Comparison of the performance of a commercial real-time RT-PCR kit with an in-house PCR assay for dengue detection

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ABSTRACT

Introduction: Introduction: Dengue virus (DENV) is the etiological agent of dengue fever. The global statistic indicates a steady trend of dengue pandemic with the highest cases recorded in 2023, affecting more than 80 countries. Rapid confirmation of dengue infection is crucial for timely clinical management. In virology unit Institute for Medical Research (IMR), an in-house ZDC-DENV qRT-PCR test was used to differentiate dengue from other arboviruses infection, without serotyping ability. Concurrently, VIASURE Dengue Virus Real Time PCR Detection Kit (Certest Biotec) was also utilized in the lab to detect as well as serotype DENV. Hence, the aim of this study is to compare the interrater reliability of VIASURE kit against in-house ZDC-DENV qRT-PCR for dengue detection as an alternative standalone assay. **Materials and Methods:** This is a retrospective, single center diagnostic test evaluation study. For data collection, all nationwide samples from September 2023 until January 2024 received in IMR for routine dengue diagnostic qRT-PCR testing were selected. A total of 463 samples, which includes plasma, serum, CSF and tissues samples were tested using VIASURE kit and ZDC-DENV qRT-PCR, respectively. Descriptive statistics and Cohen's κ were used to analyze the data and to determine the agreement between these two diagnostic tests. **Results:** There was a significant agreement between VIASURE kit and ZDC-DENV qRT-PCR, $p<0.001$. A kappa (κ) of 0.904 represents an almost perfect agreement between the two diagnostic tests, $\kappa = 0.904$ (95% CI: 0.866 to 0.943). **Conclusion:** Analyses of data for dengue detection using commercially available VIASURE kit and our in-house ZDC-DENV qRT-PCR showed an agreement in terms of dengue detection. This indicates the reliability of the VIASURE kit as a diagnostic assay for detection and serotyping of DENV. However, testing on more samples and comparison against the gold standard method would provide more conclusive and reliable result.