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**Laboratory Risk Assessment**  
**For a Suspect Patient with a High Possibility of Ebola Virus Disease (EVD)**  
**Revised: August 25, 2014**

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 in handling specimens from patients who may be at risk of having Ebola virus infection. This risk assessment represents reasonable precautions for this level of risk, but given the lack of experience and data, laboratories may want to elevate precautions even 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 from patients with suspected infection with Ebola Virus Disease. 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>

For questions please contact:

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Procedure	Potential Hazard(s)	Control	Comment
<p><b>A. Collection of Specimen in the Isolation Room</b></p>	<ul style="list-style-type: none"> <li>• Percutaneous Injuries/Needlesticks</li> <li>• Breakage of the Specimen Container</li> <li>• Care Should be Taken to Avoid Contamination of the External Surfaces of the Container</li> </ul>	<ul style="list-style-type: none"> <li>• Alert laboratory that potentially hazardous specimens are being collected.</li> <li>• Patient is in contact and droplet precautions.</li> <li>• 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.</li> <li>• Do not collect specimens in glass containers.</li> <li>• Limit the use of sharps.</li> <li>• Before packaging specimen for transport to the lab, wipe down all containers with hospital disinfectant.</li> <li>• Place specimens in sealed plastic bags.</li> <li>• Wipe the outside of the plastic bags with hospital disinfectant.</li> <li>• Place plastic bags into a durable, leak proof secondary container for transport within the hospital.</li> <li>• Wipe the outside of the container with hospital disinfectant before it leaves the room.</li> </ul>	<ul style="list-style-type: none"> <li>• Establish a communication protocol between the lab, providers, and clinical units. Include relevant leadership e.g., lab, infection control, infectious diseases, emergency department, &amp; nursing. The laboratory must be alerted so that special precautions are in place.</li> <li>• 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).</li> </ul>
<p><b>B. Transport of Specimens</b></p>	<ul style="list-style-type: none"> <li>• Breakage of the Specimen Container.</li> </ul>	<ul style="list-style-type: none"> <li>• Specimens should be transported in a clearly labeled, durable, leak-proof secondary container directly to the specimen handling area of the laboratory.</li> <li>• Hand carry all specimens to the laboratory.</li> </ul>	<ul style="list-style-type: none"> <li>• Do not use pneumatic tubes or other automated transport systems.</li> <li>• If signs of breakage or leakage – <b>do not open bag</b>. Consult with the Laboratory Director.</li> </ul>
<p><b>C. Preparation of Specimens for Testing</b></p>	<ul style="list-style-type: none"> <li>• Aerosolization/Splash/Splatter</li> </ul>	<ul style="list-style-type: none"> <li>• Minimize the number of workers handling the specimens</li> <li>• The following PPE must be used: fluid resistant back-closing gown, double</li> </ul>	<ul style="list-style-type: none"> <li>• No exposed skin inside the BSC.</li> <li>• Immediately change gloves if contamination is visible or</li> </ul>

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		<p>gloves, N95 respirator and goggles, or full face shield, (eyes and mucous membranes covered).</p> <ul style="list-style-type: none"> <li>Limit the traffic around the BSC.</li> <li>Work inside a certified class II Biosafety Cabinet (BSC) with the sash at the appropriate level. Alternately, work behind a plexiglass splash guard.</li> <li>In the BSC, work over a disinfectant moistened paper towel.</li> <li>Use only pipette tips with barrier filters.</li> <li>Have a dedicated sharps container in the BSC to which you have added disinfectant.</li> <li><u>Smear preparation</u>: Wipe underside of slide with disinfectant before removing from BSC. Fix smears inside the BSC.</li> <li><u>Aliquot tubes</u>: If possible do not open and aliquot specimens. If aliquoting is necessary, wipe outside of primary and aliquot tubes before removing from BSC.</li> <li><u>Inoculation of sample to cartridges</u>: Perform all steps in BSC as above. Wipe outside of cartridge before removing from BSC.</li> </ul>	<p>suspected.</p> <ul style="list-style-type: none"> <li>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.</li> <li>10% bleach should always be freshly prepared every 24 hours</li> <li>Minimize use of sharps. Dispose of all pipette tips and sharps in the dedicated container in the BSC.</li> <li>Specimens and materials must be decontaminated before removing from BSC.</li> <li>DO NOT set up any viral cultures</li> <li>By using the PPE listed and working in the BSC, BSL-3 practices in a BSL-2 environment are followed.</li> </ul>
<b>D. Centrifugation</b>	<ul style="list-style-type: none"> <li>Breakage and Aerosolization</li> </ul>	<ul style="list-style-type: none"> <li>If possible, do not centrifuge specimens.</li> <li>If centrifugation is necessary, load centrifugation buckets inside the BSC.</li> <li>Centrifuge specimens using aerosol safe containers with O-ring sealable tops.</li> <li>After centrifugation, bring sealed buckets back to the BSC and open the buckets inside the BSC.</li> </ul>	<ul style="list-style-type: none"> <li>Look for alternatives to centrifugation when possible.</li> <li>Centrifuge these specimens separately (no other patients in the centrifuge run).</li> <li>Be alert to any potential malfunction during the centrifugation run.</li> </ul>
<b>E. After Specimen Processing is Completed and</b>	<ul style="list-style-type: none"> <li>Accidental Transfer of Contaminated Material from the BSC.</li> </ul>	<ul style="list-style-type: none"> <li>Remove and replace gloves after specimen handling.</li> </ul>	<ul style="list-style-type: none"> <li>Disinfectant for containers and work surfaces:</li> </ul>

