

November 12, 2014

COLLECTION AND TRANSPORT OF SPECIMENS TO WADSWORTH CENTER FOR EBOLA TESTING

Review of Laboratory Risk Assessment:

As outlined in the NYS Commissioner of Health's Order on Ebola Virus Disease Preparedness, each laboratory should review their operations and protocols and update their biohazard risk assessment.

Confirmation of PUI meeting criteria for EVD laboratory testing:

If a patient presents with history and clinical presentation consistent with EVD risk factors, the facility should notify their local health department (LHD) immediately. The LHD will contact the state HD and the CDC to confirm the risk factors and decide whether Ebola virus testing is warranted.

Specimen Collection Requirements for Ebola testing:

2 plastic lavender top blood collection tubes (EDTA anticoagulant), containing minimum four (4) mls per tube collected from a PUI. Disinfected tubes after specimen collection and before they are packaged for transport, by wiping the outside of the tubes with a U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with a label claim for a non-enveloped virus. Ensure that the patient details are still clearly visible on the label. These specimens will be transported refrigerated to the Wadsworth Center for Ebola and Malaria testing.

Specimen Packaging:

Packaging of specimens from suspected (or confirmed) Ebola patients requires the use of packaging materials appropriate for shipping "Infectious Substances, affecting humans", category A [UN2814 Category A, under the Department of Transportation (DOT) Dangerous Goods Regulations, Code of Federal Regulations (CFR) 49]. Laboratories should order these shipping materials from a vendor.

Note: the NYSDOH Order Desk does not have shipping packages that can be used to ship Category A specimens refrigerated.

The NYSDOH Office of Health Emergency Preparedness (OHEP) has ordered a limited supply of Category A packaging materials that have been sent to NYSDOH regional and district offices. These will be distributed to collection end points for emergency use in the event that a facility has specimens for submission and has exhausted their internal supply of Category A materials. Note: this should not be relied upon as the routine source of shipping materials for this purpose. Each shipping container requires four (4) ice packs. Ice packs have been supplied to regional offices but may not be frozen. **Hospital laboratories must ensure frozen ice packs are available.**

Requirement for Certified Personnel for Packaging and Shipping of Specimens:

Packaging of specimens that will be transported to the Wadsworth Center for Ebola testing must be performed by certified personnel within each facility. All laboratories must comply with the

NYS Clinical Laboratory Evaluation Program's **Safety Sustaining Standard of Practice 17 (Safety S17): Compliance with Local, State and Federal Statutes and Regulations. The S17 standard states that** the director shall ensure that the laboratory complies with all applicable local, state and federal laws, regulations and requirements for packaging and shipping of infectious substances.

Laboratories that package and ship infectious substances must maintain training and certification of those staff who package and ship those specimens. Training must be performed at least every 2 years for IATA and every 3 years for DOT.

Critical Specimen Transport Protocol:

If, after consultation with the local and state HDs, and the CDC, it is decided that Ebola virus testing is warranted for a patient, the local and state health departments will activate the Critical Specimen Transport Protocol (CSTP). Under the CSTP, a DOH driver will be dispatched to the facility to collect the packaged specimen and drive it to the Wadsworth Center for testing.

Concurrently, the HD will contact the relevant Wadsworth Center scientists to alert them to the situation. Wadsworth scientists will prepare for receipt and testing of the sample and remain in contact with the HDs and transportation personnel, such that testing can proceed as soon as the specimen arrives.

Note: the CSTP and Ebola testing at Wadsworth, operate 24/7.