Nebraska Department of Health and Human Services

HEALTH ALERT NETWORK

Advisory

TO: Primary care providers, emergency rooms, OB/Gyn, pediatrics, pathology, microbiology lab coordinators, neurology, infection control, infectious Disease, labs, and public health

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RE: Subsequent Zika virus IgM antibody testing

DATE: July 5, 2016

The following CDC Health Update applies to specimens tested with a commercial PCR assay for Zika virus (ZKV). These PCR tests detect viral particle/RNA in serum or urine. There is presently no commercial serologic assay (antibody test) for ZKV. If the commercial PCR assay is negative for ZKV, patient serum should then be tested through the Nebraska Public Health Lab for the presence of ZKV-specific IgM antibodies. If PCR assay is positive for ZKV, this is confirmatory, and no additional testing is required.

Please note the following criteria for performing ZKV testing:

ZKV testing can be performed on patients who meet the following criteria:

- Individuals with one of the following symptoms: acute fever, rash, arthralgia, or conjunctivitis AND travel to an area with ongoing ZKV transmission within the previous 2 weeks of symptom onset;
- Pregnant women with clinical illness consistent with ZKV disease (one or more of the above symptoms) AND history of travel to an area with ongoing ZKV transmission the previous 2 weeks;
- Pregnant women without clinical illness consistent with ZKV disease with history of travel to an area with ongoing ZKV disease (testing should be performed 2-12 weeks after travel);
- Pregnant women who have had condomless sex with a male partner with a history of travel to an area with ongoing ZKV transmission AND the woman develops at least one sign or symptoms of ZKV clinical illness;
- Pregnant women who have had condomless sex with a male partner with a history of travel to an area with ongoing ZKV transmission AND the man has clinical illness consistent with ZKV disease or has been diagnosed with ZKV disease.
- Pregnant women who traveled to an area with ongoing transmission 8 weeks prior to conceiving.
- Suspected fetal infection.

This is an official

CDC HEALTH UPDATE

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CDC Recommendations for Subsequent Zika IgM Antibody Testing

Summary
Testing for Zika virus infection using real-time reverse-transcription polymerase chain reaction (rRT-PCR) molecular assays is now commercially available. When requesting Zika rRT-PCR testing from a commercial laboratory, providers should be aware that commercial laboratories performing rRT-PCR currently do not also offer Zika IgM enzyme-linked immunosorbent assay (ELISA) or confirmatory serologic testing (plaque reduction neutralization test, or PRNT). Therefore, if possible, providers should store a serum aliquot for subsequent Zika IgM ELISA testing if the rRT-PCR assay is negative. Otherwise, collection of an additional serum sample may be necessary.

Recommendations

- rRT-PCR (molecular) testing should be performed for patients possibly exposed to Zika virus who have symptoms consistent with Zika virus infection
- Providers who request molecular testing for Zika virus infection from a commercial testing laboratory are advised to retain and store in a refrigerator (2-8℃) an aliquot of the patient's serum for subsequent Zika IgM ELISA testing if the rRT-PCR is negative
- For specimens that are rRT-PCR negative from the commercial laboratory and no stored serum specimen is available, another serum specimen should be collected within 12 weeks of symptom onset for Zika IgM ELISA testing
- Appropriate samples for molecular testing are serum samples collected <7 days and urine samples collected <14 days after symptom onset. Urine should always be collected with a patient-matched serum specimen.

Background
Molecular assays for detection of Zika virus RNA are now commercially available under Emergency Use Authorizations (EUAs) issued by the Food and Drug Administration (FDA). CDC recommends molecular testing using rRT-PCR for serum samples collected <7 days and urine samples collected <14 days after symptom onset. A positive rRT-PCR test is confirmation of Zika virus infection. However, because of the decline in the level of viremia over time and possible inaccuracy in reporting of dates of illness onset, a negative rRT-PCR result does not exclude Zika virus infection. In such cases, CDC recommends serologic testing by ELISA for Zika IgM antibody.

Currently, commercial laboratories that offer rRT-PCR testing do not provide Zika IgM ELISA testing with PRNT confirmation and have no routine process to forward specimens to another testing laboratory. Therefore, when requesting Zika rRT-PCR testing from a commercial laboratory, providers should retain an aliquot of the serum for Zika IgM ELISA testing if the rRT-PCR testing is negative. Blood should be collected and processed per routine guidelines (collected in a serum separator tube with serum aliquots transferred to new vials), and one of the serum aliquots should be stored in a refrigerator (2-8℃) until it is known if additional IgM testing is indicated. If a serum aliquot cannot be stored or is not available, but further testing is indicated, a new blood sample should be collected. Serum samples for IgM testing should be collected from patients within 12 weeks of symptom onset. Providers should contact their local health department to discuss IgM testing of stored or newly collected serum from patients who are rRT-PCR negative.

For More Information

- Zika virus specimen collection: http://www.cdc.gov/zika/hc-providers/body-fluids-collection-submission.html.
- Interim guidance for Zika virus testing of urine: http://www.cdc.gov/mmwr/volumes/65/wr/mm6518e1.htm

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