Public Health and Environmental Laboratories, Ewing, NJ 08628

New Jersey Public Health and Environmental Laboratories
Supplemental Technical Bulletin: Zika Virus Testing

March, 2017 Guidance Update for Zika Testing at PHEL

Snapshot of Zika Testing at the Public Health and Environmental Laboratories (PHEL)

Human testing for Zika virus began at PHEL on May 16, 2016. PHEL tested 1,795 patients between May 16, 2016 and February 28, 2017. Approximately 485 patients presented within 2 weeks of symptom onset or exposure and were tested using the Trioplex rt RT-PCR; 52 of these patients tested positive for the Zika virus. Approximately 1,580 presented at greater than 2 weeks post exposure and were tested for IgM antibodies using the Zika virus IgM MAC ELISA; 102 of these patients tested equivocal or presumptive positive. These specimens were submitted to New York's Wadsworth Center for PRNT confirmation immediately for pregnant women, and upon receipt of a second specimen for non-pregnant persons.

Placental/fetal tissue testing is not included in these numbers. A table outlining specimen requirements for congenital testing is found in an attachment to this bulletin. All tissue testing submitted to PHEL/CDC requires pre-approval through the Communicable Disease Service (CDS). Clinicians may contact CDS directly during regular business hours at 609-826-5964.

Mosquito pool testing for *Aedes* species mosquitoes ran from August 20 through November 1, 2016 in alignment with the *Aedes albopictus* biting season in New Jersey. PHEL tested 1,194 mosquito pools using a multiplex panel for Zika, West Nile, Chikungunya and Dengue viruses. In that time frame all pools tested negative for the Zika virus. To date, no local Zika transmission has been detected in New Jersey and in 2016, *Aedes aegypti* was not detected in the environment.

Change in PHEL Zika Testing Algorithm

With a year's worth of Zika testing data and recommendations from the CDC and New York's Wadsworth Center, PHEL has changed the testing algorithm for non-pregnant, symptomatic persons.
Effective February 27, 2017 PHEL will forward all Presumptive Positive, Equivocal, or Inconclusive Zika IgM specimens to Wadsworth for PRNT confirmatory testing. Second/convalescent specimens will no longer be requested from non-pregnant patients.

Patient Information and Test Requests

PHEL has experienced repeated problems with SRD-1 form submissions for Zika virus testing.

A completed and accurate SRD-1 form is required for proper execution of the test request. CLIA 42 CFR 493:1241 (c) (1-6, 8) states the following:
The test requisition must include the following information:

1. The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or alert values.
2. The patient's name or unique patient identifier.
3. The sex and age or date of birth of the patient.
4. The test(s) to be performed.
5. The source of the specimen, when appropriate.
6. The date, and if appropriate, time of specimen collection.
7. Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

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Specimen Collection Guidelines for Infants with Suspected Congenital Zika Virus Infection

Report infants delivered with a concern for congenital Zika virus exposure to CDS.
Additional assistance will be provided on assessing the infant.

Most Common Test Request Problems:

1. **Patient name on the SRD-1 form does not match patient name on the specimen**.

   The name on the form must match the name on the specimen.
   a. **Local health departments:** Confirm with the physician the patient's correct name before entering it on the SRD-1 form. Physician offices should have a copy of a picture ID for the patient on file (e.g., Driver's License). Assign the NJZ#.
   b. **Physicians:** Verify the name on the SRD-1 form before releasing to the patient for specimen collection.
   c. **Hospital laboratories (collection facilities):** Contact physicians or local health departments before submitting if the name on the SRD-1 form does not match the patient identification your laboratory has collected. **Collection date/time MUST be provided.**

2. **Incomplete clinical information**

   a. **Local health departments:** Zika tests are ordered based on the clinical information provided. Collect and record all information required by the Communicable Disease Service testing criteria: pregnancy status, symptomatic/asymptomatic, source of exposure (country/travel/sexual) and exposure dates are critical.
   b. **Physicians:** Verify the information collected by the local health department for accuracy prior to releasing the form to the patient for specimen collection.

3. **Incorrect FAX numbers for submitting results**

   Clinicians and hospital laboratories are forwarded results at the fax number indicated on the form. If the fax # has changed from previous submissions, note on the SRD-1 form that the number being provided is new.

Failure to provide requested information on the SRD-1 form each time a specimen is collected could lead to delays in reporting.

