



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Mary T. Bassett, MD, MPH
Commissioner

2016 DOHMH Advisory #2: Zika Diagnostic Laboratory Updates

- Several Zika IgM positive specimens tested at commercial labs show no evidence of Zika virus infection following repeat testing at the New York State Wadsworth Center laboratory.
- Zika IgM specimens with a positive test result must be confirmed by plaque reduction neutralization testing at Wadsworth Center.
- Do not base decisions about managing pregnant women on positive IgM testing alone.
- Use venipuncture only, not heel sticks, to collect blood specimens from infants to reduce risk for hemolysis.

January 30, 2017

Dear Colleagues,

The New York City Health Department has found that 43% of patients with a positive* Zika IgM test performed at a commercial laboratory had no evidence of Zika infection on confirmatory testing by Wadsworth Center (WC) at the New York State Department of Health.

Commercial laboratories are required to send specimens to WC for any patient with any positive Zika IgM test result. For these specimens, WC repeats the Zika IgM test and also performs two additional tests: microsphere immunoassay (MIA) for IgM, IgG and IgA antibodies and the plaque reduction neutralization test (PRNT). Among 74 patients who were Zika IgM positive at a commercial laboratory and for whom confirmatory testing was completed at WC, 32 (43%) had no laboratory evidence of Zika virus infection. Twenty were negative on repeat IgM testing and had no detectable antibodies to both Zika and dengue viruses on PRNT. Another 12 were negative on repeat IgM and had no detectable antibody to Zika on PRNT; dengue virus antibodies were detected on PRNT, suggesting dengue infection at an undetermined time. The reason for the discrepant results is unknown at this time, though it may be that commercial lab assays are detecting cross reactive antibodies for other Flaviviruses.

Providers should not base decisions about managing pregnant women on positive IgM testing alone. Providers should wait for additional test results from WC or another reference laboratory, such as CDC, before making any decisions regarding a pregnant woman. All commercial laboratories testing NYC residents are required to forward all specimens with a non-negative Zika IgM result to WC for both repeat IgM and PRNT. It may take up to 4 weeks for WC to report final results back to the commercial laboratory that submitted the specimen. Interpretation of the final panel of results can be challenging. Providers are encouraged to call the Health Department at 1-866-692-3641 for assistance.

The 32 specimens with Zika positive IgM test results includes all of the following: 'presumptive positive' (18), 'possible positive' (2), 'positive' (4), 'equivocal' (8). Test result interpretations reported by commercial labs will vary depending on which assay is used to test for evidence of Zika IgM antibodies.

Table 1. Zika IgM Test Interpretations and Results that May be Reported by Commercial Labs

Zika IgM Test Performed	Result reported	Additional Zika testing needed?	Commercial lab will automatically forward specimen to Wadsworth Center for repeat Zika IgM and PRNT?
MAC ELISA Assay	Positive	Yes	Yes
	Equivocal	Yes	Yes
	Negative	No	No
InBios Assay	Presumptive Zika Positive	Yes	Yes
	Possible Zika Positive	Yes	Yes
	Negative	No	No
	Presumptive Other Flavivirus Positive	No	Yes

Specimens from Infants

Providers are also reminded that specimens need to be collected correctly from infants. Of the over 200 serum specimens collected from NYC infants and submitted for Zika IgM testing at PHL, about half have had visible hemolysis. Hemolysis can interfere with the test assay. For Zika IgM testing of infants, please collect a minimum of 3 mL whole blood through venipuncture to reduce the likelihood of hemolysis. Serum should be centrifuged and frozen as soon as possible after collection to maintain integrity of the specimen and optimize the chance of attaining an interpretable result.

For more information about Zika virus testing in NYC including guidance on which tests to order, where to obtain testing and interpretation of test results, please see (www.nyc.gov/zika/provider).

For questions about testing, or to discuss a case, please call **1-866-692-3641**. To follow up on laboratory reports, please call the PHL at **1-212-447-2864**.

We appreciate your continued diligence and cooperation as NYC responds to Zika virus.

Sincerely,



Jay K. Varma, MD

Deputy Commissioner, Division of Disease Control

New York City Department of Health and Mental Hygiene