Office of the Provincial Health Officer

Recommendations for Ebola Virus Disease (EVD) Laboratory Processes

Provincial Ebola Expert Working Group – Laboratory Sub-Working Group
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Contents

Preamble

While the probability of a person with Ebola virus disease (EVD) in British Columbia is low, preparedness to ensure health care workers can safely and effectively care for patients is essential. Preparedness relies on clear algorithms and clinical process, appropriate personal protective equipment supply and deployment and appropriate training for staff in the processes and equipment.

This document is intended to summarize recommendations and provide guidance on laboratory matters associated with EVD, including sample collection, testing, transport and disposal.

EVD is spread through direct contact (via broken skin or mucous membranes of the eyes, nose or mouth) with the blood/body fluids[1] of an EVD-infected person, or of EVD-blood/body fluid-contaminated items. The risk of transmission increases with the amount of infectious material to which the individual is exposed. EVD-associated waste that has been appropriately incinerated or autoclaved is not infectious, does not pose a health risk, and is not considered to be regulated medical waste or a hazardous material.

The Ebola virus is not communicable before the onset of symptoms, but communicability increases with each subsequent stage of illness. The risk of transmission of EVD is considered lower in the early stages (e.g., when the patient presents with fever, with or without fatigue and myalgia, with minimal diarrhea and vomiting, when the patient's body fluids are contained), and higher in later stages of their illness when viral load rises and they experience copious fluid loss due to diarrhea, vomiting or hemorrhage.

Guiding Principles

1. Along with the safety and care of patients, health care worker safety is of paramount importance.
2. The number of health care workers entering the room/handling EVD specimens should be kept to the minimum required to provide medically necessary care.[2] All health care workers entering the room must be tracked and documented.
3. Laboratory recommendations will be built on recommendations from other expert working groups to allow for as much integration and consistency as possible (i.e., alignment to site clinical care capacity, infection control, and waste management).

[1] Body fluids include stool, emesis, urine, saliva, semen and sweat.
[2] *Recommendations Personnel for Persons under Investigation, Probable and Confirmed Ebola Virus Disease (EVD) Cases* (www.health.gov.bc.ca/pho/pdf/recommended-personnel-for-evd-cases.pdf)

General Recommendations

A syllabus of standard operating procedures should be formulated to cover the necessary laboratory processes in the handling of EVD patients or samples. Listed below are the major processes that should be covered, supplemented with working group recommendations for each point.

Personal Protective Equipment

- PPE worn by laboratory personnel in the laboratory should be at a minimum[3]:
  - double gloves, a fluid-resistant or impermeable gown (solid-front, rear-closing); and a combination of an approved particulate respirator (e.g., N95) and eye protection (e.g., goggles or face shield)
  - impermeable, cleanable shoes or booties are recommended for footwear
- PPE should be worn when:
  - working with a suspect/confirmed EVD patient; and
  - manipulating and performing laboratory tests on non-inactivated suspect/confirmed EVD samples.
- Specimen manipulation should be done with two technologists – one who is handling the specimen and a second technologist who is assisting and observing the PPE donning and doffing processes and the specimen handling processes.
- Provincial recommendations for donning and doffing of PPE should be in followed[4], with the appropriate training undertaken.

Outpatient Management

- In the unlikely event of an outpatient presenting in person to access the laboratory service, a process outlining the management of these scenarios should be in place.
- Sample collections from a person under investigation[5], or confirmed[6] EVD patients should not occur in outpatient areas.
- The medical microbiologist or designate should be contacted directly and the patient should be diverted to the emergency department immediately (or other designated area).

[3] Note: This is aligned with expected federal guidance, and may be updated if/when federal guidance changes.
[4] www.health.gov.bc.ca/pho/physician-resources-ebola.html
[5] Defined as anyone with a potential exposure to the Ebola virus, any symptoms compatible with EVD, and laboratory result pending.
[6] Defined as anyone with laboratory confirmation of EVD infection.

Sample Collection

- Procedures should be developed based on the principle of minimum number of healthcare workers entering the isolation room.[7]
- Order of draw needs to be considered to minimize risk of cross-contamination to maintain sample integrity.
- If sample collection is required from a person under investigation or from a confirmed case, the specimen should be collected at a hospital site that can clinically support these cases (i.e., Type Two or Three facilities[8]).
- Sampling from intravenous lines is preferred to support the principle of a minimum number of health care workers in the isolation room.
- Suggested order of draw for intravenous and peripheral blood (this order can be altered for site-specific reasons):
    1. Non additive tube to discard if drawn from an IV start or intravenous access device.
    2. First set of blood cultures.
    3. Non-additive containers if required.
    4. Containers with clot activators.
    5. Containers with heparin.
    6. Containers with EDTA.
    7. Second set of blood cultures.

