

New Jersey Public Health and Environmental Laboratories Technical Bulletin

May 13, 2016

Zika Virus Testing for New Jersey Patients-UPDATE

Effective Wednesday, May 18, 2016, The Public Health and Environmental Laboratories (PHEL) will begin in-house testing for Zika virus and two other related viruses - Dengue and Chikungunya - in clinical specimens.

Zika Virus Disease continues to be a priority for public health preparedness and response especially as mosquito season approaches. PHEL has the capability to perform three diagnostic CDC-developed tests for Zika virus: Zika reverse transcription Real-Time PCR (rtRT-PCR) assay, Trioplex real time rtRT-PCR assay, and the Zika MAC ELISA IgM test. The Zika rtRT-PCR test is specific for the detection of Zika virus and the Trioplex assay allows for the detection and differentiation between RNA from Zika, Dengue, and Chikungunya viruses. The Zika MAC ELISA IgM assay is a qualitative test for the presumptive detection of IgM antibodies to Zika virus. All presumptive positive or equivocal IgM results will be confirmed using the Plaque Reduction Neutralization Test (PRNT). PHEL will continue to refer positive/equivocal IgM tests to the Centers for Disease Control and Prevention (CDC) or another State Public Health Laboratory for the PRNT test. PHEL will not report presumptive positive or equivocal results until confirmatory results are received.

Newly available data have shown that Zika RNA persists in urine longer than in serum and at a slightly higher concentration. PHEL continues to require submission of serum and urine collected at the same date for each Zika virus test request. Other specimens requested for testing (*e.g.* cerebrospinal fluid and amniotic fluid) must also be accompanied by serum collected at the same time as the fluids.

Please note that all tests are not applicable to all the specimen types listed above. The tests that are ultimately performed are determined by PHEL. Test selection will be dependent on the type of specimen received, the patient's clinical history and/or CDC Zika virus epidemiological criteria, and any initial results obtained.

There are two notable changes to the collection and submission of specimens:

- 1. Only one set of urine and serum specimen is now needed; duplicate aliquots of urine and sera are no longer required.
- 2. Serum and urine specimens collected Monday-Thursday should be refrigerated at <u>4°C</u> and shipped on cold packs using overnight next day priority delivery. (Receipt at PHEL within 24hrs of collection.)
- 3. Collection and shipment of specimen on Fridays should be avoided call if must ship Fridays. Additional details on the collection and submission of specimen are provided on page 2 of this bulletin

• 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 or the PHEL website at: http://NJ.gov/health/phel/index.shtml

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 tested 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.

NJDOH-PHEL Laboratory Information for Zika Virus Testing (May 13, 2016)

