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Comparison of Abbott ID Now and Abbott m2000 methods for the detection of SARS-CoV-2 from nasopharyngeal and nasal swabs from symptomatic patients

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Running Head: Comparison of Abbott ID Now and m2000

The ID NOW COVID-19 (IDNCOV) assay performed on the ID Now Instrument (Abbott Diagnostics, Scarborough, Inc. Scarborough, ME) is a rapid diagnostic test that can be performed in a point of care setting equivalent to CLIA waived testing. The assay utilizes isothermal amplification and can reportedly deliver results in approximately 5-13 minutes. As this assay could provide significant improvements to workflow in our hospital system, we sought to compare the performance of this test with our current COVID-19 assay, the Abbott RealTime SARS-CoV-2 (ACOV) assay performed on the Abbott m2000 system (Abbott Molecular Inc. Des Plaines, IL).

We compared the results from 524 paired foam nasal swabs (NS) tested on IDNCOV with nasopharyngeal swabs (NPS) placed in viral transport media tested on ACOV collected consecutively from symptomatic patients meeting current criteria for a diagnosis of COVID-19 (1). Five locations were included in the evaluation including three emergency departments (ED) and two immediate care centers (IMCC). IMCC A and ED 2 were experienced users of the IDNow platform. The other sites were new users of the platform and received training specifically for the IDNCOV. All ACOV testing was performed by one central clinical laboratory, and all NPS were heat inactivated for 30 minutes at 60^{o}C prior to testing. NS were tested directly on the IDNCOV from IMCCs were performed on-site. NS from the EDs were transported to the clinical microbiology laboratory in sterile transport containers (urine cups or conical tubes) and tested by laboratory personnel at each separate location. Statistical analysis was performed using SPSS v.26.

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The overall positivity rate in this sample collection was 35%, ranging from 22%-60% among the five sites. Overall agreement was 75% positive agreement (67.74, 80.67) and 99% negative agreement (97.64, 99.89) between IDNCOV and ACOV for all specimens tested. Agreement at individual sites varied (see Table 1). Two subjects tested positive on IDNCOV that were initially negative on ACOV. In case one, a repeat sample was positive on ACOV (repeat IDNCOV was not performed), and the case was resolved as a true positive. For case two, all repeat testing (both IDNCOV and ACOV) was negative and was resolved as a likely false positive. This sample was collected during the first day of testing and could have been operator error.

Fleiss kappa analysis comparing the performance at each of the sites demonstrated that strength of agreement between the sites (Table 1) was rated as good to very good with comparable standard error. We interpret this to mean that a site's ability to run the test (or lack of experience) did not necessarily contribute to the variability in positivity that was found in this evaluation. When compared to the ACOV cycle numbers (CN) (which are similar but not directly comparable to cycle thresholds from other RT-PCR assays due to the unique ACOV assay design) a significant proportion, but not all, discordant samples were at higher cycle numbers (Figure1). The mean CN for concordant positive samples was 12.71 (11.76, 13.67), and ranging from 2.99-31.01, with a standard deviation of 5.5. The mean CN for discordant samples (ACOV+/IDNCOV-) was 21.07 (19.55, 22.60), ranging from 6.79-30.63, with a standard deviation of 5.1. These differences are statistically different (p=6.75e-16). The stated limit of detection in the published instructions for use is 100 copies/ml for ACOV (2) and approximately 3,225 copies/mL when calculated based on the published genomes/reaction for IDNCOV (3). Based on the distribution of cycle numbers

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seen in Figure 1, and performance agreement among the sites, negative results on IDNCOV are likely related to both a higher limit of detection on IDNCOV and pre-analytical sampling error.

Overall the ID NOW COVID-19 assay demonstrated significantly different performance characteristics when compared to the Abbott RealTime SARS-CoV-2 assay.

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References

1. Illinois Department of Public Health Guidelines for Diagnosis and Testing of Persons Under Investigation for COVID-19. https://www.dph.illinois.gov/topics-services/diseases-and-conditions/diseases-a-z-list/coronavirus/health-care-providers

2. Abbott RealTimeSARS-CoV-2 Instructions for Use. 51-608445/R2. March, 2020

3. ID NOW COVID-19 Instructions for Use. IN190000 Rev. 1 2020/03

Figure 1. Boxplot of Cycle Numbers of Concordant and Discordant Paired Results.

Distribution of cycle numbers from IDNCOV positive/ACOV positive samples (including a single data point (CN 31.01) outlier beyond the standard error) compared to INDCOV negative/ACOV positive samples.

92 Table 1. Agreement between ACOV and IDNCOV (95% confidence interval)

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Site	Total Samples Tested	ACOV+/ INDCO+	ACOV+/ INDCO-	ACOV-/ INDCO+	ACOV-/ INDCO-	Positivity	Positive Agreement	Negative Agreement	Performance Agreement (Kappa)
IMCC A	208	33	13	1	161	22%	71.74 (56.32, 83.54)	99.38 (96.09, 99.97)	.783 (.779, .788)
IMCC B	125	39	17	0	69	44%	69.64 (55.74, 80.84)	100.0 (93.43, 100.0)	.711 (.706, .717)
ED 1	105	26	11	0	68	35%	70.27 (52.83, 83.56)	100.0 (93.33, 100.0)	.751 (.744, .757)
ED 2	31	12	3	0	16	50%	80.0 (51.37, 94.69)	100 (75.92, 100.0)	.803 (.792, .814)
ED 3	55	29	3	1	22	60%	90.63 (73.83, 97.55)	95.65 (76.03, 99.77)	.852 (.844, .861)
Overall	524	139	47	2	336	35%	74.73 (67.74, 80.67)	99.41 (97.64, 99.89)	

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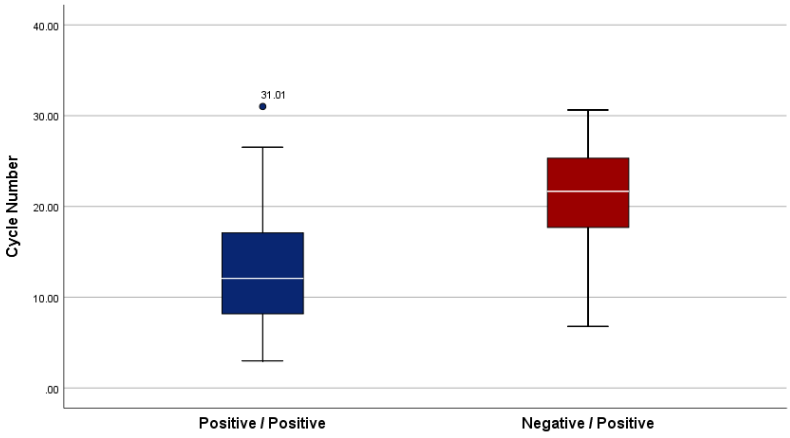

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