

Nonprescription at-home COVID-19 test receives emergency approval

March 9 2021



The U.S. Food and Drug Administration granted emergency use

authorization (EUA) last week to two at-home tests to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), including the first home test that does not require a prescription.

On Friday, the agency announced the EUA of the Cue COVID-19 Test for Home and Over The Counter (OTC) Use, a molecular nucleic acid amplification test intended to detect genetic material from SARS-CoV-2 in anterior nasal swab specimens. This test is authorized for nonprescription home use in adults who self-swab and children 2 years and older who are swabbed by an adult. It can be used in individuals with or without symptoms.

The test kit includes a nasal swab, test [cartridge](#), test cartridge reader, and mobile app. The cartridge reader runs the test cartridge and communicates the results to the mobile app in about 20 minutes. Data have shown the Cue COVID-19 Test for Home and OTC Use correctly identified 96 percent of positive samples from symptomatic individuals and 100 percent of positive samples from asymptomatic individuals. Cue Health says it expects to produce more than 100,000 tests per day by this summer.

Also last week, the FDA issued an EUA for the Quidel QuickVue At-Home COVID-19 Test, an antigen test for prescription home use with self-collected anterior nasal swabs in people ages 14 years and older and for children 8 years and older whose swabs are collected by an adult. This [test](#) is authorized for individuals whose [health care providers](#) suspect COVID-19 within six days of symptom onset.

The FDA has now authorized more than 330 tests and collection kits for detecting SARS-CoV-2. "The FDA will continue to expand Americans' access to testing to help us in the fight against this pandemic, which has claimed over half a million lives in the United States," Acting FDA Commissioner Janet Woodcock, M.D., said in an agency news release.

More information: [More Information - Cue COVID-19 Test](#)
[More Information - Quidel QuickVue At-Home COVID-19 Test](#)

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