Sample Tube Disinfection

- Disinfection of sample tube and container surfaces at the time of collection and upon receipt of sample in biological safety cabinet should be outlined.
- Demographic information should be maintained on the sample label after disinfection.
- An approved disinfectant suitable for non-enveloped viruses should be used per manufacturer's instructions, ensuring the surface of the tube is wet and the indicated contact time is used.

[7] *Recommendations Personnel for Persons under Investigation, Probable and Confirmed Ebola Virus Disease (EVD) Cases* (www.health.gov.bc.ca/pho/pdf/recommended-personnel-for-evd-cases.pdf)

[8] *Roles of Provincial Facilities for Care of Potential or Confirmed Ebola Virus Disease Patients* (www.health.gov.bc.ca/pho/pdf/hospital-designation-evd-patients.pdf)

Sample Transport and Distribution within the Health Care Facility and Laboratory

- Samples should be transported in a durable, leak-proof container by laboratory personnel. An option is to transport the samples inside a Type 1A container(s).
- Pneumatic tube systems must not be used for sample transport.
- A designated receiving area in the laboratory should be identified. The container should be placed into the designated biological safety cabinet.
- Intra-laboratory sample flow process needs to be developed.
- Specimens should be transported within the laboratory within a suitable container. Also see process step 13 below (re: documentation of sample handling).

Sample Testing

- The following procedures should be outlined:
  - Use of a biological safety cabinet.
  - Process for sample inactivation and centrifugation if required. If centrifugation is required, sealed buckets must be loaded and unloaded in the biological safety cabinet.
  - Procedures for use of testing equipment, such as point of care-type equipment.
- Using point of care analyzers within the laboratory in a dedicated, isolated space with a biological safety cabinet minimizes risk to the main laboratory service and the potential for spills.
- Malaria testing should be performed at the hospital site using a rapid test for Plasmodium falciparum and the use of appropriately fixed (after air drying in the biological safety cabinet, thin blood smears should be fixed with absolute methanol for 30 minutes, after which the slides could be either dry-heat inactivated [e.g., 95°C for at least 30 minutes, 60°C for at least 1 hour] or formalin-inactivated) thin smears for microscopic detection of other species.
- Work-up of organisms from positive blood cultures should be done off the secondary subculture plates.
  - After a blood culture bottle is positive, primary subculture plates should be inoculated, sealed and incubated. Each isolate grown on the primary plates should then be individually subcultured onto secondary plates and sealed for subsequent work-up after incubation.

Sample Transport out of Facility

- Transportation of blood samples via ground or air falls under Transport of Dangerous Goods Regulation due to category A, risk group 4 classification.
- Special packaging and transport is conducted by personnel with Transport of Dangerous Goods certification and requires the activation of the Emergency Response Assistance Plan (ERAP). ERAP should be activated in consultation with the BCCDC medical microbiologist on call.
- Use of the transport instructions and support package can be found in *Sending Site Transport and ERAP Procedure for Suspect EVD Testing – BCCDC Requirements and ERAP Transport Kit*. (pod/lmlabs/resources/ebola/Ebola%20%20Patient%20Transport/Forms/AllItems.aspx)

Decontamination

- Point of care and associated equipment should be decontaminated as per manufacturer's instructions.
- Supplies requiring reuse should be sterilized through autoclaving or other means.
- After testing is complete, the biological safety cabinet and work surfaces should be disinfected using an approved disinfectant suitable for non-enveloped viruses per manufacturer's instructions, ensuring the surfaces are wet and the appropriate contact time is used.

Sample Segregation and Storage

- Samples should be clearly marked and stored separately from regular samples until a confirmed rule-in or rule-out of EVD is complete.
- Laboratories should designate a separate storage area for samples being tested.

Sample Disposal

- Confirmed EVD negative samples can be disposed through regular laboratory biohazard waste.
- Confirmed EVD positive samples should be managed similar to EVD clinical waste and disposed via a certified biological waste management company or autoclaved.

