



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



Contents lists available at ScienceDirect

Diagnostic Microbiology and Infectious Disease

journal homepage: www.elsevier.com/locate/diagmicrobio

Implementation of the Abbott ID Now COVID-19 assay at a tertiary care center: a prospective pragmatic implementation study during the third wave of SARS-CoV-2 in Ontario

Vincent Deslandes^{a,b,c,*}, Eric Clark^{a,b,d}, Venkatesh Thiruganasambandamoorthy^{a,b,d}, Marc Desjardins^{a,b,c}

^a University of Ottawa, Ottawa, ON, Canada

^b The Ottawa Hospital Research Institute (OHRI), Ottawa, ON, Canada

^c Eastern Ontario Regional Laboratory Association (EORLA), Ottawa, ON, Canada

^d Department of Emergency Medicine, The Ottawa Hospital, Ottawa, ON, Canada

ARTICLE INFO

Article history:

Received 29 July 2021

Revised in revised form 30 October 2021

Accepted 21 November 2021

Available online 27 November 2021

Keywords:

ID Now

SARS-CoV-2

Rapid diagnostic

ABSTRACT

The Abbott ID Now COVID-19 assay is a point-of-care molecular diagnostic tool for the detection of SARS-CoV-2. We prospectively monitored implementation of the assay in a tertiary care hospital emergency department (ED) for the diagnosis of early symptomatic patients. A total of 269 paired nasopharyngeal swabs were tested in parallel with the ID Now and laboratory-based molecular methodologies, 191 of which met selection criteria for testing based on symptoms description and duration. Forty-six and 48 samples were positive for SARS-CoV-2 with the ID Now and reference molecular assays respectively. Percent positive and negative agreement were high (93.8% and 99.6% respectively), as were the sensitivity and specificity (93.8% and 99.5%). ID Now results were available 17.47 hours earlier than qRT-PCR. In symptomatic patients seen in ED within 7 to 10 days of symptoms onset, the ID Now COVID-19 assay allows for rapid and accurate detection of infection.

© 2021 Elsevier Inc. All rights reserved.

1. Introduction

As of May 2021, the SARS-CoV-2 pandemic had caused nearly 160 million cases worldwide, with cases reported in almost every country (WHO Coronavirus). Following a first wave of cases in North America in the first quarter of 2020, clinical microbiology laboratories faced numerous challenges ranging from securing appropriate test kits and consumables supplies to shortages in qualified laboratory technologists. During the second wave in the fall of 2020, laboratories were overwhelmed with test requests and interest grew for rapid, point-of-care (POC) assays for the detection of SARS-CoV-2 (Tasker-Health, 2020). Implementation of these assays has been slow in Ontario, possibly due to the discrepancy between public expectations that these tests can rule out SARS-CoV-2 infections or allow for relaxation of social distancing measures and the fact that these assays were approved by Health Canada primarily for the acute diagnosis in symptomatic individuals.

The ID Now is intended as a POC diagnostic device, and the ID Now COVID-19 assay allows for rapid isothermal molecular detection of the SARS-CoV-2 RNA-dependent RNA polymerase (RdRp) gene in symptomatic patients within 7 days of symptoms onset (Abbott). Previously published evaluations have reported positive percent agreement (PPA) ranging from 48 to 94.9% when compared to laboratory-based RT-PCR testing (Basu et al., 2020; Farfour et al., 2021; Harrington et al., 2020; Jin et al., 2020; Lee and Song, 2021; Lephart et al., 2021; Mitchell and George, 2020; Moore et al., 2020; Procop et al., 2021; Rhoads et al., 2020; Serei et al., 2021; Smithgall et al., 2020; Thwe and Ren, 2020; Tu et al., 2021; Tworek et al., 2021; Zhen et al., 2020). Discrepancies in published performance are likely a result of differences in sample types (anterior nasal or nasopharyngeal swabs), and most studies pre-date the FDA advisory warning on the reduced performance of the assay when swabs are transported in universal or viral transport media (Office of the Commissioner 2020). Only 2 of these were prospective studies with dry nasopharyngeal swabs (Thwe and Ren, 2020; Basu et al., 2020): in both cases the ID Now instruments were kept in a centralized laboratory, and suboptimal percent positive agreements of 53.3% and 54.8% when compared to the reference methods were noted. The nature of patient symptoms was not defined and overall

Abbreviations: Ct, cycle threshold; ED, emergency department; GI, gastrointestinal; POC, point-of-care; MC, meeting criteria; NMC, not meeting criteria

* Corresponding author. Tel.: 613-737-8899 ext 74124; fax: 613-737-8324.

