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To: Local health departments and health care providers  
From: Shereen Semple, MS  
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New Jersey Department of Health (NJDOH)  
Infectious & Zoonotic Disease Program  
Date: March 4, 2016  
Subject: Updated guidance on Zika virus disease (Zika) testing criteria, obtaining specimens, and clinical and prevention guidelines

The NJDOH is sending this message to local health departments (LHDs) and health care providers to provide updated guidance about Zika virus disease (Zika) testing criteria, obtaining specimens, and clinical and prevention guidelines. Information new to this LINC document has been highlighted.

Zika is a mosquito-borne disease that historically has been found in tropical Africa and southeast Asia. In May 2015, the Pan American Health Organization/World Health Organization (PAHO/WHO) reported the first autochthonous (local) transmission of Zika in the Americas. Local transmission is now being reported across many countries and territories in the Americas, as well as some islands in the Pacific and Africa. The Centers for Disease Control and Prevention (CDC) website is updated daily as new active transmission is identified; health care providers are reminded to frequently check this website at <http://www.cdc.gov/zika/geo/active-countries.html>.

As a reminder, clinicians and laboratories must report confirmed cases of any arboviral diseases (e.g. Zika, Chikungunya, West Nile, Dengue) to the LHD where the person resides. A list of LHDs can be found at <http://localhealth.nj.gov>. Prior LINC documents regarding Zika can be found at <http://www.nj.gov/health/cd/zika/techinfo.shtml>

**Beginning March 7, 2016:**

- Urine will be requested in addition to serum
- The NJDOH Public Health and Environmental Laboratories (PHEL) SRD-1 laboratory ordering form will replace the CDC 50.34 DASH form
- All specimens approved for Zika virus testing will be shipped to the NJDOH Public Health and Environmental Laboratories (PHEL)
  - PHEL will coordinate the testing of all specimens at an approved public health laboratory

**Contact Information**

**For questions regarding the approval of specimens, contact:**

NJDOH Communicable Disease Services (CDS) during business hours at: 609-826-5964

**For questions regarding the shipping and handling of specimens:**

E-mail the PHEL Zika Team at: [Zika.phel@doh.nj.gov](mailto:Zika.phel@doh.nj.gov)

Please refer to **Exhibit A. Zika Testing Flow Chart/Instructions for Clinicians and Laboratories** at the end of this document for a compact visual of the process for specimen approval, collection, and shipping.

### **ZIKA TESTING GUIDANCE (UPDATED March 4, 2016):**

Companion document is the attached “Update: Interim Guidelines for Health Care Providers Caring for Infants and Children with Possible Zika Virus Exposure.” MMWR, Volume 65, February 19, 2016. <http://dx.doi.org/10.15585/mmwr.mm6507e1er>

### **Criteria for Testing**

Health care providers may consult with their LHD or the NJDOH during regular business hours to discuss laboratory testing of the following individuals with travel history to a Zika-affected area:

- All pregnant women (symptomatic and asymptomatic) who traveled to an area with Zika transmission at any point during the current pregnancy
  - If symptomatic, specimen collection date is within 7 days of symptom onset
  - If asymptomatic, preferred specimen collection date is 2–12 weeks after travel
- Symptomatic non-pregnant individuals (regardless of age or gender) with two or more Zika-compatible symptoms (fever, rash, arthralgia, and/or conjunctivitis) within two weeks of travel
- Infants with microcephaly or intracranial calcifications (detected prenatally or after birth), whose mother traveled to or resided in an area with Zika transmission while pregnant
- Infants born to mothers who had a positive or inconclusive Zika virus test result while pregnant
- Symptomatic infants, who within the first 2 weeks of life develop two or more Zika-compatible symptoms (fever, rash, arthralgia, and/or conjunctivitis), and whose mothers traveled to an area with Zika transmission within two weeks of delivery (perinatal transmission)
- Individuals with Guillain-Barré syndrome who traveled to an area of Zika transmission and have no other suspected causative agent

### **Pre-approval for Zika Testing**

Health care providers seeking Zika testing for an individual who meets one of the above criteria should contact their LHD or the NJDOH during normal business hours at (609) 826-5964. Specimens will **not** be accepted without pre-approval from state health departments. Criteria for approval may change; health care providers are encouraged to check LINC message for additional guidance as it becomes available.

