



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Dennis R. Schrader, Secretary

December 23, 2016

Dear Colleague:

We are writing to make you aware of an FDA safety communication issued today, “ZIKV Detect IgM Capture ELISA by InBios International, Inc: FDA Safety Communication – Wait for Confirmatory Test Results Before Making Patient Management Decisions.”

The FDA is alerting physicians who care for pregnant women meeting CDC Zika virus clinical criteria and/or CDC Zika virus epidemiological criteria that Laboratory Corporation of America (LabCorp) has reported some false positive results from the ZIKV Detect test. The full communication can be accessed at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm534538.htm>.

DHMH recommends providers utilize the DHMH public health laboratory for Zika IgM testing of pregnant women. Providers who desire IgM testing to be performed at DHMH should seek test approval from their local health department prior to specimen submission, as has been instructed previously.

Specific recommendations from the FDA include:

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. Laboratories should be notified of the patient’s pregnancy status.

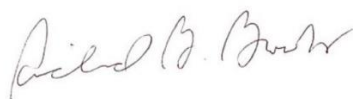
The FDA urges health care providers to:

- 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.

Please continue to contact your local health department or the Infectious Disease Epidemiology and Outbreak Response Bureau at (410) 767-6700 if you have questions or concerns.

Sincerely,

A handwritten signature in cursive script, appearing to read "Richard B. Brooks".

Richard B. Brooks, MD, MPH
Epidemic Intelligence Service Officer, Centers for Disease Control and Prevention
Maryland Department of Health and Mental Hygiene