Comparison of Real-Q 2019-nCoV and DaAn Gene 2019-nCoV polymerase chain reaction assays for the detection of SARS-CoV-2

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Abstract

Background: Various nucleic acid amplification assays for the diagnosis of SARS-CoV-2 infection have been developed, and there is a need to assess their test performance relative to one another. The aim of this study was to compare the performance characteristics of the Biosewoom Real-Q 2019-nCoV assay targeting the E and RdRP genes to DaAn Gene 2019-nCoV kit targeting the N gene and ORF1ab in the diagnosis of SARS-CoV-2.

Methods: We performed a diagnostic comparison study by testing nasopharyngeal samples for SARS-CoV-2 using the two reverse transcription polymerase chain reaction (RT-PCR) assays. Assay agreement was assessed by overall percent agreement, negative percent agreement, positive percent agreement, and Cohen's kappa coefficient.

Results: A total of 48 nasopharyngeal samples were tested using the two assays. One sample was invalid, and three showed inconclusive results with Real-Q; hence, 44 were included for the comparative analysis. Overall, percent agreement between the assays was 93.2% (95% CI 81.3%-98.6%), Positive percent agreement (PPA) was 86.4% (95% CI 65.1%-97.1%) and negative percent agreement (NPA) was 100% (95% CI 84.6%-100%). The kappa coefficient was 0.86 (95% CI 0.72-1.01). Three samples (6.8%) were positive with DaAn gene kit and negative with Real-Q. The fluorescence intensity for Real-Q reporter dyes was low.

Conclusion: The two kits showed high levels of concordance in their detection of SARS-CoV-2 despite having different gene targets. The Biosewoom kit can be improved through addressing the fluorescence intensity of the target dyes, and feedback was given to the manufacturer.