

# A Final Laboratory Validation Study and Comparative Performance Evaluation of The Abbott ID NOW™ COVID-19 Assay in A Coastal California Tertiary Care Medical Center

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## ABSTRACT

The Abbott ID NOW™ COVID-19 assay is a rapid molecular diagnostic test particularly designed for on-site, rapid turnaround point of care (POC) testing. The utilization of rapid diagnostic tests is integral to optimizing workflow within the hospital and/or procedural-based clinics. The capability to provide both rapid disposition and correct patient classification during this COVID-19 pandemic is critically important with broad infection control implications for both patients and healthcare staff. A tightly controlled, extended laboratory validation was performed at our medical center to determine the negative test agreement of the Abbott ID NOW™ compared with the BD MAX™ analyzer and/or Hologic Panther™, laboratory-based, two target, molecular analyzers with a sensitive level of detection (LoD). This article is a follow-on evaluation from a preliminary smaller data-set study in which 117 patient's results were included. The current data set includes a sample size of 1304 patients (over a 10-fold increase) allowing for a more robust statistical power analysis. There was strict adoption of the procedures listed in the Abbott ID NOW™ Instruction for Use (IFU) [1] insert delineating preferred practices for "optimal test performance" that also incorporates the revised Emergency Use Authorization (EUA) amendment of 17 September 2020 allowing for the use of dry nasopharyngeal (NP) swabs. Our institutional experience demonstrates an overall negative agreement of 1163 of 1178 (98.7%). Of interest, however, 11 of the original discordant results in the April to August time frame were able to be retested and 55% of the original ID NOW™ false negatives with nasal swabs that were retested with NP swabs proved to be positive, and 45% that remained false negatives (FN) even with NP swabs had Ct values > 35. As such, one could hypothesize that if dry NP swabs had been implemented months ago, that the negative test agreement could be as high as 99.4%, which equates to a 99.1% concordance similar to a previously reported correlation study [2]. It also demonstrates a LoD cutoff inflection point where sensitivity diminishes appears to be a Ct value around 35.

## INTRODUCTION

The Abbott ID NOW™ COVID-19 assay, which received Food and Drug Administration Emergency Use Authorization (FDA EUA) approval on 27 March 2020, is a rapid molecular diagnostic test particularly designed for on-site, rapid turnaround point of care (POC) testing. The analyzer uses isothermal nucleic acid amplification of a single unique region of the RNA-dependent RNA

polymerase (RdRp) genome using a self-contained, combined collection and testing kit. By mid-April 2020, Cottage Health (CH) adopted the use of the Abbott ID NOW™ analyzer and validated utilizing archived positive and negative specimens in viral transport media (VTM) as well as direct smears from known positive and negative patients. Our validation with direct smears demonstrated 100% concordance; however, there was only 80% concordance

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with the archived VTM specimens. Our analysis of this false negative discordance was coincident with the published studies from Northwell Health [3] and media reports about Cleveland Clinic [4] highlighting this issue. Given the proposed use of the Abbott ID NOW™ to test predominantly symptomatic hospital admissions in the context of the uncertainty imparted by these studies, Cottage Health purposely designed a process using dry swabs only with immediate on-site testing to comprehensively ascertain the actual negative test performance of the Abbott ID NOW™.

## STUDY DESIGN AND METHODS

The key conceptual elements of this prospective validation study were originally designed by CH senior infectious disease physicians and operationalized by emergency department (ED) and laboratory leadership. This study was initiated with the general design to test all COVID-19 prospective hospital admissions in the ED with the Abbott ID NOW™ and, if negative, recollect expeditiously and test on a laboratory-based molecular analyzer. The medical center in which this study was performed is a major referral center for Santa Barbara and adjoining counties in mid-coastal California. At the inception of this extended validation study, the county had just reached its peak and the laboratory-tabulated prevalence of COVID-19 was slightly above 10%, which according to the Infectious Disease Society of America (IDSA) guidelines [5] would have been classified as high prevalence. As the peak subsided the final average over the time interval of the study vacillated in the intermediate to low prevalence [5]. As such, the Abbott ID NOW™ with their proprietary nasal swabs was the frontline testing platform and the Becton Dickinson BD MAX™ and/or Hologic Panther™ selected as the laboratory-based platforms. To optimize clinical test sensitivity, the decision was made to adopt the practice of collecting nasopharyngeal (NP) swabs and occasionally an additional oropharyngeal (OP) swab. Another important design feature is that the Abbott ID NOW™ was collected and tested immediately on-site in the ED diminishing any significant testing delay and reducing any

potential RNA degradation associated with room-temperature, dry swab storage. Finally, a cardinal design feature to this prospective study was the deliberate recollection to occur within a short time interval (measured predominantly in single digit hours but all less than 24 hours) in order to focus specifically on testing the negative agreement concordance between the Abbott ID NOW™ and two mainline platforms rather than test clinical sensitivity variability associated with different swabs types. Our initial study was designed to specifically focus on the comparative performance of the different testing analyzers, but we also wanted to ascertain through retesting the second specimen, whether an NP swab had some degree of enhanced sensitivity compared with a nasal swab.

## RESULTS

From 16 April 2020 to 27 September 2020, a total of 1304 patients were collected and the patients ranged from 11 to 97 years. There was a significant negative percent agreement with 1163 out of 1178 patients correlating for a 98.7% concordance. In this nearly 6-month time interval, 15 out of 1178 specimens were determined to be FN (Table 1). In the 15 discordant FN specimens, we had enough sample for 11 of the 15 to retest on the Abbott ID NOW™. In other words, we took an aliquot from 11 recollected samples with NP swabs in viral transport media (VTM) that tested positive with one of the two mainline analyzers and retested the sample with the Abbott ID NOW™. We recognized that these could result negative due to VTM dilutional effect as noted earlier [3,4]; however, 6 of the 11 (55%) repeated as positive essentially confirming that NP swabs have a higher sensitivity than nasal swabs (ultimately confirming the rationale for the amended FDA EUA to include dry NP swabs as an acceptable source). Of interest, we found that 5 of the 11 (45%) that remained negative on the Abbott ID NOW™ had Ct values > 35. If we had used dry NP swabs from the inception of the study, hypothetically our final discordant rate could have been 7 out of 1170 translating into a negative concordance rate of 99.4%.

Table 1.

Abbott ID NOW™ to 2 Comparators	BD MAX™ or PANTHER™ NEG	BD MAX™ or PANTHER™ POS	% Agreement
1178 Abbott ID NOW™ Negative	1163	15	98.7% (95% CI; 97.9-99.3)

## CONCLUSION

Our institutional results are correlated with a previously reported correlation study [2] performed from 8-22 April 2020 at the Everett Clinic, Washington in which the Abbott ID NOW™ was compared to the Hologic Panther Fusion®, a laboratory-based, two target, molecular analyzer. The concordance rate of negative results was determined to be 99.8% with 932 out of 934 Abbott ID NOW™ negative results concurring with the comparator platform, relatively similar to our concordance rate of 98.7% and even closer to a hypothetical concordance of 99.4% if dry swabs were to have been used rather than nasal swabs. A possible conclusion to our institutional laboratory validation is that dry NP swabs, which are tested immediately upon or shortly after collection, enhances the sensitivity and reduces the FN rate. Similar to the Abbott Binax NOW™ that has a cutoff Ct value (Ct = 33) representing an inflection point with decreased analytic sensitivity [6] due to LoD limitations of a POC instrument compared with mainline analyzers, the cutoff Ct value for the Abbott ID NOW™ in our limited sample size appears to be 35.

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