



PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES TECHNICAL BULLETIN

November 2014

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New Jersey Implements Testing For Ebola Virus Disease (EVD)

Effective today, Wednesday, November 12, 2014, the New Jersey Department of Health (NJDOH), Public Health and Environmental Laboratories (PHEL), will start performing the Department of Defense (DOD) real time- PCR Ebola Zaire Assay. Note that this test is specific for Ebola Zaire species (the causative agent of the outbreak in West Africa) and does not detect other Ebola species or other VHF etiologies.

Ebola virus belongs to the family Filoviridae, which is one of 4 families of viruses with species known to cause Viral Hemorrhagic Fevers (VHF) in humans and non-human primates. There are five identified Ebola virus species; four have been associated with outbreaks in humans, so far limited to the African subcontinent. They are Ebola virus Zaire, Sudan virus (Sudan ebolavirus); Taï Forest virus (Taï Forest ebolavirus, formerly Côte d'Ivoire ebolavirus); and Bundibugyo virus (Bundibugyo ebolavirus). To date, Reston virus (Reston ebolavirus), has been reported to cause disease in non-human primates only.

While sporadic outbreaks periodically occur in Central Africa, 2014 marked the first recorded Ebola virus outbreak in West Africa. Between March and November 2014, the virus has infected over 13,000 individuals, leading to approximately 5,000 deaths. At least 300 health care workers have succumbed to the disease. The expedience of travel has complicated control of the disease and this has resulted in imported cases from the affected countries to five countries outside of West Africa, including the United States.

In response to the international threat that this Ebola outbreak poses, the DOD developed an assay, real time- PCR Ebola Zaire that gained FDA approval for use under Emergency Use Authorization (EUA). Before deploying the assay for use in select state and local public health laboratories, the DOD embarked on a process of training and verifying the competency of the staff that will be performing the test. In collaboration with the Centers for Disease Control and Prevention (CDC), Laboratory Response Network (LRN) Program office, 27 State and Local Public Health Laboratories nationwide are now approved to perform the DOD Ebola Zaire Assay.

Test Approval Process:

Infection with Ebola virus is an immediately reportable condition to the local health department (LHD) where the person resides (or where the hospital is located). The LHD is then required by NJAC 8:57 to immediately notify the New Jersey State Department of Health (NJDOH), Communicable Disease Service (CDS). If the LHD cannot be reached, the hospital or physician can contact NJDOH, CDS directly at the numbers provided below. The two agencies (in consultation with the CDC) will assess the case and determine whether testing is warranted and notify PHEL BioThreat Response Laboratory staff. Information relating to laboratory testing is provided in the attached table.

Communicable Disease Service:	Day: 609-826-5964; Night, holiday, weekends 609-392-2020
BioThreat Response Laboratory:	Day: 609-530-8522, 8523, 8524: Night, holiday, weekends 609-209-9004
Laboratory Outreach:	Day: 609-406-6878 Night, holiday, weekends: 609-571-0388

References:

CDC Fact Sheet: Viral Hemorrhagic Fevers

http://www.cdc.gov/ncidod/dvrd/spb/mnpages/dispages/Fact_Sheets/Viral_Hemorrhagic_Fevers_Fact_Sheet.pdf

MedLine Plus: Ebola Hemorrhagic Fever

<http://www.nlm.nih.gov/medlineplus/ency/article/001339.htm>

2014 Ebola Outbreak in West Africa

<http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/index.html>

Ebola Zaire (EZ1) rRT-PCR (TaqMan®) Assay

<http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM408334.pdf>

Information for Ebola Virus Disease Testing (November 2014)*

Decontaminate all work surfaces promptly. It is important to keep a record of all staff members handling Ebola specimens.

