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Comparison of Abbot ID Now Method with Eurobioplex RT-PCR SARS-Cov-2 Multiplex Method for Detection of SARS-Cov-2 from Nasopharyngeal and Oropharyngeal Samples

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Abstract

Background: COVID 19 created an urgent demand for rapid diagnosis to encircle this pandemic and improve patient management. In this context, we evaluated the concordance of the ID NOW test compared to the Eurobioplex RT-PCR test in the rapid diagnosis of SARS-CoV-2. ***Methods:*** To evaluate the concordance of the assay at different viral loads, 154 positive samples were selected to represent the full range of Ct values observed on the Eurobioplex RT-PCR assay, ranging from 14 to 38 cycles. Positive concordance for the ID Now assay was calculating dusing Eurobioplex RT-PCR as the reference test. An additional 70 negative samples were selected to assess negative concordance. ***Results:*** Compared to Eurobioplex RT-PCR, the overall positive agreement was 79% with ID Now. Negative agreement was 100% for ID Now. ID Now showed 100% positive agreement for medium and high viral concentrations (Ct value <30). However, for Ct values >30, the positive agreement was 33.3% for ID Now. ***Conclusions:*** This study shows a major limitation of ID Now for specimens collected in universal transport media with lower viral concentrations. Further studies are necessary to evaluate the performance of ID Now for dry nasopharyngeal swabs (manufacturer's recommended method).

Keywords: COVID-19, RT-PCR, SARS-CoV-2, EurobioPlex, ID now.

INTRODUCTION

Coronavirus disease 2019 is an emerging viral zoonotic infectious disease caused by the SARS-CoV-2 strain of coronavirus. The most common symptoms are fever, cough, fatigue and respiratory discomfort. In the most severe forms, the onset of acute respiratory distress syndrome can lead to death, especially in people who are more fragile because of their age or in case of comorbidities. The most widely used diagnostic test is the detection of the virus genome by RT-PCR (reverse transcription gene amplification) on nasopharyngeal or oropharyngeal swabs. The first quantitative RT-PCR test for the detection of SARS-CoV2 was designed and distributed in January 2020 by the World Health Organization (WHO) [1]. In Morocco, different RT-PCR test kits have been used to control the pandemic however these tests have too slow response time which makes the possibility of containing the pandemic is difficult.

In response to this problem, the international community is mobilizing to accelerate the generation of knowledge about this virus, the disease it causes (Covid-19), and the means of diagnosis, treatment and prevention. Different rapid tests for SARS-CoV-2 have been approved by the Emergency Use Authorization (EUA) and the US Food and Drug Administration (FDA), such as Xpert Xpress SARS-CoV-2 (Cepheid, Sunnyvale, CA) and ID Now SARS-CoV-2 (Abbott, Chicago, IL) [2]. These tests provide results in 13 minutes and 45 minutes respectively [2]. The objective of our work is to evaluate the concordance of the ID NOW test compared to the Eurobioplex RT-PCR test in the rapid diagnosis of SARS-CoV-2.

METHODS

This is a retrospective study performed at the Mohammed V Military Training Hospital in Rabat. A total of 224 nasopharyngeal and oropharyngeal swabs

collected in 3 ml of universal transport medium (UTM; Becton Dickinson and Co., Franklin Lakes, NJ) were included. The samples were collected from November 01 to November 20, 2020 and included 224 adults. We worked on RNA extracts and frozen samples of SARS-Cov-2 virus stored in our laboratory.

To evaluate the performance of the assay at different viral loads, 154 positive samples were selected to represent the full range of Ct values observed on the Eurobioplex RT-PCR SARS-coV-2 multiplex assay (eurobio scientific, France), ranging from 14 to 38 cycles. Positive concordance for the ID Now assay was calculating using Eurobioplex RT-PCR as the reference test. An additional 70 negative samples were selected to assess negative concordance.

The EurobioPlex assay uses RT-PCR to amplify and detect three viral targets: RdRp1, RdRp2 and N gene. The sample is positive if the Ct <40 of three targets.

The ID Now assay uses proprietary isothermal nucleic acid amplification technology for qualitative detection of the SARS-CoV-2 RdRp gene using fluorescent probes. The result provided is qualitative, positive, negative or invalid.

