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BRIEF REPORT

The Utility of Rapid Nucleic Acid Amplification Testing to Triage Symptomatic Patients and to Screen Asymptomatic Preprocedure Patients for SARS-CoV-2

Joseph A. Tworek,[1] Faisal Khan,[3] Matthew D. Sekedat,[3] Caleb Scheidel,[4] and Anurag N. Malani[2,5]

[1]Department of Pathology, St Joseph Mercy Hospital, Ann Arbor, Michigan, USA, [2]Division of Infectious Diseases, Department of Internal Medicine, St Joseph Mercy Hospital, Ann Arbor, Michigan, USA, [3]Warde Medical Laboratory, Ann Arbor, Michigan, USA, [4]Methods Consultants of Ann Arbor, Ypsilanti, Michigan, USA, and [5]Department of Infection Prevention and Control, St Joseph Mercy Hospital, Ann Arbor, Michigan, USA

We investigate the utility of the ID Now when compared to RT-PCR to triage patients suspected of having COVID-19 presenting to emergency rooms (ERs) and to screen asymptomatic patients presenting for pre-procedural testing. We find it useful when prevalence of COVID-19 is high in symptomatic patents and potentially useful in asymptomatic patients who are likely to be retested if symptoms emerge.

Keywords. COVID-19; molecular; rapid; SARS-CoV-2; testing.

Recent studies have cast doubt on the sensitivity and utility of the Abbott ID Now instrument to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) when compared with conventional reverse transcription polymerase chain reaction (RT-PCR) [1–5]. However, finding a role for rapid testing platforms, such as the ID Now, would help to reduce demands on RT-PCR assays. We investigated the utility of the ID Now when compared with RT-PCR to triage patients suspected of having coronavirus disease 2019 (COVID-19) presenting to emergency rooms (ERs) and to screen asymptomatic patients presenting for preprocedural testing.

For the symptomatic population, we studied 1569 patients suspected of having COVID-19 across 5 community teaching hospital ERs from April 15 through April 25, 2020 in Southeast Michigan. For the asymptomatic population, we studied 386 patients scheduled for elective surgical procedures between April 15 and May 15, 2020. All asymptomatic patients passed a symptom screening questionnaire at the time of collection, typically 2 days before the procedure.

In both populations, a foam nasal swab (NS) was collected for testing by the ID Now, and a sequential nasopharyngeal swab (NPS) was also collected immediately after collection of the NS. The NPS was sent for conventional RT-PCR if the ID Now results were negative in the symptomatic ER patient population. The NPS was always sent for RT-PCR in the asymptomatic population from preprocedural screening, as this was the local practice standard for several weeks. Internal validation studies of the ID Now before its clinical use supported not submitting the NPS for RT-PCR when the antecedent NS ID Now was positive. RT-PCR was performed on either the Abbott *m*2000 (Abbott RealTime SARS-CoV-2 Assay, Abbott Molecular Inc., Des Plaines, IL, USA) at a central reference laboratory or on the Cepheid GeneXpert (Xpert Xpress SARS-CoV-2, Cepheid Sunnyvale, CA, USA) at an on-site microbiology laboratory (St. Joseph Mercy Hospital Ann Arbor [SJMAA]). The turnaround time (TAT) was generally 2 to 3 days for the Abbott *m*2000, 6 to 8 hours for the Cepheid GeneXpert, and 2 hours for the ID Now. NS were transported in conical tubes to the local on-site laboratory, along with NPS transported in viral transport media. NS were tested on the ID Now by certified medical technologists.

Data were collected as part of routine clinical care, and written consent was not obtained. The retrospective collection of data was approved by the SJMAA Institutional Review Board. Statistical analysis was performed using R, version 3.6.0, and the epiR package. RT-PCR was considered the gold standard. Samples from symptomatic patients with a positive ID Now test and no RT-PCR result were assumed to be positive for SARS-CoV-2.

In symptomatic patients, the overall positive rate was 17.58%, and the overall false negative rate (FNR) was 12.42% (Table 1). The FNR decreased as the prevalence of COVID-19 increased for hospitals with significant volume (sites 1–3). The performance agreement (Fleiss Kappa value) shows strong agreement (>0.80) among sites. In asymptomatic patients, the positive rate was 0.78% by RT-PCR; all 3 patients who were positive by RT-PCR had negative results by ID Now. One patient in retrospect was thought to have symptoms that were not captured by the symptom screen questionnaire.

