VDH/DCLS Guide to Interpreting Zika Virus Test Results

Test Type	Test Result	Lab Interpretation[1]	Caveats/Comments	Pregnancy Registry Eligibility[2]
Zika PCR	Detected	Evidence of recent infection with Zika virus		Yes
Zika PCR	Not detected	No evidence of recent infection with Zika virus by RT-PCR	If collected >7 days after onset of symptoms, virus may have declined below detectable levels. Serology should be performed.	No
Zika IgM antibody only	Positive	Presumptive Positive: Serological evidence of possible recent Zika virus infection identified by Zika MAC-ELISA. Additional testing is required.	Specimen will be forwarded to CDC	Further determination by PRNT, if available
Zika IgM antibody only	Equivocal	Zika MAC-ELISA results were equivocal for the presence of anti-Zika virus antibodies. This result should not be considered negative or presumptive positive. Additional testing is required.	Specimen will be forwarded to CDC	Further determination by PRNT, if available
Zika IgM antibody only	Inconclusive	Inconclusive	Attributes of the sample interfered with test interpretation. Collect and submit specimen >7 days after onset of symptoms or last known exposure	No
Zika IgM antibody only (specimen collected ≥7 days after onset of symptoms or last known exposure)	Negative	Negative: No evidence of recent Zika virus infection detected by Zika MAC-ELISA. No additional testing is required.	If collected >12 weeks after exposure, IgM antibodies may have waned.	No
Zika IgM antibody only (specimen collected <7 days after onset of symptoms or last known exposure)	Negative	Negative: No evidence of recent Zika virus infection detected by Zika MAC-ELISA. This result reflects testing performed during the acute phase of illness. Submit a sample collected >7 days post symptom onset for additional testing.	If collected <7 days after onset (or last date of potential exposure if asymptomatic), IgM antibodies may not yet have reached detectable levels.	No
Plaque-reduction neutralizing antibody test (PRNT)	Zika PRNT titer ≥10 & dengue or other flavivirus PRNT titer <10	Evidence of recent infection with Zika virus		Yes
Plaque-reduction neutralizing antibody test (PRNT)	Zika PRNT titer <10 & Dengue or other flavivirus PRNT titer ≥10	Evidence of recent infection with dengue virus (or other flavivirus)		No
Plaque-reduction neutralizing antibody test (PRNT)	Zika PRNT titer ≥10 & dengue or other flavivirus PRNT titer ≥10	Evidence of recent infection with flavivirus, unspecified		Yes

[1]Virginia's Division of Consolidated Laboratory Services (DCLS) is using the Zika MAC-ELISA (for the detection of Zika virus IgM antibodies in serum and cerebral spinal fluid) and the Trioplex Real-time RT-PCR Assay (for RNA detection of Zika virus, chikungunya virus and dengue virus in serum and urine (Zika only) under FDA's Emergency Use Authorization (EUA). FDA also issued an EUA to authorize emergency use of Focus Diagnostics, Inc.'s Zika Virus RNA Qualitative Real-Time RT-PCR test (for RNA detection of Zika virus in serum). Fact sheets for healthcare providers, patients, and pregnant patients are available on FDA's website at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm#zika.

[2]CDC's pregnancy registry was established to collect information about Zika virus infection during pregnancy and congenital Zika virus infection. Persons eligible for the registry are: 1) Pregnant women in the US with laboratory evidence of Zika virus infection (positive or inconclusive test results (i.e., evidence of recent flavivirus infection where Zika virus disease cannot be ruled-out), regardless of whether they have symptoms) and prenatally or perinatally exposed infants born to these women; 2) Infants with laboratory evidence of congenital Zika virus infection (positive or inconclusive test results, regardless of whether they have symptoms) and their mothers. For more information, see CDC's Pregnancy Registry website at: http://www.cdc.gov/zika/hc-providers/registry.html.