Some at-home tests may miss Omicron in early stages of infection

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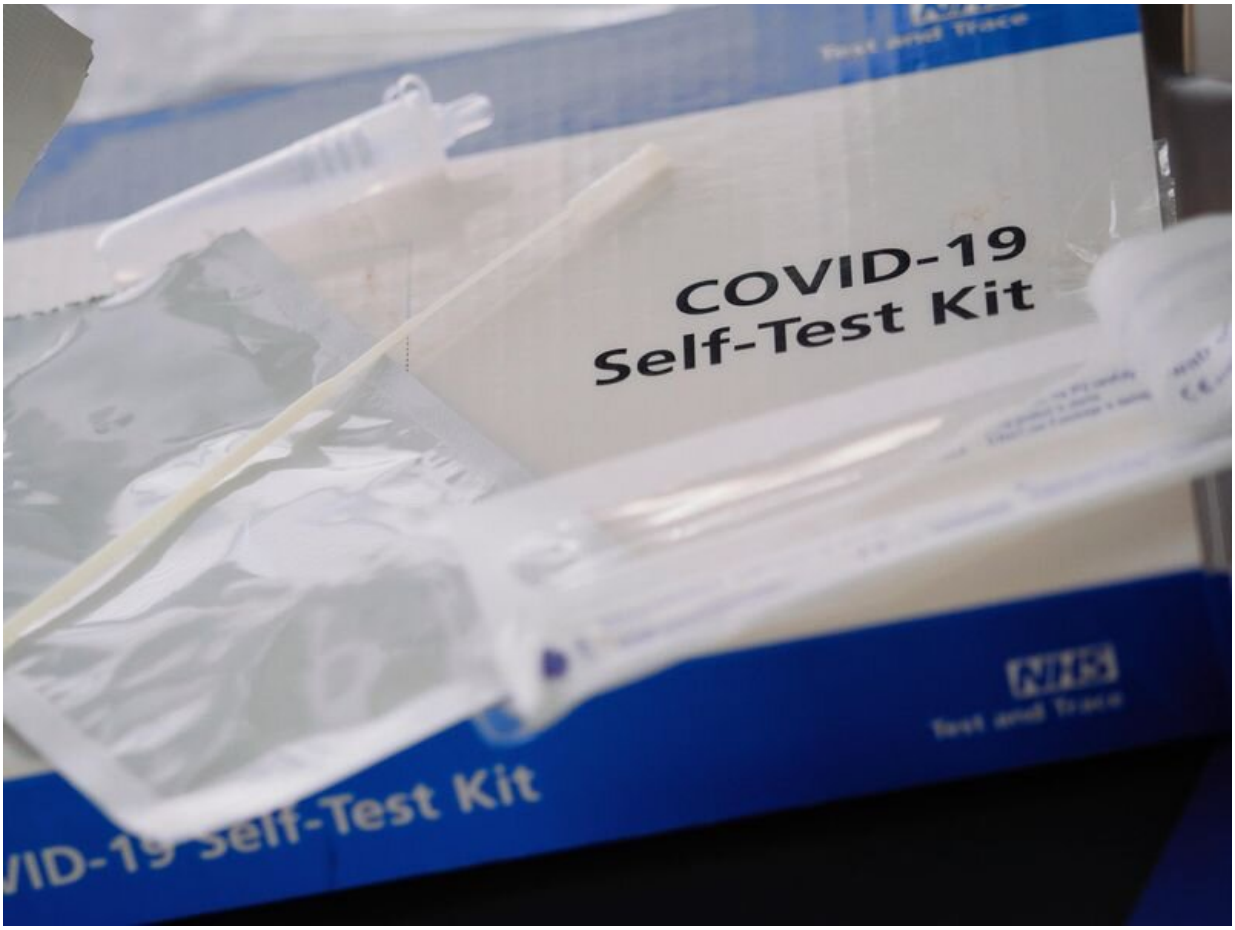

(HealthDay)—The Abbott BinaxNOW and Quidel QuickVue—two

widely used rapid at-home COVID tests—may sometimes fail to spot evidence of the Omicron variant in the first days after infection, even when people are carrying substantial levels of the virus, preliminary research suggests.

The researchers focused on 30 people infected with COVID at five workplaces that experienced what were most likely outbreaks of the Omicron variant last month. The people received both saliva-based PCR tests (the gold standard) and rapid antigen-based tests involving nasal swabs.