Health care providers and LHDs seeking approval for Zika testing should be prepared to provide the following information when consulting with the NJDOH as incomplete information may result in delayed testing:

- Travel history, including dates of travel and specific location
- Pregnancy status and, if applicable, gestational week(s) at travel and/or symptom onset
- Current symptom status (symptomatic, formerly symptomatic, asymptomatic)
  - If applicable, symptom onset date and list of clinical signs and symptoms

- Vaccination history, including year of vaccination for: Japanese encephalitis, tickborne encephalitis, and/or yellow fever
- History of past flavivirus infection (e.g., Dengue, West Nile, St. Louis encephalitis virus) or arboviral infection (e.g., Chikungunya)
- If applicable, relevant prenatal or postnatal testing, including results of ultrasounds

### **Specimen Collection at Hospital-based Laboratories is Recommended**

As of MONDAY, March 7, 2016, a new pre-filled test ordering form from PHEL – the SRD-1 – will be used, urine will be requested in addition to serum, and all collected specimens will be shipped to PHEL.

If Zika testing is approved, the NJDOH will provide the ordering physician with the new approved laboratory ordering form (SRD-1) and the technical guidance on specimen collection from the NJDOH PHEL. Laboratory testing for Zika is not available at commercial laboratories. It is recommended that providers refer their patients to hospital-based laboratories that are best suited to address the required specimen handling procedures.

### **Required Documents**

Clinicians should provide the following documents to patients approved for Zika Virus testing prior to specimen collection:

- Prescription for Zika Virus testing that says: “Serum for Zika Testing” and “Urine for Zika Testing”
  - Include a diagnostic code to facilitate billing for specimen collection/handling
- Pre-approved specimen ordering form (SRD-1) provided by NJDOH
- NJDOH PHEL 2-page Technical Bulletin
  - Available at <http://nj.gov/health/phel/index.shtml>

The NJDOH may also request one or more of the following additional specimens for testing, based on patient circumstances (this list is subject to change):

- Cerebrospinal fluid (if collected for a purpose other than Zika)
- Amniotic fluid
- Serum from umbilical cord
- Serum from placenta
- Tissue (e.g., fetal, umbilical cord, placental)

Additional consultation is needed for collection of non-serum specimens. Serum will always be required, even if other specimens are considered for testing.

### **Available Zika tests**

Testing type will be determined by travel dates, pregnancy status, and, if applicable, symptom onset. Possible tests include reverse transcription-polymerase chain reaction (RT-PCR) for Zika RNA, and/or Immunoglobulin M (IgM) ELISA. If indicated, plaque reduction neutralization test (PRNT) will also be conducted. Symptomatic patients meeting testing criteria will be tested for Zika, dengue, and chikungunya viruses.

As testing for Zika may take upwards of a month or longer, providers may want to consider dengue or chikungunya virus testing at a commercial laboratory. If dengue is suspected, providers are reminded to

avoid recommending aspirin or other NSAIDs until dengue has been ruled out, as these analgesics can increase the risk of hemorrhage in patients with dengue.

### **Zika Results**

The timeframe for obtaining Zika virus test results will vary based on the specimen testing volume at the laboratory as well as the time required to conduct antibody and cross-reactivity tests, if indicated. Some results may not be available for four weeks or longer. NJDOH will send negative results to the provider and laboratory via fax or encrypted e-mail. If results are positive, NJDOH will notify LHDs and call the ordering provider using the phone number listed on the Zika test forms.

Convalescent samples may be requested for further testing. All convalescent samples should be collected at least three weeks from the time the original sample was collected. The NJDOH or LHD will facilitate the pre-approval for the convalescent sample.