E-mail address: vdeslandes@eorla.ca (V. Deslandes).

<https://doi.org/10.1016/j.diagmicrobio.2021.115609>

0732-8893/© 2021 Elsevier Inc. All rights reserved.

number of detected SARS-CoV-2 infections were low (15 and 31, respectively).

Given the availability of the ID Now instruments in Ontario, we sought to determine how the assay could be used to manage admission of symptomatic patients suspected of having COVID-19 infection from the emergency department (ED) of a tertiary health care hospital to COVID-19 wards or other units. Data was collected prospectively to assess tests characteristics, overall usage of the instrument, and time to diagnostic in comparison to the gold-standard laboratory-based assays.

2. Materials and methods

2.1. Patient selection

Patient seen in the ED at The Ottawa Hospital – General campus, a 1000 bed tertiary care University-affiliated hospital, were deemed eligible for testing with the Abbott ID Now (Chicago, IL) if they presented with symptoms compatible with SARS-CoV-2 infection within 7-10 days of symptoms onset and required admission to the hospital for ongoing management. Eligible symptoms included respiratory symptoms (cough, shortness of breath) and/or fever and/or other symptoms such as sore throat, rhinorrhea, anosmia and dysgeusia. A total of 273 patients were selected for dual-nasopharyngeal swabbing for parallel-testing using laboratory-based, highly sensitive molecular methodologies (first swab collected) and testing with the ID Now COVID-19 assay (second swab collected) between March 3, 2021 and May 11, 2021. While the manufacturer states that patients should be tested within 7 days of symptoms onset, interim results prompted us to expand the symptoms duration criteria to 10 days. As the usage of the device within the study parameters were considered standard of care in Ontario (COVID-19), ethics review was not required for sample collection. Patients that tested positive for the presence of SARS-CoV-2 either with standard laboratory-based methods or with the ID Now were deemed infected for clinical purposes and admitted to the COVID ward.

2.2. Project management

Daily logs of the previous day's testing were generated through our laboratory-information system and data relating to patient presentation and symptoms duration was collected from the hospital-information system without personal identifiers. This was reviewed daily by the medical microbiologist overseeing the project. This proposal was reviewed by the Ottawa Hospital Research Institute (OHRI) Research Ethics Board (REB) and found to fall within the context of a quality insurance evaluation, and review by the REB was waived.

Tests performed with the ID Now platform were classified as "meeting criteria" (MC) or "not-meeting criteria" (NMC) based on the defined testing criteria, regardless of results. Time from test ordering in the hospital information system to sample collection, time from collection to reception in the main microbiology laboratory and time from reception to resulting were also collected for the samples tested with the ID Now, when available, in order to provide opportunities for improvements and to assess the potential impact of testing on the main laboratory workflow.

2.3. SARS-CoV-2 diagnosis: laboratory-based methods

The Eastern Ontario Regional Laboratory Association (EORLA) virology laboratory provides centralized microbiology testing for the Eastern Ontario region. For the purpose of this study, nasopharyngeal swabs collected in appropriate media for viral nucleic acid stability were tested by qRT-PCR or transcription mediated amplification (TMA) on various automated platforms. Of the 270 samples received, 211 were extracted and tested for SARS-CoV-2 using either the SeeGene Allplex™ SARS-CoV-2 Assay (E gene, N gene and RdRP gene

detection) (Seegene, Toronto, ON), 24 were tested using the cobas® SARS-CoV-2 Test (E gene, Orf1a gene) on the cobas® 6800 platform (Roche Diagnostics Canada, Laval, QC), and the remaining 35 were tested with either the Panther Fusion® SARS-CoV-2 Assay (Orf1a and Orf1b gene regions) or the Aptima® SARS-CoV-2 Assay (TMA) (Orf1a and Orf1b gene regions) (Hologics Canada ULC, Mississauga, ON). Internal validation studies have demonstrated similar SARS-CoV-2 limits of detection for these devices (data not shown). For the SeeGene Allplex™ assay, nucleic acid was extracted either on a Starlet (SeeGene) (107 samples) or MGI (BGI, Cambridge, MA) (105 samples) liquid handler, and the amplification reactions were done in a CFX96 Touch Real-Time PCR Detection System.

