

TAB C2A

LABORATORY SPECIMEN COLLECTION, TESTING, AND TRANSPORT

JUNE 2019

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# Ebola Virus Testing

**Testing Employed at the North Carolina State Laboratory of Public Health (NCSLPH):** Specimens **will not** be accepted without prior consultation. The NCSLPH utilizes two CDC Ebola virus rRT-PCR assays (EBOV VP40 and EBOV NP) that have been granted FDA Emergency Use Authorization for the in vitro qualitative detection of Ebola virus RNA. Acceptable specimens for Ebola testing are listed in the table below. If the PUI’s symptoms have been present for <3 days, a second sample collected 72 hours after onset of symptoms is required to definitively rule out Ebola. The estimated turn-round-time for NCSLPH results is 6 hours for a single specimen and up to 24 hours for multiple specimens. CDC testing can include: rRT-PCR with multiple primer probe sets for Ebola, tests for other hemorrhagic fever viruses, virus isolation, and serology when indicated by the clinical or epidemiological presentation.

- **CDC GUIDANCE FOR COLLECTION, TRANSPORT and SUBMISSION of SPECIMENS FOR EBOLA VIRUS TESTING** can be found at: <https://www.cdc.gov/vhf/ebola/laboratory-personnel/specimens.html>
- **USE APPROPRIATE PRECAUTIONS WHEN COLLECTING SPECIMENS FOR EBOLA TESTING.** Staff who collect specimens from PUIs should wear appropriate PPE and should refer to <https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html>
- All specimen submissions must be accompanied by a completed **Bioterrorism and Emerging Pathogens (BTEP) Specimen Submission Form** (<https://slph.ncpublichealth.com/Forms/5010-BT-EmergPathogens-20180508.pdf>), a **CDC 50.34 DASH Form** (<https://slph.ncpublichealth.com/Forms/CDC50-34DASHForm120517.pdf>) and a **Viral Special Pathogens Branch Diagnostic Specimen Submission Form** (<https://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>) when appropriate.
- Packaging of specimens should follow packing instruction 620, IATA guidelines for Category A, which utilizes a triple packaging system (<https://www.cdc.gov/vhf/ebola/laboratory-personnel/shipping-specimens.html>). We anticipate active discussion with all entities requesting diagnostic testing for Ebola and we will provide more specific guidance on a case-by-case basis.

Appropriate Specimens for Ebola rRT-PCR Testing at NCSLPH			
Specimen Type	Minimum Quantity	Testing	Transport
Whole blood with EDTA anticoagulant (purple top tube) in non-glass collection tube	<ul style="list-style-type: none"> <li>➤ Adults 4ml</li> <li>➤ Pediatric 1ml</li> </ul>	rRT-PCR	Refrigerated (4°C), placed on cold packs. Package specimens using Category A guidelines.
Serum		<ul style="list-style-type: none"> <li>➤ 3ml</li> </ul>	

Plasma		➤ 3ml	
Urine*		➤ 3ml	
<b>Appropriate Specimens for Testing Conducted at the CDC</b>			
Uncoagulated whole blood (purple, yellow, or blue top) in non-glass collection tube	➤ 4ml	Culture, PCR Culture,	Refrigerated (4°C), placed on cold packs if shipment is to be received within 72 hrs. For delays exceeding 72 hrs. freeze serum at -70°C & ship on dry ice.
Serum (red top, collected in non-glass tube)	➤ 4ml	PCR, Serology	Refrigerated (4°C), placed on cold packs if shipment is to be received within 72 hrs. For delays exceeding 72 hrs. freeze serum at -70°C & ship on dry ice.
Formalin-fixed or paraffin-embedded tissues	As Appropriate	Immuno-histochemistry	Ship at room temperature. Note: An autopsy or surgical report must accompany the specimen.
Fresh frozen tissue	1 cm <sup>3</sup> (except for biopsies)	Culture, PCR	Ship specimen frozen on dry ice in a plastic container.

\*Urine will only be tested when it is submitted alongside a blood specimen from the patient.

**CONTACT THE BTEP UNIT, 24/7 (919-807-8600), PRIOR TO ANY SHIPMENT OR IF YOU HAVE QUESTIONS.**

Address all specimen shipments as follows:

Attention: Bioterrorism & Emerging Pathogens Unit  
North Carolina State Laboratory of Public Health  
4312 District Drive  
Raleigh, NC 27607-5490

### Routine Laboratory Testing on Suspect EVD Cases

- Clinicians should ensure that laboratory staff are aware if a diagnosis of EVD is being considered so that appropriate precautions can be taken in the laboratory when handling routine or diagnostic specimens.
- The NCSLPH encourages institutions to conduct an internal risk assessment to review all handling and testing procedures that are associated with specimens from a suspect Ebola case. The NCSLPH highly recommends the use of professional judgment to determine the need for enhanced safety precautions.
- The NCSLPH strongly recommends that laboratories consider the following guidelines for handling of routine laboratory specimens from persons under investigation for Ebola: CDC laboratory guidelines: <https://www.cdc.gov/vhf/ebola/laboratory-personnel/safe-specimen-management.html>