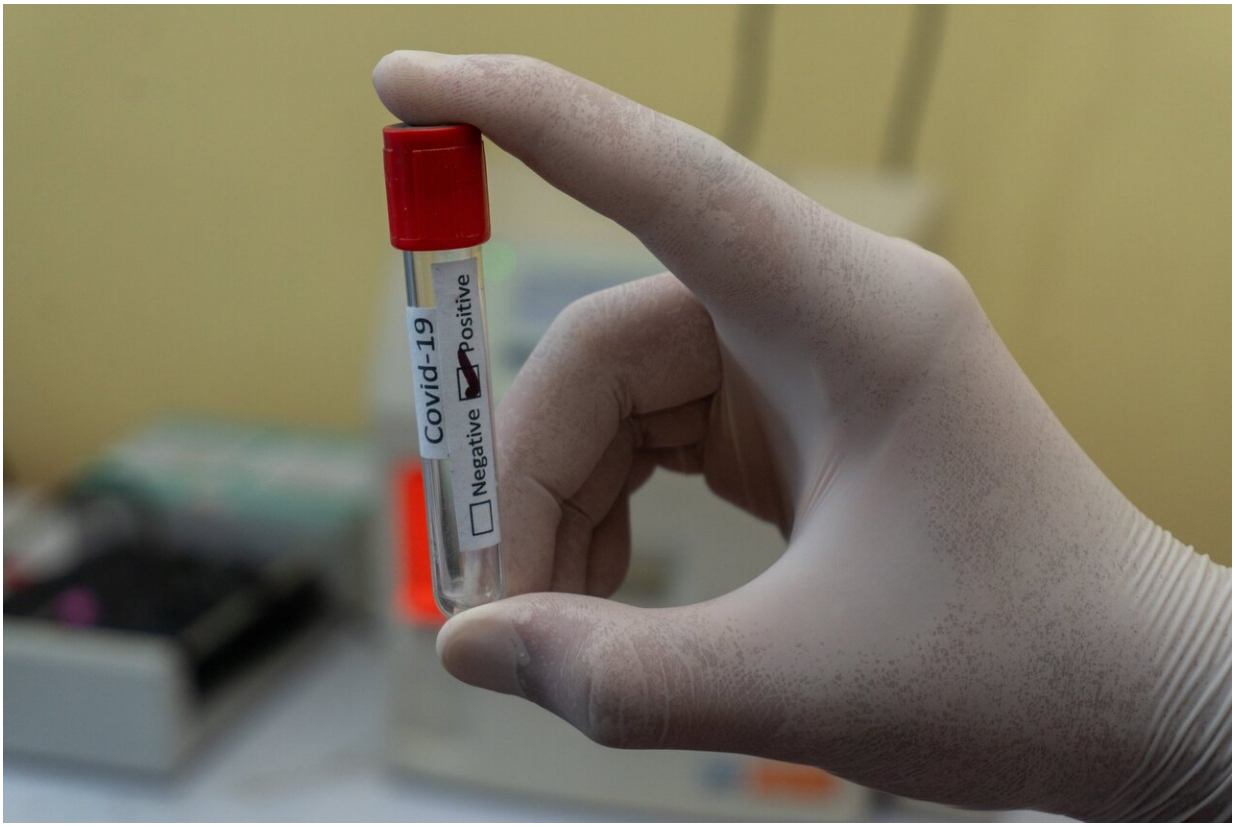
Is saliva testing better? Five things to know about the new COVID-19 test

August 21 2020, by Kathleen Raven



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Early in the pandemic, it became clear that testing for COVID-19 might be key to controlling outbreaks. But the existing tests have presented logistical challenges. Health officials have been clamoring for a cheaper,

easier, and quicker test that would boost the country's testing capability, which is needed to paint a more accurate picture of the virus's spread. Patients who test positive could be notified sooner. And quicker implementation of measures to prevent the spread, such as quarantines, could slow transmission rates.

Early research has suggested that a saliva test may be a step in the right direction—and now the Food and Drug Administration (FDA) has given emergency use authorization (EUA) to SalivaDirect, a diagnostic test method created by Yale researchers. (The laboratory development and validation of SalivaDirect was performed by Chantal Vogels, Ph.D., a Yale School of Public Health postdoctoral fellow, and Doug Brackney, Ph.D., adjunct assistant clinical professor.)

One of the benefits of SalivaDirect is its simple design. Basically, a patient spits into any sterilized container—a special vial is not needed—and hands the sample over to a medical professional. The sample is then sent to a lab for processing.

To detect the virus, lab technicians rely on enzymes, as well as PCR technology currently used by other COVID-19 tests. But the researchers' decision to use commonly available enzymes—and not specialized reagents that have sometimes been in short supply—is just one example of how they simplified the testing process.

