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ID NOW: A NAAT System Solution for the Rapid and Accurate Detection of SARS-CoV-2 with VTM Sampling †

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Abstract: ID NOW™ COVID-19 is a rapid molecular test for the detection of SARS-CoV-2. According to its instructions for use, this point-of-care test should be performed on dry nasopharyngeal swab (NPS) specimens. However, this method completely consumes the swab, with the limitation that additional analyses cannot be performed if required. The aim of this work was to evaluate the analytical performance of the ID NOW™ COVID-19 using NPS sampled on a viral transport medium. When compared to a reference RT-PCR, the positive and negative percent agreement was 86% and 100%, respectively. False negatives were associated with high RT-PCR Ct values.

Keywords: point-of-care; SARS-CoV-2; rapid diagnostic

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1. Introduction

A real-time polymerase chain reaction (RT-PCR), the gold standard method for viral RNA identification, is highly effective. However, it can be time-consuming and requires specialized equipment and operator training. In some situations, a long time to result is not suitable for patient management, such as in emergency departments or for controlling airplane traveler infections during a pandemic.

Point-of-care (POC) tests based on RT-PCR or other nucleic acid amplification technologies are growing exponentially for the detection of human viral infections. Lower costs and developed technologies have had a real impact on viral diagnostics and patient management, not only because these easy-to-use assay kits allow for the decentralization of testing but, most importantly, because of the reduction in the sample-to-answer turnaround time. The COVID-19 pandemic over the last few years has provided living proof of this. Such systems have great potential for the diagnosis of SARS-CoV-2 or other viruses, especially in settings with limited resources or where PCR is not available.

The ID NOW™ COVID-19 assay was developed at the beginning of the pandemic and has been implemented in several countries. According to the manufacturer, the ID NOW™ COVID-19 should be performed on dry nasopharyngeal swabs (NPS) with the swab entirely consumed. A second swab is required in case of invalid results or if further analysis is required.

In the present study, we aimed to assess the analytical performance of the ID NOW™ COVID-19 using NPS sampled on viral transport media (VTM) compared to the reference (RT-PCR).

2. Materials and Methods

This study was conducted at the Molecular Pathology Unit of the SYNLAB Central Laboratory, Lisbon, Portugal. NPS were collected in the VTM between 4 August and

9 September 2021 from hospitals (emergency room, urgent care, and hospitalized patients) and community assessment centers (AC) and were sent to the laboratory for SARS-CoV-2 molecular detection. All NPS were first processed for diagnosis using the gold standard RT-PCR assay (Alinity m SARS-CoV-2, Abbott Molecular, Des Plaines, IL, USA) and were then tested using the Abbott ID NOW device. All samples were tested within 24 h of collection.

The ID NOW™ COVID-19 assay is an isothermal nucleic acid amplification system that specifically detects a unique region of the *RdRp* gene segment with fluorescently labeled molecular beacons and includes an internal control. The assay was performed on 107 NPS according to the manufacturer's instructions with the following modification: the use of 100 µL of NPS collected in VTM. All data were analyzed using Microsoft Excel 2016 (Microsoft Corporation, Redmond, WA, USA) and SPSS software v.28, (IBM, Chicago, IL, USA). For all statistical analyses, a p-value < 0.05 was considered statistically significant.

3. Results

3.1. Sample Population Analyses

A total of 107 NPSs were analyzed, including 53 samples from COVID-19 AC and 54 from hospital centers, 45.8% (49/107) females and 54.2% (58/107) males, aged <1–94 years (median 33 years), representing 21.5% of children and 78.5% of adults. In the RT-PCR (Alinity m SARS-CoV-2 assay), 98/107 (91.6%) were positive, with a range of cycle threshold (Ct) values from 11.9 to 33.1 (median 19.1, interquartile range [IQR] 16.3–26.9).

3.2. Analytical Performance of ID NOW™ COVID-19 Assay

The ID NOW™ COVID-19 assay detected 84 (85.7%; 95 CI 77.9–91.7) of the 98 positive NPS, with the remaining 14 testing as false negatives (14.3%; 95% CI 8.8–23.2) (Table 1). None of the nine negative SARS-CoV-2 samples gave a false positive result, with the ID NOW™ COVID-19 assay, and no invalid results were found in all samples. The overall, positive, and negative percent agreements were 86.9%, 85.7%, and 100%, respectively (Table 1). The agreement analysis comparing the performance of ID NOW showed that the agreement was considered moderate with a Kappa value of 0.502 (50.2%).

Table 1. Performances of ID NOW™ COVID-19 using clinical specimens versus reference RT-PCR.