2.4. SARS-CoV-2 diagnosis: ID Now COVID-19 assay

The instrument was installed within a biosafety cabinet in the main microbiology laboratory area. Over a span of 2 weeks preceding the study, all the microbiology technologist within this area were trained on using the device in accordance to the manufacturer's instruction, with the intention of providing results within 60 minutes of receiving the sample, 24-hours a day and 7-days a week. Dry nasopharyngeal swabs collected in the emergency department were sent to the microbiology in a sterile closed 15-ml conical tubes. Samples generating invalid results were not repeated using the method described by Abbott due to biosafety concerns. Physicians were informed of the invalid result and instructed to wait for the standard laboratory-based test.

2.5. Data analysis

Data analysis was performed in Microsoft Excel. Positive and negative concordance along with positive and negative predictive values were calculated for the ID Now COVID-19 assay, compared to the laboratory-based molecular method as the gold-standard. When available, cycle threshold (Ct) values generated by the laboratory-based assay were collected.

3. Results

3.1. Project implementation and patient characteristics

Of the 273 patients tested during this study, 191 met testing criteria on the ID Now. Dual-swab results were available for 269 patients. In one instance a swab was received in viral transport media instead of a dry tube for testing on the ID Now device; in 3 cases no swab was submitted for gold-standard laboratory-based molecular testing. The most common symptoms in the MC group were shortness of breath (67.4%), fever (40.1%), cough (31.6%) and weakness (16.6%), in keeping with the defined test criteria (Table 1). In the NMC group, shortness of breath (25%) and weakness (20%) were frequent but other frequent symptoms included confusion (17.5%) and vomiting (17.5%).

The percentage of samples belonging to the NMC group gradually declined from a high of 40-50% during the first week of implementation down to 28.8% after 8 weeks (Fig. S1, Supplementary Material). The detection rate increased over the course of the study to reach 17.2% by the end of the study. An average of 4 samples per day was submitted for testing on the ID Now platform, with an average time from collection to result of 77 minutes (Table 2). Time from collection of a sample to reception in the microbiology laboratory was variable and decrease gradually over time. The rolling 7-day average remained stable at 20 to 30 minutes over the last 3 weeks.

3.2. ID Now COVID-19 assay test performances

There were 46 and 48 samples with detectable SARS-CoV-2 viral sequences with the ID Now COVID-19 assay and the reference laboratory-based molecular methods respectively, with overall positive and

Table 1
Patient demographic and clinical presentations.

	MC	NMC
Female (%)	95 (49.2%)	37 (46.2%)
Average age	67	65
Duration of symptoms (days)	3.4	10.8
Symptoms		
Shortness of breath	67.4%	25%
Fever	40.1%	5%
Cough	31.6%	8.8%
Weakness	16.6%	20%
Confusion / Altered LoC	12.4%	17.5%
Chest pain	10.4%	13.8%
Sick contact	9.3%	1.2%
Vomiting	8.8%	17.5%
Nausea	7.8%	11.3%
Diarrhea	4.1%	8.8%

LoC = level of consciousness; MC = meeting criteria; NMC = not meeting criteria. The 4 most common symptoms in each group are shown in bold.

Table 2
ID Now COVID-19 assay collection and testing data.

	Average (IQR)
Order to collection	93.6 (38 – 119) min
Collection to laboratory	51.0 (12 – 56) min
Reception to result	27.5 (20 – 30.1) min
Collection to result	77.1 (37 – 85) min
ID Now to qRT-PCR	17.47 (12.4 – 21.6) h

IQR = interquartile range.

negative percent agreement of 93.8% and 99.6% (Table 3). There were 4 samples with discrepant results (Table 4). Of those, 3 had no detectable signal on the ID Now but were deemed positive by reference molecular methodologies. Ct values for 2 samples showed detectable signal in all targets in the multiplex reaction. The other sample yielded a relative light unit signal of 1279 on the Aptima® SARS-CoV-2 Assay. In our experience, this would correlate to Ct values anywhere between 20 and 35 by qRT-PCR.

