Study shows rapid COVID-19 tests done at home are reliable

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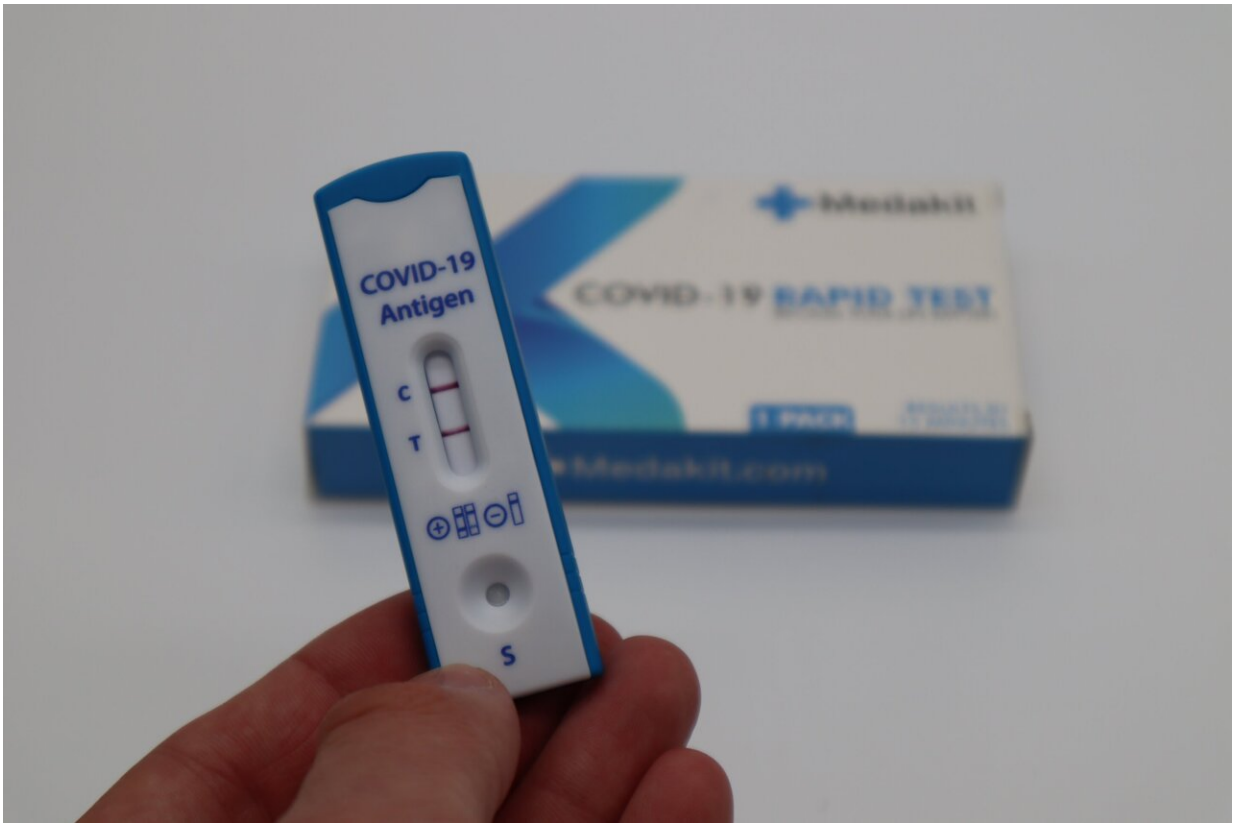

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In a study involving nearly 1,000 patients seen at the Baltimore Convention Center Field Hospital (BCCFH) during a five-month period in 2022—researchers at Johns Hopkins Medicine, the University of

Maryland School of Medicine and five other collaborators report that a rapid antigen test (RAT) for detecting SARS-CoV-2, the virus that causes COVID-19, can be used at home with accuracy comparable to the same test being administered by a health care professional.