	Alinity m RT-PCR		**Total**	**Percent Agreement**
	Detected	**Not Detected**		
ID NOW				
Positive	84	0	84	85.7%
Negative	14	9	23	100%
Total	98	9	107	86.9%

When stratifying by Ct, all NPS with a Ct $\leq$ 25.0 by RT-PCR were positive for ID NOW™ COVID-19, whereas only 18 (56.3%) of the 32 NPS displaying a Ct > 25.0 were positive. Of the 14 false negatives, half had a Ct between 25.0 and 30.0, and the other 7 were between 30.0 and 33.0. False negative cases (ID NOW negative/RT-PCR positive) had a higher Ct, suggesting a lower viral load. The mean Ct for concordant positive samples was 19.6 (95% CI, 18.4–20.8), ranging from 11.9 to 33.1, with a standard deviation of 5.6. The mean Ct for discordant samples was 29.6 (95% CI, 28.3–30.9), ranging from 25.4 to 32.9, with a standard deviation of 2.4.

The estimated diagnostic performance of the ID NOW™ COVID-19 assay is shown in Table 2.

Table 2. Estimated diagnostic performance ID NOW™ COVID-19.

Measurement	Diagnostic Performance
Sensitivity	85.7% (84/98); CI: 77.9–91.7
Specificity	100% (9/9)
Positive predictive value (PPV)	100% (84/84)
Negative predictive value (NPV)	39.1% (9/23); CI: 21.1–59.4

CI—95% Confidence interval.

The sensitivity of the ID NOW assay for RT-PCR-positive samples with Ct values less than 30.0 was 92.9% (78/84 cases) (Table 3).

Table 3. Sensitivity of ID NOW™ COVID-19 by cycle threshold.

Ct Value	Positive ID NOW/Positive RT-PCR	Sensitivity (%)
≤25	66/66	100%
25–30	12/19	63.2%; CI: 40.8–82.2
30–33	6/13	46.2%; CI: 21.6–72.1
Ct > cut off *	0/0	NA

* Ct values [33.7–38.7]; CI—95% Confidence interval.

4. Discussion

The development of POC assays improved access to diagnostic testing during the COVID-19 pandemic, which was advertised as rapid, accurate, and relatively easy to perform. However, caution is required because POC diagnostics have both advantages and potential pitfalls, including low sensitivity, as their use is recommended only for acute infections; the increased risk of and inappropriate use of the diagnostic tests; the misinterpretation of test results; and lack of quality control procedures when the diagnostics are removed from the specialized, controlled diagnostic laboratory environment.

In this study, we evaluated NPS sampled in VTM for the presence of SARS-CoV-2 RNA and found good performance (86% sensitivity and 100% specificity), with an overall agreement of 86.9, which was higher than that obtained in other studies [1]. In addition, some invalids have been previously reported with the ID NOW™ COVID-19 [2,3]. However, no invalids were obtained in the present study, suggesting that the rate of the invalids of ID NOW™ COVID-19 was probably low. These performances are slightly lower than conventional RT-PCR but much higher than those of antigenic tests [4]. Therefore, the ID NOW™ COVID-19, when available, could probably replace rapid antigenic tests. The ID NOW device provides a rapid qualitative result (positive, negative, uninterpretable) that does not require specialized interpretation.

Overall, our results showed an NPV of 39.1%, with false negatives occurring for samples with Ct values > 25.0. However, the NPV was 100% for Ct values > 33.0. This is in line with the majority of studies [1,5,6]. Additionally, the lowest performance was obtained for samples displaying Ct values between 30– and 33 with a positive percent agreement of 46.2%, which is slightly higher than that observed in other studies [1,5]. False negatives on ID NOW appear to be strictly related to the viral load, based on the distribution of false negative Ct values obtained and confirmed by the higher limit of detection of Alinity m (100 copies/mL vs. 3225 copies/mL for ID NOW).

In this study, the ID NOW™ COVID-19 assay demonstrated good performance for the detection of SARS-CoV-2 strains compared to the Alinity m SARS-CoV-2 RT-PCR assay. Approximately one year after the declaration of a state of emergency, this test was implemented in some hospital centers (acute care) to guarantee a turnaround time of 2 h and in Portuguese airports to respond quickly to the control of infected passengers, especially in a situation of stopovers between flights. All discrepant and invalid results were confirmed by RT-PCR in the central laboratory. This method allowed us to obtain the quick and appropriate response needed to minimize SARS-CoV-2 transmission.

5. Conclusions

In the case of the ID NOW™ COVID-19 assay, the use of NPS sampled on VTM has the great advantage of allowing repeat testing on the same sample without a significant loss of sensitivity. However, as for other POC assays, the results of this high-speed assay should be interpreted in a clinical and epidemiological context. In our opinion, POC assays are a promising tool for screening acute medical admissions with urgency to ensure the prompt treatment of patients or minimize nosocomial transmission.

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Institutional Review Board Statement: Ethical review and approval were waived for this study since this study was carried out on surplus samples that were sent to the laboratory as part of the molecular diagnosis of SARS-CoV-2 and under no circumstances would the use of samples in this study jeopardize the diagnosis.

Informed Consent Statement: Patient consent was not required as surplus samples that arrived at the laboratory with a clinician's request to detect SARS-CoV-2 were used.

Data Availability Statement: Not applicable.

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Conflicts of Interest: The authors declare no conflict of interest. The manufacturer had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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