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Questions and Answers Related to Ebolavirus Disease Testing (version 1)

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Background

- EVD has a median incubation period of about 8-12 days with a range of 2-21 days. As a result a patient may arrive in BC with clinical disease or they may develop infection many days after their arrival.
- EVD is generally detected in a patient's blood sample by nucleic acid testing (NAT) by the third day of symptoms.
- Testing too early could result in a false negative. Therefore a repeat EVD NAT may be needed to reliably rule out EVD.
- Serologic testing for EVD (IgM and IgG) is available at NML, but these tests have limited utility in ruling out acute infection.

Due to Ebolavirus infectiousness, there are concerns by laboratory personnel regarding the ability to safely perform certain tests. Therefore, if a patient is considered to be at high or moderate risk of EVD, the available test menus, at present, become limited. As EVD patients need to be symptomatic for about three days before EVD NAT can reliably rule out infection, this limited testing menu will impair the ability to detect more common illnesses in travelers from affected areas, including: hepatitis, measles and arboviruses, respiratory viruses, norovirus, etc. However, malaria testing is available. In collaboration with the National Microbiology Laboratory (NML) the BC Public Health Microbiology Reference Laboratory (BCPHMRL) is working to develop procedures that will safely provide the full array of important routine tests during the EVD rule out period.

Safety risks to medical staff, healthcare workers, other allied service providers, laboratory staff and the public must be balanced against the diagnostic and treatment needs of the patient. Each EVD case needs a risk assessment involving the treating physician(s), medical microbiologists/infectious diseases specialists/the on-call medical microbiologist at the BCPHMRL and the MHO to help guide appropriate clinical care and ongoing reassessment.

General Questions and Answers related to EVD Testing

1. What samples should be submitted for EVD NAT?

Send two 5 mL EDTA tubes for EVD NAT and two 5 mL tubes gold top serum SST for other tests as determined by the assessment and differential diagnosis. *There needs to be at least three days of symptoms for the test to reliably rule in or out infection.*

2. What is the sensitivity and specificity of the test?

The sensitivity is unknown, but for a symptomatic case with at least three days of clinical signs/symptoms of EVD one would expect the sensitivity to approach ~99%. The specificity is unknown but likely ~99%.

3. At what point in the clinical course of EVD will the test have 100% sensitivity? And, would there be times (e.g. if a person has early-onset symptoms or symptoms due to another cause) when a negative test would need to be repeated to fully rule-out EVD infection?

Repeat EVD NAT testing is required if a patient is tested too early during symptomatic phase. Most people become symptomatic with 6 to 12 days post exposure depending on the type of exposure, with a range of 2 to 21 days. Patients need to be symptomatic for at least three days to reliably detect EVD by NAT. Given that the differential diagnosis for most cases will be broad, it may be important to diagnose other common infections to appropriately manage suspect cases unless EVD is at the top of the differential.

4. What are the hours and days that the test will be offered?

Testing will be available 24/7. An immediate teleconference will be convened with the MHO, clinician, local micro/ID and BCPHMRL med micro on-call to agree on the risk assessment and the testing plan.

5. What is the test ordering protocol to collect and send specimens?

Testing will be coordinated with Clinician/MHO/local Med Micro/ID/PHMRL Med Micro on-call. The team will also coordinate sample transport using ERAP to ship samples to the BCPHMRL/BCCDC.

6. Does the BCPHMRL EVD NAT replace sending specimens to the NML

Sites will not send directly to NML unless approved by BCPHMRL. Screening EVD NAT will be done by BCPHMRL. Any positive results are preliminary until confirmed by NML.

7. What is the expected turnaround time for results and at what point can hospitals react to the results?

The expected turnaround time is about 4 hrs from receipt of the sample at the BCPHMRL. The risk assessment team will reassess patient and public health management based on test results.

8. What is the reporting procedure?

Results will be called to the clinician/MHO/local Med Micro/ID/PHMRL Med Micro on- call. Based on test results, the team will update the risk assessment and communicate next steps.

9. What is the process to manage tests that have been drawn or performed prior to EVD being considered?

This will require a risk assessment by the team who will provide direction.#