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<b>Before Removal of Specimen from the BSC</b>		<ul style="list-style-type: none"> <li>• All waste must be discarded and contained inside the BSC.</li> <li>• Wipe all tubes with disinfectant before removing from BSC.</li> <li>• 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.</li> <li>• Remove gloves and dispose inside trash container in the BSC.</li> <li>• Don new gloves.</li> <li>• Wipe all trash with disinfectant.</li> <li>• Remove decontaminated items from the BSC including specimens in sealed bags and waste materials in their containers or bags</li> </ul>	<ul style="list-style-type: none"> <li>○ Any hospital-approved disinfectant such as quaternary ammonia, 10% bleach or phenolic. Ensure the minimum contact time per vendor instructions.</li> <li>○ Waste containers and sharps container with disinfectant.</li> <li>○ Dedicated waste bag for gloves and other waste.</li> </ul>
<b>F. BSC Decontamination</b>	<ul style="list-style-type: none"> <li>• Contamination of BSC Surfaces</li> </ul>	<ul style="list-style-type: none"> <li>• Wipe the inside of the BSC with disinfectant.</li> <li>• Remove all PPE and discard into medical waste stream.</li> </ul>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Other hospital-approved disinfectant such as quaternary ammonia or phenolic: Ensure the minimum contact time per vendor instructions.</li> </ul>
<b>G. Malaria Testing</b>	<ul style="list-style-type: none"> <li>• Aerosolization/Splash/Splatter</li> </ul>	<ul style="list-style-type: none"> <li>• Collect in a lavender top (EDTA) blood tube.</li> <li>• Prepare slides inside a BSC.</li> <li>• Only thin blood smears should be prepared (no thick smears).</li> <li>• Remove stopper of blood tubes with a gauze wipe soaked in hospital approved disinfectant to prevent aerosol formation.</li> <li>• Prepare a thin blood film, fix in</li> </ul>	<ul style="list-style-type: none"> <li>• Blood smears for malaria are not infectious after fixation and dry heat treatment.</li> </ul>

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		<p>methanol for 30 minutes, and then place in dry heat at 95 degrees Celsius for 1 hour to inactivate the specimen.</p> <ul style="list-style-type: none"> <li>Wipe underside of slide with disinfectant before removing from BSC.</li> <li>Stain with Giemsa and read as usual.</li> </ul>	
<p><b>H. Blood Cultures</b></p>	<ul style="list-style-type: none"> <li>Aerosolization/Splash/Splatter/Contact with Blood</li> </ul>	<ul style="list-style-type: none"> <li>Once received in the laboratory, all specimens should be opened inside a BSC.</li> <li>Wipe the outside of the bottles with hospital approved disinfectant and inspect for any signs of breakage. Place the bottles into a rigid leak proof container and carry the container to the blood culture instrument.</li> <li>Load into the blood culture instrument.</li> <li>If the blood culture bottles are flagged as positive or show visible signs of positivity, unload the bottles from the instrument into a rigid leak proof container. Carry the container to the BSC to prepare the smear for Gram staining.</li> <li>Prepare slides for Gram stain examination and allow to dry.</li> <li>Fix the slide in methanol for 30 minutes, followed by dry heat at 95 degrees Celsius for 1 hour to inactivate the specimen.</li> <li>Perform testing of the Gram stain QC smear in the same manner as described above.</li> <li>Wipe underside of slide with disinfectant before removing from BSC.</li> <li>The smears can be carefully taken out of the BSC, processed and read as usual.</li> <li>Inside the BSC, inoculate plates as per protocol based on Gram stain result.</li> <li>Seal the sub-cultured plates with</li> </ul>	<ul style="list-style-type: none"> <li>Use plastic bottles if available.</li> <li>Do NOT perform direct testing on positive blood cultures. Perform testing on positive blood cultures only after two subcultures, thereby minimizing the risk of contact with blood from the patient.</li> </ul>

