「FDA authorizes first at-home COVID-19 self-test」

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On Nov 17th, the U.S. FDA issued an emergency use authorization (EUA) for the first COVID-19 diagnostic test for self-testing at home and that provides rapid results in 30 minutes. [1]

The single-use test, Lucira COVID-19 All-In-One Test Kit, is developed by the California-based company Lucira Health. This test requires a prescription from a health care provider and allows people over the age of 14 to perform the test on themselves. But with a relatively simple nasal swab, the test can return results in about half an hour, and is projected by the company to cost $50 or less, according to the product's website. Clinicians can also run the test on patients, including children under the age of 14, potentially delivering answers during a single visit to a care center or pharmacy, instead of routing a tough-to-collect sample through a lab. [1, 2]

Until now, people have had to visit a doctor's office, clinic, hospital or some other site to have a sample taken and tested. Some tests have also been authorized for samples to be collected at home, but those samples must then be sent away to a lab for analysis. Lucira is the first one authorized for use at home.

The test is a molecular test (real-time loop mediated amplification reaction, LAMP) that is intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. LAMP repeatedly copies genetic material until it reaches detectable levels, making it possible to identify the virus even when it is present at only very low levels in the respiratory tract. While faster and less cumbersome than RT-PCR, LAMP is generally thought to be less accurate. According to Lucira Health, the tests have a sensitivity of about 94.1% and a specificity of 98%. The test works by swirling the self-collected sample swab in a vial that is then placed in the test unit. In 30 minutes or less, the results can be read directly from the test unit's light-up display that shows whether a person is positive or negative for the SARS-CoV-2 virus. [1, 3]

An important component to successful at-home testing is the ability to efficiently track and monitor results. As noted in this EUA, prescribing health care providers are required to report all test results they receive from individuals who use the test to their relevant public health authorities in accordance with local, state and federal requirements. Lucira Health, the test manufacturer, has also developed box labeling, quick reference instructions and health care provider instructions to assist with reporting. [1, 4]

Jeff Shuren, the director of the FDA's Center for Devices and Radiological Health, said that the test represents "a significant step toward the FDA's nationwide response to COVID-19." "Now, more people who may have COVID-19 will be able to take immediate action, based on their results, to protect themselves and those around them," Shuren said. Testing shortages have been a massive problem since

the pandemic began, crippling the nation's ability to fight the spread of the virus. The recent surge in cases has again put additional strain on the nation's precarious coronavirus testing system, especially as more people try to get tested ahead of the holidays. [5]

Reference:

1. 17 Nov 2020. "Coronavirus (COVID-19) Update: FDA Authorizes First COVID-19 Test for Self-Testing at Home" *FDA news release.*
2. K atherine J. Wu. 18 Nov 2020. "F.D.A. authorizes the first at-home coronavirus test." *The New York Times nes.*
3. Phil Helsel and Wilson Wong. 18 Nov 2020 "FDA authorizes first at-home Covid-19 test that gives users results quickly" *NBC news.*
4. Dave Muoio. 18 Nov 2020. "FDA authorizes first COVID-19 test for self-testing at home" *Mobi Helath news.*
5. VANESSA ROMO. 17 Nov 2020. "FDA Approves 1st At-Home Coronavirus Test" *n.p.r. news.*