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Comparative Evaluation of the ID NOW™ Test (Abott) and RT-PCR for the Detection of the SARS-CoV-2 Genome in Travellers

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Abstract: *Introduction*: The persistence of the COVID-19 pandemic, which has become a global public health problem, means that the implementation of effective and affordable diagnostic strategies is essential, particularly in developing countries, to contain the disease. Rapid, reliable and inexpensive molecular or antigenic tests enable early detection of cases and rapid clinical management. The method based on reverse transcription-polymerase chain reaction (RT-PCR) is the benchmark for diagnosing SARS-CoV-2 infections. However, this method requires highly qualified human resources, complex equipment, consumables and reagents that are usually expensive and imported from developed countries. Given these technical and financial constraints and the limited capacity of molecular platforms in developing countries, point-of-care can be considered a very good alternative. The aim of this study was to evaluate the performance of the ID NOW™ COVID-19 test for the detection of SARS-COV-2 from nasopharyngeal swab samples collected in tubes containing viral transport medium compared with RT-PCR. *Method*: The evaluation was carried out on 59 travellers from whom a nasopharyngeal swab was taken in 3 ml of viral transport medium (VTM). A swab from the ID-NOW kit was dipped into each sample and then deposited in the sample recipient in order to assess the performance of the ID-NOW test compared with RT-PCR. *Results*: In our study, we found a sensitivity of 92.6% (23/25) and a specificity of 100%. However, 2 false negatives were found with samples that had CT values of 36. No cross-contamination between samples was observed in this study. *Conclusion*: Our data showed that the ID NOW™ COVID-19 test would be an excellent tool for screening suspected cases in clinical departments.

Keywords: SARS-CoV-2, COVID-19, ID-NOW, RT-PCR

1. Introduction

The COVID-19 pandemic, caused by SARS-CoV-2, which appeared in China in December 2019, is a real public health problem [1]. Senegal confirmed its first case of COVID-19 on 02 March 2020 [2]. Since then, several strategies have been deployed with the increasing number of cases to control the disease. Early detection of SARS-CoV-2 is an essential means of controlling the progression of the pandemic. The rapid spread of SARS-CoV-2 in infected patients presents a real diagnostic challenge. A rapid, reliable and inexpensive diagnostic method is essential to effectively control the progression of the COVID-19 pandemic, particularly in countries with limited resources. The method based on reverse transcription - polymerase chain reaction (RT-PCR) from samples obtained by nasopharyngeal swab is the gold standard for diagnosing SARS-CoV-2 infection [3]. Molecular tests such as RT-PCR are very expensive, require complex equipment, skilled human resources and very long analysis

times. Because of these technical and financial challenges and the limited capacity of molecular RT-PCR platforms in developing countries, point-of-care testing can be considered a good alternative to overcome these limitations.

The ID NOW™ COVID-19 assay (Abbott Molecular Diagnostics, Des Plaines, IL, USA) is a rapid, highly sensitive and easy-to-use molecular diagnostic tool for the early detection of SARS-CoV-2 [4, 5]. This automated test is based on isothermal amplification technology. It enables qualitative detection of specific regions of the SARS-CoV-2 genome by targeting the *RdRp* gene, with an estimated detection limit of 125 genome equivalents/ml, according to the manufacturer. Fluorescently labelled molecular beacons are used to specifically identify each of the amplified RNA targets, including an internal control. ID NOW provide rapid results from samples obtained by swabbing the upper respiratory tract (nose, nasopharynx, etc.) with or without a virus transport medium [6]. This easy-to-perform test gives a result (negative or positive) within 20 minutes at most [7, 8]. The aim of this study was to evaluate the performance of the ID NOW™ COVID-19 test compared with multiplex RT-PCR for the detection of COVID-19 from nasopharyngeal swabs.

