

DIVISION OF EPIDEMIOLOGY, ENVIRONMENTAL AND OCCUPATIONAL HEALTH PO BOX 369

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To: Local health departments and health care providers

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Date: May 5, 2016

Subject: Zika: Commercial laboratory testing for Zika virus

Beginning May 2, 2016, the U.S. Food and Drug Administration (FDA) has approved some commercial laboratories to conduct <u>limited</u> Zika virus testing.

<u>Testing Available Through Some Commercial Labs – RT-PCR</u>

The FDA Emergency Use Authorization (EUA) is currently available for the Zika Virus RNA Qualitative Real-Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) test. RT-PCR tests look for Zika virus RNA. RNA may be detected in serum within 7 days of symptom onset. Therefore, RT-PCR testing is indicated for patients within the first week of clinical illness.

¹A negative test for Zika virus RNA in the specimen means that RNA from Zika virus is not present in the specimen at the detection level of the assay. However, a negative result does not rule out infection with the virus and should not be used as the sole basis for treatment or other patient management decisions. Negative RT-PCR tests are known to occur in Zika infection, particularly if testing was conducted more than 7 days after onset of symptoms or in asymptomatic individuals. Serological testing of negative serum specimens may be appropriate to consider if a patient's travel history and/or clinical illness raise suspicion of Zika infection.

Serologic Testing

Serologic testing may be available 2-12 weeks after symptom onset or for patients meeting certain criteria (e.g., asymptomatic pregnant women with travel history to a Zika-affected area). Currently serologic testing is only available at limited approved public health laboratories. The current clinical and epidemiologic criteria for Zika testing is described in the April 6, 2016 LINCS message #103106-4-6-2016-PHUP and is available at: http://nj.gov/health/cd/zika/techinfo.shtml. Requests for serologic testing must be approved by the NJDOH.

Testing Available Through the NJDOH

Patients approved by the NJDOH for Zika virus testing will have RT-PCR conducted if indicated. If not indicated, or if the RT-PCR is negative, serologic testing will be automatically conducted on the specimen. Additional convalescent specimens may be requested based on the time the specimen was drawn and/or the results of the serologic testing.

Additional Information

For additional information on Zika virus disease and managing cases in CDRSS, please contact your NJDOH Regional Epidemiologist or the NJDOH CDS Zika Team during regular business hours at (609) 826-5964.

Further information on Zika virus infection for healthcare providers is available at: http://www.cdc.gov/zika/hc-providers/index.html

¹Information on Zika virus RT-PCR test and interpretation is summarized from:

CDC's EUA Fact Sheet: http://www.cdc.gov/zika/state-labs/index.html

Quest Diagnostics's EUA: http://www.questdiagnostics.com/home/physicians/testing-

services/condition/infectious-diseases/zika