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LETTER TO THE EDITOR

Evaluation of the BinaxNOW COVID-19 Rapid Antigen Test in an Asymptomatic Patient Population Undergoing Preprocedural Screening

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As of September 2021, coronavirus disease 2019 (COVID-19) cases have exceeded 220 million and resulted in more than 4 million deaths worldwide, as reported by the Johns Hopkins COVID-19 Resource Center (https://coronavirus.jhu.edu/map.html). Molecular testing has been the most common method for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of COVID-19. These tests have received emergency use authorization (EUA) by the U.S. Food and Drug Administration (FDA) for symptomatic patients. However, asymptomatic individuals represent a significant source of transmission of SARS-CoV-2, as the virus may be present at high levels even before a patient develops symptoms. As a result of increasing case counts and the need for broader testing capabilities, alternative approaches have been developed, including rapid antigen tests. Antigen testing has several benefits compared to laboratory-based molecular assays, including a more rapid turnaround time (e.g., <20 min), lower cost, and clinical laboratory improvement amendments (CLIA) waiver for some antigen assays, allowing them to be performed outside of a traditional laboratory setting. However, there are several significant limitations of rapid antigen tests, including lower analytical sensitivity and concerns related to their specificity (1–4). The possibility of false-positive results is of particular importance when the disease prevalence is low.

There are currently limited data on the performance of rapid antigen tests in the asymptomatic population, despite this being a common group undergoing SARS-CoV-2 screening (5). In this study, we sought to compare the performance of routine molecular testing and a rapid antigen assay (BinaxNOW; Abbott Rapid Diagnostics, Lake Forest, IL) in asymptomatic patients undergoing COVID-19 preprocedural/surgical screening. Patients (n = 997) who reported no symptoms related to COVID-19 at the time of testing and who were undergoing routine preprocedural/surgical COVID-19 screening between 19 November 2020 and 29 January 2021 were eligible for this study. Following receipt of written informed consent, each patient had a nasopharyngeal swab collected for routine COVID-19 molecular testing, as well as an anterior nares swab for the BinaxNOW rapid antigen test. Routine molecular COVID-19 testing was performed by either the Aptima SARS-CoV-2 transcription-mediated amplification (TMA) method (Hologic, San Diego, CA) or a laboratory-developed real-time PCR (6). Testing by both the Aptima TMA assay and the BinaxNOW rapid antigen test was performed according to the manufacturers' instructions.

Following testing of 997 study participants, 8 (0.8%) had an abnormal (i.e., nonnegative) result by either the standard molecular test (n = 7) or the BinaxNOW rapid antigen test (n = 1). Among the seven patients with a nonnegative molecular result, four

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TABLE 1 Laboratory and clinical characteristics of patients with a nonnegative SARS-CoV-2 molecular or rapid antigen test result

Patient	Molecular test result	Rapid antigen result	Notes
1	Negative	Positive	Seen for possible Crohn's ileitis; likely false-positive Ag[a]
2	Positive[b]	Negative	Previously diagnosed (34 days prior) with COVID-19
3	Positive[c]	Negative	Previously diagnosed (49 days prior) with COVID-19
4	Positive[d]	Negative	Previously diagnosed (23 days prior) with COVID-19
5	Positive[e]	Negative	First time diagnosis of COVID-19; chronic lung disease
6	Indeterminate[f]	Negative	Molecular test was positive the following day for COVID-19
7	Indeterminate[g]	Negative	Molecular test was positive the following day for COVID-19
8	Inconclusive	Negative	Molecular test was negative the following day for COVID-19

[a]Ag, antigen.
[b]Real-time PCR cycle threshold (C_T) value of 35.
[c]Real-time PCR C_T value of 33.3.
[d]Real-time PCR C_T value of 29.7.
[e]Real-time PCR C_T value of 30.0.
[f]Real-time PCR C_T value of 35.
[g]Real-time PCR testing the following day yielded an indeterminate result. Transcription-mediated amplification (TMA) assay yielded a relative light unit (RLU) value of 1,031.

patients had a positive result, two had an indeterminate result (i.e., low-level PCR signal; confirmed as positive the following day), and one had an inconclusive result (i.e., possible interfering substance). These seven patients tested negative by the BinaxNOW rapid antigen test. One patient was positive by the BinaxNOW antigen test but negative by the routine molecular test (Table 1). A limitation of this study was the low number of patients testing positive by the molecular and/or antigen tests, which limits any conclusions that can be made about the sensitivity of antigen testing.

In conclusion, 6 (0.6%) of 997 patients were confirmed by molecular testing to be positive for SARS-CoV-2 RNA, and antigen was negative in each of these cases. Of these six patients, three had been previously diagnosed with COVID-19 >20 days prior, so the molecular results likely suggest persistent viral RNA. Three other patients were positive for the first time for SARS-CoV-2 RNA, but all were asymptomatic at the time of testing. The rapid antigen test demonstrated high specificity (99.8%) with only one false-positive result out of 991 samples that were negative by molecular testing. In areas of low disease prevalence, screening of asymptomatic patients with a molecular test prior to a procedure or surgery will likely maximize sensitivity and reduce potential exposure to health care staff.

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