2. Methodology

In this study, we evaluated the performance of the ID NOW™ COVID-19 test using a series of 59 samples received at the molecular biology unit of the National Public Health Laboratory in Thies. The results were then compared to the reference method. The nasopharyngeal swab samples came from 59 travellers who had come to the laboratory for an RT-PCR test for COVID-19. The swabs were dipped into a tube containing virus transport medium (VTM) and handled on the same day. Residual samples were stored at -80°C. As this was a retrospective study to evaluate the performance of the ID-NOW point of care, we were unable to obtain free and informed consent from the participants.

Screening for COVID-19 was carried out by the multiplex RT-PCR method using the Allplex ™ SARS-CoV-2 Assay kit (Seegene, South Korea) at the National Public Health Laboratory in Thies, Senegal. This test simultaneously amplifies and detects 4 SARS-CoV-2 specific genes in a single tube. The test detects the *RdRP, S* and *N* genes specific to SARS-CoV-2, and the *E* gene for all sarbecoviruses, including SARS-CoV-2. The exogenous internal control supplied with the kit was added to the sample during extraction to monitor the whole process sampling, genome extraction and to check for any inhibition of PCR. Real-time PCR was performed on the ABI 7500 Fast DX automated platform (Applied Biosystems, USA) and the target genes *RdRP/S*, SARS-CoV-2-specific *N*, the *E* gene and the internal control were detected in the ROX, Cy5, FAM, HEX and VIC canals respectively. The manipulations were carried out in suitable and certified biosafety cabinet by trained personnel. The viral genome was isolated using 140 µl of nasopharyngeal samples by the QIAMP viral RNA kit (Qiagen GmbH, Germany) according to the supplier's instructions. A final volume of 10 µl of the eluate was then used for the assay. For the amplification, briefly, a master mix of 5 µl of MOM, 5 µl of buffer and 5 µl of RNase-free water was mixed. Then 15 µl of master mix was dispensed into each well of the plate. Subsequently 5 µl of sample, 5 µl of positive control or 5 µl of RNase-free water (for the negative control) were added to the corresponding wells of the PCR plate. Plates were then centrifuged at 2500 rpm for 3 to s and analysed using an ABI 7500 fast Dx real-time RT-PCR machine [9]. Results were considered as positive if viral RNA was detected at threshold cycle (Ct) values ≤ 35 and as negative at Ct values > 38. Positive, negative and internal controls were used for quality control.

For statistical tests we chose RT-PCR as the reference method, and we determined sensitivity, specificity, positive and negative predictive values, overall agreement, percentage positive agreement (PPA) and percentage negative agreement (NPA) to assess performance of the point of care.

3. Results

In total 59 samples (25 positive and 34 negative samples with RT-PCR), tested by Abott ID Now SARS-CoV-2 RNA, positives samples were detected in 23 (38.98%) and 25 (42.37%) cases by POCT and RT-PCR assay respectively. The specificity was 100%. However, the sensitivity of the point of care was 92.6% with 2 samples being falsely negative out of the 25 samples that were tested positive with RT-PCR. The 2 false-negative samples had TC values in the range 36-40. Figure shows the distribution of RT-PCR results according to CT value and the proportion of false-negative results with ID-NOW.

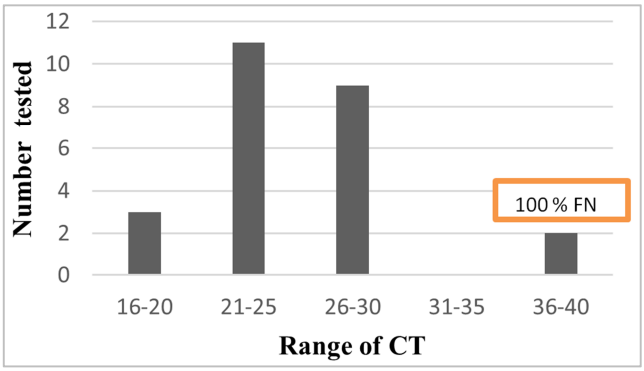

Figure 1. *Distribution of RT-PCR results according to CT value and false-negative results.*

The overall agreement between Allplex™ SARS-CoV-2 Real-Time and ID NOW™ COVID-19 assay was 96.6%. The percentage of positive categorisation agreement was 92% and the percentage of negative categorisation agreement was 100% The table 1 shows the results of the parameters used to compare the 2 methods. We alternated positive and negative samples at the time of analysis to assess cross-contamination evaluation period, but we did not observe any in the study.