Test information	Description	Comments
Test Approval Process	Request for Ebola testing must be preapproved by the New Jersey Department of Health (NJDOH) Communicable Disease Service (CDS). Contact information on front page. If approved, an NJDOH case number will be assigned.	Specimen will not be processed without the NJDOH approval & case #
Test Location	PHEL, BioThreat Response Laboratory @ 3 Schwarzkopf Dr., Ewing NJ 08628 Attn: Nelson Delgado (609) 209-9004 (Responsible Person)	Contact info for lab is on the front page of this Brief.
Specimen Requirement	Two full, 4 ml lavender top EDTA tubes of blood are required. One tube is used for initial test for Ebola at the State Public Health Laboratory; the second tube is for confirmatory testing at CDC for positives or when special studies at CDC are required on negative samples. These samples cannot be shared for any other laboratory tests. Use plastic collection tubes only.	If the institution uses 3ml EDTA tubes for CBC, the tubes are acceptable as long as both tubes are filled. No glass tubes.
Submittal of Test Request**	Complete 1) BTRL Lab-5 with chain of custody form; 2) CDC DASH form; 3) CDC VSPB requisition; 4) CDC Chain of Custody form; and 5) Dangerous Goods Shippers Declaration for each request. Fill in case # in space provided on Lab-5 and in the "And/or SPHL Spec. ID" box on pg. 2 DASH form.	Keep completed forms in a plastic bag, separate from the specimen.
Test Methods	rRT-PCR [‡] : PHEL test for Ebola only; CDC tests for Ebola and other VHF viruses	
Testing Frequency	Lab testing is scheduled in consultation with CDS	
Turnaround time (TAT)	24 hrs. after receipt at PHEL (most specimens received by 8 am are resulted by PHEL by 6 pm); CDC confirmatory: 24 hrs. after receipt at CDC laboratory	Any specimen problems or shipping delays to CDC could increase the TAT.
Specimen Collection, Accession & Receiving	<ul style="list-style-type: none"> Take all the necessary supplies for collection of the two lavender EDTA blood tubes into the patient room. Do not take the request forms or any of the packaging and shipping components into the room. Collect the 2 tubes of blood. Label each with patient name, NJDOH case number, date of collection, DOB and initial the tube. Change gloves. Decontaminate the rubber stoppers, place the tubes in a specimen bag and seal the bag. Decontaminate outside of specimen bag with a 1:10 dilution (v/v) of household bleach (0.5% sodium hypochlorite). The bleach solution must be prepared fresh daily. Alert the appropriate laboratory personnel for specimen pickup. Personnel responsible for receiving Ebola specimen should pick up specimens using a rigid specimen carrier without entering patient room and transport the specimen in the carrier to the designated lab area. Take sample out of carrier and transfer to clean, emptied Biosafety cabinet if available. If not, work on a bench area overlaid with absorbent bench pads. Repeat decontamination of specimen bag. Without opening the specimen bag, verify that information on tubes matches information on the request forms. Follow usual protocol to accession and receive samples to obtain lab specimen ID. Place the lab labels with the lab forms in a dedicated plastic bag (separate from the specimen) and seal the bag. The specimen is now ready for packaging by a lab staff certified in packaging and shipping. 	
Specimen Packaging and Shipping	Specimen must be shipped on cold packs: An Overpak box must be used in addition to the primary specimen packaging kit. Follow all requirements of USDOT 49 CFR, 173.196 regs. for shipping <i>Category A Infectious Substance</i> . Identify technical name on this form (Not on the box) as <i>Suspected Ebola virus</i> .	Certified personnel must be utilized to package and ship this specimen. Refer to the referenced regulations.
Specimen Storage	Accession, package and transport/ship immediately after collection. If any unforeseen delay is experienced, the package may be stored at 2-8°C until picked up by the courier. Secure package in limited access refrigerator.	
Specimen Transport	Currently, specimen is being picked up by the NJ State Police. PHEL staff is responsible for making arrangements for pickup from the hospital and delivery of specimen to the PHEL for testing. The transfer to State Police must be entered in the COC form. The bag with labels/forms must be attached to the package.	The State Police must contact the BTRL manager before leaving the pickup site: see contact info below
Result Reporting	PHEL= Presumptive Positive for Ebola Zaire RNA or Negative for Ebola Zaire CDC confirmatory= Negative or Positive for any of the VHF agents measured.	Negative result is final. Confirmatory on positives.
Report Generated	Email to submitting Hospital, NJDOH agencies: LRN Messenger report to CDC	
Specimen Rejection Policy	Specimen may be rejected if all of the requirements are not met. All attempts will be made to resolve any issues before rejecting a specimen.	e.g. safety risk- sample improperly packaged

For questions relating to any information on this bulletin, please contact, Dr. Nelson Delgado, BTRL Program Manager @ (609)-209-9004 nelson.delgado@doh.state.nj.us or Susan Mikorski, Laboratory Outreach Coordinator @ (609)-406-6878, susan.mikorski@doh.state.nj.us.

* Note: The guidelines and protocols for laboratory handling and processing of Ebola specimens are very dynamic at this time. This technical bulletin may be updated as necessary. **Retain copies of all forms prepared for your records. [‡] rRT-PCR: real time reverse transcription polymerase chain reaction