Zika Virus Collection, Processing and Shipping

An Overview for Specimen Collection Sites

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Ron Limberger, PhD NYSDOH  Director, Division of Infectious Diseases, Wadsworth Center
Stephanie Ostrowski, PhD NYSDOH  Associate Director, Division of Epidemiology
Objectives

At the conclusion of this webinar, Zika specimen collection sites will be able to:

• Describe the types of specimens that must be collected to diagnose Zika virus exposure

• Articulate NYSDOH’s requirements for specimen processing, storage, and shipment

• Recognize the needs and requirements for being a Zika virus specimen collection center
Zika Virus

• Single stranded RNA Virus
• Genus *Flavivirus*, Family *Flaviviridae*
• Closely related to dengue, yellow fever, Japanese encephalitis and West Nile viruses
• Transmitted to humans primarily by *Aedes* species mosquitoes
Zika Virus

- Prior to 2015, Zika virus outbreaks occurred in areas of Africa, Southeast Asia, and the Pacific Islands
- In May 2015 - the first confirmed Zika virus infections in Brazil
- No local transmission to date in the continental United States
Modes of Transmission

- Mosquito Bite
  - From infected to uninfected humans and primates by bite of a mosquito
- Maternal-fetal
  - Intrauterine
  - Perinatal
- Other
  - Sexual Transmission
  - Blood transfusion
- Theoretical
  - Organ or tissue transplantation
  - Breast milk
Zika Virus Imported Cases in the U.S.

• Approximately 45 cases of Zika virus diagnosed in the continental U.S.
  • All but one are travel-associated/imported
  • One report of sexual transmission
  • NO local vector-borne transmission

• New York State
  • 16 cases → All imported/travel-associated (2/11/16)

• With outbreaks in the Americas, cases among U.S. travelers will likely increase

• Imported cases may result in virus introduction and local spread in some areas of U.S.
Diagnostic Testing for Zika Virus

- **No commercially-available diagnostic tests at present**
  - CDC is working with commercial laboratories to address this issue in the near future

- Testing is available at NYSDOH’s Public Health Laboratory – The Wadsworth Center
  - No cost for laboratory testing

- CDC is working to expand laboratory diagnostic testing to other state and large urban area public health laboratories
Diagnostic Testing for Zika Virus

1. **PCR** assay to detect viral RNA in serum and urine

2. **Serological assays** to detect either IgM or IgG in serum collected ≥4 days after illness onset

3. **Plaque reduction neutralization test (PRNT)** to detect a ≥4-fold rise in Zika virus-specific neutralizing antibodies in paired sera
February 9, 2016

TO: Healthcare Providers, Hospitals, Local Health Departments (LHDs)
FROM: NYSDOH Bureau of Communicable Disease Control (BCDC) and Wadsworth Center (WC)

HEALTH ADVISORY: ZIKA VIRUS TESTING PROCESS

NYSDOH Zika Testing Procedures

• Physician verifies that the patient meets testing criteria and authorizes specimens collection (doctor’s order or script)
• The physician contacts the local health department (LHD) where the patient resides to coordinate a review of their case and received prior authorization
• The LHD will complete the NYSDOH Zika virus testing authorization questionnaire with the patient and physician.
NYSDOH Zika Testing Procedures

• If testing is approved by the LHD, an authorization form will be emailed to the patient to present at the collection site
  – Collection sites will accept a printed ticket or an image on a smartphone
  – If patient does not have an email address, LHD can fax the form to the patient, provider, or directly to the specimen collection site
NYS DOH - Authorization for Zika Virus Testing

Thank you for registering with us. Please print the Registration Ticket below and bring it with you to your selected hospital. This ticket will help to reduce wait time at your event.

Recipient

Jane Doe

Event Information

Campaign: MattD - Zika test Campaign
Form: MattD Zika Form
County: NYS DOH
Zika Registration
Selected Hospital: Albany Memorial Hospital

Public Notes - Additional information to share with people want to be test for the Zika virus.

ID# 3184
NYSDOH Zika Testing Procedures

• Physician will provide the patient with orders, the LHD prior authorization* and completed Infectious Diseases Requisition (IDR) form
Please identify the name of the collection site somewhere on the form.
NYSDOH Zika Testing Procedures

• The LHD will provide a list of specimen collection sites and the patient can choose the site most convenient for them


• Physician should advise patients to call the collection site to find out if an appointment is required
NYC Residents - Zika Testing Process

• NYCDOHMH is using a different specimen collection and transportation procedure for NYC residents only

• If the patient resides in NYC, see NYCDOHMH guidance http://www1.nyc.gov/assets/doh/downloads/pdf/cd/lab-instructions-zika.pdf

• Providers should contact the New York City Department of Health and Mental Hygiene’s (NYCDOHMH) Provider Access Line for questions and other assistance at:
  – 1-866-692-3641
Specimens

Serum
Collect whole blood in red top tubes
minimum 6ml

Centrifuge and remove serum
minimum 3ml

Freeze serum and urine -70 to -80°C

Urine
Minimum 3ml
Specimen Collection

• 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 patient’s first and last names
• Identify each tube as containing either urine or serum
Specimen Processing

• 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 6 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 Zika virus RNA in the samples.

• Serum collected for convalescent evaluation does not have to be frozen at -70 to -80 degrees Celsius and can be shipped on ice packs.
Packaging, Shipping, and Certification

IATA
DOT
Certification
Specimen Transport for Non-NYC Residents

• Wadsworth’s Infectious Diseases Requisition (IDR) form 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).
Optimal shipping temperature

Generally, freezing at ultra low temperatures preserve the viral RNA best. But we do not have data for optimal Zika virus shipping temperature.

- Wadsworth is conducting stability studies that should be available soon
- We will then advise the best method for shipping
- In the meantime we will continue to request shipping on dry ice
Comments

• If necessary, specimens could be batched for delivery 3 days per week

• Please mark outer container with large letters – store frozen

• Wadsworth will accept deliveries 24/7, but not necessary unless otherwise indicted by ordering physician

• Patient should have the IDR*, LHD authorization, and physician order upon arrival
Zika Specimen Collection Sites

- NYSDOH is posting on the secure Health Commerce System (HCS) a list of facilities that have been designated as collection sites for healthcare providers

- Collection sites must consider their hours of operation, distance from main laboratory with -70 to -80 degrees Celsius freezers, timing of couriers, ability to freeze specimens within 6 hours following collection, access to dry ice, and ability to accept out of network patients

- If you would like to sign up to be a collection site please provide: name of facility, address, directions, hours of operation, contact information
Zika Specimen Collection Sites

Reimbursement
NYS DOH in collaboration with the hospital associations are working to establish a reimbursement rate

Rates will include:
- Shipping boxes
- Dry ice
- Shipping
- Staff time

Div_Epi@health.ny.gov
Zika Resources

- CDC’s Zika Virus Information Page

- NYSDOH’s Zika Virus Information Page
  - Testing process advisory posted
  - Testing process one page information sheet for the public to be posted
  - Webinars posted
  - Testing algorithm and interpretation will be posted

- PAHO’s Zika Virus Information Page
Questions?

Contact the NYSDOH Zika Information Line at:
1-888-364-4723
9AM-6PM weekdays