MICHIGAN DEPARTMENT OF HEALTH & HUMAN SERVICES

BUREAU OF LABORATORIES

August 2, 2016

Zika Virus Testing Available at MDHHS

Page updated 8/2/2016 to include new Zika protocol for pregnant patients, both symptomatic and asymptomatic, (diagram below).

What's New?

In response to the emergence of Zika virus, the MDHHS laboratory is now able to provide testing. Since Zika, dengue and chikungunya viruses show similar clinical presentations in patients and are spread by the same mosquito genus in the same geographic region, testing for dengue and chikungunya viruses is performed when Zika virus testing is requested.

Preapproval is required before submission of specimens for testing. Accurate dates for symptom onset and travel to Zika-endemic areas, as well as unprotected sex with someone (male or female) who has traveled to a Zika-endemic area, are required. Call your local health department (contact numbers can be found at: http://www.malph.org/directory) or MDHHS epidemiologists at 517-335-8165 for approval.

Specimen Collection and Submission

Serum tests include the **CDC Trioplex Real-Time RT-PCR** (polymerase chain reaction) assay for viral nucleic acid, the CDC **IgM capture MAC-ELISA** assay for Zika antibodies, and an InBios IgM capture ELISA for dengue and chikungunya IgM antibodies.

Urine, cerebral spinal fluid (CSF) and amniotic fluid specimens will be accepted for Zika PCR testing **ONLY** if they are accompanied by serum specimens.

Specimen collection and submission guidelines may be found here.

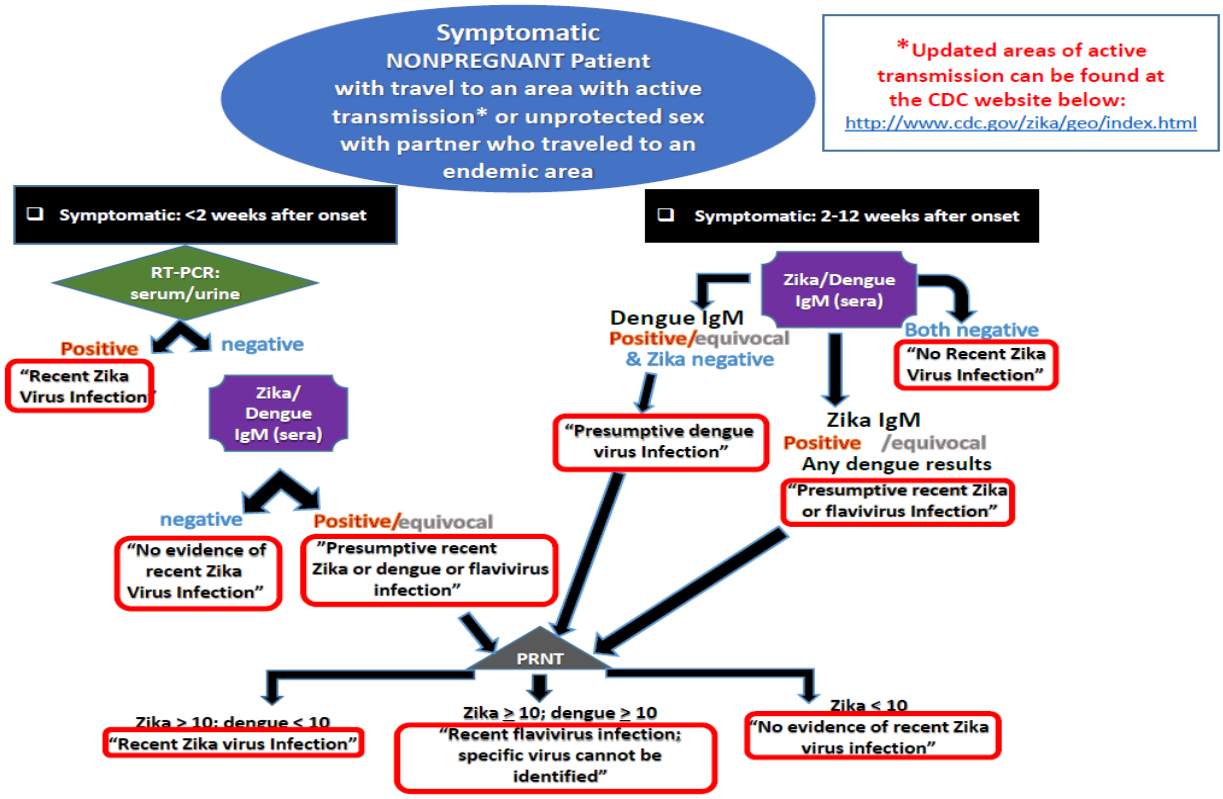
IgM serology (ELISA) test information may be found here.

PCR test information may be found here.

All specimens must be accompanied by a test requisition and a supplemental questionnaire.