### **ZIKA CLINICAL GUIDANCE:**

The following section summarizes CDC's current clinical guidance ([http://www.cdc.gov/mmwr/zika\\_reports.html](http://www.cdc.gov/mmwr/zika_reports.html) and [http://www.cdc.gov/mmwr/early\\_release.html](http://www.cdc.gov/mmwr/early_release.html)):

#### **For all individuals with suspected Zika**

Testing will be approved if symptoms presented within seven days of travel. There is no vaccine to prevent or specific medicine to treat Zika infections. Providers are reminded to avoid recommending aspirin or other NSAIDs until Dengue has been ruled out (and in children <6 months), as these analgesics can increase the risk of hemorrhage in patients with dengue. During the first week of infection, individuals should prevent new mosquito bites.

#### **For infants or children with suspected Zika**

Zika should be suspected in minors with at least two Zika-compatible symptoms (fever, rash, conjunctivitis, or arthralgia) who have a travel history, or in a symptomatic infant within the first two weeks of life whose mother has a travel history within two weeks of delivery (perinatal transmission). Evidence suggests that children with Zika are asymptomatic or have mild illness.

Arthralgia can be difficult to detect in infants and young children and can manifest as irritability, walking with a limp (for ambulatory children), difficulty moving or refusing to move an extremity, pain on palpation, or pain with active or passive movement of the affected joint.

If an infant in the first two weeks of life presents with Zika-compatible symptoms, but did not travel to a Zika-affected area, both the mother and the infant should be tested (perinatal transmission may be suspected).

The decision to obtain additional laboratory tests, diagnostic studies, and infectious disease consultation should be based on clinical judgment as guided by findings from a complete history and physical examination. Until more evidence is available to inform recommendations, the CDC advises routine pediatric care for these infants and children.

### **For infants with suspected congenital Zika virus or limited prenatal assessments:**

Congenital Zika should be suspected in:

- Infants who present with microcephaly, intracranial calcifications, or other central nervous system anomalies and whose mothers traveled to a Zika-affected area during pregnancy
- Infants whose mothers tests positive or inconclusive for Zika virus while pregnant

The results of previous prenatal ultrasounds and maternal Zika testing should be reviewed, and a thorough newborn physical examination, with assessment of head (occipitofrontal) circumference, length, and weight, should be performed. For infants whose mothers have a travel history, but who were not tested for Zika during pregnancy or who do not have an ultrasound, it is reasonable for providers can consider a postnatal ultrasound.

When an infant is born with a normal head circumference, normal prenatal and postnatal ultrasounds (if performed), and normal physical examination, routine care is recommended.

Because information on the effects of congenital Zika virus infection is limited, health care providers should exercise clinical judgment in the assessment of newborns with abnormalities other than microcephaly or intracranial calcifications who were born to mothers who traveled to or resided in an area with active Zika virus transmission during pregnancy. For these infants, health care providers should consider testing the mother before testing the infant.

Detailed clinical guidelines for the clinical evaluation of infants with suspected congenital Zika virus can be found in the January 29 2016 LINC message “LINC Zika and Infants, January 29” Message #103048-1-29-2016-PHUP. CDC guidelines can be found at <http://dx.doi.org/10.15585/mmwr.mm6507e1er> and [http://www.cdc.gov/mmwr/volumes/65/wr/mm6503e3er.htm?s\\_cid=mm6503e3er\\_e](http://www.cdc.gov/mmwr/volumes/65/wr/mm6503e3er.htm?s_cid=mm6503e3er_e).

### **For pregnant women with suspected Zika:**

At this time, testing will be approved for women who traveled to a Zika affected area while pregnant. Supportive care is recommended if a woman presents with symptoms, as described above. Serial ultrasounds are recommended to monitor the growth of the fetus. Male partners of pregnant women who traveled to a Zika-affected area should correctly and consistently use condoms or avoid sex (oral, anal, and vaginal) for the entire duration of the pregnancy.

### **ZIKA PREVENTION GUIDANCE**

The following section summarizes current prevention guidance.

#### **Pregnant women advised to postpone travel to affected areas:**

The CDC currently advises pregnant women to postpone travel to areas with ongoing Zika virus transmission. Please visit the CDC’s Zika-affected Areas webpage at <http://www.cdc.gov/zika/geo/active-countries.html> for the most updated list of countries and territories with ongoing Zika transmission.