One patient had detectable signal on the ID Now but lack of detection on initial parallel testing with the Allplex assay (Table 4). Testing was repeated on the cobas® 6800 on a new sample collected the following day and was confirmed as a false positive. After resolution of discrepant results, a sensitivity and specificity of respectively 93.8% and 99.5% was calculated for the ID Now COVID-19 assay. A total of 10 true positive samples were from patients that had been symptomatic for > 7 days. All were correctly identified by the ID Now COVID-19 assay. One sample had detectable signal at 14 days both on the ID Now and on the cobas® 6800 platform. Five of those ten samples had available Ct values, which ranged between 13.41 and 29.67.

SARS-CoV-2 prevalence was higher in the MC group (23.6%) than in the NMC group (3.8%). Four patients tested positive for COVID-19 in NMC group. Of those, 2 exceeded the symptoms duration criteria (12 and 14 days) but otherwise had classic COVID-19 symptoms: one had fever, cough and contact with a known positive case, while the other was experiencing shortness of breath and cough. The 2 remaining patients did not meet symptoms criteria: one was asymptomatic but had tested positive for COVID-19 during surveillance testing at a long-term care institution 8 days prior, while the other had been symptomatic for 4 days and presented with purely gastrointestinal complaints. For the latter, testing on the ID Now platform was ordered after imaging studies showed suspicious pulmonary findings.

3.3. Impact on patient care

Result were available from the ID Now on average 77 minutes after collection, on average 17.47 hours before the reference laboratory molecular test results were made available (average turn-around-time: 18.75 hours). The 46 patients that tested positive for

Table 3
Positive and negative percent agreement (PPA/NPA) between the ID Now COVID-19 assay and reference molecular methods.

	Reference methods	
	POS	NEG
ID Now POS	45	1
ID Now NEG	3	221
PPA/NPA	93.8%	99.6%

SARS-CoV-2 with the ID Now platform where thus cohorted out of the ED to COVID-specific wards faster, freeing scarce isolation rooms in the ED for new incoming symptomatic patients.

4. Discussion

While Canada has now exited its third national COVID wave, the potential role for rapid testing in our overall testing strategy remains to be properly defined and uptake has been slow. Despite a clear need for rapid, accurate assays, the implementation of low-throughput molecular methodologies remains challenging. While the ID Now COVID-19 assay is intended for point-of-care testing, the high-sensitivity of the assay increases the risk of false positive results if standard laboratory practices are not applied (ID NOW COVID-19). Furthermore, reports from Public Health England indicate that the elution buffer within the instrument sample receiver does not reliably lead to complete viral inactivation (Public Health, 2021). Given those concerns, we elected to keep the ID Now instrument within the main microbiology laboratory at our institution with trained microbiology technologists knowledgeable of good molecular microbiology practices as end users. Criteria for testing were established in order to meet the manufacturer's recommendations, but also in order to limit the potential impact of this new assay on other services offered by the main microbiology laboratory. Various resources have been in short supplies during this pandemic, but one of the least publicized has been that of trained microbiology technologists and technicians (Pointdexter, 2021) which has impacted testing. Testing volumes remained manageable throughout the implementation phase, in-laboratory turn-around-time remained stable at 25 to 30 minutes (Fig. S2, Supplementary Material), and the proportion of patients tested meeting criteria for testing gradually increased over time. While it is tempting to conclude that the feedback sessions organized between laboratory and ED partners 2 weeks, 4 weeks, 5 weeks and 8 weeks post-implementation may have contributed to this, with noticeable decreases in the 7-day rolling percentage of NMC patients after the first and second meeting (Fig. S1, Supplementary Material), the temporal evolution of the SARS-CoV-2 positivity rate may have had a greater impact. We encountered our first positive ID Now COVID-19 test after 16 days of implementation, and the lack of positive result to that point may have played a bigger role in tempering test orders. The subsequent sharp rise in the positivity rate as the province of Ontario entered its third COVID wave prompted increased testing, including in patient not-meeting test criteria, which stabilized thereafter. Those feedback sessions however allowed us to optimize time intervals between sample collection and testing, largely as a result of our decision to stop relying on porters to transport samples to the microbiology laboratory and use our pneumatic tube system instead.