The study was first posted online Feb. 13, 2024, in the journal *Microbiology Spectrum*.

The researchers say their findings show that self-administered RATs rivaled the clinician-administered tests in both sensitivity (the ability, according to the National Institutes of Health (NIH), to provide a positive result for a person infected with SARS-CoV-2) and specificity (the ability, also according to NIH, to yield a negative result for a person not infected with the virus).

They added that both the self-administered and clinician-administered rapid tests evaluated in the study were comparable to the sensitivity and specificity of the established standard test for COVID-19—the polymerase chain reaction (PCR) assay.

"We found the results between the self- and clinician-administered rapid tests were statistically similar in sensitivity—83.9% to 88.2%, respectively—and specificity—99.8% to 99.6%, respectively," says study senior author Zishan Siddiqui, M.D., assistant professor of medicine at the Johns Hopkins University School of Medicine. "We believe this is an important finding because it suggests physicians can feel confident prescribing treatment based on patient-reported, self-administered tests with positive results."

The first step for both the PCR and rapid antigen tests is obtaining a sample from a patient, either by nasal swab or collected saliva. The difference lies in how the sample is processed and analyzed. A PCR test takes a tiny bit of SARS-CoV-2 genetic material from a sample and

reproduces it thousands of times so it can be more easily detected.

A rapid antigen test uses laboratory-produced antibodies to seek out and latch onto proteins on the surface of SARS-CoV-2 particles in the sample. The PCR test requires a skilled laboratory technician, special equipment and up to an hour or more to process. Testing on a massive scale can only be conducted at a large, centralized testing facility, such as a hospital laboratory.

On the other hand, rapid antigen testing uses a premade kit with a reagent that contains antibodies specific for SARS-CoV-2. The test can be conducted by anyone, administered anywhere and provides results in approximately 15 minutes.

For their study, the researchers enrolled 953 adult patients being seen at the BCCFH during the period of Feb. 12 to July 15, 2022. The study group was 60.6% female, 58.6% white, and 98.2% English-speaking. The median age was 34.

Participants reporting at least one COVID-19 symptom were categorized as symptomatic, while those reporting no symptoms were marked asymptomatic. Attending staff conducted both rapid antigen and PCR tests on the participants, and then had them independently perform a RAT. The patients were asked to report their own results, which the researchers re-read and assessed.

In an earlier study at the BCCFH, the researchers showed that RATs could be broadly, quickly and effectively applied to a large community such as Baltimore.

"What we determined from our previous work was that while the PCR test may be a better test from a clinical perspective—as it's basically 100% accurate at detecting SARS-CoV-2—the rapid antigen test

provided significant advantages from a public health standpoint because of its ease of use, and the fact that it proved to have sufficient accuracy, specificity and reliability for detecting the coronavirus in a high-volume setting," says study lead author Mary Jane Vaeth, a clinical assistant at the field hospital, which is now closed.

"The first study suggested that a health care system can provide an equitable response to COVID-19, with RATs making it possible to test all socioeconomic levels of a large population quickly and repeatedly," says Siddiqui. "The new study bolsters that belief by showing comparable accuracy between self- and physician-performed RATs and, therefore, helping build clinician confidence in patient-reported results from at-home tests."

"Despite the robust findings of our latest study, there were some limitations," says Vaeth. "The main one, of course, was the fact that we evaluated the self- and clinician-administered accuracy of only one brand of RAT, and therefore, future studies should look at an array of brands across a broader demographic spectrum so that our results can hopefully be confirmed and amplified."

The rapid antigen test used in this study is the BinaxNOW COVID-19 test manufactured by Abbott and supplied at no cost by the Maryland Department of Health.

More information: Mary Jane E. Vaeth et al, Self-administered versus clinician-performed BinaxNOW COVID rapid test: a comparison of accuracy, *Microbiology Spectrum* (2024). DOI: 10.1128/spectrum.02525-23

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