If patients, particularly pregnant women, travel to affected areas, advise them to prevent mosquito bites. The mosquitoes that transmit Zika, dengue, and chikungunya viruses are aggressive biters and are present during the daytime and early evening. Health education materials are available English, Spanish, and Portuguese. They can be found on the New Jersey Department of Health (NJDOH) website: <http://www.state.nj.us/health/cd/zika/>

**Prevention of Zika or other mosquito-borne diseases when traveling to an affected area:**

The CDC currently advises travelers to areas with ongoing Zika virus transmission to take extra precautions to avoid mosquito bites. Travelers can take the following steps to minimize their chances of a mosquito bite:

- Wear long-sleeved shirts and long pants
- Stay in places with air conditioning and window and door screens, or use a mosquito bed net
- Use Environmental Protection Agency (EPA)-registered insect repellents, as directed
- Treat clothing and gear with permethrin or purchase permethrin-treated items

**Recommendations to prevent the spread of Zika and mosquito-borne diseases if sick:**

Individuals who suspect they are infected with Zika or another mosquito-borne disease should take precautions to prevent the spread of the disease to new mosquitos during the first week of infection by preventing new mosquito bites using the tips above. Preventing a new bite could keep an un-infected mosquito from becoming infected and transmitting the virus to someone new.

**Recommendations to Prevent Sexual Transmission of Zika:**

For men with a pregnant partner who have been to an area with Zika transmission, condoms should be used correctly every time they have sex (oral, anal, or vaginal), or they should not have sex during the entirety of the pregnancy.

For men with a non-pregnant partner who have been to an area with Zika transmission and who are concerned about sexual transmission of Zika to a partner, they can be counseled to consider using condoms correctly every time they have sex (oral, anal, or vaginal), or to consider not having sex.

Zika virus can last in semen longer than in blood, but it is unknown how long. Zika testing for the sole purpose of assessing risk for sexual transmission is not recommended, as interpreting test results for this purpose is not defined. Men who present with symptoms within two weeks of travel meet current testing criteria for serum (see above). **Current published sexual transmission cases involve men who were symptomatic, but transmission via asymptomatic male has not been definitely ruled out yet.**

**Recommendations to Prevent Zika Transmission through the Blood Supply:**

The US Food and Drug Administration (FDA) is closely monitoring the spread of Zika virus. Donors should self-defer for 4 weeks post potential exposure or symptom resolution. Providers can refer to the FDA Zika website for additional details on blood and tissue donation.

<http://www.fda.gov/emergencypreparedness/counterterrorism/medicalcountermeasures/mcmissues/ucm485199.htm>

**FOR MORE INFORMATION**

- Contact the NJDOH during regular business hours at (609) 826-5964
- NJDOH Zika virus website: <http://www.nj.gov/health/cd/zika/index.shtml>
- NJDOH Zika LINCS messages: <http://www.nj.gov/health/cd/zika/techinfo.shtml>
- CDC Zika virus website: <http://www.cdc.gov/zika/>
- CDC's Current Zika-affected Areas: <http://www.cdc.gov/zika/geo/>

