



Health Alert Network

Tri-County Health Department

Serving Adams, Arapahoe and Douglas Counties

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The pages that follow contain information critical to protecting the health of your patients and the citizens of Colorado.

HAN UPDATE

Number of pages including cover: 7

Subject: **Update - Recommendations for Subsequent Zika IgM Antibody Testing**

Message ID: 6/29/2016 11:15:00 AM

Recipients: HAN Community Members.

From: TRI-COUNTY HEALTH DEPARTMENT

Adams, Arapahoe and Douglas County, Colorado

Recipient Instructions: Please find updated instructions outlined by Tri-County Health Department related to Zika IgM Antibody Testing, updated information from CDC on testing at commercial labs and a CDPHE Q&A on Zika Virus Diagnostic Testing.

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Info Service/Public Health Brief: Provides general information that is not necessarily considered to be of an emergent nature.

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<http://www.tchd.org/259/Health-Alert-Network>



HEALTH UPDATE

Recommendations for Subsequent Zika IgM Antibody Testing, June 29, 2016

****Health care providers: Please distribute widely in your office****

Diagnostic Testing for Zika: Key Points for Providers

Who should be tested for Zika virus?

Pregnant women who traveled to a Zika-affected area:

- Who had one or more of the following symptoms during or within two weeks of travel: acute onset of fever, rash, arthralgia or conjunctivitis.
- Who traveled within the past two to 12 weeks and had no symptoms of Zika.
- During the eight weeks before conception can be tested within two to 12 weeks of that exposure.

Pregnant women who did *not* travel to a Zika-affected area:

- Who had unprotected sexual contact with a male partner who traveled to a Zika-affected area, where the male partner was diagnosed with, or had symptoms of Zika infection.
- Who became symptomatic after having unprotected sexual contact with a male partner who traveled to a Zika-affected area but remained symptom free.

All others:

- Who traveled to a Zika-affected area and had one or more symptoms of Zika virus infection during or within two weeks of travel.
- Who became symptomatic after unprotected sexual contact with a male partner who traveled to a Zika-affected area, where the male partner was diagnosed with, or had symptoms of Zika infection.

Note: Men and non-pregnant women who are asymptomatic are not being tested at this time.

How can patients access Zika virus testing?

Zika virus testing is only available when requested by a health care provider. The state health department lab cannot collect samples directly from patients.

Recommendations for testing

Testing should include the following (*Note: All specimens require a CDPHE lab 270 form and a CDC 50-34 lab form*):

1. For symptomatic persons:
 - a. Day 1-7: send both urine and serum for PCR
 - b. Day 8-14: send urine for PCR and serum for serology
 - c. If > 14 days, send serum for serology
2. For asymptomatic pregnant woman: send serum for serology

Testing can also include:

- a. Amniotic fluid:
 - i. Symptomatic women: by PCR day 1-7 and by serology if > 7 days
 - ii. Asymptomatic women: by serology
- b. CSF: symptomatic persons by PCR day 1-7 and by serology > 7 days
- c. IgM testing can also be requested on serum, CSF and amniotic fluid samples \geq 4 days following symptom onset.

Attachments:

- 1) CDC Recommendations for Subsequent Zika IgM Antibody Testing, June 21, 2016
- 2) CDPHE Q & A's: Zika Virus Diagnostic Testing, June 2, 2016

Serving Adams, Arapahoe and Douglas Counties ▼ www.tchd.org

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This is an official **CDC HEALTH UPDATE**

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June 21, 2016, 1140 EDT (11:40 AM EDT)
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>

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

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
HAN Info Service Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, epidemiologists, HAN coordinators, and clinician organizations##



Q & A's: Zika Virus Diagnostic Testing

June 2, 2016

This is an evolving situation.

Recommendations will be updated as more information becomes available.

Who should be tested for Zika virus?

Pregnant women who traveled to a Zika-affected area:

- Who had one or more of the following symptoms during or within two weeks of travel: acute onset of fever, rash, arthralgia or conjunctivitis.
- Who traveled within the past two to 12 weeks and had no symptoms of Zika.
- During the eight weeks before conception can be tested within two to 12 weeks of that exposure.

Pregnant women who did *not* travel to a Zika-affected area:

- Who had unprotected sexual contact with a male partner who traveled to a Zika-affected area, where the male partner was diagnosed with, or had symptoms of Zika infection.
- Who became symptomatic after having unprotected sexual contact with a male partner who traveled to a Zika-affected area.

All others:

- Who traveled to a Zika-affected area and had one or more symptoms of Zika virus infection during or within two weeks of travel.
- Who became symptomatic after unprotected sexual contact with a male partner who traveled to a Zika-affected area, where the male partner was diagnosed with, or had symptoms of Zika infection.

*Men and non-pregnant women who are asymptomatic are not being tested at this time.

What testing is available and where?

PCR:

- Triplex RT-PCR Assay to detect dengue, chikungunya and Zika virus RNA [available at the state health lab].
- RealStar RT-PCR to detect Zika virus RNA [available through commercial labs].

