



Commercially Available Zika Virus Diagnostic Assays: Considerations for Use

There are a number of commercially available Zika virus assays on the market today. Several have received Emergency Use Authorization (EUA) and others are available as Research Use Only (RUO) or Analyte Specific Reagents (ASR) requiring validation in laboratories to be used as a Laboratory Developed Test (LDT). With the introduction of these and other forthcoming Zika virus assays, public health can anticipate seeing increased testing in the private sector. While this is a welcome development, providing critically important increased laboratory capacity, public health laboratories and other public health partners should be aware of the following considerations.

Use of Zika Virus EUA Assays in the Private Sector

Follow EUA Labeling Instructions Exactly

FDA maintains that assays issued EUA must be performed exactly as intended in the Labeling Instructions. Modifications of any kind are not allowed. This includes addition of automated platforms or use on specimen types for which data were not included in the FDA submission.

Establish Strategies to Ensure IgM Antibody Testing

As of August 9, 2016 Nucleic Acid Amplification Testing (NAAT) is the only commercially available EUA test method for Zika virus. Commercially available antibody tests of any kind have not received EUA, making public health and select Department of Defense laboratories the only source of antibody testing in the US. This gap in testing capability within the private sector may result in patients with negative PCR results failing to receive IgM antibody testing and if necessary Plaque Reduction Neutralization Testing (PRNT) in accordance with CDC's testing algorithm. Because it is recommended that all specimens from Zika suspects with a negative Zika NAAT result receive IgM antibody testing, health departments must work with their providers and clinical and commercial laboratories to establish a mechanism to ensure that antibody testing is ordered and performed at the jurisdictional Public Health Laboratory on patients that meet the criteria for testing.

In a [Health Alert Network message](#) distributed on June 21, CDC advised providers requesting molecular testing (e.g. NAAT) for Zika virus infection from a clinical or commercial testing laboratory to retain and store (refrigerate at 2-8°C) an aliquot of the patient's serum for subsequent Zika IgM ELISA testing if the rRT-PCR is negative. If a retained specimen is not available or was not collected within the appropriate time frame for antibody testing, another specimen must be collected.

Be Aware of Specimen Type Limitations

NAATs available under EUA have been approved for use on varying specimen types. Public Health Laboratories and partners should be aware of these differences and limitations specimen type may have on assay performance. For example, urine may not be an approved specimen type on all EUA assays while data have shown that Zika virus can be detected up to 7 days longer in urine than serum.

Develop mechanisms to ensure that your providers are aware of which specimen types can be tested using the various commercially available assays and any performance limitations that may imply.

Understand Potential Reporting Gaps

Increased testing in the private sector can result in lack of or delayed reporting to appropriate health jurisdictions and/or inadequate demographic data included with reports requiring more extensive follow-up on identified cases.

Suggested Actions

In light of these potential gaps public health laboratories in collaboration with other jurisdictional partners should consider taking the following actions:

- Be aware of what is currently available. Check FDA's [website](#) frequently for new EUAs or updates to existing EUAs. APHL has developed a [table](#) summarizing the features of commercially available EUA Zika assays.
- Work with epidemiologists in your jurisdiction to develop fact sheets for providers likely to utilize commercial assays that describe any limitations associated with the assays, approved specimen types and procedures for assuring timely access to serology testing.
- Ensure that providers and laboratories using commercially available Zika diagnostics are aware of reporting requirements for Zika cases including demographic data that are required for reporting. Consider distributing a form or checklist to aid in comprehensive data collection.
- Where possible and appropriate, work with clinical and commercial laboratories to facilitate reporting of positive results as well as submission of specimens for additional testing when warranted.

Use of Zika Virus LDTs in the Private Sector

APHL and CDC have been made aware of utilization of LDTs for the identification of Zika virus infection in some clinical laboratories. FDA does not condone use of LDT's for the diagnosis of Zika Virus. Public Health Laboratories should discourage use of these assays by clinical and commercial laboratories. Public Health Laboratories should consider their role in confirming the results of any Zika assay that does not have EUA.