FDA APPROVES RAPID CORONAVIRUS TESTS FOR HOME USE

RESULTS WITHIN MINUTES AND UP TO 90% ACCURACY

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Rapid coronavirus tests are now approved for home use by The Food and Drug Administration (FDA). These rapid tests let people test in the comfort of their own home and know within minutes whether they are positive for the novel COVID-19 virus. These recently FDA-approved tests may prove valuable in reducing the spread of the virus in the next few months before most Americans are vaccinated against the pathogen.

These newly approved rapid coronavirus tests are not to be confused with home collection kits that have been previously available. The previous home collection kits are available for $110 to $150 at retailers such as Costco, Walmart, or testing companies, including LabCorp and Quest Diagnostics. With collection kits, a person swabs their nostrils or expectorates saliva into a vial. The sample is then sent for processing at a lab. It typically takes 24 to 48 hours to get results.

The FDA has authorized more than 225 COVID-19 diagnostic kits, with more than 25 of these approved kits being used for at-home collection of samples. The samples are then sent to a lab for testing. What makes the three recently authorized home tests distinct from the home collection kits, is that a person swabs their nostrils and can get results as quickly as within 15 minutes. Confidio breaks down these newly approved rapid coronavirus tests for you.

Approved on November 17, Lucira Health's "All-In-One" is the first home test that received emergency use authorization from the FDA. It is a molecular-based, single-use home test. It is expected to sell for less than $50. It has two hurdles, however. The first is that the Lucira test will not be obtainable nationally until early spring 2021. The company is currently in the beginning stages of planning for large-scale manufacturing. Secondly, the home test requires a prescription from a doctor so clinicians can report test results agencies tracking COVID-19 cases.

Users of the Lucira test will swirl their nasal specimen into a solution, wait 30 minutes and then see their results via a portable, battery-operated device that will indicate their results with a light.

Figure 1 - Insidenova.com

The FDA followed that approval to authorize a second rapid home test made by Australian company Ellume. It does not require a prescription. Authorized on December 15, 2020, the Ellume test will cost $30. It is expected to be available the first week of January. Initial supplies will be limited. However, Ellume expects to build manufacturing to 1 million kits per day by mid-2021.

A nasal swab sample from individuals 2 years of age and older will be used for the Ellume test. To learn their results, users are required to download a smartphone app.

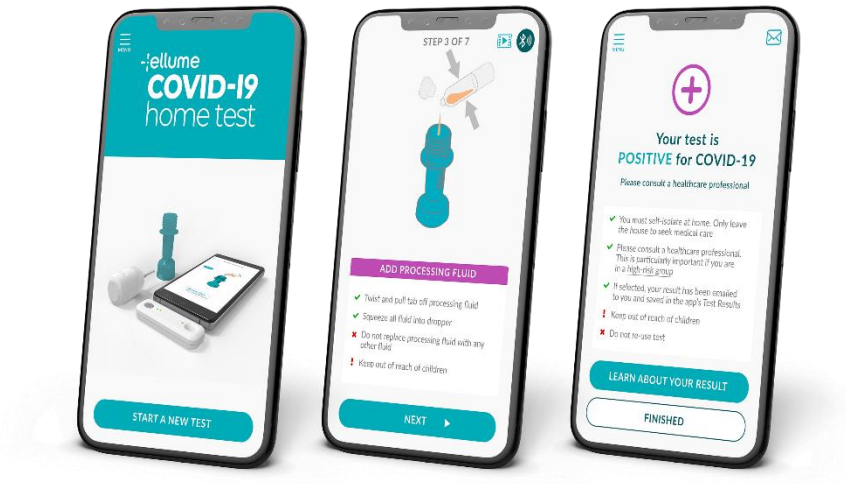

Figure 2 - Marketplace.org

The third rapid home test, BinaxNOW by Abbott Laboratories, was approved by the FDA on December 16. Abbott Laboratories anticipates being able to produce 30 million tests in the first quarter of 2021 and upwards to an additional 90 million in the second quarter. It will carry a price of $25.

Previously, the U.S. federal government has been providing Abbott BinaxNOW tests to nursing homes and schools, administered under the management of health-care workers. The newly approved home version is fundamentally alike but involves ordering through a smartphone app called Navica, after answering health questions. To ensure consumers use the approved home version correctly, certified guides from eMed will supervise the administration of the kit by video. For qualifying customers, the collection kits will be shipped by eMed to their door. Those with COVID-19 symptoms or those who have been exposed have been receiving the test at no cost because both insurance companies and the federal government have been reimbursing the cost of tests. The FDA is touting 90 percent accuracy in detecting the COVID-19 virus from three rapid home tests and avoiding false test results.

Downstream, some experts worry that the public will use results from such tests as inferred consent to disregard the precautions of social distancing guidelines. It may also be possible that the rapid home tests provide false negatives in people who were recently infected and do not have enough virus to detect.

Per the Washington Post, “the Lucira test is expected to be available to patients of Northern California’s Sutter Health and South Florida’s Cleveland Clinic in the near future but not reach the national market until early spring”[1].

Ellume is planning to announce a U.S.-based partnership with a larger retailer and the company is also in talks to supply the test kits directly to companies and universities.

Key drivers of the pandemic are asymptomatic people. Both insurance companies and the federal government have been advised by industry experts to cover testing those who are asymptomatic. Federal officials have indicated they want many of the newly authorized tests to be used for asymptomatic people, but it is not clear whether federal officials will issue policies that would require asymptomatic testing to be covered by insurance.

Both Lucira and Abbott BinaxNOW are available only by prescription, which makes reimbursement of their $50 and $25 costs for use more likely. However, the home collection kits sold at major retailers for $110 to $150 are not reimbursable.

While the customers are paying for the testing kit and the convenience of testing at home; the cost of processing the sample in the lab is reimbursed by insurance or the government.

Confidio will continue to monitor the test kit market, as it is expected that the FDA will approve additional testing kits that may prove to be more accurate and carry a lower price tag.

PBM Specific Communication:
CVS:
The claim will only pay if:

- Client has contracted to cover COVID-19 testing under their pharmacy benefit (they have to sign an addendum) and
- On the benefits coding side, CVS has included that specific NDC to be covered and
- There's a valid NPI submitting for that claim (i.e. pharmacy NCPDP #)

ESI:
ESI is not currently reviewing any COVID tests for coverage. If a current ESI client wishes to cover them, they will need to add them to their existing drug coverage rules.

Optum:
COVID-19 test kits are not being automatically included for coverage. Plan sponsors would need to add coverage of the kits to their benefits.

References:

1. https://www.washingtonpost.com/nation/2020/11/18/home-test-coronavirus-covid-fda/