Laboratory Waste

- Confirmed **EVD negative samples** waste can be disposed through regular laboratory biohazard waste.
- Confirmed **EVD positive samples** should be either decontaminated, autoclaved or disposed of via a certified biological waste management company.

Spills

- The medical microbiologist and/or designate should be notified immediately in the event of a spill. In consultation with the microbiologist, the patient's EVD status will determine any further action required for the spill. Emergency Response Action Plan activation may be required for spills and will be co-ordinated through the provincial medical microbiologist as appropriate.
- For spills outside the biological safety cabinet, evacuate area to settle any aerosols for minimum 30 minutes.
- For on-site spills containing EVD-associated human fluids (blood, emesis, urine, stool, etc.), only individuals trained to don/doff appropriate personal protective equipment and dispose of waste should be involved in the cleanup.
- Spill kits should be made available for use in designated assessment/care areas.
- The following measures should be followed:
    a. Wear appropriate personal protective equipment as previously described.
    b. Allow fluid and droplets to settle.
    c. Put disposable paper towels down to cover the material so it doesn't spread further.
    d. To avoid any splashes and splatter, **do not spray** disinfectant onto spill and **do not use a wet vacuum**.
    e. Over the paper towels, gently apply (do not spray) a disinfectant according to the manufacturer's instructions (use a product with a broad spectrum virucidal claim and a drug identification number).
    f. Allow the product to remain in place to ensure a minimum contact time of 10 minutes or as per manufacturers' instructions.
    g. Pick up and dispose of towels and organic material.
    h. Disinfect the floor. Start at one end of the affected area and move in one direction until the whole surface has been disinfected. Do not use a circular motion.

Decontamination

- A chain of custody or tracking list of staff involved in sample handling or testing should be kept, including the date, time, and the staff member's contact number.
- If there is a breach in procedure that places the staff member at risk, the supervisor and occupational health should be contacted immediately.

Test Panels Available per Site

This test menu is current as of Dec. 8, 2014 and is subject to change. See Section E for reference laboratory testing. Samples can be transported to different sites as necessary in conformance with Transport of Dangerous Goods and Emergency Response Action Plan, and under appropriate consultation with the medical microbiologist or designate.

HA	Site	Type[9]	Testing Available		
FH	**Surrey Memorial Hospital**	3	Blood gases Electrolytes Glucose Urea Creatinine	Ionized calcium Lactate Albumin, total bilirubin, total protein, ALK, ALT, AST Creatine kinase	Hematocrit Hemoglobin Estimated white cell count Estimated platelet count Malaria – rapid and thin smear Blood cultures
PHSA	**BC Children's and Women's Hospital**	3	Blood gases Electrolytes Glucose Urea Creatinine	Ionized calcium Lactate Albumin, bilirubin CRP	Estimated hemoglobin Estimated white cell count Malaria – rapid and thin smear Blood cultures
VCH	**Vancouver General Hospital**	2	Electrolytes Glucose Creatinine	Lactate Total bilirubin, AST Troponin	CBC with auto-differential Malaria – rapid and thin smear Blood cultures
PHC	**St. Paul's Hospital**	2	Electrolytes Glucose Urea Creatinine	Calcium Albumin, total bilirubin, total protein, ALK, ALT, AST	Hemoglobin Malaria – rapid and thin smear Blood cultures
NH	**University Hospital of Northern BC – Prince George**	2	Electrolytes Glucose Urea Creatinine		CBC with auto-differential Malaria – rapid and thin smear Blood cultures
IHA	**Kelowna General Hospital**	2	Blood gases Electrolytes Urea Creatinine	Ionized calcium Lactate	Hemoglobin Estimated white cell count Estimated platelet count Malaria – thin smear Blood cultures
VIHA	**Royal Jubilee Hospital**	2	Blood gases Electrolytes Glucose Urea Creatinine	Ionized calcium Lactate Troponin	Estimated white cell count Estimated platelet count Malaria – rapid and thin smear Blood cultures
HA	Site	Type	Testing Available		

[9] *Roles of Provincial Facilities for Care of Potential or Confirmed Ebola Virus Disease Patients* (www.health.gov.bc.ca/pho/pdf/hospital-designation-evd-patients.pdf)

VIHA	**Victoria General Hospital**	2	Blood gases Electrolytes Glucose Urea Creatinine	Ionized calcium Lactate Troponin	Estimated white cell count Estimated platelet count Malaria – rapid and thin smear Blood cultures
VCH	**Richmond Hospital**	2	Sample collection only; testing not available on site and is performed at VGH.		
	All Other Sites	1	Laboratory testing will not be conducted.		

