CDC's Response to Zika

TABLE 1. Interpretation of results¹ of nucleic acid and antibody^{2,3} testing for suspected Zika virus infection — United States (including US territories), 2017

| Zika NAT (serum)⁴ | Zika NAT (urine)⁴ | Zika virus IgM⁵ | Zika virus PRNT | Dengue virus PRNT | Interpretation and recommendations |
|--|------------------------------|---|---|-------------------|---|
| Positive | Positive | Any result | Not indicated | Not indicated | Acute Zika virus infection |
| Negative | Positive | Positive | Not indicated | Not indicated | Acute Zika virus infection |
| Negative | Positive | Negative | Not indicated | Not indicated | Suggests acute Zika virus infection Repeat testing on original urine specimen If repeat NAT result is positive, interpret as evidence of acute Zika virus infection If repeat NAT result is negative, repeat Zika virus IgM antibody testing on a serum specimen collected ≥2 weeks after symptom onset or possible exposure or specimen collection date If repeat IgM antibody result is not positive, interpret as evidence of acute Zika virus infection If repeat IgM antibody result is not positive, interpret as no evidence of Zika virus infection |
| Positive | Negative or not performed | Positive | Not indicated | Not indicated | Acute Zika virus infection |
| Positive | Negative or not performed | Negative | Not indicated | Not indicated | Suggests acute Zika virus infection Repeat testing on original serum specimen If repeat NAT result is positive, interpret as evidence of acute Zika virus infection If repeat NAT result is negative, repeat Zika virus IgM antibody testing on a serum specimen collected ≥2 weeks after symptom onset or possible exposure or specimen collection date If repeat IgM antibody result is positive, ⁶ interpret as evidence of acute Zika virus infection If repeat IgM antibody result is not positive, interpret as no evidence of Zika virus infection |
| Negative | Negative or not performed | Any non-negative result ⁷ | ≥10 | <10 | Zika virus infection; timing of infection cannot be determined. For persons without prior Zika virus exposure, a positive IgM result represents recent Zika virus infection |
| Negative | Negative or not performed | Any non-negative result ⁷ | ≥10 | ≥10 | Flavivirus infection; specific virus cannot be identified; timing of infection cannot be determined • For persons without prior Zika virus exposure, a positive IgM result represents recent unspecified flavivirus infection |
| Negative | Negative or not performed | Any non-negative result ⁷ | <10 | Any result | No evidence of Zika virus infection |
| For areas where PRNT is not recommended ³ | | | | | |
| Negative | Negative or not performed | Positive for Zika virus AND negative for dengue virus | Not performed because PRNT is not recommended | | Presumptive Zika virus infection; timing of infection cannot be determined [®] |
| Negative | Negative or not performed | Positive for Zika virus AND positive for dengue virus | Not performed because PRNT is not recommended | | Presumptive flavivirus infection; specific virus cannot be identified; timing of infection cannot be determined ⁸ |
| Negative | Negative or not performed | Equivocal (either or both assays) | Not performed because PRNT is not recommended | | Insufficient information for interpretation Consider repeat testing |
| Negative | Negative or not performed | Negative on both assays | Not performed because PRNT is not recommended | | No laboratory evidence of Zika virus infection |

Abbreviations: IgM = immunoglobulin M; NAT = nucleic acid test; PRNT = plaque reduction neutralization test.

1 Final interpretations of results of Zika virus tests should be performed after all testing is complete.

2 Serology test results that indicate flavivirus infection should be interpreted in the context of circulating flaviviruses.

3 Currently, PRNT confirmation is not routinely recommended for persons living in Puerto Rico.

4 Serum must be submitted for all persons tested for Zika virus infection; a urine specimen for Zika virus NAT testing should always be submitted concurrently with a serum specimen.

5 Dengue virus IgM antibody testing is recommended for symptomatic pregnant women, as well as for asymptomatic pregnant women residing in areas where PRNT confirmation is not recommended. For laboratory interpretation in the presence of dengue virus IgM results, refer to https://www.cdc.gov/dengue/clinicallab/ laboratory.thml.

6 Positive results include "positive," "presumptive Zika virus positive," or "possible Zika virus positive." These are examples of assay interpretations that might accompany test results; positive serology terminology varies by assay. For explanation of a specific interpretation, refer to the instructions for use for the specific

assay performed. Information on each assay can be found at https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm#zika under the "Labeling" for the specific assay.

7 Non-negative results include "positive," "equivocal," "presumptive positive," or "possible positive." These are examples of assay interpretations that might accompany test results; nonnegative serology terminology varies by assay. For explanation of a specific interpretation, refer to the instructions for use for the specific assay performed. Information on each assay can be found at https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm#zika under"Labeling" for the specific assay.

8 Zika virus IgM positive result is reported as "presumptive positive or flavivirus infection" to denote the need to perform confirmatory PRNT titers against Zika virus, dengue virus, and other flaviviruses to which the person might have been exposed to resolve potential false-positive results that might have been caused by cross-reactivity or nonspecific reactivity. In addition, ambiguous test results (e.g., inconclusive, equivocal, and indeterminate) that are not resolved by retesting also should have PRNT titers performed to rule out a false-positive result. However, PRNT confirmation is currently not nonshelve recommended for persons living in Puerto Rico.