We elected to not require pre-approval by a microbiologist for testing with the ID Now as this would have been counter-productive to the rapid nature of the test. We instead reviewed patients' clinical characteristic the day following testing to prospectively inform proper test utilization. The list of symptoms commonly seen in the NMC group was interesting: many had shortness of breath, but this was often explained by a cardiac etiology. Of note, gastrointestinal (GI) symptoms were more common in this group, with vomiting, nausea and diarrhea all being more common in the NMC group than

Table 4
Analysis of discordant results.

ID Now (date)	C2R (min)	Reference	Assay/instrument	Ct values / RLU	Resolution
NEG (03/20)	97	POS (03/20)	Allplex/MGI	31.85/34.69/37.05	FN ID Now
NEG (04/22)	43	POS (04/22)	Allplex/MGI	25.27/28.69/26.71	FN ID Now
NEG (04/23)	48	POS (04/23)	Aptima/Hologic	RLU: 1279	FN ID Now
POS (05/02)	-	NEG (05/02)	Allplex/MGI and cobas® 6800	Not detected	FP ID Now

C2R = time from collection of the ID Now sample to result reporting; FN = false negative; TP = true positive; FP = false positive; RLU = relative light units.

Table 5
Test characteristics post-resolution.

	ALL (n = 270)	MC (n = 191)
Sensitivity	93.8%	93.3%
Specificity	99.5%	99.3%
PPV	97.8%	97.7%
NPV	98.7%	98.0%
Prevalence	17.8%	23.6%

MC = meeting criteria for testing; NMC = not meeting criteria; PPV = positive predictive value; NPV = negative predictive value.

the MC group (17.5%, 11.3% and 8.8% vs 8.8%, 7.8% and 4.1% respectively). While these symptoms occurred in both groups, only in one case were GI symptoms the main presentation for a COVID-19 positive patient. In fact, only 7 out of 48 COVID-19 cases did not have respiratory symptoms (shortness of breath, cough, dyspnea) listed; 5 had however had recent confirmed contacts with other COVID-19 cases along with symptoms such as fever, weakness and myalgias of short duration (<4 days), while the other 2 both had fever along with abdominal discomfort or nausea and vomiting.

We noted that many patients presented with high-risk symptoms for COVID-19 and were tested with the ID Now platform despite not meeting the symptoms duration criteria. This had initially been set at 7 days based on manufacturer recommendation but was eventually increased to 10 days after multiple positive results were noted with the rapid molecular assay. A total of 9 patients presented with symptoms duration > 7 days and had amplifiable signal by the ID Now instrument. This may indicate that clinical presentation with respiratory symptoms may have more weight as a selection criterion for testing than the symptoms duration. It should be noted that symptoms duration is a very subjective variable: while some patient may calculate duration based on their first episode of fever, cough or shortness of breath, others may simply refer to the earliest time point they can recall not feeling in their normal state of health, or simply feeling “off.” In the context of an ED visit, it is not always possible to tease out this information with absolute certainty.

Time from sample collection to processing and resulting for ID Now samples was on average higher than the recommended 60 minutes (Fig. S2, Supplementary Material), but this did not impact the sensitivity of the assay. Of the 3 samples that were likely false negative results on the ID Now, one had a 97 minutes interval between collection and resulting. Given that the paired swab tested by qRT-PCR yielded Ct values > 30, implying a lower viral load, we can't rule out that this sample may have been adversely affected by the delay in testing. Regardless, the ID Now COVID-19 assay performed very well during this implementation, with high positive percent (93.8%) and negative percent agreement (99.6%) with the reference assays. There were only 5 discrepant results, which we resolved while relying on both technical and clinical data. For the 3 patients that had no detectable signal with the ID Now but detectable signal with the reference assays, we elected to resolve the discrepancy in favor of the molecular assays based on strength of signal detection and higher expected test sensitivity. It should be noted that while the ID Now package inserts claims a limit of detection (LoD) of 125 genome copies/ml, published data have shown an LoD ranging from 262 to 20,000 copies/ml (Zhen et al., 2020; Lephart et al., 2021) in clinical samples. Our own limited internal LoD determination using probit analysis showed an LoD closer to 1000 copies/ml (data not shown). Finally,