Provincial Reference Laboratory Testing Availability

HA	Site	Level	Testing Available		
PHSA	**BC Public Health Microbiology and Reference Laboratory**	N/A	▸ Ebola Virus Disease Nucleic Amplification Testing (EVD NAT) with 4-5 hour turnaround time from specimen receipt. Available 24/7.	▸ NAT for respiratory viruses, gastroenteric viruses, measles and mumps. ▸ Diagnostic testing for HIV, hepatitis A, hepatitis B and hepatitis C. Also available for needlestick injuries. ▸ Malaria testing is also available.	Transport time: ▸ Lower mainland area – less than six hours. ▸ Designated Level 2 sites outside lower mainland – less than 12 hours. ▸ All other provincial sites – approximately 24 hours.

Appendix

Clinical Patient Care Capacity		Lab Service Capacity	Lab Sites
Type 3	Yes persons under investigation Yes confirmed EVD	Yes collections Yes onsite testing Yes Emergency Response Action Plan	BC Children's and Women's Surrey Memorial
Type 2	Yes persons under investigation Yes confirmed EVD	Yes collections Yes onsite testing Yes Emergency Response Action Plan	St. Paul's Vancouver General UHNBC – Prince George Kelowna General Royal Jubilee Victoria General
Type 2	Yes persons under investigation Yes confirmed EVD	Yes collections Yes onsite testing Yes Emergency Response Action Plan	Richmond
Type 1	No persons under investigation No confirmed EVD	No collections No testing No Emergency Response Action Plan	All other sites

Additional References and Resources

Main Web Resources and Support Information

Web Site Owner	Page Title Link (URL)	Summary of Website Contents
Lower Mainland Laboratories	Ebola Virus Disease – Planning and Implementation pod/lmlabs/resources/ebola/Pages/default.aspx	• Patient screening/risk assessment • Personal protective equipment • Sample Collection and Transport • Sample Disposal and Patient Disposition • Communications/News • Educational Resources
Ministry of Health, Government of B.C.	Provincial Health Officer's Ebola Web-Site for B.C. Health Care Providers www.health.gov.bc.ca/pho/physician-resources-ebola.html	• PPE for low and high risk scenarios with checklists • Primary care guidelines • Roles of Provincial Facilities
Public Health Agency of Canada	Pathogen Safety Data Sheet for Ebolavirus www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/ebola-eng.php	• Hazard identification • Stability and viability • First aid • Laboratory hazards • Exposures/personal protection • Handling and storage
	Biosafety Guidelines for Laboratories Handling EVD Specimens www.phac-aspc.gc.ca/id-mi/vhf-fvh/ebola-biosafety-biosecurite-eng.php	• Personal protective equipment • Testing guidelines • Decontamination • Disposal • Spill Considerations • Additional operational considerations • Transportation

Other Web Resources/Supplemental Information

Web Site Owner	Page Title Link (URL)	Summary of Website Contents
Center for Disease Control (USA)	Information for Healthcare Workers and Settings www.cdc.gov/vhf/ebola/hcp	• Infection control • Personal protective equipment • Handling human remains • Medical transport • Specimen collection, packaging, transport, testing, submission • Waste management and survivability • Preparedness checklists
Advisory Committee on Dangerous Pathogens (UK)	Management of Hazard Group 4 Agents www.gov.uk/government/uploads/system/uploads/attachment_data/file/377143/VHF_guidance_document_updated_19112014.pdf	• Specimen collection • Specimen testing and precautions • Personal protective equipment • Accidental exposure • Decontamination • Spills • Waste treatment and disposal
Department of Health, Government of Australia	Laboratory Procedures and Precautions for Samples Collected from Suspect VHF Patients health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-other-vhf.htm *Note: Separate documents for designated and non-designated isolation hospitals*	• Specimen collection • Specific testing instructions • Designate receiving area requirements • Sample inactivation • Personal protective equipment and exposure • Cleaning and decontamination of facilities and equipment • Waste disposal
World Health Organization	WHO Best Practices for Injections and Related Procedures Toolkit whqlibdoc.who.int/publications/2010/9789241599252_eng.pdf?ua=1	• Best practices in phlebotomy