

FDA Authorizes First Prescription At Home Molecular Test for COVID-19

Lucira Health test provides lab-quality result in 30 minutes or less from home

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Emeryville, CA—Late yesterday the U.S. Food and Drug Administration (FDA) authorized the first prescription molecular diagnostic test for COVID-19 that can be performed entirely at home. The FDA issued an Emergency Use Authorization (EUA) to Lucira Health, Inc. for its single-use, user-friendly COVID-19 All-In-One Test Kit that can produce a positive or negative result at home within 30 minutes. Lucira's test kit is differentiated by its simple 'swab, stir and detect' design. Clinical trials showed 100% of patients were successfully able to perform the Lucira test in about two minutes. That is significantly faster than labs which currently take two to seven days to generate similarly accurate test results.

The Lucira™ COVID-19 All-In-One Test Kit is expected to be available to patients served by Sutter Health in Northern California, and Cleveland Clinic Florida in Miami-Ft. Lauderdale, in the near future. By early spring 2021, it is expected to be available nationally through health care providers.

"There are currently two types of COVID-19 tests that detect whether a person is infected and potentially infectious," said Lucira Health CEO Erik Engelson. "Antigen tests detect viral proteins and can provide results quickly. However, they are not diagnostically definitive and are more likely to miss an active coronavirus infection, or positive result, compared to molecular tests. Molecular tests like Lucira's are 50 to 60 times more sensitive than antigen tests, and considered the 'gold standard' for determining if someone is infected."

The streamlined Lucira COVID-19 All-In-One Test Kit, which fits in the palm of a hand, extracts genetic material from the virus and amplifies it. This process takes up to 30 minutes, but a positive test result can be generated in as few as 11 minutes.

The Lucira COVID-19 All-In-One Test Kit comes with everything needed to perform a single COVID-19 test. Users open the box containing the test device, sample vial, swab and simple instructions. Two AA batteries are inserted in the device and the sample vial is placed in the test unit. Next, the user opens the test swab packet and rotates the swab in each nostril five times. The swab is then stirred in the sample vial, and then pressed down in the test unit to start the test. The "ready" light will blink until a "positive" or "negative" green light is illuminated within 30 minutes. For guidance on care and public health reporting, patients will report their test results to the medical office that prescribed the test.

"Being able to quickly determine if a person is infected or not has been a global problem," said Dr. John Chou, physician with the Palo Alto Foundation Medical Group, affiliated with Sutter Health and a Principal Investigator on the Lucira Health Community Testing Study submitted to the FDA. "We believe this highly mobile test can make a big difference by providing lab-quality results expeditiously and conveniently. Early, accurate detection is vital to delivering appropriate care and controlling the pandemic."

Lucira's single-use device has been developed over five years, initially as a flu test kit, that patients would eventually be able to purchase from local drug stores. When the pandemic began early this year, Lucira redirected its efforts to COVID-19.

Testing the Lucira test

To validate the test for the FDA, more than 100 people from a broad range of ages, ethnicities and education levels were enrolled in Lucira's Community Testing Study in Northern and Southern California, including the San Francisco Bay Area. Based on the trial's design, patients suspected of having COVID-19 tested themselves outside their residences under observation by trained professionals. The community-based trial reported that 100% of the individuals were able to successfully run the test.

Lucira test results were compared with one of the most reliable FDA authorized high sensitivity SARS-CoV-2 assays available. The comparative positive results agreed 94.1% of the time across all samples, and 100% of the time excluding samples containing very low levels of virus (at or below 37.5 Ct). The negative results agreed 98.0% of the time across all samples.

Lucira also has an ongoing clinical trial with the Cleveland Clinic Florida. Dr. James Roach, Emergency Department Chair and a Principal Investigator on Lucira's trial at the Cleveland Clinic Florida, said, "Immediate, on-site testing will improve patient care and throughput in urgent care environments. This test will allow patients to isolate at home while waiting for results with faster turnaround."

While Lucira scales up manufacturing capabilities, its COVID-19 test kit will initially be available on a limited basis in point of care settings and healthcare networks that prescribe the test for patients to use at home. Lucira is committed to making at home testing accessible and anticipates its test will cost around \$50.

By the second quarter of 2021, Lucira Health plans to amend its EUA or file a new EUA so people who think they're infected with COVID-19 can communicate with a medical professional online through a dedicated website to arrange a prescription and overnight delivery of the test kit, if approved. Follow-up monitoring will be available for public health reporting so people can get additional guidance and information if needed.

By current national estimates, up to 50 to 100 million COVID-19 tests may need to be conducted each month in the United States, with as many as 900 million total possible through 2021. If all U.S. airline passengers were also tested, that would require one billion tests annually. Likewise, if the country's health care workers were tested weekly for a year, that would also require around one billion tests. A variety of tests have been developed to help meet this need, with Lucira being the latest and first to get FDA authorization for prescription self-testing at home molecular diagnostic test.

Lucira Health

Lucira Health was founded in 2013 and is headquartered in Emeryville, California, near the University of California-Berkeley. Its 40 employees are reimagining infectious disease testing. Lucira developed its test kits to provide accurate, reliable and on-the-spot molecular test results anywhere, by anyone and at any time. Its robust platform with flexible hardware and multiplexed target identification capabilities is designed to enable rapid development of — and testing for — multiple assays.

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