Researchers develop a more sensitive, rapid at-home COVID-19 test

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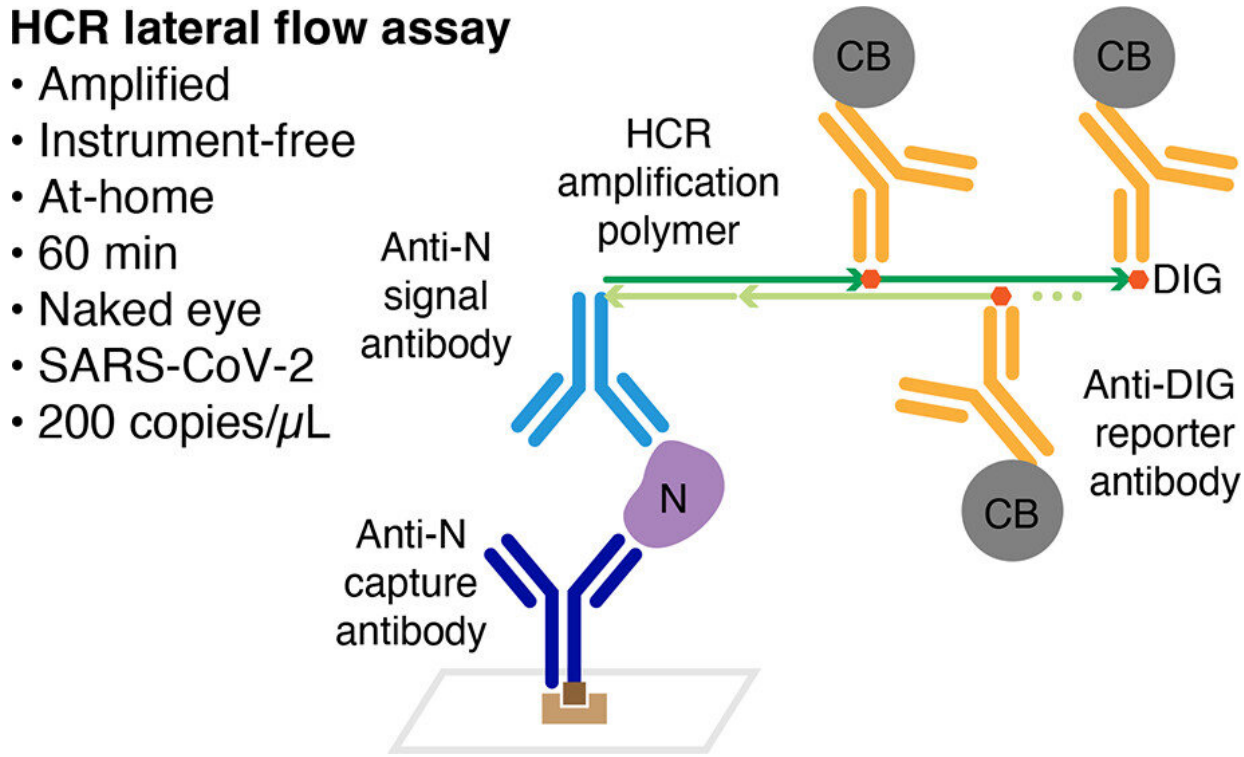

Graphical abstract. Credit: *ACS Infectious Diseases* (2023). DOI: 10.1021/acsinfecdis.2c00472

Caltech researchers have developed a new at-home test for COVID-19 that is more than twice as sensitive as current state-of-the-art antigen tests. While the test was developed for COVID-19, the technology can be used as a platform for designing tests to detect other pathogens as

well.

The research was conducted in the laboratory of Niles Pierce, professor of applied and computational mathematics and bioengineering, and executive officer for biology and biological engineering, and is described in a paper in the journal *ACS Infectious Diseases*.

"Many have thought of diagnostics as a 'solved problem,'" says Pierce. "But with the COVID-19 pandemic, we quickly learned that scaling diagnostics rapidly to the level of the human population is a huge challenge. Unfortunately, we know that we are going to face more pandemics in the future, and we need to be ready to respond."

A major challenge in instrument-free at-home testing for COVID-19 is that SARS-CoV-2 (the virus that causes the disease) can be present in a given sample in very low amounts. With laboratory-based polymerase chain reaction (PCR) testing, any fragments of the viral RNA genome that are present in a patient's sample are used to generate multiple DNA copies, yielding an amplified signal that can be detected more easily. Even a tiny amount of SARS-CoV-2 in a sample can be detected by a PCR test, making it the gold standard for detecting infection. However, lab-based PCR tests require expensive equipment and several hours to run.

At-home rapid tests, on the other hand, have the advantage of requiring no instrumentation, but generate an unamplified signal by using specially designed antibodies to stick colored reporter molecules onto any SARS-CoV-2 proteins present in the sample. If there is not very much virus in the sample, the brightness of the color—its signal—is quite faint, or even undetectable. This could lead to false-negative results, even in a case where an individual was actually positive for COVID-19.

In the new work, researchers in the Pierce lab have combined the ease of

an instrument-free at-home test with amplification techniques. To do so, they utilized a technology called hybridization chain reaction (HCR), which boosts the signal of the reporter molecules. With the new test, every viral protein captured then grows a long tail of DNA. This DNA does not encode for anything biological but rather acts as a specially designed scaffold upon which many colorful reporter molecules can attach. In this way, each viral particle emits a much "brighter" signal. In a skillful engineering process, the team designed the amplified test so that each step occurs sequentially in a disposable device about the size of a playing card without user intervention.

The team compared their new HCR test with five commercially available antigen tests. Their test was 2.5 times more sensitive than the best at-home test and 100 times more sensitive than the worst, despite not having access to the proprietary antibodies that are used in the commercial tests.

The two first authors on the paper, graduate student Samuel Schulte and postdoctoral scholar Jining Huang, each focused on developing the test from a different angle. Schulte designed a version of the HCR test to detect SARS-CoV-2 proteins, while Huang worked on making an HCR test that detects SARS-CoV-2's RNA genome. Each approach has its own advantages: While an RNA test can more quickly be reprogrammed to detect genetic material from different pathogens, the RNA test currently still requires one additional heating step that makes it less user-friendly than the protein test.

The team plans to continue improving both tests and connect with industry partners to bring the tests to the market.

Pierce notes that Schulte and Huang began work on the at-home HCR test almost immediately after COVID-19 began shutting down the United States in March 2020. "We didn't know how it was transmitted,

we didn't have a vaccine, and we did not have the ability to get tested in L.A. County," he says. "It was a courageous act for them to go into the lab and to set out to try to solve this problem at that moment in history."

"The COVID-19 pandemic is a devilish teacher," says Barbara Wold, director and Allen V. C. Davis and Lenabelle Davis Leadership Chair of the Merkin Institute as well as Bren Professor of Molecular Biology. "COVID showed us that we were not at all prepared to do the fast, inexpensive, sensitive home testing that the world desperately needed. Though there has been progress with antigen tests, the need is far from fully met, and the biology of the modern hyperconnected world says that there will be future outbreaks and pandemics for which we need better tests. At Merkin, we have been excited and gratified to see HCR thrust forward from its role as a pure research tool, now translated into a promising new test technology."

More information: Samuel J. Schulte et al, Hybridization Chain Reaction Lateral Flow Assays for Amplified Instrument-Free At-Home SARS-CoV-2 Testing, *ACS Infectious Diseases* (2023). DOI: 10.1021/acsinfecdis.2c00472

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