HEALTH ADVISORY: ZIKA VIRUS TESTING PROCESS

Please distribute to the Infection Control Department, Emergency Department, Infectious Disease Department, Obstetrics/Gynecology (including Nurse Midwives), Family Medicine, Travel Medicine Service, Pediatrics, Director of Nursing, Nurse Practitioners, Medical Director, Laboratory Service, Pharmacy, and all patient care areas.

SUMMARY

- This advisory describes the process for Zika virus testing that all healthcare providers and facilities in New York State, including those based in New York City (NYC), should follow when caring for patients.
  - Preauthorization of testing by the LHD where the patient resides is required. Contact information and hours of operation for LHDs is available at https://www.health.ny.gov/contact/contact_information/.
  - Testing through WC is available for:
    - Pregnant women who traveled to an area with active Zika virus transmission while pregnant.
    - Non-pregnant women and men who develop (or developed) compatible symptoms during or within 4 weeks of travel to an area with active Zika virus transmission.¹
    - All persons who traveled to an area with active Zika virus transmission who present with Guillain-Barré syndrome.
  - If the patient resides in another state, the healthcare providers/or facility caring for the patient should directly contact the New York State Department of Health (NYSDOH) at 1-888-364-4723 between 9AM and 6PM weekdays ²
- This process applies to all patients except neonates with microcephaly or intracranial calcifications born to women who traveled to an area with active Zika virus transmission while pregnant.
  - Healthcare providers and facilities caring for these neonates should directly contact the New York State Department of Health (NYSDOH) at 1-888-364-4723 between 9AM and 6PM weekdays for consultation and facilitation of testing or, if a NYC resident, 1-866-692-3641 anytime.
- There is no cost for laboratory testing at the NYSDOH Wadsworth Center.
- Hospitals and providers must report suspected cases of Zika virus to the LHD where the patient resides.

¹About 1 in 5 people infected with Zika virus become symptomatic. Characteristic clinical findings are acute onset of fever with maculopapular rash, arthralgia, or conjunctivitis. Other commonly reported symptoms include myalgia and headache.
²Including but not limited to Connecticut, Massachusetts, New Jersey, Pennsylvania, and Vermont.
INFORMATION FOR HEALTHCARE PROVIDERS AND FACILITIES

Below are the steps that must be taken for Zika virus testing:

1. Healthcare provider identifies a patient presenting for care who meets the following criteria:
   - Pregnant woman who traveled to an area with active Zika virus transmission while pregnant (see http://www.cdc.gov/zika/geo/index.html) OR
   - Non-pregnant woman or man who develops (or developed) compatible symptoms during or within 4 weeks of travel to an area with active Zika virus transmission OR
   - A person who traveled to an area with active Zika virus transmission and who presents with Guillain-Barré syndrome.

2. The provider must contact the local health department (LHD) where the patient resides for pre-authorization of Zika virus testing. Contact information for LHDs is available at https://www.health.ny.gov/contact/contact_information/.
   - The patient should be available to the provider during this call.
   - LHD staff will complete the NYSDOH Zika virus testing authorization questionnaire with the provider and/or patient.
   - Providers should advise patients to call the specimen collection site in advance to find out if an appointment is required. A list of specimen collection sites and telephone numbers is available at https://commerce.health.state.ny.us/hcsportal/docs/Source/hpn/preparedness/zika/ZikaCollectionSites.pdf and will be provided by the LHD during this call.
   - If the patient resides in NYC, providers should contact the New York City Department of Health and Mental Hygiene’s (NYCDOHMH) Provider Access Line at 1-866-692-3641. NYCDOHMH is using a different specimen collection and transportation procedure for NYC residents only.

3. If testing is approved by the LHD, the healthcare provider must provide the patient with a written order/prescription for Zika virus testing that specifies serum and urine for polymerase chain reaction (PCR) and serum for serology.
   - Patients must present for testing with both a written order from a NYS licensed healthcare provider and LHD authorization (described below).
   - The order/prescription must clearly indicate the name, complete address and date of birth of the patient and the NYS license number of the provider.

4. The Wadsworth Center will perform molecular tests which detect the presence of the virus, as well as both screening and confirmatory tests for antibodies against Zika and other related viruses. PCR will be performed on specimens that were collected either within one month of the onset of symptoms or within six weeks of travel. PCR results are reported in the evening of the same weekday on which the specimen is received. Testing is not performed on the weekends. Specimens collected between the day of the patient’s return from travel and 9 months of return will be accepted for serology. Screening serology testing takes up to 7 days to complete from date of specimen receipt. Some patients will need confirmatory testing by plaque reduction neutralization testing (PRNT) to rule out the possibility of cross reactivity due to other related viruses such as dengue. PRNT takes an additional 10-14 days because it is dependent on the length of time it takes for virus to grow in culture. For some patients, a second serum specimen may be needed at least three weeks after the first specimen was collected to quantify the rise in antibodies.

