Nebraska Department of Health and Human Services

HEALTH ALERT NETWORK Advisory

TO: Laboratories and Public Health

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RE: **Laboratory Guidelines for Handling Specimens from Patients Under Investigation (PUI) for Ebola Virus Disease (EVD) in Nebraska**

DATE: October 24, 2014

Inquiries regarding suspect EVD should immediately be directed to the State or Local Public Health Department:

- **DHHS Office of Epidemiology (402) 471-2937 (after hrs 402-471-1983)**
- **Douglas County (402) 444-7214 (after hrs 402-444-7000)**
- **Lancaster County (402) 441-8053 (after hrs 402-441-8000)**
- **All Other Counties please refer to the DHHS website for contact information at www.dhhs.ne.gov/lhd.**

Early recognition is critical for infection control and the protection of laboratory workers. A person that meets the case definition of a Person Under Investigation (PUI) for Ebola Virus Disease (EVD), should be isolated and public health professionals immediately notified **BEFORE** collection of specimens for laboratory testing for EVD. The availability of testing materials for EVD are limited. Every test performed at the NPHL must be approved by the CDC.

Person Under Investigation (PUI)

A person who has both consistent symptoms and risk factors as follows:

1. Clinical criteria, which includes fever of > 38.6 ° Celsius or 100.4 ° Fahrenheit, and additional symptoms such as severe headache, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage; AND
2. Epidemiologic risk factors within the past 21 days before the onset of symptoms, such as contact with blood or other body fluids or human remains of a patient known to have or suspected to have EVD; residence in—or travel to—an area where EVD transmission is active.

CDC provides updated guidance for a PUI whose epidemiologic risk factors include high or low risk exposure(s): http://www.cdc.gov/vhf/ebola/hcp/case-definition.html.

Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing)

http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html
http://www.cdc.gov/vhf/ebola/pdf/checklist-patients-evaluated-us-evd.pdf

Nebraska protocols for donning & doffing:

Donning Complete: http://app1.unmc.edu/nursing/heroes/pdf/vhfppe/donningBiologicalPPE-EbolaPatients-8.5x11-CC-v1.02.pdf

Doffing Complete: http://app1.unmc.edu/nursing/heroes/pdf/vhfppe/doffingBiologicalPPE-EbolaPatients-8.5x11-CC-v1.01.pdf

All hospital facilities are encouraged to adhere to the links above, following all evaluation recommendations and personal protective equipment (PPE) precautions, especially upon caring for potential EVD patients presenting with vomiting and diarrhea.

When Specimens Should Be Collected for Ebola Testing

Ebola virus is detected in blood only after the onset of symptoms, usually fever. It may take up to 3 days after symptoms appear for the virus to reach detectable levels using molecular assays. Virus is generally detectable by real-time RT-PCR from 3-10 days after symptoms appear. Specimens ideally should be taken when a symptomatic patient reports to a healthcare facility and is suspected of having an Ebola exposure. However, if the onset of symptoms is <3 days, a later specimen is needed to completely rule-out Ebola virus, if the first specimen tests negative. **Contact public health PRIOR to specimen collection for Ebola testing (see contact information above).**

- Phlebotomy, procedures, and laboratory testing should be limited to the minimum necessary for essential diagnostic evaluation and medical care.
- It is recommended that nursing staff, who should be trained on the new EVD CDC Guidance on PPE, collect specimens within the patient isolation area. However, if laboratorians and phlebotomists are required to enter the isolation area and collect specimens, they must follow the same CDC Guidelines, adhering to the key principles listed within the links above:
    - Prior to working with Ebola patients, all healthcare workers involved in the care of Ebola patients must have received repeated training and have demonstrated competency in performing all Ebola-related infection control practices and procedures, and specifically in donning/doffing proper PPE.
    - While working in PPE, healthcare workers caring for Ebola patients should have no skin exposed.
    - The overall safe care of Ebola patients in a facility must be overseen by an onsite manager at all times, and each step of every PPE donning/doffing procedure must be supervised by a trained observer to ensure proper completion of established PPE protocols.
- Laboratorians will be required to sign a log at entry and exit room of an Ebola patient.
- Upon approval for Ebola testing, collect two (2) EDTA (purple top either 3mL or 5mL) tubes and transport to NPHL at 2-8°C. Arrangements will be made by NPHL to transport.
- Staff in isolation room should hand off specimen to clean area as follows:
    - Place preprinted label on specimen with proper identifiers.
    - Wipe down specimen tube with 10% bleach wipe, including top of tube lid which may have remaining blood droplets.
    - Place each tube in a separate biohazard bag with absorbent material such as gauze and seal.
    - Wipe down outside of bag, with a bleach wipe, before placing into 2nd biohazard bag.
    - Again, wipe the outside of 2nd bag with a bleach wipe.
    - With a new bleach wipe, between fingertips and bag, carefully hand off bag to staff in clean area.
    - Staff in clean area with appropriate PPE, should take specimen bag with new bleach wipe between their fingertips and bag.
    - Place in durable, leak-proof container, such as a cooler. In compliance with 29 CFR 1910.1030, specimens should be placed in this container for transport within a facility and should be hand carried to laboratory. DO **NOT** use a pneumatic tube system. Do **NOT** leave specimens unattended.