In the symptomatic group, we examined RT-PCR cycle threshold (Ct) data for the 35 available samples that were positive on the Abbott *m*2000 and negative for the ID Now. From this cohort, 7 of 35 samples had Ct values <20. These 35 samples were compared with a randomly selected cohort of 35 cases from the week before the study (not tested by the ID Now) and were chosen

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Correspondence: J. A. Tworek, MD, Department of Pathology, St Joseph Mercy Hospital, 5301 East Huron River Dr., Ann Arbor, MI 48109 (joseph.tworek@stjoeshealth.org).

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Table 1. Agreement Between RT-PCR and ID Now (95% CI) in Symptomatic and Asymptomatic Patients

Site	Bed Size	Total Samples Tested	ID Now-/PCR+	ID Now-/PCR-	ID Now+/No PCR	ID Now+/PCR-	ID Now Positive Rate, %	False Negative Rate	Negative Agreement (NPV)	Sensitivity	Performance Agreement (Fleiss Kappa)
Symptomatic											
1	548	394	9 (6[a]–3[b])	352 (258[a]–94[b])	33	0	8.61	21.43 (10.30–36.81)	97.51 (95.32–98.85)	78.57 (63.19–89.70)	0.855 (0.757–0.953)
2	497	341	8	292	41	0	12.02	16.33 (7.32–29.66)	97.33 (94.81–98.84)	83.67 (70.34–92.68)	0.898 (0.792–1.003)
3	304	743	22	524	197	0	26.51	10.05 (6.40–14.81)	95.97 (93.96–97.46)	89.95 (85.19–93.60)	0.927 (0.855–0.998)
4	66	57	0	54	3	0	5.26	0.00 (0.00–70.76)	100.00 (93.40–100.00)	100.00 (29.24–100.00)	1 (0.74–1.26)
5	133	34	0	33	1	0	2.94	0.00 (0.00–97.50)	100.00 (89.42–100.00)	100.00 (2.50–100.00)	1 (0.664–1.336)
Total											
All	1547	1569	39	1255	275	0	1758	12.42 (8.98–16.59)	96.99 (95.90–97.85)	87.58 (83.41–91.02)	0.917 (0.867–0.966)
Asymptomatic											
1	548	386	3	383	0	0			99.22 (97.75–99.84)		

Abbreviations: PCR, polymerase chain reaction; NPV, negative predictive value; RT-PCR, reverse transcription polymerase chain reaction.

[a]Abbott m2000.

[b]Cepheid GeneXpert.

in the same proportion as the contributing locations in the study period. Ct values from the RT-PCR of the Abbott *m*2000 for the discordant samples ranged from 11.24 to 30.43 and showed a statistically significantly (*t* test $P < .001$) higher mean Ct (23.86) than the mean Ct of the randomly chosen positive cohort (15.66; range, 5.98–30.30). In the 3 asymptomatic patients with discordant results, the Ct values were 16.9, 27.5, and 30.91 (mean, 25.10).

Similar to other studies, Ct values in false-negative cases on the ID Now tended to be higher than in those testing positive by RT-PCR alone [1–5]. Despite the lower sensitivity of the ID Now, its utility depends on the prevalence of COVID-19 and the target population. ID Now proved useful to triage rapidly symptomatic patients presenting to ERs, particularly when prevalence was high. Patients with a positive ID Now test were considered to have COVID-19 and were admitted to a COVID-19 unit if hospitalized. Patients with negative ID Now tests were either discharged with instructions to self-quarantine until confirmatory RT-PCR results were available or hospitalized with the possibility of being moved to a COVID-19 unit if RT-PCR results were positive. In asymptomatic patients, the ID Now may be useful for screening for SARS-CoV-2, despite missing 3 of 383 patients. In this population, its usefulness may be increased by directing testing to patients who are likely to return for repeat testing, either the ID Now or RT-PCR, if symptoms of COVID-19 develop.

The supply chain for COVID-19 testing is strained given surging demand. Shortages have affected the availability of antigen tests, Abbott ID Now, and consumables for RT-PCR such as pipette tips, swabs, reagents, and viral transport media, leading to prolonged TAT [6]. More available testing options through innovative approaches for preprocedure screening and testing symptomatic hospital admissions with rapid testing such as the ID Now will optimize testing capacity.

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