

FDA authorizes first Covid-19 breath test

By Katherine Dillinger, CNN

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(CNN) The US Food and Drug Administration has granted [emergency use authorization](#) to the first Covid-19 test that spots chemical compounds associated with the [coronavirus](#) in breath, the agency said Thursday.



The InspectIR Covid-19 Breathalyzer can be used in medical offices and mobile testing sites.

The FDA said the [InspectIR Covid-19 Breathalyzer](#), which is about the size of a piece of carry-on luggage, can be used in medical offices and mobile testing sites. It can give results in less than three minutes.

The system separates and identifies chemical mixtures to detect five compounds associated with SARS-CoV-2 infection.

A study of the InspectIR Breathalyzer found that it accurately identified more than 91% of positive samples and nearly 100% of negative samples. Similar sensitivity was found in another study that focused on the Omicron coronavirus variant. However, a positive result should be confirmed with a PCR test, the FDA said.

"It's another tool, and the FDA announcement suggests it's reasonably accurate and a relatively user-friendly tool," Dr. Emily Volk, president of the College of American Pathologists, a board-certified anatomic and clinical pathologist, said Friday.

"It waits to be seen how widely this will be adopted," Volk said. "That could rely on how expensive it is."

In an email to CNN on Friday, InspectIR Systems said it is not releasing the price of the machine or when it will be available.

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The agency's authorization "is yet another example of the rapid innovation occurring with diagnostic tests for COVID-19," Dr. Jeff Shuren, director of the FDA's Center for Devices and Radiological Health, said in a statement. "The FDA continues to support the development of novel COVID-19 tests with the goal of advancing technologies that can help address the current pandemic and better position the U.S. for the next public health emergency."

CNN's Jacqueline Howard and Nadia Kounang contributed to this report.