but must be no less stringent than what is calculated below at Section II.

Keep a completed copy of this worksheet in your Biosafety Manual. The *Biosafety in Microbiological and Biological Laboratories* (BMBL) 5<sup>th</sup> Edition has additional guidance on facilities, work practices, PPE, and medical surveillance.

### Section I: Complete All Data Entry in this Section

1. Agent Used \_\_\_\_\_
2. Is a vaccine available? Yes ☐ No ☐
3. Risk Group of Agent (check [www.absa.org](http://www.absa.org)) 1 ☐ 2 ☐ 3 ☐ 4 ☐ {Inactivated agents = Risk Group 1}
4. Procedure \_\_\_\_\_
5. For Risk Group 2-3, is there a splash potential? Yes ☐ No ☐
6. For Risk Group 2-3, does the procedure generate aerosol or large concentration? Yes ☐ No ☐  
(e.g., cell culture, vortex, centrifuge, aerosol chamber, sonicate)

## Section II: Data will be calculated in this Section according to the answers entered above in Section I

### 1. Facility and Work Practices Biological Safety Levels (BSLs)

Facility BSL    1 ☐ 2 ☐ 3 ☐ 4 ☐

Work Practices BSL    1 ☐ 2 ☐ 3 ☐ 4 ☐

### 2. Biological Safety Cabinet    Class I/II ☐    Class III ☐

### 3. Personal Protective Equipment Needed for Procedure: (left to right = increased protection)

a. Gloves    latex/nitrile required

b. Eye    safety glasses ☐    goggles + face shield ☐

c. Lab coat    white ☐    blue smock/coveralls ☐    space suit ☐

d. Respirator\*    N-95/PAPR ☐    space suit ☐

### 4. Medical Protection and Surveillance

a. Medical Monitoring required ☐    b. Hearing Conservation Program ☐

c. Vaccine recommended\* ☐    d. Respiratory Protection Program ☐

### 5. Comments \_\_\_\_\_

Note: \*Vaccines and respirators require separate risk assessments.

Biosafety Officer's Signature



## Biological Risk Assessment Worksheet

Tracking # 12345 Building/Lab Room # 202 PI Name Jane Doe

Laboratory protocols consist of one or more procedures. Each procedure in the protocol needs an agent-specific Biological Risk Assessment. Once an agent-specific Biological Risk Assessment has been completed for the procedure, it can be used for multiple protocols by referencing its tracking number. The procedure may be performed with additional precautions, if desired, but must be no less stringent than what is calculated below at Section II.

Keep a completed copy of this worksheet in your Biosafety Manual. The *Biosafety in Microbiological and Biological Laboratories* (BMBL) 5<sup>th</sup> Edition has additional guidance on facilities, work practices, PPE, and medical surveillance.

### Section I: Complete All Data Entry in this Section

1. Agent Used HIV
2. Is a vaccine available? Yes ☐ No ☒
3. Risk Group of Agent (check [www.absa.org](http://www.absa.org)) 1 ☐ 2 ☒ 3 ☐ 4 ☐ {Inactivated agents = Risk Group 1}
4. Procedure EIA
5. For Risk Group 2-3, is there a splash potential? Yes ☒ No ☐
6. For Risk Group 2-3, does the procedure generate aerosol or large concentration? Yes ☐ No ☒  
(e.g., cell culture, vortex, centrifuge, aerosol chamber, sonicate)



## Section II: Data will be calculated in this Section according to the answers entered above in Section I

### 1. Facility and Work Practices Biological Safety Levels (BSLs)

Facility BSL    1 ☐ 2 ☒ 3 ☐ 4 ☐

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5. Comments \_\_\_\_\_

Note: \*Vaccines and respirators require separate risk assessments.

