Performance and Implementation Evaluation of the Abbott BinaxNOW Rapid Antigen Test in a High-throughput Drive-through Community Testing Site in Massachusetts (updated November 26, 2020)

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Background: Rapid antigen tests (RDTs) for SARS-CoV-2 antigens (Ag) that can be performed at point-of-care (POC) can supplement molecular testing and help mitigate the COVID-19 pandemic. Deployment of an Ag RDT requires an understanding of its operational and performance characteristics under real-world conditions and in relevant subpopulations. We evaluated the Abbott BinaxNOW in a high-throughput, drive-through, free community testing site in Massachusetts (MA) using anterior nasal (AN) swab PCR for clinical testing.

Methods: All patients presenting for testing in two of seven lanes were offered the opportunity to also receive BinaxNOW testing. Dual AN swabs were collected from symptomatic and asymptomatic children (≤ 18 years) and adults. BinaxNOW testing was performed in a testing pod with temperature/ humidity monitoring. One individual performed testing and official result reporting for each test, but the majority of tests had a second independent reading to assess inter-operator agreement. Positive BinaxNOW results were scored as faint, medium, or strong. Positive BinaxNOW results were reported to patients by phone and they were instructed to isolate pending PCR results. The paired PCR result was the reference for sensitivity and specificity calculations.

Results: Of 1764 participants, 1380 adults and 233 children had paired PCR/BinaxNOW results and complete symptom data. 974/1380 (71%) adults and 167/233 (72%) children were asymptomatic. The test had 96.5% (95% CI 90.0- 99.3) sensitivity and 100% (98.6-100.0) specificity in adults within 7 days of symptoms, and 77.8% (52.4-93.6) sensitivity and 100% (92.0-100.0) specificity in children within 7 days of symptoms. Sensitivity and specificity in asymptomatic adults were 70.2% (56.6-81.6) and 99.6% (98.9-99.9), respectively, and in asymptomatic children were 63.6% (30.8%-89.1) and 99.4% (96.5-100.0), respectively. By Ct value threshold, sensitivity in all subgroups combined (n=187 PCR-positive individuals) was 100% with Ct ≤25, 98.6% with ≤30, and 85.6% with ≤35. Six false positive BinaxNOW results (out of 1613 tests) were observed; in all six, test bands were faint but otherwise normal, and were noted by both readers. Inter-operator agreement (positive versus negative BinaxNOW result) was 100% (n = 1535/1535 double reads). Each operator was able to process 20 RDTs per hour. In a separate set of 30 specimens (from individuals with symptoms ≤7D) run at low temperature (46-58.5°F), sensitivity was 66.7% and specificity 95.2%.

Conclusions: Performance findings and recommendations for use: The BinaxNOW had very high specificity in both adults and children and very high sensitivity in newly symptomatic adults. Overall, 98.6% sensitivity was observed with Ct ≤ 30. These data support public health recommendations for use of the BinaxNOW test in adults with symptoms for ≤7 days without PCR confirmation. Positive results in asymptomatic individuals do not need confirmation under current

rates of community transmission in MA; with lower prevalence, confirmation (by PCR or an orthogonal RDT) could be considered. The test is not recommended for use in individuals with symptoms > 7 days. Operational findings: Excellent inter-operator agreement indicates that an individual can perform and read the BinaxNOW test alone. A skilled laboratorian can perform and read 20 tests per hour. Careful attention to temperature is critical.