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

Abbott ID now COVID-19 assay performance: a year in review

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As new commercial SARS-CoV-2 assays have received Emergency Use Authorization (EUA) from U.S Food and Drug Administration (FDA) throughout the pandemic, some existing assays have also been updated for improved sensitivity and specificity. While several studies have assessed the initial performance of new testing platforms and/or assays during the early phase of the pandemic, there is very little information about the reassessment of any test systems. In 2020, we reported the performance characteristics of ID NOW COVID-19 assay (Abbott, Lake Forest, IL), in comparison to those of RT-PCR platforms (Thwe and Ren, 2020). Here, we analyzed the data gathered within the past year to reassess the ID NOW COVID-19 assay performance.

While our 2020 report was based on a limited sample size, the data collected for this study represented the testing performed from May 2020 through April 2021, with a total of 3320 paired nasopharyngeal swabs (NPS). The dry NPS were first tested by ID NOW, and second testing was performed on 1 of the RT-PCR/TMA platforms (GeneXpert Infinity, Hologic Panther Fusion or Hologic Panther TMA) within 2-18 hours of recollection of NPS in viral and/or universal transport media (VTM/UTM) after initial testing by ID NOW. A major difference between this study and our 2020 report was that our institution imposed a time limitation (1 hour maximum) for testing on ID NOW, as recommended by the manufacturer (Abbott ID NOW COVID-19 Package Insert. 2020. https://www.fda.gov/media/136525/download). However, in general, we did not reject the samples that could not be tested within the 1 hour time frame. Therefore, there were 23.5% of total samples in this study were tested by ID NOW beyond 1 hour of collection.

The overall percent agreement (OPA) between all RT-PCR/TMA platforms against ID NOW was 92.3%, with 70.3% positive percent agreement (PPA) and 95.3% negative percent agreement (NPA) (kappa value 0.64, 95% CI: 0.60 to 0.68) (Table 1A). A breakdown of OPA, PPA, and NPA for each platform (GeneXpert Infinity, Panther Fusion, and Hologic Panther TMA) against ID NOW is presented in Table 1B and D.

Among the total of 257 discrepant results, 119 samples were ID NOW-negative and/or PCR-positive whereas 138 were ID NOW-positive and/or PCR-negative. Upon review of the cycle threshold (Ct) values of thirty-one ID NOW-negative and/or PCR-positive samples performed by GeneXpert Infinity Xpert Xpress SARS-CoV-2 assay, 98% of them had Ct values of high 30s to low 40s. Throughout the pandemic, the application of Ct values in determining COVID-19 disease severity has been vastly controversial among laboratory and clinical professionals (Pujadas et al., 2020; Rhoads et al., 2021; Westblade et al., 2020). While the prediction of viral loads based on Ct values is discouraged for qualitative assays (IDSA and AMP joint statement, 2021), there is still a relative relationship between the 2 factors. It is highly unlikely that any samples with Ct values near the detectable threshold of 1 platform will necessarily reproduce the same results on a different platform. On the contrary, ID NOW-positive and/or PCR-negative samples were not repeated on a different PCR platform. Since the sample collection requires 2 different sample types – dry NPS versus NPS in VTM/UTM, several variables could have contributed to discrepancies.

Although the OPA and NPA in the group of samples tested beyond 1 hour of collection by ID NOW are similar to those tested within 1 hour of collection, the PPA was significantly lower for the samples tested beyond 1 hour than within 1 hour of collection (Table 2). Statistical analysis showed a significant correlation between testing beyond an hour of collection and potentially false-negative results by ID NOW (Fisher's test, $P < 0.05$). These findings indicated that deviating from the recommended testing time likely contributed to the potential ID NOW false-negative results. One potential reason for the poor ID NOW sensitivity and/or PPA when the dry swabs were stored longer than 1 hour could be that, after swabbing the nasopharyngeal, the swabs not only carry viruses but also various cellular enzymes (such as proteinases and RNases) which can degrade the viruses and viral RNA.