Table 1. *Characteristics of ID NOW COVID-19 ASSAY compared to RT-PCR.*

RT-PCR (REFERENCE METHODE			
ID-NOW	**Positive**	**Negative**	**Total**
Positive	23	0	23
Negative	2	34	36
Total	25	34	59
Sensibility [IC 95%]	92,6 [76,6 to 97,9]		
Specificity [IC 95%]	100 [89,8 to 100]		
VPP	100 [86,7 to 100]		
VPN	94,4 [0.819 to 0.985]		
Positive% agreement (PPA) [IC 95%]	92 [75-97.8]		
Negative% agreement (NPA)	100 [89.9-100]		
Overall agreement	96.6 [88.5-99.1]		

4. Discussion

In this work, we evaluate the diagnostic performance of the ID NOW COVID-19 assay on series of 59 travellers presenting to the National Public Health Laboratory, Thies, Senegal. Accurate, rapid and high-quality diagnostic tests are the key to effectively controlling and limiting the spread of an epidemic. The ID NOW COVID-19 test can provide positive results within 5 to 13 minutes and negative results within 13 to 20 minutes from dry nasal swabs [7, 8]. The manufacturer has recommended that samples taken from the VTM are no longer acceptable for the ID NOW COVID-19 test, due to the lower sensitivity [7]. In our study, we achieved sensitivity (92.6%) by testing residual nasopharyngeal swab samples from VTM with ID NOW ™ COVID-19 assay. *Mitchell SL et al* carried out a similar study and found a much lower sensitivity of 71.7% [6]. Another study reported an improved sensitivity from 48% to 64% when the nasopharyngeal swab in the VTM was used in place of the dry swab [10]. However, in our series, we had 2 samples that were detected as false negatives with ID NOW assay. These 2 samples were weakly positive with Ct values between 36 and 40 (figure 1). A Ct value ≥ 36 could be considered as a non-contagious threshold or associated with a low risk of contamination. The estimated probability of virus recovery from samples with a Ct > 35 was 8.3% (95% CI: 2.8%-18.4%) [11]. RT-PCR test results are presented as threshold cycle (Ct) values, corresponding to the number of cycles required for the fluorescent signal to cross the threshold. Ct values are inversely correlated with SARS-CoV-2 viral load. The lower the Ct value, the higher the viral load, which generally corresponds to a high risk of infection [12]. A high Ct value corresponds to a low viral load [6] and a lower risk of infection. However, a low viral load may be due to an incubation period or convalescence phase, or to multiplication of the virus in other parts of the body [13]. Similarly, other studies also reported the inability to culture virus from cases with high C*T* values [14]. Evaluation of NOW ID using residual nasopharyngeal swab samples in VTM stored at -80°C showed that the test performed very well for moderately and strongly positive samples, but that its sensitivity was significantly reduced for Ct values ≥ 36. We were unable to evaluate the device on nasopharyngeal swab samples. The limitations of our study were the small number of samples tested and the absence of a simultaneous RT-PCR test on the same thawed samples.

5. Conclusion

In this study we aimed to evaluate the ID NOW™ COVID-19 test. We found a specificity of 100% and a sensitivity of 92.6%. We noted that there were 2 samples tested falsely negative with point-of-care when they were weakly positive with RT-PCR. Overall agreement was 96.6%. The percentage of agreement for positive categorisation was 92% and the percentage of agreement for negative categorisation was 100%. No cross-contamination was observed during the study. In the light of these results, it can be said that the ID NOW™ COVID-19 performs well for strongly to moderately positive samples (CT ≤ 36). Therefore, the ID NOW™ COVID-19 test would not be optimal for screening travellers for COVID-19 due to false negatives for low-positive samples with CT values between 36 and 40, but would be an excellent tool for screening suspected cases in clinical departments.

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Ethical Approval

Not applicable.

Declaration of Competing Interests

The authors declare no competing interests.

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