another study highlighted that the LoD of the ID Now is 100-fold higher than the expected LoD of the Roche assay which was used in our study (Cradic et al., 2020). Two of 3 false negatives samples had detectable signal for all 3 gene targets with qRT-PCR-based reference assays, with Ct values that were on average < 35 (Table 4). Based on prior validation work done in our laboratory, all samples with similar signal had reproducible reactions on other platforms when re-tested. The last sample had relative light unit (RLU) value of 1279 on the Aptima assay. While the manufacturer of the assay does not list the cut-off RLU value, from our experience with testing of a vast number of clinical samples on this platform the lowest recorded RLU values on positive samples have been around 620 RLU. By contrast, samples with RLU > 1000 have consistently shown repeatable detection with qRT-PCR-based assay in our laboratory (data not shown). A recent study, which included samples tested with the Aptima assay, estimated a very low false positive rate for SARS-CoV-2 detection with fully automated instruments (0.04%) (Chandler et al.). In this study, the 2 false positive results for this assay had low RLU values (614 and 615). Overall sensitivity (93.8%) and specificity (99.5%) were very high, as were positive and negative predictive values (97.8% and 98.7% respectively). High performance was observed in both the MC (Table 5) and NMC group (data not shown), but overall performance in the latter should be taken lightly given the small number (3) of positive patients.

From a clinical perspective, EDs and inpatient units have struggled with isolation needs and overall capacity during this pandemic. Strict infection prevention and control rules require prompt isolation of suspected COVID-19 cases, and most EDs do not have adequate number of isolation rooms that would allow all patients to stay in one space throughout their ED stay. Additionally, overall emergency department efficiency is challenged by personal protective equipment needs for staff and the isolation needs of the patients. This has negatively impacted patient flow through the ED. If patients can be accurately and quickly cohorted into appropriate groups for care then the ED visit will be safer and more efficient for both the patient and the care team. Use of the ID Now assay has allowed admitted patients testing positive for SARS-CoV-2 to be placed in the most suitable ward many hours earlier than with standard testing. This allowed for quicker flow out of the department, again easing emergency department congestion and crowding, but also allowed for faster initiation of COVID-19-specific active and supportive care. Furthermore, extending the use the ID Now COVID-19 assay to symptomatic patients who might be discharged from ED could allow for more accurate prognostication, limit inappropriate antibacterial prescriptions while also allowing for faster initiation of contact tracing and home isolation.

There are limitations with our study. First, this study does not represent a direct comparison between the ID Now COVID-19 assay and a specific molecular test as our testing armamentarium includes numerous platforms. It should be noted that all these platforms have been locally cross-validated and shown to have comparable performances. Potential false negative reactions on the ID Now platform involved separate reference assays, and positivity rates for the Starlet and MGI extractors and cobas® 6800 platform were all similar (20.6%, 18.1%, and 16.7%, respectively). While the Hologic platform had a lower positivity rate (8.6%), this would not have impacted our data since this would have been expected to lead to a higher rate of perceived false positive reactions on the ID Now. Counterintuitively, another limitation to this study may be its timing. While the third wave of COVID-19 in Ontario ensured a steady supply of SARS-CoV-2

positive patients during the second half of our implementation, this also led to an unrealistically high pre-test probability of 23.2% in the MC group. As we exit this most recent COVID wave and other respiratory viruses make a return, a clinically similar group of patients would likely have a much lower pre-test probability for SARS-CoV-2 and this could eventually have an impact on the positive and negative predictive values of the assay. The context of this study also needs to be considered: patients presenting to the emergency department and requiring admission are more likely to have more severe presentations, and thus likely higher viral burden. It is unclear if the high sensitivity seen in our study would hold up in outpatients, or if it will remain the same as rates of vaccination increase. Finally, while it can be hypothesized that faster initiation of COVID-19-specific active and supportive care may positively impact outcomes (Hyun et al., 2021), a larger case control study would be required to clearly establish the presence or absence of clinical benefits.

In summary, our implementation of the ID Now COVID-19 assay for patient requiring admission from the emergency department was successful. Feedback sessions may have contributed to reinforcing adherence to proper testing criteria and to optimizing time from collection of samples to testing. Extending the symptoms duration criteria from the recommended 7 days to 10 days did not yield false negative results. Sensitivity and specificity of the assay in this context were excellent at 93.8% and 99.5% respectively overall.

Declaration of competing interest

The authors report no conflict of interest.

