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BRIEF REPORT

Detection of the Omicron Variant Virus With the Abbott BinaxNow SARS-CoV-2 Rapid Antigen Assay

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We assessed the ability of the BinaxNow rapid test to detect severe acute respiratory syndrome coronavirus 2 antigen from 4 individuals with Omicron and Delta infections. We performed serial dilutions of nasal swab samples, and specimens with concentrations of ≥100 000 copies/swab were positive, demonstrating that the BinaxNow test is able to detect the Omicron variant.

Keywords. BinaxNow; diagnostic test; rapid antigen; SARS-CoV-2; viral load.

The US Centers for Disease Control and Prevention recommends rapid testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection as a key element of epidemic control [1]. One such assay, the Abbott BinaxNow, has been recommended for in-home testing and implemented in public health screening campaigns [2–6]. The diagnostic validity of the assay has been demonstrated in laboratory-based and clinical settings, with a sensitivity ranging from approximately 50% to 90%, depending on disease stage and degree of symptom, and a specificity >99%, compared with laboratory-based polymerase chain reaction (PCR) assays [3, 4, 7, 8].

Notably, test performance of chromatographic immunoassays, such as the BinaxNow, is dependent on specific viral antigens and may be impacted by changes in viral protein structure. In November 2021, the Omicron variant of SARS-CoV-2 was first reported in Southern Africa, and it quickly disseminated globally [9]. The initially identified lineage of the Omicron variant contains >50 mutations and deletions in comparison with ancestral lineages, including 4 mutations in the nucleocapsid gene, which is the target for the BinaxNow assay. Abbott, the manufacturer of the assay, has reported in a press release that the assay is predicted to detect the Omicron variant of SARS-CoV-2 infection [10]. However, there are no published data on the validity of the assay with clinical specimens.

We conducted a laboratory-based validation of the BinaxNow assay with anterior nasal (AN) swab specimens from participants in a study of coronavirus disease 2019 (COVID-19) virology [11]. We recruited individuals testing positive for COVID-19 PCR at an academic medical center. Positive AN swabs were stored in viral transport media and evaluated by viral load quantification and whole-genome sequencing [12]. We selected 2 Omicron variant specimens and 2 Delta variant specimens and produced serial dilutions to create swabs of 2.5×10^5, 1.0×10^5, 2.5×10^4, and 2.5×10^3 viral copies with each specimen. These dilutions were chosen to create concentrations both above and below previously reported limits of detection of the assay in a laboratory-based evaluation [8]. To do so, we initially created viral concentrations of 5.0×10^4, 5.0×10^5, 2.0×10^6, 5.0×10^6 copies/mL in phosphate-buffered saline, then immersed swabs from the BinaxNow kits into 50 µL of each dilution until the material was fully absorbed, as previously described [8]. An additional specimen with only phosphate-buffered saline was used as a negative control. The swabs were then tested according to the manufacturer's instructions, and results were interpreted by 3 readers, blinded to the specimen variant and concentration, as positive, negative, or discordant (if not all 3 readers agreed).

The 4 specimens with concentrations of ≥100 000 copies/swab were positive with both the Delta and Omicron variant specimens (Figure 1). Assay sensitivity was diminished below that, with positive results in one-fourth of Omicron specimens and one-third of Delta specimens (with the fourth Delta specimen resulting in discordant reads between reviewers). All specimens with 2500 copies/swab were interpreted as negative.

Omicron variant SARS-CoV-2 infections were detected in a laboratory-based assessment of the BinaxNow rapid antigen assay. This is the first report to our knowledge of this assay being formally assessed with the Omicron variant, especially in light of concerns that certain rapid antigen tests may have lower sensitivity when detecting the Omicron variant [13]. One strength of this study is the use of patient samples containing live virus, which is preferred over heat-inactivated samples. Although this study does not intend to identify a limit of detection for this assay, our results are qualitatively similar to previously published results suggesting that the BinaxNow assay has a limit

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Figure 1. Results of a laboratory-based analytic validation of the BinaxNow SARS-CoV-2 rapid antigen assay across a range of concentrations with both Delta and Omicron variant viruses. For the discordant result, 2 reviewers reported a negative result and 1 reported a positive result. [a]Discordant results indicate those in which there was not agreement between the 3 blinded readers of each test. Abbreviation: SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

of detection of approximately $2.0 \times 10^4 - 7.0 \times 10^4$ viral copies/swab [8]. Our study is limited by a small sample, with evaluation of only 2 specimens per variant. Specimens were self-collected by participants, but tested in a central laboratory, so the data should not be extrapolated to represent point-of-care test performance in real-world settings. Nonetheless, these data offer proof of concept that the BinaxNow rapid antigen assay can detect Omicron variant SARS-CoV-2 infections. Future work should more thoroughly assess the diagnostic validity and range of detection of the assay for this novel variant, as well as its performance in clinical, public health, and self-testing scenarios.

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Patient consent. Study procedures were approved by the institutional review board of Mass General Brigham, and participants gave written consent for specimen testing for research purposes.

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