NEW YORK STATE | Department of Health
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NYS/NYC GUIDANCE FOR LABORATORY TESTING AND MANAGEMENT OF PERSONS-UNDER-INVESTIGATION, FOR VIRAL HEMORRHAGIC FEVERS (VHF) IN NON-DESIGNATED HOSPITALS

Purpose:

To provide guidance on how hospitals and off-campus emergency departments in New York State (NYS) can safely perform the laboratory testing necessary for the management of persons-under-investigation (PUI) for VHF and for ruling in or out alternative diagnoses, while VHF 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. Guidance is also available from the Centers for Disease Control and Prevention (CDC) at: Infection Prevention and Control Recommendations for Patients in U.S. Hospitals who are Suspected or Confirmed to have Selected Viral Hemorrhagic Fevers (VHF).

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 near 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 Department of Health (NYS DOH), to transfer the PUI to a designated hospital, to conduct VHF testing and/or while awaiting results of VHF 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 VHF, 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 VHF is ruled out. **All** hospitals must be prepared to package specimens for shipment to a public health laboratory for VHF testing in accordance with specifications at: https://www.cdc.gov/viral-hemorrhagic-fevers/php/laboratories/specimen-packing.html?CDC_AAref_Val=https://www.cdc.gov/vhf/ebola/laboratory-personnel/specimens.html.

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, [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. Coagulation tests, liver function panels and magnesium levels.
4. 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).
5. 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.
6. COVID and influenza testing.
7. Malaria testing should be performed, if the laboratory has a parasitology permit, using a rapid diagnostic test and a thick and/or thin Giemsa-stained blood smear. Note: rapid diagnostic assays and microscopy for malaria have poor sensitivity compared to nucleic acid amplification-based tests and negatives should be confirmed by molecular methods.
   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. 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 or NYS DOH must be consulted to determine whether VHF testing is warranted and whether the PUI should be transferred to a designated hospital. If laboratory specimens need to be drawn and sent for VHF testing immediately, the hospital will be notified which public health laboratory will be performing the testing (NYC DOHMH Public Health Laboratory 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.

Repeat testing is recommended for negative VHF PCR results on specimens collected less than three days following onset of symptoms if the patient is still symptomatic, unless VHF 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 CDC safety guidelines described at Guidance on Performing Routine Diagnostic Testing for Patients with Suspected VHFs or Other High-Consequence Disease | Viral Hemorrhagic Fevers (VHFs) | CDC should be followed.

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 II Biosafety Cabinet (BSC) for splash protection and to define contaminated area. While a Class II BSC is recommended, especially where tube-to-tube transfers are required, a splash protection shield or other physical containment device may be acceptable if space limitations preclude use of a biosafety cabinet.
- i-STAT® (Abbott Diagnostics)
- pocH-100i™ (Sysmex)
- CoaguChek® (Roche)
- Piccolo® (Abbott Diagnostics)
- Slide maker
- Benchtop Coulter counter

In addition, reagents, test kits, controls, basic laboratory consumables, appropriate Personal Protective Equipment (PPE), and refrigerator for appropriate storage 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 II BSC 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: waste_management_guidance.pdf.
3. There must be designated clean and dirty areas for donning and doffing (respectively) of PPE. Additional information can be obtained at:

https://www.cdc.gov/viral-hemorrhagic-fevers/hcp/guidance/index.html.

4. There must be appropriate space and supplies available to package specimens for VHF 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: https://www.cdc.gov/viral-hemorrhagic-fevers/php/laboratories/specimen-packing.html?CDC_AAref_Val=https://www.cdc.gov/vhf/ebola/laboratory-personnel/specimens.html.

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 according to CDC guidelines: https://www.cdc.gov/viral-hemorrhagic-fevers/hcp/guidance/index.html.

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.

3. All laboratory staff should be trained and proficient in methods of donning/doffing PPE and should be monitored by a “buddy” during the process, as described in the CDC link in 1. above.

4. At least one individual must be trained by an IATA-certified trainer responsible for packaging and shipping for all VHF-related laboratory samples. https://www.cdc.gov/viral-hemorrhagic-fevers/php/laboratories/specimen-packing.html?CDC_AAref_Val=https://www.cdc.gov/vhf/ebola/laboratory-personnel/specimens.html.