Laboratory Guidelines for the Safe Handling and Specimen Submission for a Patient Suspected of Ebola Virus Disease (EVD); October 3rd, 2014

Risk Assessment for Specimen Handling.

Ebola virus is a high consequence pathogen and there has been limited experience in handling specimens that have been contaminated by such pathogens in a clinical laboratory using currently available specimen handling procedures and automated instrumentation. This risk assessment is presented for enhanced precautions in handling specimens from patients who may be at risk of having an Ebola virus infection and represents reasonable precautions for this level of risk, but given the lack of experience and data, laboratories may want to elevate precautions further based on their individual assessments and resources. If more information becomes available on the risk of transmission, this risk assessment may change.

The CDC has released Interim Guidance for Specimen Collection, Transport, Testing, and Submission of Specimens for Patients under investigation for Ebola Virus Disease in the United States. This laboratory risk assessment is based on these guidelines. Please see the link below:
http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html

Collection of Specimens in the Isolation Room

Potential Hazard(s)	Percutaneous injuries/needlesticks
	Contamination of the external surfaces of the container
Control	✓ Alert laboratory that potentially hazardous specimens are being collected.
	✓ Patient is in contact and droplet precautions.
	✓ PPE for phlebotomy: full face shield or goggles and mask to cover all of nose and mouth, gloves, fluid resistant or impermeable back-closing gowns. Additional PPE may be required in certain situations.
	✓ Limit the use of sharps. Collect specimens in plastic containers. Avoid glass.
	✓ Before packaging specimen for transport to the lab, wipe down all containers with hospital disinfectant.
	✓ Place specimens in sealed plastic bags.
	✓ Wipe the outside of the plastic bags with hospital disinfectant.
	✓ Place plastic bags into a durable, leak proof secondary container for transport within the hospital
	✓ Wipe the outside of the container with hospital disinfectant before it leaves the room.
Comment	☆ Establish a communication protocol between the lab, providers, and clinical units. Include relevant leadership e.g., lab, infection control, infectious diseases, emergency department, & nursing. The laboratory must be alerted so that special precautions are in place.
	☆ Wiping down the surfaces requires all surfaces be wet and that the contact time is sufficient to kill the virus. Use for example a bucket of 10% bleach or a spray bottle (minimum contact time = 10 minutes) and use disinfectant saturated pad(s).

Transport of Specimens

Potential Hazard(s)	Breakage of the specimen container
Control	✓ Specimens should be transported in a clearly labeled, durable, leak-proof secondary container directly to the specimen handling area of the laboratory.
	✓ Hand carry all specimens to the laboratory.
Comment	☆ Do not use pneumatic tube or other automated transport systems.

Preparation of Specimens for Testing

Potential Hazard(s)	Aerosolization/Splash/Splatter
	Breakage of the specimen container
Control	✓ Minimize the number of workers handling the specimens
	✓ The following PPE must be used: fluid resistant back-closing gown, double gloves, N95 respirator or mask, goggles or full face shield, (eyes and mucous membranes covered).
	✓ Work inside a certified class II Biosafety Cabinet (BSC) with the sash at the appropriate level. Alternately, work behind a plexiglass splash guard.
	✓ Limit the traffic around the BSC.
	✓ In the BSC, work over a disinfectant moistened paper towel.
	✓ Use only pipette tips with barrier filters.
	✓ Have a dedicated sharps container in the BSC to which you have added disinfectant.
	✓ Smear preparation: Fix smears inside the BSC. Wipe underside of slide with disinfectant before removing from BSC. Fix smears inside the BSC.
	✓ Aliquot tubes: wipe outside of primary and aliquot tubes before removing from BSC
	✓ Inoculation of sample to cartridges: Perform all steps in BSC as above. Wipe outside of cartridge before removing from BSC
Comment	☆ No exposed skin inside the BSC.
	☆ Immediately change gloves if contamination is visible or suspected.
	☆ Bring all necessary material into the BSC before starting to work. Do not enter and re-enter BSC once specimen processing begins. A co-worker in full PPE should bring additional materials to the BSC if necessary.
	☆ 10% bleach should always be freshly prepared every 24 hours
	☆ Minimize use of sharps. Dispose of all pipette tips and sharps in the dedicated container in the BSC
	☆ Specimens and materials must be decontaminated before removing from BSC
	☆ Blood smears (e.g., for malaria) are not infectious for Ebola after fixation in solvents.
	☆ DO NOT set up any viral cultures
	☆ By using the PPE listed and working in the BSC, BSL-3 practices in a BSL-2 environment are followed.

Centrifugation

Potential Hazard(s)	Breakage and aerosolization
Control	✓ Look for alternatives to centrifugation when possible.
	✓ Load centrifugation buckets inside the BSC
	✓ Centrifuge specimens using aerosol safe containers with O-ring sealable tops.
	✓ After centrifugation, bring sealed buckets back to the BSC and open the buckets inside the BSC.
Comment	☆ Centrifuge these specimens separately (no other patients in the centrifuge run).
	☆ Be alert to any potential malfunction during the centrifugation run.

After Specimen Processing is complete and before removing from BSC

Potential Hazard(s)	Accidental transfer of contaminated material from the BSC.
Control	✓ Remove and replace gloves after specimen handling.
	✓ All waste must be discarded and contained inside the BSC.
	✓ Wipe all tubes with disinfectant before removing from BSC.
	✓ Place specimens in sealed plastic bags (new bags). Wipe the outside of the bags with disinfectant. Place specimen bags into a rigid leak proof container. Wipe outside of container with disinfectant.
	✓ Remove gloves and dispose inside trash container in the BSC.
	✓ Don new gloves.
	✓ Wipe all trash with disinfectant Remove decontaminated items from the BSC including specimens in sealed bags and waste materials in their containers or bags
Comment	☆ Disinfectant for containers and work surfaces: Any hospital-approved disinfectant such as quaternary ammonia, 10% bleach or phenolic. Ensure the minimum contact time per vendor instructions. Waste containers and sharps container with disinfectant. Dedicated waste bag for gloves and other waste.

