

## COMPARATIVE EVALUATION OF RT-PCR KITS AVAILABLE IN SRI LANKA FOR DIAGNOSIS OF SARS-CoV-2

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Identifying the gene targets by real-time reverse transcriptase PCR (RT-PCR) is considered as the gold standard in diagnosis of severe acute respiratory syndrome coronavirus 2 (SARS CoV-2) infection. Although many commercial RT-PCR kits are currently used in Sri Lanka, analytical performance of these kits have not been investigated adequately. The current study aimed to evaluate the analytical performance of five commercially available COVID-19 RT-PCR kits that have been widely used in Sri Lankan clinical settings. The evaluation was carried out, using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel as the standard reference. The selected kits for this study were TaqPath™ COVID-19 CE-IVD RT-PCR kit, Real Star® SARS-CoV-2 RT-PCR kit, STANDARD-M nCoV Real-Time PCR kit, COVID-19 Real-Time PCR (HBRT-COVID-19) kit, AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR kit. SARS-Cov-2 positive (n=62) and negative respiratory samples (n=32) collected from symptomatic individuals and asymptomatic healthy individuals, respectively were used for the study. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and Cohen's kappa coefficient were analyzed. Based on pairwise t-test statistics, the comparison of Ct values for individual gene targets among the five commercial kits revealed heterogeneity ( $p < 0.05$ ). Discrepancies were observed between the manufacture declared value and tested values for sensitivity and specificity, while all the evaluated kits demonstrated an acceptable range of performance, with sensitivity and specificity both exceeding 90% and a near-perfect agreement value ( $> 0.81$ ) for the kappa coefficient. Among them, the TaqPath™ COVID-19 CE-IVD RT-PCR kit showed the highest sensitivity (98.4%), and inter-rater reliability (0.976). The HybriBio COVID-19 Real-Time PCR kit showed the lowest sensitivity (91.9%), specificity (93.7%) and inter-rater reliability (0.838). Although the five RT-PCR kits exhibited varying sensitivity, specificity, and Ct values, it can be concluded that all of them are suitable for the routine diagnosis of COVID-19 as all values are above 90 %.

**Keywords:** COVID-19 diagnosis, Ct value, SARS-CoV-2 RT-PCR, Sensitivity, Specificity