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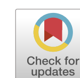
Abbott® ID NOW™ COVID-19 rapid molecular assay versus Hologic® Panther Aptima™ SARS-CoV-2 assay in nasopharyngeal specimens: results from 1-year retrospective study in an emergency department



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ABSTRACT

We compared ID Now™ and Hologic® Panther Aptima™ for the detection of SARS-COV-2. ID Now™ showed a positive and negative percent agreement of 86.9% and 99.7% respectively. This facilitates faster clinical decision-making, along with the rapid implementation of infection control measures, and improvement of patient flow in the emergency department toward inpatient wards.

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Rapid and accurate diagnosis is essential to control the pandemic caused by SARS-CoV-2 since January 2020. The Hologic® Aptima™ platform utilizes transcription-mediated amplification (TMA) targeting the *ORF1ab* gene; it doesn't exist a relationship between relative light units (RLU) signal and qPCR Ct values. This method with a limit of detection (LoD) of 83 copies/mL [1], used as the reference method in our laboratory for the detection of SARS-CoV-2 on NP swabs, provides qualitative results in 3h30 [2]. The ID NOW™ system is a point-of-care (POC) device targeting the *RdRp* gene that uses an isothermal nucleic acid amplification technique to obtain qualitative results within 13 minutes or less if the results are positive. The declared LoD in package insert is 125 copies/mL (Abbott); another study declared an LoD of 3225 copies/mL (Harrington) and a more recent study established the LoD at 64 copies/mL [3–5]. To improve the early diagnosis of COVID-19 patients, 2 ID NOW™ analyzers were installed in the emergency department (ED) on July 11, 2020. ID NOW™ tests were performed in parallel with Aptima™ assays solely for patients who would be admitted to the hospital. The patients screened were either symptomatic patients showing respiratory symptoms that suggested COVID-19 infection or asymptomatic individuals awaiting transfer into a medical or surgical ward. An NP swab was taken from 1 nostril (randomly) in order to immediately perform the ID NOW™ test in the ED; another NP swab was taken from the other nostril and placed in 2 mL PBS (Vacuette, Greiner one®) prior to performing TMA assays on the Aptima™.

One year later, in order to evaluate the performance of SARS-CoV-2 detection using either ID NOW™ or Aptima™, we carried out a monocentric retrospective study of patients between July 11, 2020, and July 12, 2021. The study enrolled 3980 inpatients, of whom 44 were excluded (invalid results with ID NOW™). Among the 3936 remaining patients, 126 were positive for SARS-CoV-2 by both ID NOW™ and Aptima™ assays, 19 were positive only with the Aptima™ assay, and 10 were positive only with the ID NOW™ assay, and 3781 were negative for both (Table 1). The positive and negative predictive values of the ID NOW™ test were 92.6% and 99.5%, respectively; positive and negative percent agreement was 86.9% (95% CI, 81.4, 92.4) and 99.7% (95% CI, 99.6, 99.9), respectively. Overall percent agreement was 99,3% (95% CI, 99.2, 99.5). The kappa coefficient was 0.898 (95% CI, 0.879, 0.917).

Nineteen patients had discordant results, showing a negative ID NOW™ and a positive Aptima™ (false negatives). RT-PCR being considered as the gold standard assay, Qiastat-Dx® Respiratory SARS-CoV-2 (Qiagen®) was chosen in this study to resolve these discrepancies and to evaluate viral load according to Ct values targeting 2 genes: that is, (*RdRp* and *E* genes) with a manufacturer's claimed LoD of 500 copies/mL [6]. Among the 19 false negatives, 5 were positive with Qiastat-Dx®, with Ct values between 29 and 38, suggesting a

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Table 1
Comparison of Abbott® ID now™ to Hologic® Panther Aptima™.