"This saves one or two hours of work and removes up to 75% of the costs," says Nathan Grubaugh, Ph.D., an assistant professor at the Yale School of Public Health, who led the research efforts together with associate research scientist Anne Wyllie, Ph.D. And price was top of mind with the researchers—they designed the test so that it would only cost a couple of dollars for the enzymes and other chemicals needed to process it. "We expect that labs will only charge about $10 to $20 per sample," Grubaugh says.

With dozens of reports on SalivaDirect online and in the news, we spoke with Yale researchers to determine the five most important things you need to know about the SalivaDirect test method.

1. The EUA is for the protocol; it's not a kit

The FDA'a website provides this description of the EUA: "[It] can be granted for the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives."

EUAs are only given during public health emergencies. Even though approval is based on limited data, agency officials agree that the potential benefits would outweigh any potential risks.

The agency has given EUAs for other COVID-19 diagnostic tests, including other saliva tests and even at-home nasopharyngeal (NP) tests, as well as repurposed drugs and medical devices that can be used to fight COVID-19.

A key difference here is that this EUA was issued by the FDA for a protocol—not a physical test kit. So, there isn't a SalivaDirect kit available for purchase; instead the researchers have made the directions and materials needed to create and process the test freely available online.

"Widespread testing is critical for our control efforts," Wyllie says. "If cheap alternatives like SalivaDirect can be implemented across the country, we may finally get a handle on this pandemic, even before a vaccine."

It's important to note, say the researchers, that SalivaDirect can be

processed only in designated high-complexity CLIA-certified labs, which must meet strict quality standards set by federal agencies. The lab can then return test results to patients.

2. So far, no COVID-19 tests are perfect

Until now, the standard testing method for COVID-19 has been the NP swab test, which requires professionals to insert a very long cotton swab into a patient's nose. (An oropharyngeal [throat] swab sample is an option, but researchers have found NP tests to be more accurate.)

Also used for diagnosing seasonal flu, an NP swab aims to capture a lot of viral material, which is usually concentrated in the back of the nose early in an infection.

In addition to being notoriously unpleasant, this form of testing has notable downsides. The swabs themselves can at times be in short supply. Health care workers must use lots of personal protective equipment (PPE)—still a challenge to keep in supply in many places across the country—in case patients cough or sneeze during the test. There are also shortages of the special chemicals needed for processing, causing a backlog. All of these specifications make the test expensive to run. Results can be delayed for days. Meanwhile, if patients don't quarantine while awaiting test results that turn out to be positive, infection can continue to spread.

3. Early research on SalivaDirect is promising

The researchers have already been able to validate results of SalivaDirect on different equipment and with easy-to-find reagents. "This flexibility enables continued testing if some vendors encounter supply chain issues, as experienced early in the pandemic," Grubaugh says.

Results so far have found that SalivaDirect is highly sensitive (this means the test correctly identifies patients who actually have the disease) and yields similar outcomes to NP swabbing. However, larger studies are needed to confirm that, Wyllie explains.

4. The NBA is working with Yale on a study

NBA officials contacted the researchers shortly after they posted their initial results online. The basketball league wanted its teams to safely return to competition. For that to happen, they needed a quick and easy way to test players daily.

So, the Yale team partnered with NBA teams to enroll up to 500 players and staff in a study called SWISH (Surveillance With Improved Screening and Health) to evaluate how well SalivaDirect could work for healthy, asymptomatic people. The NBA arranged to play its season in a "bubble" on the campus of Walt Disney World in Orlando. Leading up to the bubble, basketball players and staff received routine testing every two days with a combined nasal and oral swab, then had the choice of providing a saliva sample for Yale to study.

The researchers point out that this kind of frequent testing is ideal to help stop outbreaks in any situation where people cannot maintain six feet of social distancing—this could be especially relevant to essential workers and students returning to school.

5. At-home saliva tests aren't yet available at the pharmacy

The EUA applies to the testing method, which can be scaled up quickly for use across the nation—and, perhaps, beyond—in the coming weeks, the researchers said.

So, SalivaDirect is not an at-home rapid test. It must be done by a CLIA-certified lab. In the future, patients may be able to order a test kit online and mail the sample back to a lab or company for processing. For now, though, it's not clear when the general public will be able to obtain a test.

Still, health officials believe the saliva test may be a game-changer in the fight against COVID-19.
"Testing for SARS-CoV-2 has been a major stumbling block in the fight against the pandemic, with long delays and shortages of testing," says Wyllie. "Some experts have said that up to 4 million tests are needed per day. SalivaDirect provides one pathway toward that goal."

Provided by Yale University