Best laboratory practices to handle specimens on suspected EVD patients

- Laboratory testing should be limited to only tests essential to patient care, but should not compromise care.
- Use of Point-of-Care instruments and rapid test methods, if available, inside or nearby patient's isolation room, to provide reduced specimen transport and limit need for testing in the routine laboratory. This may be a preferred option, especially if patient has tested positive for EVD.
- If transport is required to the clinical laboratory, see guidelines for transport within hospital in section "When Specimens Should Be Collected for Ebola Testing" above.
- Centrifugation and open tube testing SHOULD NOT BE DONE in a BSL-2 clinical laboratory setting.
- Wash hands frequently. Keep hands away from nose, mouth and eyes.
- Do NOT use personal items in lab (cell phones, lip balm, etc.) that are taken out of the laboratory.
- Protocols for occupational exposure should be reviewed prior. Consult with infection control or other proper authority if a potential exposure occurs, please contact public health immediately (see contacts above).

Packaging and Shipping Clinical Specimens to the NPHL

The Ebola virus is classified as a Category A infectious substance by the Department of Transportation (DOT) and, when transported in commerce, is regulated by DOT's Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180). Only those employees who have been trained and certified to be a Category A shipper are allowed to package, mark, label or complete the documentation for packages being offered for Ebola testing.

Medical personnel are required to contact the State and/or local public health department PRIOR to collection or transport of samples for Ebola virus testing. After consultation, if the patient is considered to be at risk of being infected with Ebola virus, patient specimens, including blood, will be accepted for transport using the shipping materials provided by NPHL and transported by FedEx or other arranged transport service.

Patient specimens that are approved to be tested for Ebola virus, will be tested at the NPHL and must follow the NPHL Division 6.2 Packaging & Shipping Program (detailed instructions found at http://nphl.org/), provided for all sentinel laboratories. No specimens should be sent directly to the CDC. In summary, these specimens should adhere to these guidelines:

- Classified as a Category A, using the proper shipping name "infectious substance, affecting humans" and assigned to UN2814.
- Be properly packed in UN specification packaging according to IATA packaging instruction 620 before being offered for transport.
- A shipper's declaration form must be completed using either FedEx compliance checking software or software approved by FedEx to accompany packages.
- Use "suspected category A infectious substance" as the technical name on the shipper's declaration form but do not put the technical name on the outer packaging.

FedEx will **only** accept patient specimens from a PUI for EVD. FedEx will **not** accept or transport patient specimen's positive for Ebola virus by molecular assay or culture, therefore will require NPHL to arrange transport with couriers who accept risk group 4. Contact the NPHL for consultation under these circumstances.

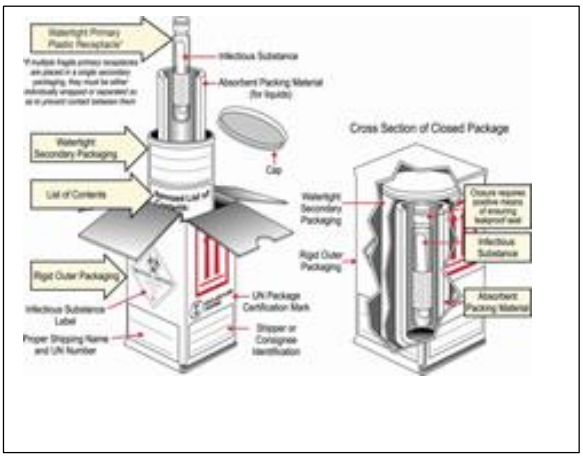
Specimens collected for EVD testing should be packaged and shipped without attempting to open collection tubes or aliquot specimens.

Specimens transported for EVD testing must be accompanied by a completed NPHL requisition, to include date of onset and as much patient history as possible, name of facility, physician, and name of

State or local public health official giving approval. Write in comments area of the requisition "PUI for Ebola Testing by PCR."

The following steps should be used in submitting samples to NPHL:

- NO specimens will be accepted without prior approval from a public health authority.
- For consultation call the NPHL 24/7 pager at **402-888-5588**.
- Contact NPHL for instructions and to arrange transport.
- Transport will be based on distance & shipper capability.
    - Sentinel Labs - use FedEx or other courier arranged by NPHL.
    - Laboratories who are not trained in Division 6.2 – NPHL will arrange courier who accepts risk group 4.



