

Evaluation of the Commercially Available Three Dengue Rapid Diagnostic Test Kits for Diagnosis of Acute Dengue Virus Infection at the Point-of-Care Setting in Myanmar

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Abstract

Early and accurate diagnosis of dengue virus (DENV) infection is important and Rapid Diagnostic Test (RDT) Kits are using as point-of-care test to confirm dengue virus infection in Myanmar. A Hospital- and Laboratory-based descriptive study was conducted at 550-bedded Mandalay Children Hospital during the peak season of dengue infection in 2018. Acute phase serum samples were collected from 202 dengue suspected patients to evaluate the efficacy of RDT Kits for diagnosis of DENV infection. Commercially available three RDT Kits ((i) CareUs Dengue Combo, Korea, (ii) Humasis Dengue Combo, Korea and (iii) Wongfu Dengue Combo Kit, China) that detect dengue NS-1 Antigen, IgM and IgG Antibody were evaluated against WHO-based reference standard tests such as virus genome detection by RT-PCR, IgM and IgG ELISA. 140/202 patients (69.3%) could be definitely confirmed as DENV infection. All four serotypes of dengue viruses (57 DENV-1, 7 DENV-2, 6 DENV-3 and 10 DENV-4) were identified from 80 dengue confirmed patients and DENV-1 was dominant serotype in 2018. Combining the NS-1 antigen and IgM antibody results from the CareUs Dengue Combo Kit gave the best sensitivity (92.1%, 95% CI 86.4% - 96.0%) and specificity (75.8%, 95%CI 63.3%-85.8%) and provided the best sensitivity in patients presenting at different times after onset of fever. CareUs Dengue Combo Kit results correctly identified 80.3% and only 20.3% of the primary and secondary infection respectively. But for Humasis Dengue Combo Kit and Wongfu Combo Kit correctly classified 78.9% and 74.6% of primary infection and 65.2% and 63.8% of secondary infection, respectively. In conclusion, this study provided the evidence for usefulness of commercially available RDT Kits at the point-of-care setting for diagnosis of acute dengue infection.