## CDC Guidelines and Associated Q&As

- CDC's Interim Guidelines: Interim Guidelines for Health Care Providers Caring for Infants and Children with Possible Zika Virus Exposure: <http://dx.doi.org/10.15585/mmwr.mm6507e1er>
- CDC's Interim Guidelines for Pregnant Women and Women of Childbearing Age with Possible Zika Virus Exposure:
  - Updated (2/5/16): [http://www.cdc.gov/mmwr/volumes/65/wr/mm6505e2er.htm?s\\_cid=mm6505e2er\\_w](http://www.cdc.gov/mmwr/volumes/65/wr/mm6505e2er.htm?s_cid=mm6505e2er_w)
  - Original (1/22/16): <http://www.cdc.gov/mmwr/volumes/65/wr/mm6502e1er.htm>
  - Q&As: <http://www.cdc.gov/zika/pdfs/questions-answers-clinicians.pdf>
- CDC's Interim Guidelines for the Evaluation and Testing of Infants with Possible Congenital Zika Virus Infection — United States, 2016: [http://www.cdc.gov/mmwr/volumes/65/wr/mm6503e3er.htm?s\\_cid=mm6503e3er\\_e](http://www.cdc.gov/mmwr/volumes/65/wr/mm6503e3er.htm?s_cid=mm6503e3er_e)
  - Q&As: <http://www.cdc.gov/zika/hc-providers/qa-pediatrician.html>
- CDC's Interim Guidelines for Prevention of Sexual Transmission of Zika Virus: [http://www.cdc.gov/mmwr/volumes/65/wr/mm6505e1er.htm?s\\_cid=mm6505e1er\\_w](http://www.cdc.gov/mmwr/volumes/65/wr/mm6505e1er.htm?s_cid=mm6505e1er_w)
  - Q&As: <http://www.cdc.gov/zika/hc-providers/qa-sexual-transmission.html>
- CDC Health Travel Advisories (including Zika): <http://wwwnc.cdc.gov/travel/notices>

## Additional Resources:

- Protection against mosquitoes for travelers: <http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-2-the-pre-travel-consultation/protection-against-mosquitoes-ticks-and-other-insects-and-arthropods>
- EPA-registered Insect Repellents: <http://www.epa.gov/insect-repellents/find-insect-repellent-right-you>
- CDC's Clinician Outreach and Communication Activity (COCA): <http://emergency.cdc.gov/coca/calls/>
- CDC's MMWR Zika Reports: [http://www.cdc.gov/mmwr/zika\\_reports.html](http://www.cdc.gov/mmwr/zika_reports.html)
- Pan American Health Organization: <http://www.paho.org/>

**Exhibit A: ZIKA TESTING FLOW CHART / INSTRUCTIONS FOR CLINICIANS AND LABORATORIES**

**Clinician seeking Zika testing for person who meets criteria (see “Zika Testing Criteria”)**

- Contact New Jersey Department of Health (NJDOH) Communicable Disease Service (CDS) for approval at (609) 826-5964 M-F 8 AM – 5 PM

**NJDOH CDS approves request and faxes to clinician:**

- Pre-filled test ordering form (SRD-1) including unique NJDOH Zika test approval number
- NJDOH public Health and Environmental Laboratories (PHEL) Technical Bulletin “Zika Virus Testing for New Jersey Patients” and Technical Bulletin Supplement “Zika Testing: Specimen Collection, Processing, Packaging and Shipping”

**Clinician refers person to hospital outpatient clinic for blood and urine sample, and person brings the following paperwork to their appointment:**

- Pre-filled test ordering form (SRD-1)
- Prescription for Zika virus testing (for both serum and urine)
  - Include a diagnostic code to assist billing for the specimen collection and handling
- NJDOH PHEL Technical Bulletin and Technical Bulletin Supplement

**Hospital outpatient clinic collects blood and urine sample:**

- Follow instructions from NJDOH PHEL Technical Bulletin and Technical Bulletin Supplement
- For laboratory questions, please contact PHEL at: Zika.phel@doh.nj.gov

**Hospital laboratory prepares and ships specimens to NJDOH PHEL:**

- Follow instructions from NJDOH PHEL Technical Bulletin and Technical Bulletin Supplement
- For laboratory questions, please contact PHEL at: Zika.phel@doh.nj.gov

<p><b><u>Negative result:</u></b></p> <ul style="list-style-type: none"> <li>• NJDOH PHEL will fax result to clinician/laboratory</li> </ul>	<p><b><u>Positive result:</u></b></p> <ul style="list-style-type: none"> <li>• NJDOH PHEL will fax result to clinician/laboratory</li> <li>• NJDOH CDS will phone result to clinician</li> </ul>	<p><b><u>Inconclusive results:</u></b></p> <ul style="list-style-type: none"> <li>• NJDOH PHEL will fax result to clinician/laboratory</li> <li>• NJDOH CDS will phone clinician if convalescent specimen requested request</li> </ul>
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