Evaluation of the Zika IgM antibody capture enzyme-linked immunosorbent assay from the Centers for Disease Control and Prevention (CDC Zika MAC-ELISA) for diagnosis of Zika virus (ZIKV) infection during surveillance and outbreak scenarios

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Clinical diagnosis of Zika virus (ZIKV) infections is challenging because of its resemblance with other diseases. Furthermore, structural similarities between ZIKV and dengue virus (DENV) can result in cross-reactivity in serological tests. This study evaluated the accuracy of the CDC Zika MAC-ELISA assay in febrile patients with ZIKV and DENV infections, and in blood donors. To determine the assay sensitivity, we used sera from ZIKV RT-PCR-confirmed cases identified between May-Jul/2015 during a surveillance study for acute febrile illness in Salvador, Bahia (6 with acute- and 8 with paired acute- and convalescent-phase sera) and during an outbreak in Campo Formoso, Bahia, in Apr/2016 (7 acute- and 11 convalescent-phase sera, that were classified in early, intermediate, and late convalescence). To determine specificity, we used sera from DENV RT-PCR-confirmed patients (60 acute- and 60 paired convalescent-phase), and 23 blood donors, collected before ZIKV introduction in Brazil (2009–2011 and 2013, respectively). We excluded samples with inconclusive results from the analysis. Of the 183 tested samples, 173 (94.5%) presented a valid result. Overall sensitivity for acute-phase samples was 21.1% (4/19); 7.14% (1/14) for the surveillance samples (mean number of days post symptoms onset (DPSO): 2.2) and 60.0% (3/5) for the outbreak samples (mean DPSO: 5.6). Convalescent-phase sensitivity for the surveillance samples was 100% (8/8) (mean DPSO: 27) and for the outbreak samples obtained at early, intermediate and late convalescence were 66.7% (2/3) (mean DPSO: 52), 100% (2/2) (mean DPSO: 260), and 0.0% (0/2) (mean DPSO: 725), respectively. The assay specificity was 100% (59/59) and 96.5% (55/57) for acute- and convalescent-phase sera of dengue patients, and 100% (23/23) for blood donors. The assay had an optimal performance for early and intermediate convalescent-phase samples, consisting in an accurate method for Zika diagnosis during surveillance and outbreak investigations.