BSC Decontamination

Potential Hazard(s)	Contamination of BSC surfaces
Control	✓ Wipe the inside of the BSC with disinfectant.
	✓ Remove all PPE and discard into medical waste stream
Comment	☆ If 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.
	☆ Other hospital-approved disinfectant such as quaternary ammonia or phenolic: ensure the minimum contact time per vendor instructions

Testing Specimens on Automated Instruments

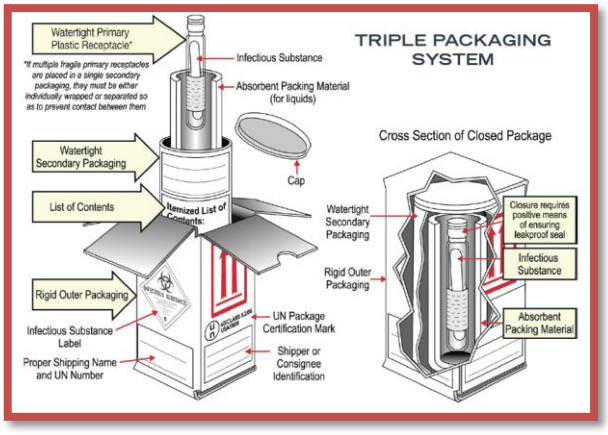
Potential Hazard(s)	Aerosolization/Splash/Splatter
	Contamination of Equipment
Control	✓ The use of automated instruments, the lab environment where they are located, the risk for aerosolization, and the ease of decontaminating the instrument and work space are all issues that need to be carefully considered and dealt with before utilizing automated instruments.
	✓ Consider the use of PPE: fluid resistant back-closing gown, gloves, mask or N95 respirator, goggles or full face shield (eyes and other mucous membranes covered). Work behind plexiglass splash guard when possible. Consider decontamination of automated instruments after the test run.
	✓ Microscopes: Use approved disinfectant to wipe all surfaces of the scope and work area. Dispose of slides in sharps container
Comment	☆ Point of care testing is advisable to avoid running chemistry and hematology tests in the core lab, increasing potential exposures.
	☆ The manufacturer recommendations should be followed regarding decontamination of instruments and waste.

Storage and Disposal of Specimens

Potential Hazard(s)	Breakage and aerosolization
Control	✓ All specimens should be isolated from other specimens in the laboratory and disposed of in an appropriate manner as soon as testing is completed.
	✓ Autoclave specimens if available. Alternatively, inactivate specimens in 10% bleach for 24 hours, then place in standard biohazard infectious waste disposal.
Comment	☆ This is to reduce the risk of contamination after the specimens leave the lab.
	☆ Use of automated track systems may require special steps to retrieve specimens after testing.

Specimen Submission

- The Scientific Laboratory Division (SLD) will not accept specimens that have not previously been approved for submission by the Epidemiology and Response Division (ERD)
- Shipments must follow IATA regulations for Category A substances.



Collection Of Suspect Ebola Specimens	• Minimum 4mL of Whole Blood in Plastic Collection Tube • EDTA Preferred, SPS, Citrate, or w/Clot Activator OK
Do Not Submit in Glass or Heparinized Collection Tubes!	• It is Not Necessary to Remove Serum or Plasma from Primary Collection Tube • Two forms of ID Should Be Applied to Both the Specimen & Test Request Form
All Collections Must Follow OSHA Bloodborne Pathogen Standards	• Decontaminate Tube & Place in Specimen Bag, Decontaminate Specimen Bag • Specimens Should be Placed in a Durable Secondary Container. • Decontaminate Secondary Container Prior To Transport
SLD General Clinical Request Form	• Fill Out all Highlighted Areas on SLD's Clinical Request Form • In Serology, Analysis Requested area select "Other" and write in Ebola: ☑ Other: Ebola
CDC 50.34 Form	• Fill out the CDC form as completely as possible • Attach the form to the SLD General Clinical Request Form • CDC form located at http://www.cdc.gov/laboratory/specimen-submission/form.html
Ship specimens at 2-8°C or frozen on cold packs to the Scientific Laboratory Division.	• Get ERD approval prior to submission (505-827-0006)
Shipping Address	• Send To: SLD, Attn: Virology/Serology 1101 Camino de Salud, NE Albuquerque, NM 87102

Select Agent Regulations

Ebola virus is regulated as a "select agent" in accordance with the HHS Select Agent Regulations (42 CFR Part 73). The CDC has an interim guidance regarding compliance with Select Agent Regulations for those handling patient specimens that are known or suspected to contain Ebola virus:
http://www.cdc.gov/vhf/ebola/hcp/select-agent-regulations.html

For questions, please contact:

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Additional Resources

CDC Ebola Case Definition
http://www.cdc.gov/vhf/ebola/hcp/case-definition.html

Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Patients with Suspected Infection with Ebola Virus Disease
http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html

Monitoring and Movement recommendations
http://www.cdc.gov/vhf/ebola/hcp/monitoring-and-movement-of-persons-with-exposure.html

Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals
http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html

Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus
http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html

Sequence for Removing Personal Protective Equipment (PPE)
http://www.cdc.gov/vhf/ebola/pdf/ppe-poster.pdf

Ebola Virus Disease Information for Clinicians in U.S. Healthcare Settings
http://www.cdc.gov/vhf/ebola/hcp/clinician-information-us-healthcare-settings.html