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A comparative field study of novel commercial Antigen Detection Enzyme-Linked Immunosorbent Assay (ELISA) with Reverse Transcription Polymerase Chain Reaction (RT-PCR) assay for early definitive laboratory diagnosis of dengue viral infection in Sri Lanka

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Dengue is an important mosquito borne viral infection in South East Asia. Early definitive laboratory diagnosis of infection would help in management of patients and reducing the case fatality rate. The objective of this study was to determine the accuracy of novel commercial Antigen Detection Enzyme-Linked Immunosorbent Assay (ELISA) using Non Structural protein 1 (NS1) (Bio Rad) for early definitive laboratory diagnosis of dengue infection under field conditions in Sri Lanka. A panel of acute serum samples collected from 99 patients clinically suspected of having dengue fever (≤5 days) warded at the North Colombo Teaching Hospital, Ragama, Sri Lanka were used for the present study. Serum samples were tested using Antigen Detection ELISA according to the method described by the manufacturer. Results of this novel assay were compared with RT-PCR assay using Chi-squared test. Two variables were analyzed at a 95% confidence interval and P value <0.05 was considered as significant. Twenty two and 65 patients were positive and negative, respectively, for dengue infection by both assays. Nine patients were confirmed as dengue by the Antigen Detection ELISA only. Three patients were confirmed as dengue by RT-PCR assay only. Antigen detection ELISA showed 88% of agreement with the RT-PCR assay. According to the Chi-squared test, there was no significant difference between the two assays for early diagnosis of dengue infection ($\chi 2=46$, P=0.0000). Novel commercial Antigen Detection ELISA kit (Bio-Rad 72830) can be used for early definitive laboratory diagnosis of dengue infection in Sri Lanka under field conditions.

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