Preliminary Testing at NPHL

Once a specimen is received at the NPHL, the NPHL personnel will consult further with the CDC Emergency Operation Center (EOC) to confirm acceptability for testing. Once approved, the sample will be tested by the in-house validated CDC-PCR assay. Testing during normal work hours may take up to 6 hours to complete and testing during 2nd-3rd shifts or on weekends may be delayed due to travel time of personnel to the NPHL for testing. Upon completing testing, the preliminary results will be reported immediately to State and local public health as well as the ordering facility.

Effective immediately, suspect Ebola samples that produce a negative test result may be reported as a final negative without confirmatory testing being performed at CDC. Negative results will be reported with the following comment, "If fever or symptoms have been present for less than 72 hours, a repeat test may be required to rule out Ebola virus infection."

Specimen Handling for Other Laboratory Testing

Routine laboratory testing includes traditional chemistry, hematology, and other laboratory testing used to support and treat patients. Precautions as described above offer appropriate protection for healthcare personnel performing laboratory testing on specimens from PUI for EDV. These precautions include both manufacturer installed safety features for instruments and the laboratory environment as well as PPE specified above.

All laboratorians and other healthcare personnel collecting or handling specimens must follow established standards compliant with the OSHA bloodborne pathogens standard, which includes blood and other potentially infectious materials. These standards include wearing appropriate PPE and following all safety rules for all specimens regardless of whether they are identified as being infectious.

Recommendations for risk assessment to staff: All laboratory directors should first perform risk assessments, review their procedures and evaluate their facility resources to determine what routine laboratory testing can be performed on a PUI. Appropriate training and experience should be taken into account. Risk assessments should be conducted by each laboratory director, biosafety officer, or other responsible personnel to determine the potential for sprays, splashes, or aerosols generated from laboratory procedures including waste generated from analyzers. They should adjust, as needed, PPE requirements, practices, and safety equipment controls to protect the laboratorian's skin, eyes, and mucous membranes.

Recommendations for laboratory testing by staff: Any person testing specimens from a patient with a suspected case of EVD should at minimum wear gloves, water-resistant gowns, full face shield or goggles, and masks to cover all of nose and mouth, and as an added precaution use a certified class II Biosafety cabinet or Plexiglass splash guard with PPE to protect skin and mucous membranes. All manufacturer-

installed safety features for laboratory instruments should be used. **(Ebola testing will ONLY be performed at NPHL)**

Environmental Cleaning and Disinfection

See the Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus for recommendations regarding the cleaning and disinfection of patient care area surfaces including the management of blood and body fluid spills. These recommendations also apply to cleaning and disinfecting in a laboratory where specimens are being processed from persons under investigation, or with probable or confirmed Ebola virus infections.

In the case of a spill in the laboratory, consult with infection control or other proper authority if a potential exposure occurs, please contact public health immediately (see contacts above). The basic principles for blood or body substance spill management are outlined in the United States OSHA Blood Borne Pathogens Standards. There are no disinfection products with specific label claims against the Ebola virus. Enveloped viruses such as Ebola are susceptible to a broad range of hospital disinfectants used to disinfect hard, non-porous surfaces. In contrast, non-enveloped viruses are more resistant to disinfectants. As an added precaution, use a disinfectant with a higher potency than what is normally required for an enveloped virus to disinfect potentially Ebola-contaminated surfaces. EPA-registered hospital disinfectants with label claims against non-enveloped viruses (e.g., norovirus, rotavirus, adenovirus, poliovirus) are broadly antiviral and capable of inactivating both enveloped and non-enveloped viruses.

Management of Laboratory Waste

The Ebola virus is classified as a Category A infectious substance by the Department of Transportation (DOT) and, when transported in commerce, is regulated by DOT's Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180). Any item transported in commerce that is contaminated or suspected of being contaminated with a Category A infectious substance must be packaged and transported in accordance with the HMR. This includes medical equipment, sharps, linens, and used health care products, such as soiled absorbent pads or dressings, kidney-shaped emesis pans, portable toilets, used PPE (gowns, masks, gloves, goggles, face shields, respirators, booties, etc.) or byproducts of cleaning contaminated or suspected of being contaminated with a Category A infectious substance.

Waste generated during laboratory testing should be placed in leak-proof containment. To minimize contamination of the exterior of the waste bag, place this bag in a rigid waste container designed for this use. If available, steam sterilization (autoclave) or incineration as a waste treatment process can inactivate the virus and reduces waste volume. For equipment that drains directly into the sewer system, the United States sanitary sewer system handling processes (e.g., anaerobic digestion, composting, and disinfection) are designed to safely inactivate infectious agents. However, check with your state's medical waste program for more guidance and coordinate your waste management activities for the laboratory area with your medical waste contractor.