FDA Warns Health Care Providers Against Relying Solely on Zika Virus Serological IgM Assay Results; Reminds them to Wait for Confirmatory Test Results Before Making Patient Management Decisions: FDA Safety Communication

Date Issued:

December 22, 2016

Audiences:

- Health care providers
- Pregnant women potentially exposed to Zika

Medical Specialties:

Primary care, Obstetrics and Gynecology, and Infectious Disease

Product:

The ZIKV Detect IgM Capture ELISA is manufactured by InBios International, Inc.

The test is used for the preliminary (presumptive) detection of Zika virus IgM antibodies in human sera collected from patients with a history of clinical signs and symptoms associated with Zika virus infection (Centers for Disease Control and Prevention [CDC] clinical criteria for Zika virus) and/or a history of residence in or travel to a geographic region with active Zika transmission at the time of travel (CDC Zika virus epidemiological criteria).

This test is intended for use in laboratories in the U.S. that are certified under federal law (the Clinical Laboratory Improvement Amendments of 1988) to perform high complexity tests, or by similarly qualified non-U.S. laboratories, consistent with the latest CDC guidelines for the diagnosis of Zika virus infection. Health care professionals may use the results to aid in their clinical diagnosis or to help evaluate possible treatment decisions.

Purpose:

The FDA is alerting physicians who care for pregnant women meeting CDC Zika virus clinical criteria and/or CDC Zika virus epidemiological criteria, that the U.S. commercial testing facility, Laboratory Corporation of America (LabCorp), has reported some false positive results from the ZIKV Detect test.

While the FDA has not yet determined if the reported false positives are related to the ZIKV Detect test or the commercial testing facility, it is important to remember that IgM tests remain useful in ruling out Zika exposure but require confirmatory testing.

Summary of Problem and Scope:

In August of this year, the FDA authorized the ZIKV Detect IgM Capture ELISA manufactured by InBios International, Inc. as the first commercially available Zika serological IgM test. Since then, several commercial laboratories have started migrating their serological testing from the CDC assay authorized at the beginning of this year to the new commercial assay.

The CDC test and the ZIKV Detect test report only presumptive positive results, and samples have to be sent for confirmation. Past performance characteristics indicate most of the presumptive positive results from both tests have been ultimately confirmed.

After transitioning to the ZIKV Detect test, LabCorp observed higher than expected false positive results. The CDC confirmed less than half of those presumptive positive results captured by LabCorp through the ZIKV Detect test.

Because confirmation tests may take a week to a month to complete, the FDA is issuing this alert so that health care providers and patients know about a higher likelihood of false positive results.

Recommendations for Health Care Providers:

The FDA urges health care providers to be aware that:

- Positive IgM Zika virus results are only presumptive for the detection of antibodies to Zika virus.
- Confirmation of IgM Zika virus presumptive or possible positive results requires additional testing by CDC or by qualified laboratories.
- The confirmatory testing may take a week to a month to be performed, but can be prioritized if CDC is aware that the sample is from a pregnant woman.

The FDA urges health care providers to:

- Inform their patients that presumptive positive results need to be confirmed, so that pregnant women are not making health care decisions based on incomplete information.
- Not rely on presumptive positive Zika virus IgM test results as the sole basis of significant patient management decisions. Take the following into consideration before diagnosing Zika virus infection in pregnant women:
    - clinical observations,

    - patient history,
    - epidemiological information, and;
    - results from other testing such as follow-up confirmatory testing.
- Notify the laboratory of the patient's pregnancy to facilitate prioritization of confirmatory testing by CDC or qualified laboratories.

Recommendation for Patients:

- If you have been tested for exposure for the Zika virus by this test and have received a preliminary positive result, this test result should be confirmed. There is a chance that a preliminary positive test result may incorrectly show that you have been exposed to the Zika virus. If you have any questions, please contact your health care provider.

FDA Actions:

The FDA is currently working with CDC, LabCorp, and InBios to identify the root cause of the problem. The FDA will continue to monitor the situation to assure the safety and effectiveness of these tests, and will keep the public informed if significant new information becomes available.

Additional Resources:

- Centers for Disease Control and Prevention General Zika Virus Information (https://www.cdc.gov/zika/about/index.html)
- Centers for Disease Control and Prevention Zika Information for Pregnant Women (https://www.cdc.gov/zika/pregnancy/index.html)

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks related to the use of medical devices. If you suspect or experience a problem with the ZIKV Detect IgM Capture ELISA or any other Zika virus tests, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm). Health care personnel employed by facilities that are subject to FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm20057 should follow the reporting procedures established by their facilities.

Contact Information:

If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041, or 301-796-7100.

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