NJDOH-PHE	L Laboratory Information for Zika Virus Testing	(May 13, 2016)
Test	Description	Comments
Information		
	Requests for Zika testing must be preapproved by the New Jersey Department of Health	Specimen will not be
Test Approval:	(NJDOH) Communicable Disease Service (CDS). Contact CDS during regular business	processed without an
	hours (Monday–Friday 8 AM-5 PM) at (609)-826-5964. If approved, an NJDOH case	NJDOH case number.
	number will be assigned.	
Submission of	If testing is approved, CDS will provide the clinician with a laboratory test request form	
Test Request:	(SRD-1) for the patient to take with them to the hospital laboratory for specimen collection.	
	Follow all OSHA Blood borne Pathogen healthcare requirements for blood collection and	Refer to the <i>Biosafety in</i>
	sharps disposal. For manipulation of specimens within the hospital laboratory follow	Microbiological and
Biosafety:	Biosafety Level 2 practices and procedures. Perform aliquoting of serum and urine within	Biomedical Laboratories
-	a Biosafety Cabinet Class II and utilize appropriate PPE.	(BMBL) 5 th Edition
	http://www.cdc.gov/biosafety/publications/bmbl5/	
Specimen	SERUM and URINE are required for each test request	Label urine tube with the word
Requirements:	SERUM: 3 ml aliquot of sera in a leak-proof tube	"URINE". Label serum tube
	URINE: 3 ml aliquot of a urine specimen without preservative in a leak-proof tube	with the word "SERUM".
	SERUM AND URINE	UNACCEPTABLE:
	Serum: Collect sufficient blood in a serum separator tube (tiger top, speckle top, or gold	Blood in anticoagulant or
	top) to obtain a total of 3 ml of serum. Allow blood to clot for 30 min.at room temp. before	plain red top tubes.
Specimen	centrifugation. Aspirate 3 ml of serum into a leak-proof, screw-capped tube.	<u>Urine</u> in a tube with
Collection:	<u>Urine:</u> Collect urine in a clean container, pour off 3ml into a clean plastic, leak proof,	preservative or submitted in
	screw capped tube. Ensure cap is properly aligned to avoid leakage in transit.	a cup.
	Label all specimens with patient's full name, DOB, date and time of collection, and	Other specimens: Contact
	type of specimen. Store all specimens at 4°C until ready for packaging and shipping.	zika.phel@doh.nj.gov
	Amniotic, cerebrospinal fluids, cord blood, and placental specimens are acceptable on CDS approval.	
	Zika Virus RNA by rtRT-PCR; Trioplex Real Time rtRT-PCR; Zika MAC (IgM) ELISA;	CDC approved methods and
Test Methods:	Positive IgM serum screen samples confirmed by Plaque Reduction Neutralization Test	New York State Wadsworth
	(PRNT). When applicable, follow-up testing on convalescent specimens performed with	Center approved methods
	CDS approval (Contact: [609]-826-5964).	are performed.
Specimen	PHEL encourages Monday through Thursday specimen collection only.	If -70° C freezer is lacking &
Storage:	Specimens collected Mon–Thursday: Store at 4°C until shipped, Mon-Thurs (within 24 h)	Friday draw is unavoidable,
	Specimens collected Friday–Sunday: Freeze at -70° to -80° C for dry ice shipment on Mon	email: zika.phel@doh.nj.gov
	Mon-Thurs Specimen Collection : Condition the serum and urine at 4°C for a minimum	Specimens are kept at 4°C to
	of one hour. Fill the box with refrigerated cold packs, and follow the International Air	ensure the stability of
Specimen	Transport Association (IATA) packaging instructions 650 for Biological Substances,	potentially low levels of
Packaging:	Category B, UN 3373. Packaging must be conducted by certified personnel in accordance	virus during transit. Please
	with IATA regulations. Fri – Sun Specimen Collection: Specimens collected Fri–Sun	use sufficient cold packs to
	must be frozen at -70° to -80° C and shipped on dry ice on Monday. Follow instructions	maintain refrigeration
	for shipping specimens on Dry Ice in the Zika Technical Bulletin Supplement on	during transit. DO NOT FREEZE AT -20°C.
	Packaging and Shipping Zika Specimens 3/4/16. http://nj.gov/health/phel/index.shtml Ship to PHEL Monday—Thursday ONLY at:	Emergency contact for
Specimen	NJ Public Health and Environmental Laboratories, 3 Schwarzkopf Drive, Ewing, NJ	shipments in transit is
Shipping:	08628. ATTN: Dr. Nelson Delgado (609)-209-9004	(609)-209-9004
empping.	<u> </u>	` ′
g •	Specimens are received at PHEL Monday-Friday, 8 AM-5 PM	Saturday delivery requests
Specimen	Special arrangements must be made for Saturday receipt at PHEL. If special arrangements	are discouraged. Contact
Transport:	have been made with PHEL for Saturday receipt, be sure to request Overnight <u>Delivery for</u>	zika.phel@doh.nj.gov for
Dogulta	Saturday. Carriers do not routinely deliver on Saturday. Possults reporting very depending on the combination of tests that are performed. Penert are	more information.
Results	Results reporting vary depending on the combination of tests that are performed. Report are not finalized until all indicated tests are completed. Links to CDC Fact sheets are provided	
Reporting: Turnaround	For RT-PCR, urine and/or serum is 7 days Serum IgM if negative is 7 days	Times stated excludes
Turnaround Time (TAT):	Serum IgM, if positive is 20 days Serum PRNT is 20 days Serum PRNT is 20 days	weekends and holidays
Report	Via secured email or fax to CDS, ordering physician, submitting hospital laboratory, and if	weekends and nondays
Generated:	positive, Centers for Disease Control and Prevention (CDC).	
Specimen Specimen	Specimens may be rejected if all the requirements are not met. All attempts will be made to resolve	Questions regarding
Rejection	any issues before rejecting a specimen, i.e., tubes leaking, broken in transit, unlabeled, or mislabeled,	specimen acceptability:
Policy:	& unapproved request, incorrect name, no specimen identified, or a urine cup etc.	Zika.phel@doh.nj.gov
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For questions relating to any information on this bulletin, please contact PHEL Zika Team at zika.phel@doh.nj.gov

Note: The guidelines and protocols for laboratory handling and processing of Zika specimens are dynamic at this time. This technical bulletin may be updated as necessary. Retain copies of all forms prepared for your records $page \ 2 \ of \ 2$