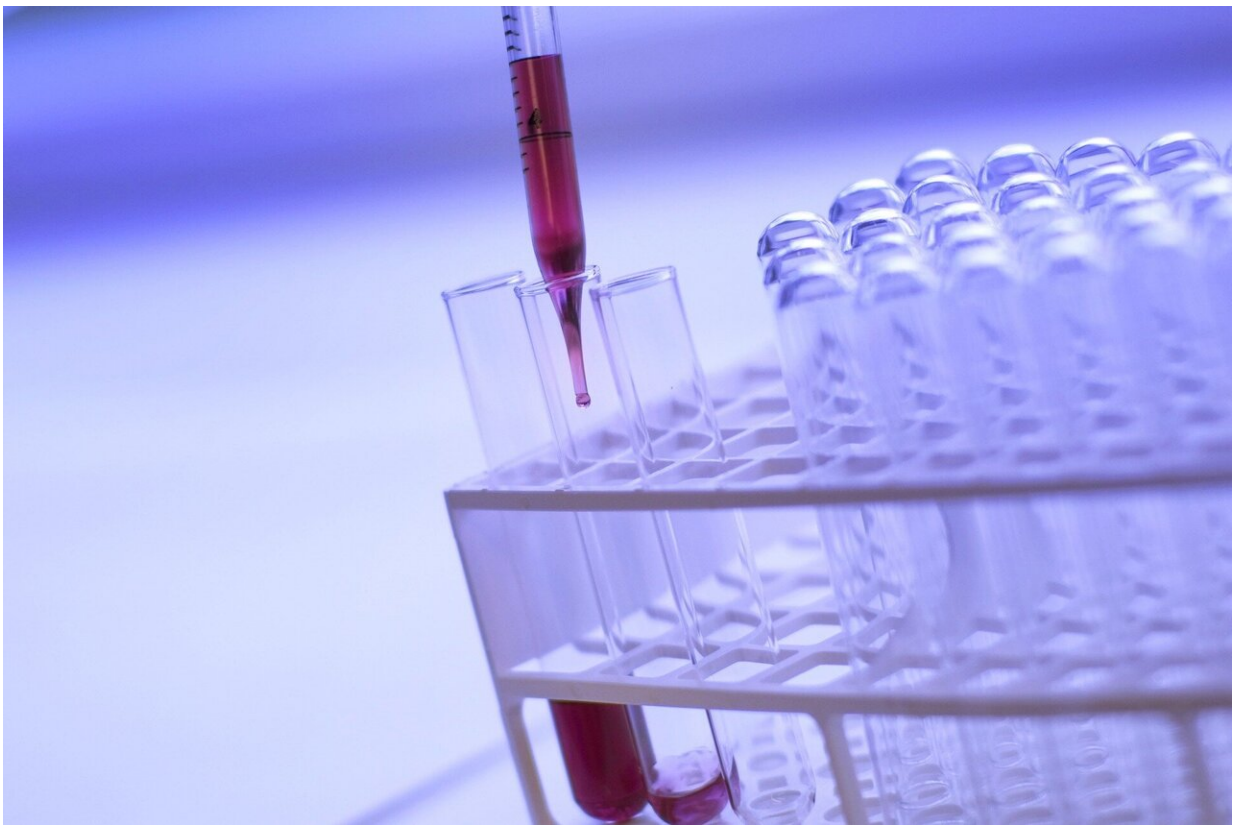
Start-up enters COVID-19 testing game with low-cost kit that delivers results in 10 minutes

July 30 2020, by Mike Freeman



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San Diego start-up Truvian Sciences has received federal emergency approval for a blood test that detects COVID-19 antibodies in as little as

10 minutes.

Called Easy Check, the portable test will be sold by Truvian to health professionals for about $15 and has an accuracy rate in excess of 98 percent, according to the company. The test is available immediately.

"It's a test cassette that reminds you a little bit of a pregnancy test," said Jeff Hawkins, Truvian's president and chief executive. "It's in a single-use package. You add a drop of blood, a drop of buffer from an eye-dropper bottle that is in the kit, and 10 minutes later you get a read-out."

The company, which is developing a compact blood testing machine that aims to deliver results faster, with less blood and at a lower cost than current systems., has agreements with U.S.-based manufacturers to produce up to 500,000 Easy Check COVID-19 kits per day if necessary, said Hawkins.

Unlike nasal swab molecular tests that determine if someone is infected with COVID-19, antibody tests are used to tell if someone has ever been exposed to the novel coronavirus.

That is important to understanding immunity and the overall prevalence of the virus in communities, especially since some people report having only mild or no symptoms.

"Truvian's antibody test will aid in providing key data that will allow us to better estimate the number of people previously infected to inform public health measures," said Dr. Jerry Yeo, a pathology professor at the University of Chicago, "and may assist in the broader availability of treatments such as convalescent plasma, which requires blood donations from individuals previously exposed to COVID-19."

Antibody tests in general fell into disfavor early in the pandemic because

of accuracy problems. The Food and Drug Administration subsequently pulled a few previously approved Emergency Use Authorizations and raised the accuracy thresholds for antibody testing.

Truvian's test was validated by healthcare scientists at UC San Diego, the University of Chicago and the Frederick National Laboratory for Cancer Research. It exceeded the current FDA accuracy requirements by correctly detecting the presence of COVID-19 antibodies in 98.44% of positive samples and correctly finding no antibodies in 98.9% of negative samples.

The company's current FDA Emergency Use Authorization allows the test to be performed in healthcare labs. But Truvian is seeking a second authorization that will enable Easy Check to be used outside of centralized medical facilities, including at workplaces or pop-up testing sites that deliver fast results.

"Companies are doing a mix of different things, especially in healthcare settings, manufacturing, food processing," said Hawkins. "There are a lot of industries that can't go virtual, and they are using sort of a mix of PCR detection of the virus from a swab, but they are also using antibody testing as a complement to that."