Original Article

Comparison of Two Real-time Polymerase Chain Reaction Assays for the Detection of Severe Acute Respiratory Syndrome-CoV-2 from Combined Nasopharyngeal-Throat Swabs

Oves Siddiqui, Vikas Manchanda, Abhishek Yadav, Tanu Sagar, Sanchita Tuteja, Nazia Nagi, Sonal Saxena
Department of Microbiology, Maulana Azad Medical College, New Delhi, India

Abstract

Context: In the absence of effective treatment or vaccine, the current strategy for the prevention of further transmission of severe acute respiratory syndrome (SARS) CoV-2 (COVID-19) infection is early diagnosis and isolation of cases. The diagnosis of SARS-CoV-2 is done by detecting viral RNA in the nasopharyngeal and throat swabs by real-time polymerase chain reaction (PCR). Many commercial assays are now available for performing the PCR assay. **Aims:** The aim was to evaluate the performance of the SD Biosensor nCoV real-time detection kit with the real-time PCR kit provided by the Indian Council of Medical Research-National Institute of Virology (ICMR-NIV), Pune (NIV Protocol). **Subjects and Methods:** A total of 253 pairs of nasopharyngeal-oropharyngeal swabs combined in a single viral transport medium were tested for viral RNA by both the protocols. The sensitivity and specificity of the SD Biosensor were calculated considering the ICMR-NIV kit as the gold standard. Matched pairs of recorded cycle threshold values (Ct values) were compared by Pearson's correlation coefficient. **Results:** Concordant COVID-19 negative and positive PCR results were reported for 113 and 77 samples, respectively. The SD Biosensor kit additionally detected 62 cases, which were found negative by the NIV protocol. In all discordant positive results by the SD Biosensor kit, the average Ct values were higher than the concordant positive results. A total of forty samples tested positive for E gene by SD Biosensor and having Ct values <25 had 100% concordance with NIV protocol results and 39 samples tested positive for E gene by SD Biosensor having Ct value >32 were all found negative by the NIV protocol. **Conclusions:** The results highlight the need for careful evaluation of commercial kits before being deployed for screening of COVID-19 infections.

Keywords: COVID-19, molecular diagnostics, real-time polymerase chain reaction, severe acute respiratory syndrome-CoV-2, test comparison

Introduction

Coronaviruses are a large group of RNA viruses known to cause illnesses that may vary from insignificant respiratory infection like common cold[1] to severe diseases including severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS-CoV).[2,3] SARS-CoV caused an outbreak in 2003 that originated in China and spread to 37 countries causing 8098 cases and 775 deaths.[4,5] MERS was reported in Saudi Arabia in 2012 where it caused 1621 cases and 584 deaths.[6]

A novel strain of coronavirus was found responsible for a cluster of pneumonia cases in the 2nd week of December 2019 in Wuhan city, Hubei province of China, which was later named as SARS-Cov-2.[7-9] Very quickly after its appearance, the virus crossed the international borders and reached countries such as Italy, Iran, Spain, Germany and the USA. Within 3 months of

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Address for correspondence: Dr. Oves Siddiqui, 138 First Floor Pathology Block, Maulana Azad Medical College, New Delhi, India.
E-mail: oves16@gmail.com

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