



NYS/NYC GUIDANCE FOR LABORATORY TESTING AND MANAGEMENT OF PERSONS-UNDER-INVESTIGATION, FOR EBOLA VIRUS DISEASE (EVD) IN NON-DESIGNATED HOSPITALS

Purpose:

To provide guidance on how hospitals and off-campus emergency departments in New York State can safely perform the laboratory testing necessary for the management of persons-under-investigation (PUI) for EVD and for ruling in or out alternative diagnoses, while EVD testing is in progress or while a decision to transfer the patient is being made.

Scope of Guidance:

This guidance is intended to be used in conjunction with the biohazard risk assessment and protocol that each hospital and off-campus emergency department must develop for its clinical laboratory, in accordance with the NYS Department of Health (NYSDOH) Commissioner's Order dated October 16, 2014 and available at the following website:

http://www.health.ny.gov/diseases/communicable/ebola/docs/commissioner_order.pdf.

Guidance is also available from the Centers for Disease Control and Prevention (CDC) at:

<http://www.cdc.gov/vhf/ebola/hcp/safe-specimen-management.html>.

A hospital has two options for performing clinical laboratory testing on a PUI. The first option is to perform this testing in the hospital core laboratory. The second option is to perform this testing in a Point-of-Care (POC) laboratory set up in close proximity to the patient isolation room in the emergency department. With either option, the hospital should be capable of maintaining necessary laboratory testing capability for a minimum of 24 hours while decisions are made, in consultation with the NYC Department of Health and Mental Hygiene (NYC DOHMH) and NYS DOH, to transfer the PUI to a designated hospital, to conduct EVD testing and/or while awaiting results of EVD testing being performed by a public health laboratory (NYC DOHMH Public Health Laboratory or NYS DOH Wadsworth Center Laboratory). It is understood that smaller hospitals may need additional guidance. The NYC DOHMH and the NYS DOH Wadsworth Center should be consulted on a case-by-case basis to find appropriate solutions.

Note that, for NYC hospitals, if the decision is made to test for EVD, the patient will likely be transferred to a designated hospital. Regardless of timing of the decision, ALL hospitals in NYC must be prepared to appropriately stabilize and care for a PUI until the patient is transferred or EVD is ruled out. ALL hospitals must be prepared to package specimens for shipment to a public

health laboratory for EVD testing in accordance with specifications at:
http://www.health.ny.gov/diseases/communicable/ebola/docs/specimen_collection_shipping.pdf.
and
<http://www.nyc.gov/html/doh/downloads/pdf/cd/ebola-specimens-guidelines.pdf>

Minimum Laboratory Testing Capability to Manage a PUI:

For a PUI the following testing should be available and should be performed in the hospital core laboratory or POC laboratory.

1. Basic blood chemistry and hematology, such as that provided by an i-STAT[®] [blood gas, lactate, electrolytes, hemoglobin/hematocrit, chemistry panel (sodium, potassium, chloride, carbon dioxide, blood urea nitrogen (BUN), creatinine, calcium, glucose), troponin I].
2. Complete blood count (CBC) with differential and platelet count.
3. Urinalysis – can be done manually within a designated area in the patient room with appropriate PPE and splash protection (splash shield, “dead-air hood” or other physical, transparent barrier to protect the operator).
4. As determined by clinical need and hospitals’ biohazard risk assessment, blood cultures may be performed. The early initiation of blood cultures may be important, even if the patient will be transported prior to positivity, as blood cultures may be an essential component of the ultimate diagnosis. Blood cultures should be performed in **plastic bottles only**, which can be incubated in the hospital core laboratory.
5. Coagulation tests, liver function panels and magnesium levels.
6. Malaria testing should be performed, if the laboratory has a parasitology permit, using the Binax NOW[®] malaria rapid diagnostic test and a thin blood smear with fixation. Note: rapid diagnostic assays for malaria have poor sensitivity and negatives should be confirmed by another method.

In laboratories that do not have a permit to perform parasitology testing, a methanol-fixed, thin manual differential smear may be read to provide an indication of the presence or absence of parasites such as malaria under the laboratory’s hematology permit and this would be reported as presumptive and used to manage the patient until a formal identification can be made by a laboratory with a parasitology permit.

After initial isolation in the emergency department, and clinical evaluation including laboratory testing, the NYC DOHMH and NYS DOH must be consulted to determine whether EVD testing is warranted and whether the PUI should be transferred to a designated hospital. If laboratory specimens need to be drawn and sent for EVD testing immediately, the hospital will be notified which public health laboratory will be performing the testing (NYC DOHMH or NYS DOH Wadsworth Center Laboratory) and will be provided with guidance on how to collect and prepare the specimens for transport to the laboratory. The testing lab will arrange for shipment of specimens to CDC if necessary. The guidelines for packaging and shipping of specimens can be found at the following links:

http://www.health.ny.gov/diseases/communicable/ebola/docs/specimen_collection_shipping.pdf.
and

<http://www.nyc.gov/html/doh/downloads/pdf/cd/ebola-specimens-guidelines.pdf>

Repeat testing is recommended for negative EVD PCR results on specimens collected less than three days following onset of symptoms if the patient is still symptomatic, unless EVD is no longer being considered in the differential diagnosis.