		ABBOTT® ID now™ results		
		Positive	Negative	Total
Hologic® Panther Aptima™ results	Positive	126	19	145
	Negative	10	3781	3791
	Total	136	3800	3936
Performances	Positive predictive value	92.6%	Positive percent agreement	86.9% (95% CI 81.4, 92.4)
	Negative predictive value	99.5%	Negative percent agreement	99.7% (95% CI 99.6, 99.9)

very low viral load. Interestingly, for 3 of 5 patients, ID NOW™ assays were repeated with PBS swabs after the initial discordant result and came out positive, suggesting a possible difference in the quality of sampling between the 2 nostrils or a mistake during the processing of the ID NOW™ testing in ED. Two of the 5 patients had low RLU on the Aptima™ test (between 624 and 681, only 1 target detected) and were retested 2 days after the initial discordant result and were negative in both ID NOW™ and Aptima™ tests, suggesting a very low viral load, as reported for COVID-19 convalescence. By contrast, 14 were negative for SARS-CoV-2 with Qiastat-Dx®. Eight of 14 patients had a history of proven COVID-19 disease in the previous month suggesting a very low viral load only detected by the method with the smallest LoD. Six of 14 patients consulted in the ED with symptomatology different from COVID-19 disease (febrile aplasia, rhabdomyolysis, fall with the loss of consciousness); when obtaining Aptima™ results, clinicians had identified these patients as asymptomatic for COVID-19 disease. For these 6 patients, we could not totally exclude false positives with the Panther Aptima™ test although different LoDs can explain these results.

Ten patients had discordant results consisting of a positive ID NOW™ and a negative Panther Aptima™ (false positives). No second NP swabs to confirm these discrepancies had been performed. Moreover, for each, it was verified that a positive patient had not been tested before on the ID NOW™ (which may lead to suspicion of contamination). Routinely, the Qiastat-Dx® test was not used because our reference method Aptima™ had a smaller LoD than Qiastat-Dx®. As part of this retrospective study, we had not able to reanalyze these samples because we stored only positive samples on Aptima™ beyond 1 week at -80°C. Finally, remember that ID NOW™ tests were performed in the ED from NP swab taken from one nostril and discarded immediately after the process (with no retesting possibility). Four of 10 patients had a history of proven COVID-19 disease in the previous month suggesting a possible difference in the quality of sampling between the 2 nostrils. Six of the 10 patients had clinical history different from COVID-19, and the reasons for admission were diverse (renal colic, pyelonephritis, naked fever). Clinicians had identified these 6 patients as ID NOW™ false positives.

In this comparative analysis involving 3936 specimens, the ID NOW™ assay showed very good performance in comparison to the Aptima™ test as other studies have shown [7,8]. Some publications have reported lower positive agreement for the ID NOW™ assay mainly relating to false negatives. These studies focused on a smaller number of samples and evaluated NP swabs eluted in transport media and/or nasal swabs [4,9–11], while our study compared assays performed with 2 NP swabs under the manufacturer's recommendations. The majority of false negatives with ID NOW™ in our study corresponded to weakly positive specimens, as evidenced by the 14/19 individuals negative with ID NOW™ who remained negative by RT-PCR Qiastat-Dx. Therefore, when clinical history is consistent with SARS-CoV-2 infection, negative results from ID NOW™ assays should be retested on a different molecular platform with lower LoD. The false positive rate was very low, as reported by other studies [4,8,9]. The risk of cross-contamination and subsequent false positives may be higher when testing is performed outside of a controlled laboratory. In our hospital, a half-day of training was provided to all users in order to raise awareness of risks relating particularly to personal protective equipment. This training led us to recommend a systematic ID NOW™ disinfection after each test.

To conclude, the ID NOW™ assay delivers the shortest turnaround time combined with reliable results. This facilitates faster clinical decision-making, along with the rapid implementation of infection control measures, and improvement of patient flow in the ED toward inpatient wards. Staff training is a key element for optimal use of this POC system.

Authors' contributions

Aurore Bousquet: data curation, data analysis, writing, reviewing, and editing; Sébastien Larréché: reviewing and editing; Christine Bigaillon: reviewing and editing; Alexandre Woloch: installation of Abbott ID NOW™ analyzers and study design; Léa Thomas: installation of Abbott ID NOW™ analyzers and study design; Pierre Louis Conan: study design, reviewing, and editing; Audrey Mérens: data curation, data analysis, writing, reviewing, and editing.

Ethical approval

This monocentric retrospective study obtained approval from HIA Bégin Ethic and Research Committee in accordance with the French MR004 method.

Declaration of competing interests

All authors declared that there is no conflict of interest in conducting this study.

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