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To: Clinical Laboratories, Healthcare Providers, Hospitals, Healthcare Facilities, and Local Health Departments (LHDs)

From: New York State Department of Health (NYSDOH) Wadsworth Center Laboratories and Division of Epidemiology

HEALTH ADVISORY: INTERIM NYS/NYC LABORATORY GUIDELINES FOR HANDLING SPECIMENS FROM CASES OR SUSPECTED CASES OF EBOLA VIRUS DISEASE

Please distribute immediately to the Clinical Lab Director, Infection Control Department, Hospital Administrator, Emergency Department, Infectious Disease Department, Pediatrics, Medical Director, Director of Nursing, Laboratory Service, and all patient care areas.

Interim NYS/NYC Laboratory Guidelines for Handling Specimens from Cases or Suspected Cases of Ebola Virus Disease

The following guidelines are provided for New York State and New York City clinical and public health laboratories that may receive and test specimens from patients suspected or confirmed as having Ebola Virus Disease (EVD).

Please note that they are preliminary and we welcome suggestions and comments. These can be forwarded to virology@health.state.ny.us. The vast majority of EVD patients have not been cared for in advanced medical facilities. However, the following important points should be kept in mind:

1. EVD is transmitted through direct contact with blood or body fluids, or contact with environments contaminated with blood or body fluids. There is no evidence of airborne transmission.
2. Ebola virus is readily inactivated by standard heat and chemical inactivation procedures used in microbiology laboratories.

Please refer to the following CDC website for definitions of probable and confirmed cases, and those for high risk and low risk exposures:
http://www.cdc.gov/vhf/ebola/hcp/case-definition.html

For the purposes of these guidelines, a Person Under Investigation (PUI) refers to a patient with either High or Low Risk exposure, for whom a definitive diagnosis has not yet been determined. (Note: a negative result must be received on a specimen collected at least 3 days after onset of symptoms in order for it to be definitive; otherwise the test should be repeated.)

A real-time RT-PCR assay for the detection of ebola virus RNA has recently been FDA-cleared under Emergency Use Authorization (EUA). The New York City and New York State public health laboratories have both been identified as sites to receive it. Assay validation and the implementation of clinical testing will be performed as quickly as possible. Clinicians and clinical facilities will be notified as soon as the laboratories are certified to test clinical samples on site.

Procedures for the collection, handling, and testing of specimens for EVD have been issued by the CDC and are posted at the following site:

http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patient-suspected-infection-ebola.html

The following guidance is provided for additional laboratory testing on specimens collected from PUIs or confirmed EVD cases:

GENERAL POINTS

Laboratory testing should be limited to testing essential to patient care.
(See transcript of the COCA call "What U.S. Hospitals Need to Know to Prepare for Ebola Virus Disease": http://emergency.cdc.gov/coca/transcripts/2014/call-transcript-080514.asp.)

Wherever possible, testing should be performed inside the patient's isolation room or inside the isolation facility, using Point-of-Care (POC) instruments and testing methods. This includes:

Routine blood chemistry, blood gases, hematology, and urinalysis

Testing that requires transport of samples to laboratories outside the patient's isolation room should be kept to a minimum. Specimens should be double-bagged and placed in a biohazard transportation container. The container should be wiped down with 10% bleach, **hand-carried** to the laboratory (**DO NOT** use a pneumatic tube system) and opened inside a biosafety cabinet.

Personal Protective Equipment (PPE)

ALL specimen manipulations must be performed in a certified Class 2 Biosafety Cabinet (BSC2) in a Biosafety Level 2 (or higher) laboratory, wearing appropriate PPE, including:

- Impermeable gown with back closure (front button or front snap closing laboratory coats are not acceptable)
- Double gloves
- Mask to cover nose and mouth
- Eye protection such as safety goggles

GUIDANCE FOR SPECIFIC PROCEDURES

Procedure	Recommendation
Centrifugation	Procedures requiring centrifugation should be avoided outside the patient isolation room. When performed, it must be with biohazard sealed buckets or rotor.
Chemistry and hematology	See above under "General Points".
Malaria testing	Only thin blood smears should be prepared on Ebola PUIs. These should be prepared inside a BSC2 and should not be removed from the cabinet until they have been fixed and dried. Do not perform thick smears for malaria testing.
Blood Cultures	Specimens should be double-bagged and placed into a biohazard transportation container for transport to the microbiology laboratory. Plastic blood culture bottles may be placed into a continuous monitoring system for diagnosis. Blood culture in glass bottles should be avoided.
Other specimens for bacterial culture	Do not perform "pan-cultures". If essential for patient management, perform all procedures inside a BSC2 with PPE, use shrink seal or parafilm to seal culture plates or tubes. Subsequent colonies can be placed in identification systems.
Wet preps	Should not be performed.
Viral cultures	**DO NOT perform viral culture**, including any rapid culture systems, under any circumstances on any specimen.
Viral or bacterial antigen tests	Rapid antigen tests should be performed inside patient isolation room.
Molecular testing for infectious agents	Ideally, these should be performed with a POC device inside the patient isolation room or isolation facility. Where this is not possible and testing is imperative for patient care, specimens should be transported to the laboratory as above, and initial lysis performed in a BSC2 with PPE, preferably inside a BSL-3 laboratory.
Cross-matching for blood transfusion	This should not be performed. Patient should be treated with volume boosters and, if necessary, O-negative blood transfusion.
Tissue Pathology	Should be kept to a minimum and only performed if essential for patient care. Procedures such as frozen sections and homogenization should not be performed. Tissue preparations such as touch prints and biopsies should be fixed inside the patient isolation room.
Post-mortem examinations	Should not be performed.
Specimen storage:	Long-term storage of specimens is discouraged. All specimens collected from Ebola PUIs or positive cases should be isolated from other specimens in the laboratory and disposed of in an appropriate manner as soon as testing is completed (see below).
Specimen decontamination and disposal	Autoclave specimens from all PUI if facilities are available. Alternatively, inactivate specimens in 10% bleach for 24 hours, then place in standard biohazard infectious waste disposal. **NOTE: Ebola is a Tier 1 Select Agent. If a patient tests positive for Ebola, any blood or body fluid specimens from a positive patient must be handled and disposed of in accordance with the Select Agent Regulation. Destruction on site must be documented, or specimens transferred to a Tier 1 SA Registered Lab for destruction.**

References
Hersberger et al. 2004. Clinical Chemistry. 50: 944-946.
Rollin et al. 2011. Arenaviruses and Filoviruses. In: Manual of Clinical Microbiology. (10th ed). ASM Press.

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Information on communicable disease reporting, including the list of reportable diseases, reporting guidance, and contact information for LHDs, can be found at: http://goo.gl/FBccq.

If you have any questions regarding this information, please contact your LHD or the NYSDOH Bureau of Communicable Disease Control at bcdc@health.state.ny.us or (518) 473-4439.