MedicalXpress

FDA authorizes 1st breath test for COVID-19 infection

April 15 2022

A sign for the Food and Drug Administration is seen in Silver Spring, Md., on Thursday, Dec. 10, 2020. On Wednesday, March 30, 2022, federal health advisers narrowly ruled against an experimental drug for the debilitating illness known as Lou Gehrig's disease, a potential setback for patient groups who lobbied for the medication's approval. A majority of advisers to the FDA voted 6-4 that a single study from Amylyx Pharmaceuticals failed to establish the drug's effectiveness in treating the deadly neurodegenerative disease known also as ALS, for amyotrophic lateral sclerosis. Credit: AP Photo/Manuel Balce

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The Food and Drug Administration on Thursday issued an emergency use authorization for what it said is the first device that can detect COVID-19 in breath samples.

The InspectIR COVID-19 Breathalyzer is about the size of a piece of carry-on luggage, the FDA said, and can be used in doctor's offices, hospitals and mobile testing sites. The test, which can provide results in less than three minutes, must be carried out under the supervision of a licensed health care provider.

Dr. Jeff Shuren, director of the FDA's Center for Devices and Radiological Health, called the device "yet another example of the rapid innovation occurring with diagnostic tests for COVID-19."

The FDA said the device was 91.2% accurate at identifying positive test samples and 99.3% accurate at identifying negative test samples.

"InspectIR expects to be able to produce approximately 100 instruments per week, which can each be used to evaluate approximately 160 samples per day," the agency said. "At this level of production, testing capacity using the InspectIR COVID-19 Breathalyzer is expected to increase by approximately 64,000 samples per month."