FDA authorizes Cue Health’s OTC COVID-19 test

April 2021—Cue Health has received FDA emergency use authorization for over-the-counter sale of its COVID-19 test. The Cue COVID-19 Test for Home and Over the Counter Use uses a lower nasal swab and provides results in about 20 minutes. The Cue OTC test is authorized for use by symptomatic and asymptomatic individuals, ages two and older.

“With this authorization, consumers can purchase and self-administer one of the easiest, fastest, and most accurate tests without a prescription,” Clint Sever, cofounder and chief product officer of Cue, said in a press release. “This FDA authorization will help us improve patient outcomes with a solution that provides the accuracy of central lab tests, with the speed and accessibility required to address emergent global health issues.”

The Cue Home and OTC test detects the RNA of SARS-CoV-2. The test uses the Cue cartridge reader, COVID-19 test cartridge, and sample wand; results are provided via the Cue Health App, on the user’s mobile smart device. In prospective studies to evaluate the use of the test, results were 97.4 percent agreement for positive cases and 99.1 percent agreement for negative cases compared with results from a highly sensitive EUA PCR laboratory-based test, the company said.

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