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Adaptive’s Covid-19 T-cell test hits the US

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As with antibodies, the next step will be proving that T-cells can grant immunity.

Adaptive Biotechnologies has won the race to obtain US authorisation for a T-cell test to assess possible immunity to Covid-19, pushing Oxford Immunotec – bought by Perkinelmer for $591m in January – into a likely second place.

Adaptive’s claims for the sequencing-based test’s high accuracy rest on validation studies in just a couple of hundred people. But the data have not yet been peer reviewed, and in any case no definitive link with T-cell response and protection from Covid-19 has been definitively proven. Still, this might come in future: Adaptive is believed to be working towards assessing the extent to which vaccines might grant T-cell-mediated immunity.

The T-Detect assay picks up DNA from T-cells in a blood sample and identifies the sequences for T-cell receptors associated with infection by the novel coronavirus. This is a very different approach to that of Oxford Immunotec, whose T-cell test has been submitted to the FDA and is awaiting authorisation. Oxford’s T-Spot Discovery assay filters out the cells themselves, rather than their DNA, and tests whether they react to coronavirus antigens.

Data

According to T-Detect’s authorisation summary, the positive and negative percent agreement with a molecular test for Covid-19 were 92-97% and 99-100% respectively. These figures are highly respectable, but they come from only a couple of hundred subjects and it is possible that subsequent, more robust trials could see them revised downwards.

Clinical data on Adaptive Biotechnologies' T-Detect Covid-19 test			
Study	**Positive with PCR**	**Positive with T-Detect**	**PPA***
Primary clinical study	137	133	97.1%
Secondary clinical study	38	35	92.1%
Study	**Negative with PCR**	**Negative with T-Detect**	**NPA***
Retrospective	20	20	100%
Prospective	79	78	98.7%
**PPA & NPA = positive and negative percent agreement (analogous to sensitivity and specificity respectively). PPA data at 15 days after positive PCR test. Source: FDA.*			

The FDA, however, is clearly convinced that the test, like the 70-odd antibody tests it has authorised, is a reliable way to determine whether someone has had Covid-19 in the past. This could be particularly crucial for US patients with so-called long Covid, whose insurance often does not cover their care if they did not have a positive PCR test at the time they were first ill. The accuracy of antibody tests is thought to wane over time; T-cell testing could be better at identifying former Covid-19 patients whose infections are long past.

Despite some early positive findings on Oxford Immunotec's rival test, there is still no conclusive proof that a person with a positive result on a T-cell assay will be immune to reinfection with the virus.

Adaptive has not confirmed whether clinical trials are under way to help establish such a link. But it does intend to use the test to investigate the durability of the T-cell response elicited by various Covid-19 vaccines. A spokesperson told *Evaluate Vantage* that "In future, we hope to ... be able to answer questions about vaccine efficacy and duration, such as, 'did it work?' or 'will I need a booster shot?', as well as things like disease severity."

The spokesperson said that the test would be sold to individuals at a self-pay test price of $150.

