

March, 2016

Zika Virus Testing for New Jersey Patients

The Public Health and Environmental Laboratories (PHEL) are currently validating Centers for Disease Control and Prevention (CDC) molecular and serologic methods for in-house Zika Virus testing for New Jersey patients. The PHEL Zika testing program is projected to start in mid-April. In the interim, PHEL will receive all Communicable Disease Service (CDS) approved Zika test requests for New Jersey patients, route clinical specimens to the New York State Department of Health, Wadsworth Center in Albany, NY or CDC for testing and report results back to submitters. Shipment of specimen to PHEL will start on **Monday, March 7, 2016**. Information relative to current test offering for Zika Virus is found on page 2 of this bulletin.

NOTE: This bulletin information will be updated when changes in this process are made.

- **To request Zika testing contact:**
Communicable Disease Service at (609)-826-5964 Monday through Friday from 8:00 AM to 5:00 PM.
- **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.

February of 2016, the World Health Organization declared a Public Health Emergency of International Concern (PHEIC) due to the spread of Zika virus infections in up to 32 countries. Clusters of Zika virus associated neonatal microcephaly and an increased frequency of a neurological disorder called Guillain-Barré syndrome have been identified.

Zika virus, originally described in the Zika Forest of Uganda in 1947, is an RNA arthropod-borne (arbo) virus (Flaviviridae family, genus *Flavivirus*). It has three genetically distinct strains. Although the virus is most often spread by mosquito bite, other modes of transmission have been reported including transplacental spread, blood transfusion and sexual contact. Zika virus has been shown to be present in urine and saliva, however it is not yet clear whether the virus can be spread through these bodily fluids. The virus has also been demonstrated in amniotic fluid and fetal brain tissue. Local transmission, mainly by the mosquito *Aedes aegypti*, has now been documented in most tropical countries of the Americas but has not yet been detected in the continental United States.

The virus is related genetically to the Dengue fever, Yellow fever, St. Louis encephalitis and West Nile viruses. Although up to 80% of infections may be asymptomatic, the most common clinical presentation of symptomatic Zika virus infection include fever, rash, joint pain, and conjunctivitis. Usually the disease is mild and self-limiting, lasting from a few days to a week. Hospital admission for Zika virus infection is uncommon. There is currently no vaccine available. Treatment is supportive therapy for symptoms only.

References:

<http://nj.gov/health/cd/zika/index.shtml>

<http://www.cdc.gov/zika/>

<http://www.who.int/mediacentre/factsheets/zika/en/>

<http://www.fic.nih.gov/ResearchTopics/Pages/infectiousdiseases-zika-virus.aspx>

Test Information	Description	Comments
Test Approval:	Requests for Zika testing must be preapproved by the New Jersey Department of Health (NJDOH) Communicable Disease Service (CDS). Contact CDS during regular business hours. (Monday – Friday 8 AM-5 PM) at (609)-826-5964. If approved, an NJDOH case number will be assigned.	Specimen will not be processed without an NJDOH approval number.
Submission of Test Request:	If testing is approved, CDS will provide the clinician with a laboratory test request form (SRD-1) for the patient to take with them to the hospital laboratory for specimen collection.	
Biosafety:	Follow all OSHA Blood borne Pathogen healthcare requirements for blood collection and sharps disposal. For manipulation of specimens within the hospital laboratory follow Biosafety Level 2 practices and procedures. Perform aliquotting of serum and urine within a Biosafety Cabinet II and utilize appropriate PPE. http://www.cdc.gov/biosafety/publications/bmb15/	Refer to the <i>Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition</i>
Specimen Requirements:	SERUM and URINE required for each test request SERUM: Two (2) 3 ml aliquots of sera in two separate tubes URINE: Two (2) 3 ml aliquots of urine samples without preservative	Label urine tubes with the word “URINE”.
Specimen Collection:	<u>SERUM AND URINE</u> <u>Serum:</u> Collect sufficient blood (approx. 12mls) in red top or serum separator tubes (tiger top, speckle top or gold top) to obtain a total of 6 ml of serum. Allow blood to clot for 30 mins, room temperature, before centrifuging. Then divide the serum into 3 ml aliquots each in two plastic, leak-proof, screw-capped tubes. <u>Urine:</u> Collect urine in a clean container and pour off 3mls into each of two clean plastic, leak proof, screw capped tubes. Label all specimens with, patient’s full name, DOB, date and time of collection. Label urine specimens with the word “URINE”. FREEZE Serum and Urine at -70 to -80°C within 6 hours of collection.	Blood collected in anticoagulant tubes is NOT ACCEPTABLE. Urine collected in preservative is NOT ACCEPTABLE (see rejection policy below)
Test Methods:	Zika Virus RNA by RT-PCR on serum and urine; IgM Serology for Zika, Dengue and other flaviviruses; positive IgM serum screen samples confirmed by Plaque Reduction Neutralization Test (PRNT). When applicable, follow-up testing on convalescent specimens performed with CDS approval (609)-826-5964.	CDC approved methods and New York State, Wadsworth Center approved methods are performed.
Specimen Storage:	Freeze serum and urine at -70 to -80° C or below until shipped to PHEL	
Specimen Packaging	Package and ship on dry ice following the International Air Transport Association (IATA) packaging instructions 650 for Biological Substance, Category B, UN 3373 and 954 for Dry Ice UN 1845. (<i>Frozen cold packs are not optimal but, may be used if dry ice is not available.</i>) Packaging must be conducted by certified personnel in accordance with IATA regulations: See bulletin supplement: Zika Specimen Collection, Processing, Packaging and Shipping.	Specimens are frozen (-70 to -80°C) to ensure the stability of potentially low levels of virus during transit. Please use sufficient dry ice to maintain frozen state.
Specimen Shipping	Ship package to PHEL Monday – Thursday ONLY at: NJ Public Health and Environmental Laboratories, 3 Schwarzkopf Drive, Ewing, NJ 08628. ATTN: Dr. Nelson Delgado (609)-209-9004 Store serum collected Friday - Sunday frozen at -70 to – 80°C and ship on Monday.	Emergency contact for shipments in transit is (609)-209-9004
Specimen Transport	Most commercial carriers such as FedEx and UPS will transport Biological Substances, Category B. When requesting a commercial shipment, be sure to request Overnight Delivery and a receiving signature. Hospital couriers or other private carriers may also transport specimens. PHEL is on a police campus and access will be granted for hospital couriers with ID indicating transport of Zika specimens.	Specimens are received at PHEL, Monday – Friday, 8 AM – 5 PM
Result Reporting	Zika RNA RT-PCR reported as: Positive or Negative result. Zika IgM serology screen: Reactive, Non-Reactive, inconclusive or equivocal Zika IgM serology confirmation (PRNT): serum titer.	
Turnaround Time of Specimen (TAT)	For RT PCR, urine and /or serum = 6 days: Serum IgM if negative = 7 days Serum IgM, if positive = 20 days Serum PRNT= 20 days	Times stated excludes weekends and holidays
Report Generated	Via Secured Email or fax to: CDS, ordering physician, submitting hospital laboratory and if positive, Centers for Disease Control and Prevention (CDC).	
Specimen Rejection Policy	Specimens may be rejected if all the requirements are not met. All attempts will be made to resolve any issues before rejecting a specimen. - i.e., leaking, broken in transit, unlabeled, mislabeled, unapproved	Questions regarding specimen acceptability: Zika.phel@doh.nj.gov

For questions relating to any information on this bulletin, please contact PHEL Zika Team at zika.phel@doh.nj.gov