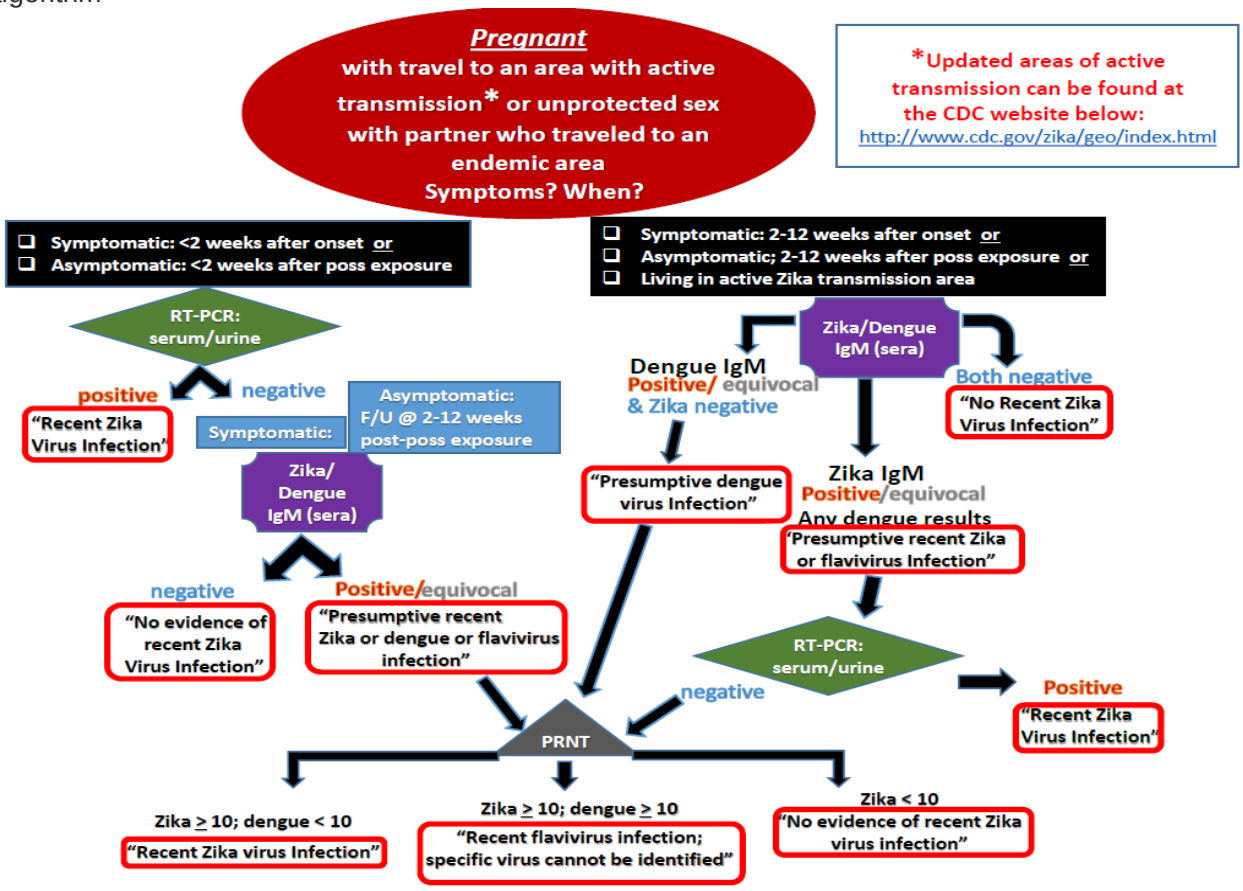
- The test requisition has been updated. Please use the **new (DCH-0583) form** found here.
    - Under TESTS THAT REQUIRE MDHHS APPROVAL, EMERGING ARBOVIRUS PANEL check the box for PCR or SEROLOGY (or both) as advised during the approval process.
- The Michigan Zika Supplemental Questionnaire form must be completed and submitted with the specimens. The **questionnaire** can be found here.

Testing Algorithm for Non-pregnant Patients



Testing Algorithm for Pregnant Women

HCP should submit both a serum and a urine sample on all potentially exposed pregnant patients. Click here to view testing algorithm



Results

Specimens with positive or equivocal results for Zika, dengue or chikungunya virus IgM must be confirmed. Plaque-reduction neutralization testing (PRNT) is used to delineate between true Zika IgM and cross-reactivity with other flaviviruses, (e.g. West Nile, dengue). All positive and equivocal serology results should be considered **PRESUMPTIVE** until further PRNT testing is performed.

For additional information on testing pregnant women, go to the MMWR site for July 25, 2016 publications on testing updates and guidance.

CDC fact sheet link for health care providers, patients and pregnant women may be found at http://www.cdc.gov/zika/state-labs/index.html#FDA-fact

The following conditions apply to CDC's Emergency Use Authorization (EUA) Zika MAC-ELISA assay:

- *This test has not been FDA cleared or approved.*
- *This test has been authorized by FDA under an EUA for use by authorized laboratories.*
- *This test has been authorized only for the diagnosis of Zika virus infection and not for any other viruses or pathogens.*
- *This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.*

For additional testing questions contact Janice Matthews-Greer, PhD, DABMM at (517) 335-8099 or matthewsgreerj@michigan.gov