

Cover Sheet

DATE: June 22, 2016

SUBJECT: CDC Recommendations for Subsequent Zika
IgM Antibody Testing

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**For LOCAL HEALTH
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DPHHS Subject Matter Resource for more information regarding this HAN, contact:

**DPHHS CDCP
Epidemiology Section
1-406-444-0273**

**DPHHS Health Alert Hotline:
1-800-701-5769**

**DPHHS HAN Website:
www.han.mt.gov**

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hhshan@mt.gov

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Information Sheet

Date: June 22, 2016

Subject: CDC Recommendations for Subsequent Zika IgM Antibody Testing

Background: To date, specimens from 68 individuals with a suspected Zika exposure who experienced related symptoms and/or were pregnant have been submitted to the Montana Public Health Laboratory (MPHL) for testing. Of these, one positive test specimen was identified, 48 others were negative, and 19 are pending. We continue to work closely with local public health jurisdictions and providers to ensure timely testing when appropriate.

Information: The attached CDC HAN Health Update regarding Zika clarifies CDC recommendations regarding testing for the Zika virus. In short, they remind us that PCR tests have limitations and supplementing these tests with serologic testing by ELISA for IgM antibody is strongly recommended. Please see the attachment for additional details.

Instructions for specimen submission to the Montana Public Health Laboratory

Collect urine specimens within 14 days post symptom onset, along with patient-matched serum specimens for those who match CDC Zika virus clinical and/or epidemiological testing criteria for Zika virus infection.

Serum: Provide 1.0 mL of the specimen in a serum separator tube or a sterile screw capped vial secured with thermoplastic, self-sealing lab film. If you are pouring specimen into a sterile vial, be sure to do so under a biological safety cabinet using proper precautions.

Urine: Provide 0.5–1.0 mL of the specimen in a sterile screw capped vial secured with thermoplastic, self-sealing lab film.

Please ensure a tight seal as leaking specimens cannot be accepted. All specimens should be stored and shipped cold, by packing in an insulated container with adequate ice packs to ensure specimen integrity.

For questions related to collection and handling, please contact Montana Public Health Laboratory (MPHL) at 1-800-821-7284.

Recommendations: Any individual who has recently been exposed to Zika virus and who is pregnant or has symptoms of concern may benefit from testing for Zika. The Montana Public Health Laboratory (MPHL) can support testing requests that have been evaluated by local public health jurisdictions and meet testing criteria. When consultation with local public health officials indicates the need for testing, DPHHS requests blood and urine samples be submitted for PCR and serologic testing. Serology testing is currently not available commercially. If not using the MPHL, consider collection and storing of a serum aliquot for serology testing in the event of a negative PCR should follow-up testing be necessary.

This is an official **CDC HEALTH UPDATE**

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CDCHAN-00392

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°C) 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°C) 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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Categories of Health Alert Network messages:

Health Alert Requires immediate action or attention; highest level of importance
Health Advisory May not require immediate action; provides important information for a specific incident or situation
Health Update Unlikely to require immediate action; provides updated information regarding an incident or situation
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