Author contribution

Vincent Deslandes contributed to the conceptualization, methodology, validation, investigation, formal analysis, data curation, writing (original draft, review, editing), visualization and project administration. Eric Clark contributed to the conceptualization, methodology, resources, investigation and writing (original draft, review, editing). Venkatesh Thiruganasambandamoorthy contributed to writing (original draft, review, editing). Marc Desjardins contributed to conceptualization, methodology, validation, resources, writing (review, editing) and supervision.

Funding

This project was supported by internal funds.

Acknowledgments

We would like to thank all the personnel at The Ottawa Hospital – General Campus ED and EORLA technologists for their contribution to the success of this implementation.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.diagmicrobio.2021.115609.

References

- Abbott. ID NOW COVID-19 Package Insert [Internet]. [cited 2021 May 11]. Available at: <https://www.fda.gov/media/136525/download>. Accessed December 15, 2021.
- Basu A, Zinger T, Inglima K, Woo K, Atie O, Yurasits L, et al. Performance of Abbott ID Now COVID-19 rapid nucleic acid amplification test using nasopharyngeal swabs transported in viral transport media and dry nasal swabs in a New York City academic institution. *J Clin Microbiol* 2020;58:. doi: 10.1128/JCM.01136-20.
- Chandler CM, Bourassa L, Mathias PC, Greninger AL. Estimating the false-positive rate of highly automated SARS-CoV-2 nucleic acid amplification testing. *J Clin Microbiol*. d.;59:e01080-21. <https://doi.org/10.1128/JCM.01080-21>.
- Cradic K, Lockhart M, Ozbolt P, Fatica L, Landon L, Lieber M, et al. Clinical evaluation and utilization of multiple molecular in vitro diagnostic assays for the detection of SARS-CoV-2. *Am J Clin Pathol* 2020;154:201–7. doi: 10.1093/ajcp/aqaa097.
- COVID-19 provincial testing guidance update [Internet]. Ministry of Health of Ontario. [cited 2021 May 25]. Available at: https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/2019_testing_guidance.pdf. Accessed December 15, 2021.
- Farfour E, Asso-Bonnet M, Vasse M, Catherinot E, Tcherakian C, Magnan A, et al. The ID NOW COVID-19, a high-speed high-performance assay. *Eur J Clin Microbiol Infect Dis* 2021;40:2041–5. doi: 10.1007/s10096-021-04243-0.
- Harrington A, Cox B, Snowdon J, Bakst J, Ley E, Grajalas P, et al. Comparison of Abbott ID Now and Abbott m2000 methods for the detection of SARS-CoV-2 from Nasopharyngeal and Nasal Swabs from symptomatic patients. *J Clin Microbiol* 2020;58:. doi: 10.1128/JCM.00798-20.
- Hyun JH, Kim MH, Sohn Y, Cho Y, Baek YJ, Kim JH, et al. Effects of early corticosteroid use in patients with severe coronavirus disease 2019. *BMC Infect Dis* 2021;21:506. doi: 10.1186/s12879-021-06221-5.
- ID NOW COVID-19 - instructions for use [Internet]. Available at: <https://www.fda.gov/media/136525/download>. Accessed December 15, 2021.
- Jin R, Pettengill MA, Hartnett NL, Auerbach HE, Peiper SC, Wang Z. Commercial severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) molecular assays: superior analytical sensitivity of cobas SARS-CoV-2 relative to NxTAG CoV extended panel and ID NOW COVID-19 test. *Arch Pathol Lab Med* 2020;144:1303–10. doi: 10.5858/arpa.2020-0283-SA.
- Lee J, Song J-U. Diagnostic accuracy of the Cepheid Xpert Xpress and the Abbott ID NOW assay for rapid detection of SARS-CoV-2: a systematic review and meta-analysis. *J Med Virol* 2021;93:4523–31. doi: 10.1002/jmv.26994.
- Lephart PR, Bachman MA, LeBar W, McClellan S, Barron K, Schroeder L, et al. Comparative study of four SARS-CoV-2 Nucleic Acid Amplification Test (NAAT) platforms demonstrates that ID NOW performance is impaired substantially by patient and specimen type. *Diagn Microbiol Infect Dis* 2021;99: 115200. doi: 10.1016/j.diagmicrobio.2020.115200.