OPTION 1. TESTING PERFORMED IN THE HOSPITAL'S CORE LABORATORY

If this approach is selected, the safety guidelines described in the Revised NYS/ NYC Laboratory Guidelines for Handling Specimens from Patients with Suspected or Confirmed Ebola Virus Disease should be followed.

http://www.health.ny.gov/diseases/communicable/ebola/docs/lab_guidelines.pdf.

OPTION 2. TESTING PERFORMED IN A POC LABORATORY

Suggested Equipment

Note that neither NYC DOHMH nor NYS DOH endorse the use of any specific commercial products. The following list is provided as guidance based on consultation with experts in the field. Information on commercial products is provided based on their CLIA status (waived or moderate complexity when possible) and as examples only.

- Class 2 Biosafety Cabinet or “dead air hood” for splash protection and to define contaminated area. While a Class 2 Biosafety Cabinet is recommended, especially where tube-to-tube transfers are required, a dead air hood or splash protection shield may be acceptable if space limitations preclude use of a biosafety cabinet.
- Basic chemistry testing: example i-STAT[®] (Abbott Diagnostics)
- Hematology: example poch-100i[™] (Sysmex)
- Prothrombin time and INR: example CoaguChek[®] (Roche)
- Liver function panels and magnesium (not available on i-STAT[®]): example Piccolo[®] (Abbott Diagnostics)
- Slide maker – for preparing thin smears and/or slides for manual differential
- Benchtop Coulter counter for CBC

In addition, reagents, test kits, controls, basic laboratory consumables, appropriate Personal Protective Equipment (PPE), and facilities for appropriate storage (refrigerator) are required.

Minimum Laboratory Physical Plant Requirements to Manage a PUI.

1. If performing the testing in a POC setting, laboratory analysis should be performed in a separate room near the patient isolation room. The laboratory, minimally, should have a Class 2 biosafety cabinet, dead air hood or splash protection shield.
2. There must be a designated area for the packaging and storage of contaminated medical waste and a documented plan to handle the regulated medical waste consistent with the specifications at: http://www.health.ny.gov/diseases/communicable/ebola/docs/2014-10-24_regulated_medical_waste_notification.pdf

3. There must be designated clean and dirty areas for donning and doffing (respectively) of PPE. Additional information can be obtained at:
<http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>.
4. There must be appropriate space and supplies available to package specimens for EVD testing in Category A packaging, for shipment to the public health laboratory (NYC DOHMH or NYS DOH Wadsworth Center), as applicable, according to guidelines at:
http://www.health.ny.gov/diseases/communicable/ebola/docs/specimen_collection_shipping.pdf
and
<http://www.nyc.gov/html/doh/downloads/pdf/cd/ebola-specimens-guidelines.pdf>

Recommendations regarding the minimum number of laboratory personnel that should be maintained for at least 24 hours. The number of staff exposed to the PUI and/or performing testing should be kept to a minimum while still maintaining full medical support of the PUI and maximizing safety.

1. Individual trained to draw blood (physician, nurse) using appropriate PPE based on CDC guidance (below) and consistent with the Commissioner’s Order found at:
http://www.health.ny.gov/diseases/communicable/ebola/docs/commissioner_order.pdf.
2. Trained laboratory personnel wearing appropriate PPE with at least two staff per shift, one for hands-on bench work and one as a “buddy” for monitoring safety practices. In smaller hospitals, flexibility in the number of laboratory staff required may be possible by utilizing nurses or medical staff for the “buddy” function. Guidance for appropriate PPE can be obtained at the following links:
http://www.health.ny.gov/diseases/communicable/ebola/docs/lab_guidelines.pdf
and
<http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>.
3. Laboratory staff should be trained and proficient in methods of donning/doffing PPE and should be monitored by a “buddy” during the process. Guidance can be obtained at:
<http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>
and
<http://www.gnyha.org/ebolatraining>
4. One individual trained by an IATA-certified trainer responsible for packaging and shipping for all Ebola-related laboratory samples in accordance with guidance at:
http://www.health.ny.gov/diseases/communicable/ebola/docs/specimen_collection_shipping.pdf
and
<http://www.nyc.gov/html/doh/downloads/pdf/cd/ebola-specimens-guidelines.pdf>