Serology:

- IgM capture (MAC) ELISA to detect Zika virus IgM [available at CDC].
- Plaque Reduction Neutralization Test (PRNT) to detect total antibody (dengue and Zika virus) [available at CDC; performed on IgM positive or equivocal samples].
- Dengue MAC-ELISA and chikungunya MAC-ELISA [available through commercial labs].

How can patients access Zika virus testing?

Zika virus testing is only available when requested by a health care provider. The state health lab cannot collect samples directly from patients.

What samples can be tested for Zika virus?

For symptomatic patients:

- Collect urine and serum for RT-PCR testing from the first day of symptoms through day 7 following symptom onset.

- Collect urine for RT-PCR testing and serum for serology testing from day 7 through day 14 following symptom onset.
- Collect CSF or amniotic fluid for RT-PCR testing from the first day of symptoms through day 7 following symptom onset.
- IgM testing can also be requested on serum, CSF and amniotic fluid samples \geq 4 days following symptom onset.

For asymptomatic pregnant women:

All testing is serological and currently performed at CDC. MAC-ELISA is available, and serum and amniotic fluid can be tested. Collect samples two to 12 weeks following travel to a Zika-affected area.

What samples should be collected and how much?

Serum:

- Use a red top, tiger top or serum separator tube.
- The state health lab requires 0.25 mL for RT-PCR testing.
- CDC requires \geq 1.0 mL of serum for IgM testing.
- If requesting both RT-PCR and IgM testing, send \geq 1.25 mL.

Urine:

- Send the sample in a sterile, screw-capped vial secured with thermoplastic, self-sealing lab film.
- The state health lab requires 0.5 to 1.0 mL for RT-PCR testing.

Amniotic fluid:

- Send sample in a sterile, screw-capped vial secured with thermoplastic, self-sealing lab film.
- CDC requires 0.5 to 1.0 mL for RT-PCR and/or IgM testing.

Cerebrospinal fluid (CSF):

- Send sample in a sterile, screw-capped vial secured with thermoplastic, self-sealing lab film.
- CDC requires at least 1.0 ml for RT-PCR or IgM testing.

What is the turnaround time for Zika testing?

- RT-PCR testing at the state health lab will take approximately 72 hours following sample receipt.
- Serology testing at CDC will take approximately 4 - 6 weeks.
- All results will be sent securely to the submitter at the fax number provided.

How do I request testing from the lab?

All samples need to be sent directly to the state health lab. The lab will not determine which test to perform, nor will it automatically send samples for CDC testing unless indicated.

All submitters **MUST** submit the Request for Analytical Services form #270/271. A separate form must be filled out for EACH sample.

- To request the form, call the state health lab (303-692-3485) or state health department (303-692-2700).
- The lab will use the form to set up an account for you if you do not already have one.

Submitters requesting IgM testing must also complete the CDC 50-34 form.

- The form is available at www.cdc.gov/laboratory/specimen-submission/pdf/form-50-34.pdf, or

- Call 303-692-2700 and we can fax or email the form to you.

The CDC 50-34 form *must be filled out completely* or testing will be delayed.

- In the ‘Test order name’ field on page 1 of the form, put *ZIKA*.
- On page 2 under ‘Relevant immunization history’ indicate if patient has a history of yellow fever or Japanese encephalitis virus vaccination.

What is the cost for testing, and is there a CPT code?

- The RT-PCR test at the state health lab costs \$260 (per sample), billed to the submitter [CPT code 87798].
- There is a \$45 handling and processing fee for IgM testing at CDC [CPT code 99001].

How do I get the sample to the state health lab?

- Specimens can be sent to the state health lab by FedEx or by the courier of your choice. The address is CDPHE Laboratory Services Division, 8100 Lowry Blvd, Denver, CO 80230.
 - The state health lab can only accept samples Monday - Friday, 8 a.m. to 5 p.m.
 - FedEx and other couriers should be directed to avoid weekend deliveries.
- Alternately, you may check our current list of pickup times and locations for the state health lab courier,
www.colorado.gov/pacific/sites/default/files/Kangaroo%20Update.7.29.14-SK.pdf
 - If your hospital lab or local health department is on the courier route, you may arrange to have the sample(s) picked up there. Call 303-692-3086 to make arrangements.

Are there special handling and packaging instructions?

Samples should be kept at 4°C and transported on cold packs. The CDPHE courier will transport at 4°C; other overnight shipments should include a cold pack. If the sample is frozen, it should be kept frozen and be shipped on dry ice.

Can samples be submitted to commercial labs for testing?

Under the FDA’s Emergency Use Authorization, some commercial labs are performing Zika virus RT-PCR testing. For more information on submitting samples to commercial labs, contact your regular commercial laboratory.

Who can I call for other questions about Zika virus?

Call the state health lab at 303-692-3485 or the state health department at 303-692-2700.

Where can I go for more information on Zika virus?

A list of countries with local transmission of Zika virus is available at www.cdc.gov/zika/geo/active-countries.html

The most up to date testing guidance is available at www.colorado.gov/pacific/cdphe/zika