- Mitchell SL, George KSt. Evaluation of the COVID19 ID NOW EUA assay. *J Clin Virol* 2020;128: 104429. doi: 10.1016/j.jcv.2020.104429.
- Moore NM, Li H, Schejbal D, Lindsley J, Hayden MK. Comparison of two commercial molecular tests and a laboratory-developed modification of the CDC 2019-nCoV reverse transcriptase PCR assay for the detection of SARS-CoV-2. *J Clin Microbiol* 2020;58:. doi: 10.1128/JCM.00938-20.
- Office of the Commissioner. Coronavirus (COVID-19) update: FDA informs public about possible accuracy concerns with Abbott ID NOW point-of-care test. FDA 2020 <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point> (Accessed May 11, 2021).
- Pointdexter E. COVID-19 pandemic highlights critical need for medical laboratory professionals [Internet]. The University of North Carolina, Chapel Hill. 2021 [cited 2021 May 27]. Available at: <https://www.unc.edu/posts/2021/02/12/covid-19-pandemic-highlights-critical-need-for-medical-laboratory-professionals/>. Accessed May 27, 2021.
- Procop GW, Brock JE, Reineks EZ, Shrestha NK, Demkowicz R, Cook E, et al. A comparison of five SARS-CoV-2 molecular assays with clinical correlations. *Am J Clin Pathol* 2021;155:69–78. doi: 10.1093/ajcp/aqaa181.
- Public Health England. SARS-CoV-2 inactivation testing: interim report - ID Now elution buffer [Internet]. Public Health England; [cited 2021 May 27]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/953556/HCM-CoV2-063-v1_Abbott_ID_NOW_COVID-19_Elu_tion_Buffer_TCF.pdf. Accessed December 15, 2021.
- Rhoads DD, Cherian SS, Roman K, Stempak LM, Schmotzer CL, Sadri N. Comparison of Abbott ID Now, DiaSorin Simplexa, and CDC FDA emergency use authorization methods for the detection of SARS-CoV-2 from Nasopharyngeal and Nasal Swabs from individuals diagnosed with COVID-19. *J Clin Microbiol* 2020;58:. doi: 10.1128/JCM.00760-20.
- Tasker JP. Health Canada approves rapid COVID testing device as Canada braces for caseload spikes | CBC News [Internet]. CBC News. 2020 [cited 2021 May 11]. Available at: <https://www.cbc.ca/news/politics/health-canada-approves-id-now-1.5744768>. Accessed December 15, 2021.
- Serei VD, Cristelli R, Joho K, Salaru G, Kirn T, Carayannopoulos MO, et al. Comparison of Abbott ID NOW COVID-19 rapid molecular assay to cepheid xpert xpress SARS-CoV-2 assay in dry nasal swabs. *Diagn Microbiol Infect Dis* 2021;99: 115208. doi: 10.1016/j.diagmicrobio.2020.115208.
- Smithgall MC, Scherberkova I, Whittier S, Green DA. Comparison of Cepheid Xpert Xpress and Abbott ID Now to Roche cobas for the rapid detection of SARS-CoV-2. *J Clin Virol* 2020;128: 104428. doi: 10.1016/j.jcv.2020.104428.
- Thwe PM, Ren P. How many are we missing with ID NOW COVID-19 assay using direct nasopharyngeal swabs? Findings from a mid-sized academic hospital clinical microbiology laboratory. *Diagn Microbiol Infect Dis* 2020;98: 115123. doi: 10.1016/j.diagmicrobio.2020.115123.
- Tu Y-P, Iqbal J, O'Leary T. Sensitivity of ID NOW and RT–PCR for detection of SARS-CoV-2 in an ambulatory population. *ELife* 2021;10:e65726. doi: 10.7554/eLife.65726.
- Tworek JA, Khan F, Sekedat MD, Scheidel C, Malani AN. The utility of rapid nucleic acid amplification testing to triage symptomatic patients and to screen asymptomatic preprocedure patients for SARS-CoV-2. *Open Forum Infect Dis* 2021;8:. doi: 10.1093/ofid/ofaa607.
- WHO Coronavirus (COVID-19) dashboard <https://covid19.who.int> (Accessed May 11, 2021).
- Zhen W, Smith E, Manji R, Schron D, Berry GJ. Clinical evaluation of three sample-to-answer platforms for detection of SARS-CoV-2. *J Clin Microbiol* 2020;58:. doi: 10.1128/JCM.00783-20.