Original Research

Evaluation of a Point-of-Care COVID-19 Testing Platform Using Self-Collected Nasal Swabs in an Urgent Care Setting

Urgent message: A validated platform effective in performing rapid point-of-care tests for SARS-CoV-2 would be ideal for use in urgent care centers. Results of this study support the use of POC testing using self-collected nasal swabs.

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Introduction

The Abbott ID NOW Point of Care (POC) system is designed to perform rapid on-site nucleic acid amplification polymerase chain reaction (PCR) testing. However, recent publications from academic settings have reported concerning and varying false negative (FN) rates with this diagnostic test.[1-4] It is unknown if the high FN rate is a function of the POC machine, the training of the clinical staff, or the specimen collection type. We therefore undertook a validation study in a "real world" community setting of symptomatic patients presenting to urgent care clinics or testing tents. Each patient had two samples collected: one for POC testing (either nasopharyngeal [NP] or nasal) and one NP specimen to run on a high-throughput diagnostic test in a commercial reference laboratory on their PCR platform (LabCorp or Quest). Samples were collected at the same time on the same patients to compare FN rates of the Abbott POC machine with traditional PCR platforms.

Methods

Though the Food and Drug Administration classified the Abbott ID NOW as a CLIA-waved test, we opted for higher standards and elected to use CLIA-defined moderate complexity standards for quality control, quality assurance, proficiency testing, and training of personnel. In addition, validation testing of known positive and known negative samples from PCR NP swabs was completed before deployment of the Abbott POC machines.

After initial validation and training, the machines were deployed in all 14 of our urgent care locations and three adjacent testing tents. All symptomatic patients who presented to urgent care or the testing tents who met local testing criteria were included in the study.

A self-collected nasal swab was obtained from supervised urgent care patients. Both nares were swabbed without use of a viral transport medium (VTM). If the POC test was negative, an NP swab was obtained by trained clinical staff, placed in VTM, and sent to a reference laboratory for traditional laboratory-based PCR testing.

This protocol allowed us to evaluate the false negative rates of the Abbott POC machine compared to traditional PCR testing, as well as to the FN rates of nasal swab when compared to NP swab collection methods.

Results

In the first stage of validation, before deploying the POC tests to our centers, 10 known PCR-positive patient specimens from hospital-based NP swabs, and 10 known negative patient specimens from hospital-based NP swabs were tested. All 20 POC results matched the laboratory PCR results.

In the second stage, the POC assay was tested with 10 separately diluted known positive PCR patient speci-

Table 1. Validation Results

Platforms	Known NP PCR positive samples		Known NP PCR negative sample
	Diluted to 1:500	Diluted to 1:1000	Diluted to 1:1000
ABBOTT ID NOW	3/3 (100%)	6/6 (100%)	1/1 (100%)
BD Max	3/3 (100%)	5/6 (83.3%)*	1/1 (100%)
Cepheid GeneXpert	3/3 (100%)	6/6 (100%)	1/1 (100%)
QIAGEN QIAstat	3/3 (100%)	5/6 (83.3%)	1/1 (100%)

*One sample had indeterminate result

Table 2. NPV, FOR, FNR and Sensitivity for Nasal and NP POC vs NP PCR

	Nasal POC	NP POC	P value
True negative (TN)	1,603	641	N/A
False negative (FN)	124	23	N/A
True positive (TP)	796	201	N/A
NPV[a] = TN/(TN+FN) FOR[a] = 1-NPV	92.8% 7.2%	96.5% 3.5%	0.0007
FNR[a] = FN/(FN+TP) Sensitivity = 1-FNR	13.5% 86.5%	10.3% 89.7%	0.1979
FNR for two POC tests[b]= FNR * FNR	1.82%	1.1%	N/A

*NP POC vs nasal POC, Chi-square test
[a]NPV: Negative predictive value; FNR: false negative rate; FOR=false omission rate
[b]Hypothesized probability of false negative for repeat POC tests in subsequent days

mens including nine positive specimens and one negative specimen. Three other laboratory PCR platforms (BD Max, Cepheid GeneXpert, and QIAGEN QIAstat) were also subjected to the same dilution specimens for comparison. In both 1:600 and 1:1000 dilution specimens, the POC assay correctly detected the presence and absence of viral targets (see **Table 1**).

After validation, the POC machines were deployed into the urgent care locations. A total of 3,509 patients were tested using the POC in Medstar Health Urgent Care or testing tents in April and May 2020. Patient consent was obtained for treatment, but not for research purposes, as this testing was part of our internal testing protocol development and data were collected retrospectively for research purposes from chart and lab results review. Of these patients, 3,388 (97%) were included in the study; patients with invalid POC results (n=27) and those without concurrent PCR sent due to patient refusal (n=94) were excluded.

Compared to PCR, nasal POC specimens (n=2,523) demonstrated an FN rate of 13.5%, sensitivity of 86.5%, and NPV of 92.8%; in comparison, the NP POC specimens (n=865) demonstrated an FN rate of only 10.3%, sensitivity of 89.7%, and NPV of 96.5% (see **Table 2**). The difference between the FN rate of nasal vs NP POC testing was not statistically significant (p=0.2). Nasal POC did have a significantly lower NPV than NP POC (p=0.0007); however that could be due to significantly higher prevalence of virus in nasal than NP POC specimens (p<0.0001). Difference in prevalence between nasal and NP POC is likely due to variation in prevalence by location of testing sites, as our urgent care and tent locations span urban and suburban areas in Baltimore and Washington, DC. The tents had a healthier prescreened patient population that did not need a physician-facing visit.

Discussion

The findings support the use of protocol-driven POC testing of symptomatic patients using self-collected nasal swabs in real-world settings. Advantages include rapid turnaround time and conservation of limited NP swab supplies throughout the country.[5] However, the data also suggest that the quality of the sample, obtaining NP vs nasal, may favorably lower the POC FN rate if NP swabs are not constrained. When NP swabs are constrained, subsequent testing with a repeat nasal POC on consecutive days to further lower the FN rate may therefore be an ideal protocol for COVID-19 testing in the outpatient setting to allow for more rapid results. ■

References

1. Rhoads DD, Cherian SS, Roman K, et al. 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(8):e00760–20.
2. Berry, J, Zhen, W. et al. Clinical evaluation of three sample-to-answer platforms for the detection of SARS-CoV-2. *J Clin Microbiol*. 2020;58(8):e00783-20.
3. 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;Jul:104428.
4. Harrington, A. Cox, B 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(8):e00798-20.
5. Péré H, Podglajen I, Wack M, et al. Nasal swab sampling for SARS-CoV-2: a convenient alternative in times of nasopharyngeal swab shortage. *J Clin Microbiol*. 2020;58(6):00721-20.

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