Biosafety Officer's Signature

# Exposure to Bodily Fluids

- Workers with percutaneous or mucocutaneous exposures to blood, body fluids, secretions or excretions:
  - Stop working
  - Immediately wash affected area with soap and water
  - If eyes are affected, immediately irrigate with water
  - Immediately notify supervisor

# Management of Workers Exposed to Bodily Fluids of a Patient with Confirmed Ebola Disease

- **Asymptomatic** workers with an unprotected exposure (lack of appropriate PPE)
  - Medical evaluation
  - Documented fever monitoring twice daily for 21 days
  - Twice daily evaluation to discuss symptoms
  - May continue to work based on hospital policy and consultation with state health officials

# Management of Workers Exposed to Bodily Fluids of a Patient with Confirmed Ebola Disease

- **Symptomatic** workers with an unprotected exposure (lack of appropriate PPE)
  - Do not report to work or stop work
  - Notify Supervisor
  - Seek medical help and testing
  - Notify Health Department (Epidemiology)
  - Comply with work exclusion until no longer infectious

# Management of Workers with Potential Exposure to Ebola

- Develop policies for monitoring and management
  - Organizations should develop their own policies concerning monitoring and management of exposed individuals by following the guidelines established by CDC and consultation with the infection control personnel at the facility.
- Facilities should develop sick leave policies for health care personnel that are non-punitive, flexible and consistent with public health guidance
- Develop policies to track who had contact with the specimens
  - Employee schedules?
  - Phlebotomists? Is the only record initials on the tube?
- Medical Alert Card

# Medical Alert Card

## Front of Card



**Medical Alert**  
Attending Physicians

This card holder works with/at [insert workplace] in areas where hazardous biological, chemical, or radioactive agents or materials may be used. In the event of a unexplained illness, please contact the supervisor(s) listed on reverse side for information on specific agents or materials to which this person may have been exposed.

**Company Clinic Hours Phone: xxx.xxx.xxxx**

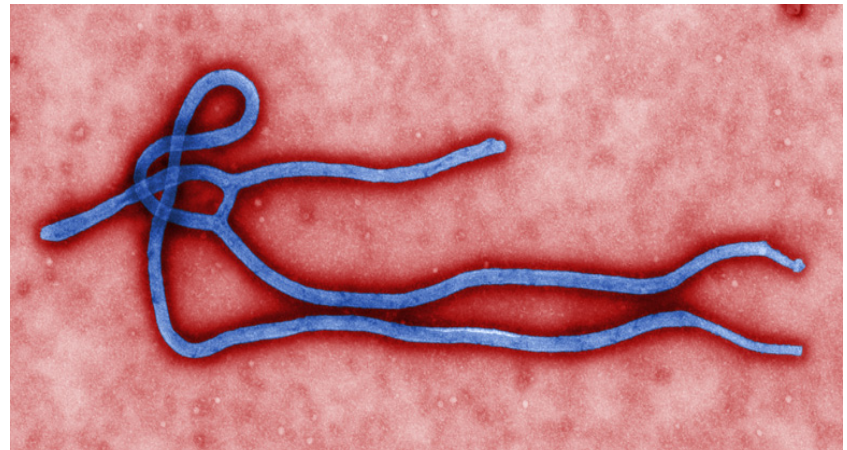
## Back of Card

- Employee Name \_\_\_\_\_
  - Employee Emergency Contact \_\_\_\_\_
  - Telephone Number \_\_\_\_\_
  - Allergies \_\_\_\_\_
  - Organizational Unit \_\_\_\_\_
  - \_\_\_\_\_
- |                           |             |                  |
|---------------------------|-------------|------------------|
| 1 <sup>o</sup> Supervisor | Work Phone: | Alternate Phone: |
| Supervisor                | Work Phone: | Alternate Phone: |

2<sup>o</sup>

# Key Take Home Point

- It is essential for laboratorians, supervisors and other workers to review laboratory safety procedures and follow the biosafety guidelines to prevent exposure to *any type of infectious agent*.



# References

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- CDC DASH Form  
<http://www.cdc.gov/laboratory/specimen-submission/pdf/form-50-34.pdf>
- TDHDLs Clinical Submission Requisition Form PH-4182  
<http://health.state.tn.us/lab/index.htm>

# EVD Tabletop Exercise...Coming Soon!

- Goal
  - Improve preparedness for the laboratory response to a patient with Ebola Virus Disease presenting at a healthcare facility.
- Objectives
  - Proper technique for Donning and Doffing of PPE
  - Identify quantity and availability of necessary PPE
  - Build confidence by practicing possible scenario drills

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