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4 This requirement includes NYC based providers and facilities caring for patients who reside outside of NYC.
5. Results of Zika virus testing will be made available to the ordering provider through the submitting laboratory and/or the LHD where the patient resides. Providers can access public health consultation for assistance with interpretation of results by calling the NYSDOH Zika Information Line at: 1-888-364-4723 between 9AM and 6PM weekdays or, if a NYC resident, 1-866-692-3641.

INFORMATION FOR SPECIMEN COLLECTION SITES

1. Specimen Collection
   - Serum: Collect at least six milliliters (ml) of blood in a serum tube (red top, serum separator tube, tiger top, speckle top, gold top). These tubes contain clot activator, so that serum can be readily obtained. Do **NOT** use blood tubes that contain anti-coagulants such as green top, yellow top or purple top. Centrifuge the blood tube, transfer the serum to a separate labeled tube (at least 3 ml serum required) and discard the clot. Seal the serum tubes with parafilm.
   - Urine: Collect urine in a sterile cup with a minimum volume of 3 ml and a maximum volume of 20 ml. Close the lid tightly and seal with parafilm. Specimens that leak will not be tested.
   - Label the specimens: Failure to properly label a specimen will result in rejection and the specimen will not be tested. Specimens must be labeled with:
     - Patient’s First and Last Names
     - Patient’s Date of Birth
     - Date and Time of Collection
     - All information on the specimen label must exactly match the information on Wadsworth’s Infectious Diseases Requisition (IDR) form (described below), including the spelling of the patient’s first and last names.

2. Specimen Handling: It is best that blood specimens be centrifuged, separated and frozen immediately. Specimens that are not directly centrifuged should be immediately refrigerated and must be centrifuged and the serum frozen within six hours. Specimens must be on cold packs when transported from the refrigerator to the freezer during this 6 hour time period. Both the urine and serum need to be frozen at -70 to -80 degrees Celsius. Freezing preserves the integrity of the RNA in the samples.

3. Specimen Transport for Non-NYC residents: Wadsworth’s Infectious Diseases Requisition (IDR) form, which is available at [http://www.wadsworth.org/sites/default/files/WebDoc/1065760803/infectious_diseases_requisition_DOH_4463.pdf](http://www.wadsworth.org/sites/default/files/WebDoc/1065760803/infectious_diseases_requisition_DOH_4463.pdf) must be completed in full and accompany each specimen being submitted on a non-NYC resident. If present, symptoms should be clearly noted on the IDR.
   - Follow shipping regulations for UN 3373 Biological Substance, Category B and UN 1875, Class 9 for dry ice.
   - Specimens must be shipped on dry ice to the Wadsworth Center, David Axelrod Institute, 120 New Scotland Avenue, Albany, NY 12208. Label the outside of the package with storage conditions (-70 to -80C).
INFORMATION FOR LHDS

1. When contacted by a healthcare provider or facility seeking Zika virus testing, verify that the patient resides in your county. If not, please give the provider contact information for the appropriate LHD. Contact information for LHDs is available at https://www.health.ny.gov/contact/contact_information/.

2. Verify that the patient meets testing criteria:
   - Pregnant woman who traveled to an area with active Zika virus transmission while pregnant (see http://www.cdc.gov/zika/geo/index.html) OR
   - Non-pregnant woman or man who develops (or developed) compatible symptoms during or within 4 weeks of travel to an area with active Zika virus transmission\(^5\) OR
   - A person who traveled to an area with active Zika virus transmission and who presents with Guillain-Barré syndrome.

3. Assist the provider (and patient, if available) with completing the NYSDOH Zika virus testing questionnaire.
   - The questionnaire is available to LHDs via NYSDOH’s Clinical Data Management System (CDMS).
   - Be certain that the provider and patient understand that specimen collection can be performed at ANY authorized specimen collection site, regardless of where the patient resides or where the provider practices. A list of specimen collection sites and telephone numbers is available at https://commerce.health.state.ny.us/hcsportal/docs/Source/hpn/preparedness/zika/ZikaCollectionSites.pdf and should be offered to the provider during the call, so that the patient can choose the site most convenient for them.
   - If the patient provides an email address for use in CDMS, the authorization ticket will be emailed to them. Specimen collection sites will accept a printed ticket or an image of the ticket on a smartphone. If they do not have an email address, the LHD should use their health department email address for retrieval of the authorization ticket and fax the ticket to the patient or directly to the specimen collection site.
   - Patients who present for testing without a written order from a NYS licensed healthcare provider and LHD authorization will be turned away.
   - LHDs should immediately notify their regional epidemiologist of the testing request.

If you have any questions, please contact your LHD or the NYSDOH Bureau of Communicable Disease Control at bcdc@health.ny.gov.

\(^5\) About 1 in 5 people infected with Zika virus become symptomatic. Characteristic clinical findings are acute onset of fever with maculopapular rash, arthralgia, or conjunctivitis. Other commonly reported symptoms include myalgia and headache.