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.

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Letter to the Editor

Comparison of abbott ID NOW COVID-19 rapid molecular assay to cepheid xpert xpress SARS-CoV-2 assay in dry nasal swabs

In December 2019, a novel coronavirus, SARS-CoV-2, causing severe respiratory symptoms (COVID-19) emerged as a global pandemic (WHO 2020). The Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) allowing the use of numerous molecular assays for *in vitro* diagnostics (IVD) in order to meet COVID-19 testing demands. However, the analytical performance characteristics of authorized assays have not been well studied. The Abbott ID NOW COVID-19 molecular point-of-care (POC) test is intended to provide COVID-19 results within minutes via isothermal amplification. In comparison, other rapid molecular platforms are RT-PCR based and may take anywhere from 1 to 3 hours to perform (Esbin et al., 2020).

In an effort to find a molecular platform that could provide accurate results within a short time (13 minutes or less) compared to our standard of care rapid molecular platform Cepheid Xpert® Xpress SARS-CoV-2 assay (45 minutes or less), a correlation study was performed using nasal swabs from symptomatic patients in the Emergency Department (ED) at Robert Wood Johnson University Hospital (RWJUH), New Brunswick, NJ. This study was approved by the Rutgers Institutional Review Board (IRB). Briefly, ED nursing staff collected 105 paired nasal swabs from adult (>18 years), non-pregnant patients under investigation for COVID-19. Two nasal swabs were collected, one swab was placed in viral transport media (VTM) for routine COVID-19 testing using the Cepheid Xpert® Xpress SARS-CoV-2 assay (Cepheid, Sunnyvale, CA) performed on the GeneXpert Infinity platform (Cepheid, Sunnyvale, CA), which is a real-time PCR test that detects the N2 and E SARS-CoV-2 nucleic acids. A second "dry" nasal swab was collected without elution in VTM, placed directly in the original package, held in a refrigerator (2-8C) for up to 12 hours from time of sample collection, and directly analyzed using Abbott ID NOW COVID-19 assay (Abbott Diagnostics Scarborough Inc., Scarborough, ME) according to the manufacturer's instructions for use (Abbott 2020). Only validated Cepheid results were reported for routine patient care. The results, Cepheid cycle threshold (Ct), and run times were compared to define the relative performance characteristics of the ID NOW (Table 1).

Table 1
Comparison of Abbott ID NOW to Cepheid Xpert Xpress.

		Cepheid Xpert Xpress		
		Positive	Negative	Total
Abbott ID NOW	Positive	12	0	12
	Negative	8	76	84
	Total	20	76	96

A total of 105 samples were analyzed on both platforms. While all samples run on the Cepheid were valid, 96 samples (91.4%) produced a valid result and 9 (8.57%) were invalid on the ID NOW. The overall positivity rate, as detected by Cepheid, was 20.8% (20/96), while the ID NOW detected just 12.5% (12/96) positive specimens. The overall positive agreement between Cepheid and ID now was 60%. Specimens that were judged to be positive using the ID NOW and Cepheid assay all demonstrated detection of the N2 gene with an average Ct of 31.3 (range: 22.2-41) and 11/12 detected the E2 gene with an average Ct of 28.6 (range: 19.7-39.7). Specimens that were judged to be positive using the Cepheid assay, but negative in the ID NOW assay had N2 gene detected in 8/8 (100%) samples, with an average Ct value of 38.4 (range: 34.1-41.3), and 6/8 (80%) of samples had E gene detected with an average Ct of 33.7 (range: 28.2-37.7).

The average time to a positive result on the ID NOW was 2 minutes 28 seconds. The time to all negative results was 10 minutes. These run-times do not include additional loading times or three minutes of sample receiver warm-up. This is in contrast to the Cepheid, where average run time was 53 minutes.

In conclusion, in comparison to the Xpert Xpress SARS-CoV-2 test, the Abbott ID NOW COVID-19 assay provides a very fast result, however, the analytical sensitivity of the assay is suboptimal, particularly at lower viral burden corresponding to a high cycle time. Most importantly, the assay is sub-optimal even when used in a patient population with a high pre-test probability, i.e. symptomatic ED patients. These results are consistent with recent studies which also found lower positive agreement for the ID NOW, ranging from 54.8%- 94%, in comparison to more sensitive molecular platforms (Basu et al., 2020, Harrington et al., 2020, Rhoads et al., 2020, Smithgall et al., 2020, Zhen et al., 2020). Many variables may influence test performance, including specimen type, collection, transport, and handling. However in this study, the dry nasal swabs specimens were collected using ID NOW kit nasal swabs, specimens were collected by health care providers for both platforms, and specimens were stored and run according to the manufacturer's instructions. Despite following the manufacturer's instructions, there was a high rate of invalid results on the ID NOW which is attributed to a certain step in the protocol requiring the user to forcefully push the sample transfer cartridge into the test base until full descent of a test indicator. It was observed that non-forceful pushing without full descent of the test indicator was the common step for some of the invalid results. Per the manufacturer's protocol, one additional test may be run using the same sample. However, since multiple users were running samples for this study, invalid results were not retested consistently. This is another limitation of the ID NOW, as invalid rate can be variable depending on the user's technique. In comparison to other published

Table 2
Cepheid and Abbott ID NOW positive results with N2 and E Ct values.

Patient	Cepheid	Cycle Threshold (N2)	Cycle Threshold (E)	ID NOW Result
1	Positive	24.2	22.1	Positive
2	**Positive**	**40.8**	**37.7**	**Negative**
3	Positive	33.4	30.3	Positive
4	Positive	34.9	32.1	Positive
5	**Positive**	**39.8**	**0**	**Negative**
6	Postitive	36.3	39.7	Positive
7	Postitive	41	0	Positive
8	**Postitive**	**40.8**	**28.2**	**Negative**
9	Postitive	22.9	20.6	Positive
10	**Positive**	**41.3**	**0**	**Negative**
11	**Positive**	**34.1**	**31.6**	**Negative**
12	Positive	22.2	19.7	Positive
13	Positive	27.7	25.9	Positive
14	Positive	37.9	37.9	Positive
15	**Positive**	**37.6**	**37.6**	**Negative**
16	**Positive**	**38.2**	**36**	**Negative**
17	**Positive**	**34.2**	**31.2**	**Negative**
18	Positive	36.8	33.3	Positive
19	Positive	35.2	32.6	Positive
20	Positive	22.7	20.4	Positive

studies to date, our study directly compared same specimen type (paired nasal swabs), eliminating many confounding factors. ID NOW could be beneficial when used in a setting of high community transmission where the viral burden is high with low Ct value. However, a negative result should prompt retesting on a different molecular platform due to the assay's suboptimal sensitivity at low viral burden. Retesting may expend scarce resources, particularly due to the need for dual sample collection (dry swab for ID NOW and swab in VTM for other molecular assays), subject the patient to unnecessary stress, and prolong time to result. Both patients and health care professionals should be aware of the limitations of the Abbott ID NOW COVID-19 assay.

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