It took three days, on average, for people to test positive on the two rapid antigen tests after their first positive PCR result, researchers reported. In four cases, people transmitted the virus to others after a negative result, according to the study, which hasn't yet been peer-reviewed.

It is not yet clear whether the infections were missed because the antigen tests are inherently less sensitive to Omicron or because saliva tests may be better at detecting the new variant, *The New York Times* reported.

One possible explanation? Omicron may replicate faster or earlier in the throat and mouth than in the nose, experts said.

"While we'll have to wait to see if the science bears out, that might be an indicator that that's where the virus is growing first," Gigi Gronvall, an immunologist and testing expert at Johns Hopkins Bloomberg School of Public Health, told the *Times*. "So if you're going to look for the virus, which is what the tests do, then you may find more of it faster in the throat swab over the nose."

Reports have also surfaced that some people who initially tested negative on antigen tests when they swabbed inside their noses went on to receive a positive result when they swabbed the back of their throats.

"There's a lot of chatter around this," Nathan Grubaugh, a virologist at the Yale School of Public Health, told the *Times*. "Obviously, that warrants further investigation."

The latest study is consistent with other preliminary evidence that the at-home tests that many Americans have come to rely on may fail to detect some Omicron cases in the early days of infection.

"The message is not that we should stop using these tests," Isabella Eckerle, a clinical virologist at the University of Geneva in Switzerland, told the *Times*.

But people should remain cautious after getting negative results, especially when they have symptoms or believe they may have been exposed to the virus.

"It's not a ticket that allows you to go back to normal or to drop any other measures," Eckerle notedd.

Why might the rapid tests be missing Omicron in the early stages of infection? They are designed to detect proteins lying on the surface of the coronavirus. If mutations in the virus change the structure of these proteins, antigen tests might miss the variant, experts said.

The researchers said they shared their results with federal officials in real time, as the outbreaks were occurring last month.

"They're aware that there are flaws with antigen testing," study author Dr. Robby Sikka told the *Times*.

The study comes a week after the U.S. Food and Drug Administration released its own update on the effectiveness of the rapid antigen tests. "Early data suggests that antigen tests do detect the Omicron variant but

may have reduced sensitivity," the agency said in a statement.

Many of those studies are early and small, and much more data is needed. The tests can deliver results at home in minutes and positive results are more reliable, scientists have said. That's an important tool alongside PCR tests that can take days to come back.

The Omicron variant has about 50 mutations, including more than 30 on the spike protein alone. Most rapid antigen tests are designed to detect more stable targets, the *Times* reported.

In September, the FDA told makers of rapid tests that they would be required to continue to test their products as new variants emerged, and, if asked, to share those results with the agency, the newspaper said.

Many companies have announced that their tests can detect Omicron, and several independent scientists said that they believed the tests should be capable of recognizing the variant, especially when present at high levels. But the new studies raise questions about the tests' sensitivity.

Last week's update from the FDA stemmed from testing done by the National Institutes of Health, Bruce Tromberg, director of the National Institute of Biomedical Imaging and Bioengineering, told the *Times*. The scientists evaluated the antigen tests using pooled nasal swab samples collected from people with either the Omicron variant or the Delta variant.

They then diluted each of these pooled samples until the antigen tests no longer detected the virus. They found the tests may be less sensitive to the new variant, Tromberg said. Still, he added, in real-world settings, "it may not translate into any different sensitivity."

FDA spokeswoman Stephanie Caccomo told the *Times* last week that

studies were underway "to confirm the reason for the apparent decreased sensitivity."

"Once that is known," she said, "adjustments to existing tests can be undertaken by each developer with support from the FDA, if appropriate."

The FDA update was not the first sign of decreased sensitivity with the rapid tests. Eckerle and her colleagues recently evaluated seven antigen tests against samples of the virus grown from specimens taken from people infected with Omicron. Overall, the researchers found, the tests were less sensitive to Omicron than to previous variants.

"They missed samples with infectious virus, and they missed samples that had quite a decent viral load," Eckerle said. The work was published in December on a preprint server.

More information: Visit the U.S. Centers for Disease Control and Prevention for more on COVID testing.

Blythe J Adamson et al, Discordant SARS-CoV-2 PCR and Rapid Antigen Test Results When Infectious: A December 2021 Occupational Case Series, (2022). DOI: 10.1101/2022.01.04.22268770

Meriem Bekliz et al, Analytical sensitivity of seven SARS-CoV-2 antigen-detecting rapid tests for Omicron variant, (2021). DOI: 10.1101/2021.12.18.21268018