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		<p>parafilm or shrink seals and place plates in a biohazard bag for incubation.</p> <ul style="list-style-type: none"> <li>Wipe the outside of the plastic bags with hospital disinfectant.</li> <li>Place plates in incubator and observe for growth.</li> <li>When growth appears, perform a subculture of the organism while working inside the BSC, onto fresh plates and incubate these plates overnight.</li> <li>Proceed with identification of growth from subcultured plates.</li> </ul>	
<p><b>I. Testing Specimens on Automated Instruments</b></p>	<ul style="list-style-type: none"> <li>Aerosolization/Splash/Splatter</li> <li>Contamination of Equipment</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> <li>Consider the use of PPE: fluid resistant back-closing gown, gloves, N95 respirator, goggles or full face shield, (eyes and mucous membranes covered). Work behind plexiglass splash guard when possible. Consider decontamination of automated instruments after the test run.</li> <li><u>Microscopes</u>: Use approved disinfectant to wipe all surfaces of the scope and work area. Dispose of slides in sharps container.</li> </ul>	<ul style="list-style-type: none"> <li>Point of care testing is advisable to avoid running chemistry and hematology tests in the core lab, increasing potential exposures.</li> <li>The manufacturer recommendations should be followed regarding decontamination of instruments and waste.</li> </ul>
<p><b>J. Storage of Specimens</b></p>	<ul style="list-style-type: none"> <li>Breakage and Aerosolization</li> </ul>	<ul style="list-style-type: none"> <li>For short term storage, all specimen containers should be wiped with hospital disinfectant and placed into double-bags that contain absorbent pads soaked with disinfectant, then</li> </ul>	<ul style="list-style-type: none"> <li>This is to reduce the risk of contamination after the specimens leave the lab.</li> </ul>

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		<p>placed in a rigid plastic, leak-proof container and kept isolated until they can be disposed of in an appropriate manner.</p> <ul style="list-style-type: none"> <li>• Long term storage of specimens is not permitted for any suspect Hemorrhagic Fever virus patient.</li> </ul>	
<p><b>K. Disposal of Specimens</b></p>	<ul style="list-style-type: none"> <li>• Breakage and Aerosolization</li> </ul>	<ul style="list-style-type: none"> <li>• All specimens must be autoclaved prior to disposal.</li> </ul>	<ul style="list-style-type: none"> <li>• If an autoclave is not available on site, call the BT 24/7 phone at 617-590-6390 for assistance.</li> </ul>
<p><b>L. Packaging &amp; Shipping of Specimens to HSLI or CDC</b></p>	<ul style="list-style-type: none"> <li>• Breakage and Aerosolization</li> </ul>	<ul style="list-style-type: none"> <li>• Call the BT 24/7 phone directly for packaging and shipping guidance.</li> <li>• Specimens should be packaged and shipped without attempting to open collection tubes or aliquot specimens.</li> <li>• Specimens must be packaged based on the triple packaging system which consists of a tube in a sealable specimen bag with absorbent material (primary receptacle) placed in a watertight, leak-proof container (secondary receptacle).</li> <li>• Place submission forms in a plastic bag between the secondary receptacle and the outer cardboard box.</li> <li>• Use ice packs, <u>not</u> wet ice and place it between the secondary receptacle and the outer cardboard box.</li> <li>• Specify on the outside of the box whether the specimen is refrigerated or frozen.</li> </ul>	<ul style="list-style-type: none"> <li>• Specimens will be shipped as a Category A or Category B based on a risk assessment performed by a DPH Epidemiologist.</li> <li>• Packaging and shipping of Infectious Substances or Biological Substances should only be performed by laboratory personnel who are trained and certified to do so.</li> <li>• Specimens should be sent to the Hinton State Laboratory for shipping to CDC unless otherwise directed in consultation with DPH staff to send directly to CDC.</li> </ul>