As companies race to produce coronavirus test kits, FDA holds up at-home samples

Gwendolyn Wu | March 30, 2020 | Updated: March 30, 2020 7:22 a.m.

Several companies say they have developed COVID-19 tests that people can use at home, but the Food and Drug Administration is blocking them from the market over concerns that they won’t be administered accurately.

At least four companies, including Everlywell of Austin, recently said they would sell at-home testing kits that use virtual doctor visits and online screening quizzes to determine test eligibility. But just days later, the FDA issued guidance barring the distribution of test kits to consumers.

Although the testing technology was approved under federal emergency use authorization, the kits can only be used in clinical settings such as hospitals and medical practices. Last week, FDA Commissioner Stephen Hahn, the former chief medical officer of the MD Anderson Cancer Center, reiterated that the agency “is not aware of any validated test” that can do home testing.

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Until the tests are validated, they run the risks of providing false negatives, leading people carrying the virus to continue going outside, or false positives, which could cause a surge of people to seek treatment in an already overwhelmed health care system, said Dr. Karl Hess, a professor at Chapman University's School of Pharmacy in Orange, Calif.

Such a surge, he said, would “divert care away from those who are truly in need.”

San Francisco-based Nurx, one of the health care companies that planned to sell at-home test kits, said its kit producer, Molecular Testing Labs of Vancouver, Wash, is in communication with FDA about the guidelines.

“They continue to have high confidence in the test characteristics and accuracy of its self-collection COVID-19 test,” said Allison Hoffman, a Nurx spokesperson.

**Testing urgency**

Commercial test kits are coming onto the market about three weeks after the Food and Drug Administration announced it would give emergency approval for public and private labs to create COVID-19 testing kits.

Extensive testing could help alleviate the burden on health care systems by convincing COVID-19 carriers to self-isolate and reducing needless patient visits, said Dr. Jeffrey Cirillo, director of Texas A&M University's Center for Airborne Pathogen Research and Tuberculosis Imaging Resources.

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“The urgency involved in getting an idea of the number of cases we have right now is so that we can better control spread,” Cirillo said.

Houston doctors have expressed frustration over the lack of equipment to diagnose cases of the new coronavirus and strict guidelines around who can be tested. Meanwhile, the county's testing sites may have to shut down as test kit supplies dwindle.
Those companies include Everlywell, which also produces at-home test kits for sexually transmitted diseases and other health issues, and Nurx, a test and medication delivery service.

**How the tests work**
In Everlywell's and Nurx's exams, patients fill out online screening quizzes and complete telehealth visits with doctors to review their symptoms.

“A doctor still needs to prescribe the test,” said Julia Cheek, Everlywell’s chief executive, “so telemedicine doctors then review these answers to determine if a person qualifies for testing, based on criteria established by the Centers for Disease Control and Prevention.

If doctors prescribed the tests, the companies would ship them to patients’ homes. Patients would swab their throat for a sample, place it in biohazard packaging to protect the specimens and ship it overnight to an FDA-approved testing lab using a provided label.

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Results would become available online 48 hours after the lab receives the sample, according to the companies. Neither disclosed the locations of their testing labs.

If a person tests positive, the telehealth doctor follows up to provide advice, included in the cost of the test. The case is then reported to state health authorities.

Everlywell will charge $135 per kit, while Nurx charges $181.

**Clinical market**
Test kits approved by the FDA's emergency guidelines can still be used in clinical settings, because doctors can validate whether the test has been performed correctly.

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Both companies have completed test validation — verifying that the product accurately diagnoses COVID-19 — in accordance with the FDA’s guidelines. But Nurx will not distribute kits until it receives a final go-ahead from the FDA and their lab testing partners, Hoffman said.

“The most important action we can take at this time is to support public trust in the FDA during this public health emergency,” Hoffman said.

The U.S. House of Representatives has also issued letters to three test kit producers, including Everlywell and Nurx, seeking information about at-home collection samples. The letters ask the companies to turn over information on kits...
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Potential customers

As companies wait for more FDA guidance, Everlywell is taking bulk orders of kits from health care systems on its website. Both companies are in talks with public health departments nationwide about distribution, but as of Sunday, no state or local officials have announced the use of their test kits.

Everlywell said it will continue to work with federal agencies on an approved at-home test kit.

“We have been meeting regularly with the FDA,” the company said in a statement. “The test will likely use a short nasal swab for easy collection and will include free telehealth consultations with an independent physician for those with positive results to receive diagnosis at home.”

Even if the test kits can’t go directly to consumers, experts said distributing them among health care providers will alleviate shortages, albeit temporarily.

“There just are not enough sites or resources without involving commercial involvement and use of alternative tests,” Texas A&M’s Cirillo.

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