Data collection was performed using Microsoft® Excel® 2007 spreadsheet software, and statistical analysis of the data was performed using SPSS software (IBM SPSS Statistics for Windows, version 13.0). Agreement was calculated using the inter-raté agreement (kappa) method. This study does not constitute human research requiring Institutional Review Board approval.

RESULTS

Of the 224 patient samples, male sex was predominant in 64%.The majority of positive and negative samples were from men (Table 1). The mean age was 49 years for both positive and negative samples.

Table 1: Sex distribution of Ct values

Eurobioplex Ct Category	Male (%)	Female (%)
Total positive	94 (62%)	60 (38%)
Low Ct (>30)	35 (74.5%)	12 (25.5%)
Medium Ct (20-30)	38 (57%)	29 (43%)
High Ct (<20)	21 (52.5%)	19 (47.5%)
Negative	50 (71.4%)	20 (28.6%)

Abbott ID Now test results Compared to Eurobioplex RT-PCR Assay, overall positive agreement with ID Now was 79% (95% confidence interval (CI): 61 - 91%) . The negative concordance was 100% (95% CI 85.6 - 100%). ID Now Assay showed 100% positive agreement for medium and high viral concentrations, defined as a Ct value <30. However, for Ct values >30, the positive agreement for ID Now was 33.3% (95% CI 21.2 - 56.8%) (Table 2).

Table 2: Agreement of positive and negative Abbot ID Now SARS-coV-2 results with Eurobioplex RT-PCR SARS-coV-2.

Eurobioplex Ct Category	ID now(%,95%CI)
Total positive	122 (79, 61-91)
Low Ct (>30)	17 (33.3, 21.2-56.8)
Medium Ct (20-30)	68 (100, 90.1-100)
High Ct (<20)	37 (100, 80.5-100)
Negative	70 (100, 85.6-100)

DISCUSSION

COVID 19 created an urgent demand for rapid diagnosis to encircle this pandemic and improve patient management. In response to this demand for rapid diagnosis, U.S. scientific societies have authorized multiple rapid molecular tests, some of which have been used at the point of care. However, there is little data on the evaluation of the performance of these tests compared to standard tests at the national and international level [3-6].

In our study, the ID Now assay showed an overall level of agreement of 79% with the Eurobioplex RT-PCR assay over the entire range of C t values tested, including low-level positives and negatives. These results are similar to those published by Stephan Mh *et al*. [2]. Reporting an overall agreement rate of 78.7% between the ID now test and the centres for disease Control and prevention (CDC) test. The ID now test also showed a high level of agreement in the range of 100% for samples with C t values <30 and negative samples but a lower agreement in the range of 33.3% for low positive samples with Ct values >30. Our data are similar to those reported in many studies [2, 7, 8]. Our results further highlight an important limitation of ID Now for low-level positive results. While all studies evaluated nasopharyngeal swabs eluted in transport

media, it is important to note that the Emergency Use Authorization (EUA) for ID NOW was recently updated to remove the indication for swabs in transport media [9]. Our data support that the EUA has been appropriately modified, as samples may become overly diluted in Viral Transport Medium (VTM) and low-level positives may falsely test negative.

Unlike routine tests, ID Now offers fast response times and easy access to services for better patient care. The test analyzes only one sample at a time, with results available in less than 13 minutes. However, concerns remain regarding test performance, quality management, and safety in the POC setting [2]. Studies of molecular POC testing for influenza and respiratory syncytial virus have shown promising results, but have also highlighted some of these concerns [10-13]. With the emergence and rapid spread of this virus and thus its variant, widespread use of POC testing has become a necessity despite the risk of contamination and false positives when these tests are performed outside of a controlled environment and by untrained laboratory personnel.

Limitations

Limitations of this study were the small number of samples; the evaluation of ID Now was performed from samples in transport media and the use of the EurbioPlex RT-PCR assay as a reference test.

CONCLUSION

ID now has shown very low positivity rates for specimens collected in viral transport media or universal media with low viral load. An evaluation of the performance of ID NOW using dry nasopharyngeal swabs (manufacturer's recommended method) versus swabs collected in viral transport media will be required.

Competing Interests: The authors declare no competing interest.

Author Contributions

Elmostafa Benaissa has been involved in drafting in the manuscript, Amal Zouaoui has revising the manuscript and Rachid Abi has given final approval of the version to be published.

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