Rapid antigen testing for COVID-19: Piecing the puzzle together

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A new study from Boston Children's Hospital and the Massachusetts Department of Health compared one of the latest rapid antigen tests for COVID-19—the Abbott BinaxNOW—with a highly accurate PCR test in a high-volume, drive-thru testing environment. They found that the rapid test detected almost all adults who tested positive by PCR if they had had symptoms lasting seven days or less. In symptomatic children with less than seven days of symptoms, the test picked up about 85 percent of true positive cases.

But no matter the age, if the patient had high amounts of virus in their nose, the test caught it 99 percent of the time. It was also able to rule out COVID-19 in almost all people who were not infected, including adults and children with and without symptoms.

"What this means is that if the BinaxNOW antigen test comes back with a positive result, that is a reliable true result," says Nira Pollock, MD, Ph.D., associate medical director of the Infectious Diseases Diagnostic Laboratory at Boston Children's Hospital, who co-led the study along with Dr. Sandra Smole, director of the Massachusetts State Laboratory. "For a negative test result, we need to think more carefully about exactly who we are testing and why."

Evaluation in a real testing environment

The Abbott BinaxNOW test is a nasal swab test that will be distributed widely throughout Massachusetts for rapid, on-site testing through funding provided by the Massachusetts Department of Public Health (DPH).

The study included 1,380 adults and 928 children who came for testing at a large drive-through community testing program run by DPH and Lawrence General Hospital in an area with a high rate of COVID-19. Each person received an anterior nasal swab—one that swabs only the inside of each nostril, not farther back—for BinaxNOW and another for PCR. The BinaxNOW test was performed on-site by trained operators, and the other swab was sent to the Broad Institute for PCR testing.

Viral load may explain the difference in testing results

In adults who had symptoms lasting seven days or less, the BinaxNOW test detected 96.5 percent of COVID-19 cases detected by PCR. In children, the number was 84.6 percent of cases, about a 12 percent difference.

But when the PCR tests were evaluated, they found that symptomatic adults and children had different viral loads, or amounts of virus in their nasal swabs.

Symptomatic adults tended to have high viral loads so they were almost all detected by the BinaxNOW test. But, the symptomatic children had a larger spread of viral burden in that first week of symptoms, which meant about 15 percent of them were missed. This likely means that the difference

in detecting symptomatic adults and children—96.5 percent versus 84.6 percent—was due to a difference in the viral load distribution between the two groups, not a problem with the rapid test itself.

Children may have more variable amounts of virus

"Researchers, including me, have found similar hints in other studies that children don't always have as much virus as adults—but we need to collect more data in children to confirm these findings, since the number of symptomatic children in this study was relatively small," says Pollock. "I think it's possible that kids as a group don't produce the same reliably high viral loads as adults early after COVID-19 infection, but they certainly can. In this study, there were plenty of children that had tons of virus but as a group there were a few more of them that didn't. Therefore, the ability of the BinaxNOW test to detect a positive result was lower than it was in adults."

In asymptomatic adults, the test picked up about 70 percent of cases compared with 65.4 percent in asymptomatic children, which Pollock says is also likely to reflect the distribution of viral loads in people without symptoms—since they don't have symptoms, they might end up getting tested early or late in their illness when the amount of virus present may be variable.

The researchers also learned that interpreting the BinaxNOW test did not vary depending on who performed the test—two independent readers got the same answer every time. "That suggests to me that you do not need more than one person to do the test," says Pollock. "That's good to know in cases where this test may be used in a school nurse's office or another site where there is only one person available to do the testing."

What comes next

"Given the difference we saw between symptomatic adults and children, we need to think carefully about what to do in children who have a negative rapid test, and whether it might sometimes be necessary to supplement that rapid test with PCR testing," says Pollock. The same is true for potential use in asymptomatic adults and children where the detection rates are even lower. "Public health officials need to thoughtfully consider the prevalence of COVID-19 in a community and the specific goals of a community's testing program when deciding how to use this rapid test," she says.

Pollock expects that her DPH colleagues will consider use of the BinaxNOW test in adults and children with symptoms of seven days or less without recommending a PCR confirmatory test. The team thinks that given the current high rates of COVID-19 transmission in many communities, positive BinaxNOW results in anyone should be trustworthy; any positive test with BinaxNOW does not routinely need a PCR test to confirm it. DPH generally updates its testing guidance as new information becomes available for new tests. In any case, the BinaxNOW test is not recommended for use in adults or children with symptoms lasting longer than seven days.

More information: Nira R. Pollock et al, Performance and Implementation Evaluation of the Abbott BinaxNOW Rapid Antigen Test in a High-throughput Drive-through Community Testing Site in Massachusetts, *Journal of Clinical Microbiology* (2021). DOI: 10.1128/JCM.00083-21

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