Requests for Zika testing must be preapproved by the Local Health Department in the patient's jurisdiction. http://www.localhealth.nj.gov .

Zika Tissue Testing and Newborn testing must be pre-approved by the Communicable Disease Service who may be reached Monday – Friday 8AM -5PM at 609-826-5964.

For laboratory questions relating to Zika Virus, email the PHEL Zika Team at: Zika.phel@doh.nj.gov General laboratory information, contact: (609)-530-8516

NOTE: Per NJAC 8:57, clinicians and laboratories must report confirmed cases of all arboviral diseases (e.g. Zika, Chikungunya, West Nile, and Dengue) to the local health department (LHD) where the person resides http://localhealth.nj.gov. If the LHD cannot be reached at the number in the directory, please call the CDS at 609-826-5964, Monday through Friday from 8:00 AM – 5:00 PM.

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LABEL ALL SPECIMENS WITH: Infant's full name, date of birth, date and time of collection, and type of specimen (FOR TISSUE, USE MOTHER'S NAME) FREEZE Serum and Urine, (NOT fixed-tissue) AT -70°C AND SHIP OVERNIGHT TO NJ PHEL ON DRY ICE AS A CATEGORY B INFECTIOUS SUBSTANCE – Ship fixed tissue at ambient temperature. 49 CFR 173.199 (CATEGORY B) AND 49 CFR 173.217 (DRY ICE)

Serum from Infant

Minimum Volume	Container	Storage	Additional Instructions
1.5-2.0 ml of serum	• Collect in serum separator tube (tiger top, speckle top, or gold top). • Aspirate 1.5-2.0 ml of serum into a leak-proof, screw-capped tube. • UNACCEPTABLE: Blood in anticoagulant or plain red top tubes.	• Freeze at -70 to -80° C and ship on dry ice. • EXCEPTION: store at 4° C only if specimens will be received at PHEL within 24 hours of collection.	For information on packaging and shipping refer to the Zika Technical Bulletins at: http://nj.gov/health/phel/index.shtml

Urine from Infant

Minimum Volume	Container	Storage	Additional Instructions
• 3.0 ml of urine • (collect on same day as serum from infant)	• Clean leak-proof screwcap tube (same tube as used for serum). • UNACCEPTABLE: Urine in tube with preservative or submitted in urine cup.	• Freeze at -70° to -80° C and ship on dry ice. • EXCEPTION: store at 4° C only if specimens will be received at PHEL within 24 hours of collection.	For information on packaging and shipping refer to the Zika Technical Bulletins at: http://nj.gov/health/phel/index.shtml.

Placenta, cord, membranes and/or other tissues

Specimens in 10% neutral buffered formalin and/or formalin fixed paraffin-embedded tissue blocks (FFPE)

Specimen Requirements	Container/Preservatives	Storage	Additional Instructions
Placenta and fetal membranes: • At least 3 full thickness pieces (0.5–1 cm x 3–4 cm) from the middle third of placental disk and at least 1 piece from the placental disk margin. • 5 x 12 cm strip of fetal membranes. • Include sections of the placental disk, fetal membranes, and pathologic lesions when possible. **Umbilical cord:** • 4 or more 2.5 cm segments of cord tissues. • Umbilical cord segments should be obtained proximal, middle, and distal to umbilical cord insertion site on the placenta.	• Tissues should be placed into one or more containers containing adequate formalin. • Volume of formalin used should be about 10x mass of tissue. • Label all specimens to identify location of sample.	• Fixed tissues should be stored and shipped at room temperature. (Please use cold packs in the shipment). • Tissue can be fixed in formalin for 3 days, and then transferred to 70% ethanol for shipping purposes or for long term storage at ambient temperature.	• Tissue testing must be pre-approved by CDS during business hours. Please process tissue according to these instructions if awaiting approval. • Include information about placenta weight and sample both maternal and fetal side of the placenta. • SHIP TO NJ PHEL AS AN "EXEMPT HUMAN SPECIMEN" IF FIXATIVE VOLUME IS LESS THAN 30ml. • IF OVER 30 ml OF FIXATIVE IS USED, CONTACT zika.phel@doh.nj.gov for shipping instructions. • Fixed tissue sample should not be shipped with frozen samples. • Use cold packs to prevent overheating of these specimens during shipment throughout the summer months.

More information about collection, handling, and shipping tissues is available at http://www.cdc.gov/zika/laboratories/test-specimens-tissues.html