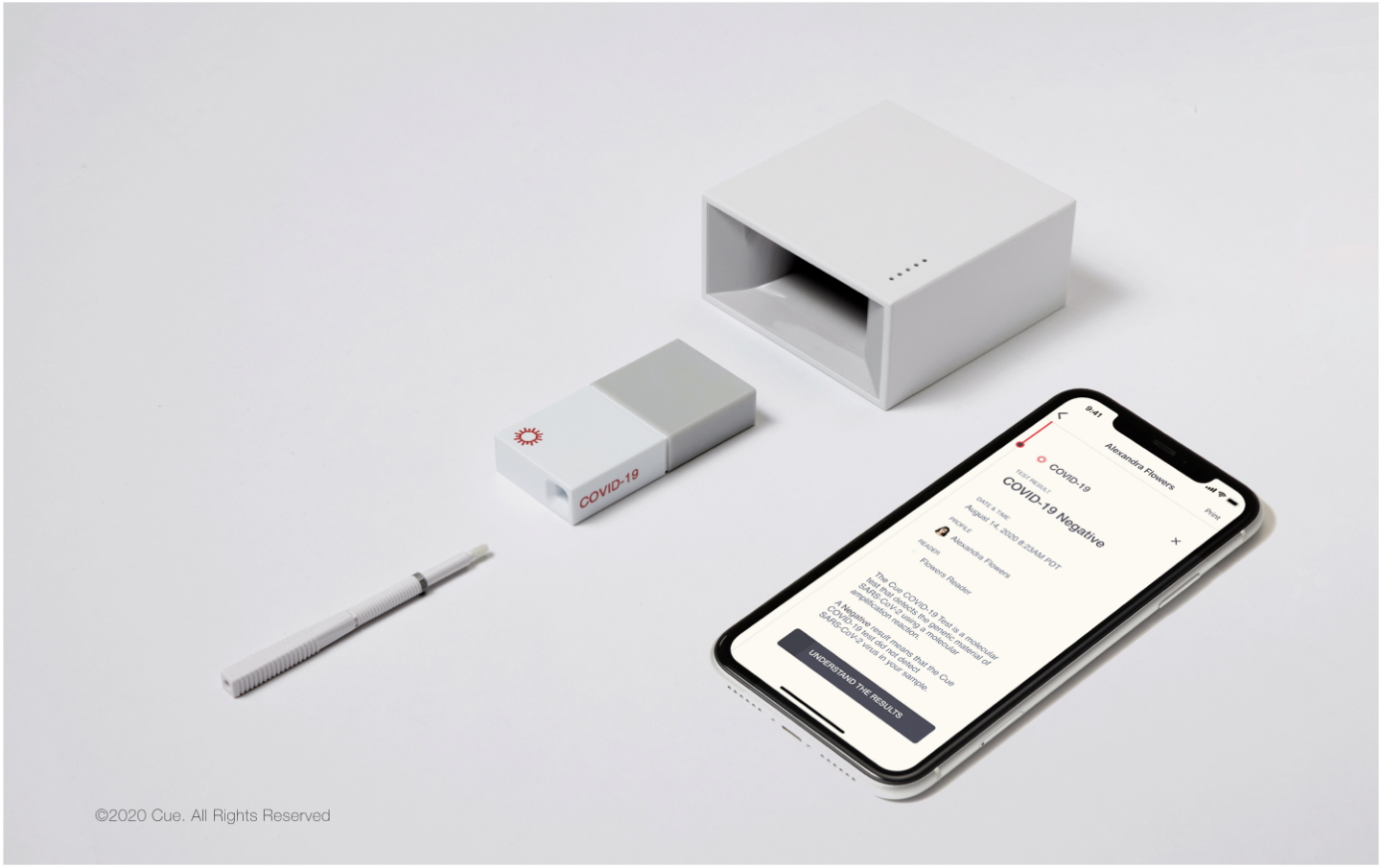
Cue

Adaptive's was not the only Covid-19 assay authorised by the FDA on Friday. The agency also rubber-stamped the Cue Covid-19 test, the first at-home, non-prescription assay for viral RNA in nasal swabs.

Cue Health's assay is not a PCR test; instead of using the complex, lab-based polymerase chain reaction to amplify the virus's nucleic acid, Cue's test employs a simpler isothermal process. This allows the test to be done using a test cartridge and cartridge reader device. Results take around 20 minutes and appear on a mobile app. Cue says the test has sensitivity of 99% and specificity of 98%.

Cue's chief executive, Ayub Khattak, has said that the reader device costs "a few hundred dollars", with the disposable cartridges "in the tens of dollars", so this will likely be used by well-off people who wish to test themselves repeatedly – such as for business travel, for instance.

This article has been updated to include comments from a spokesperson for Adaptive.



Cue Health's Cue Covid-19 test