One caveat of this study is that we could not determine if ID NOW positive/RT-PCR/TMA negative samples (137 total) were true or false positive by repeat testing from the same samples since dry NPS were utilized on ID NOW. It is also likely that sampling error during the second collection or sample dilution in VTM/UTM for confirmation with RT-PCR/TMA testing could contribute to the negative RT-PCR/TMA results. Meanwhile, we observed a higher percentage of false-positive rate by ID NOW within 1 hour of collection (5.6%) than beyond 1 hour of collection (2.3%). One speculation is that cross-contamination might arise from testing under pressure to meet the goal of 1 hour.

With a robust sample size of 3320, we believe that the performance of ID NOW COVID-19 assay is better characterized, in reference to our previous report. Performance agreement of all RT-PCR/TMA assays versus ID NOW as well as that of Fusion versus ID NOW had increased (Table 1). Overall, we believe that the performance of ID NOW has improved by adhering to the manufacturer's instruction of testing within 1 hour of sample collection. This information would be extremely helpful to clinical laboratories in strategic planning to assure adequate testing in the upcoming respiratory season.

Table 1
(A-D): 2 × 2 tables of (A) All RT-PCR/TMA methods versus ID NOW; (B) Xpert Xpress by GeneXpert Infinity versus ID NOW; (C) Panther Fusion versus ID NOW; and (D) Panther TMA versus ID NOW.

		All Reference Methods		
		POS	NEG	TOTAL
ID NOW	POS	282	138	420
	NEG	119	2781	2900
	TOTAL	401	2919	3320
		Xpert Xpress RT-PCR		
		POS	NEG	TOTAL
ID NOW	POS	56	23	79
	NEG	41	700	741
	TOTAL	97	723	820
		Panther (Fusion) RT-PCR		
		POS	NEG	TOTAL
ID NOW	POS	75	56	131
	NEG	36	879	915
	TOTAL	111	935	1046
		Panther TMA		
		POS	NEG	TOTAL
ID NOW	POS	151	59	210
	NEG	42	1202	1244
	TOTAL	193	1261	1454

POS = positive; NEG = negative; PPA = positive percentage agreement; NPA = negative percent agreement; OPA = overall percent agreement; TMA = Transcription mediated amplification).
(a)PPA: 70.3% (95% CI: 65.6 – 74.8%)
NPA: 95.3% (95% CI: 94.4 – 96.0%)
OPA: 92.3% (95% CI: 91.3 – 93.2%)
(b) PPA: 57.7% (95% CI: 47.3 – 67.7%)
NPA: 96.8% (95% CI: 95.3 – 98.0%)
OPA: 92.2% (95% CI: 90.1 – 93.9%)
(c) PPA: 67.6% (95% CI: 58.0 – 76.2%)
NPA: 94.0% (95% CI: 92.3 – 95.4%)
OPA: 91.2% (95% CI: 89.3 – 92.9%)
(d)PPA: 78.2% (95% CI: 71.7 – 83.8%)
NPA: 95.3% (95% CI: 94.0 – 96.4%)
OPA: 93.1% (95% CI: 91.6 – 94.3%)

Table 2
Overall, positive, negative percentage agreements between ID NOW and RT-PCR/TMA within and beyond ONE hour of collection.

	OPA (%) between ID NOW and RT-PCR/TMA	PPA (%) between ID NOW and RT-PCR/TMA	NPA (%) between ID NOW and RT-PCR/TMA
ID NOW performed within ONE hour of collection	91.7	74.9	94.4
ID NOW performed beyond ONE hour of collection	94.2	26.3	97.7

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Declaration of competing interest

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Phyu M. Thwe
Elphas Maiyo
Ping Ren*
Department of Pathology, University of Texas Medical Branch, TX, USA and School of Health Professions, University of Texas Medical Branch, TX, USA
*Corresponding author. Tel.: 1-409-772-5109; fax: 1-409-772-5683.
E-mail Address: piren@utmb.edu

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