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US authorises first COVID-19 diagnostic test using breath samples

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Test provides results in less than three minutes



U.S. Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for the first COVID-19 diagnostic test that detects chemical compounds in breath samples associated with a SARS-CoV-2 infection.

The test can be performed in environments where the patient specimen is both collected and analyzed, such as doctor's offices, hospitals and mobile testing sites, using an instrument about the size of a piece of carry-on luggage. The test is performed by a qualified, trained operator under the supervision of a health care provider licensed or authorized by state law to prescribe tests and can provide results in less than three minutes.

The performance of the InspectIR COVID-19 Breathalyzer was validated in a large study of 2,409 individuals, including those with and without symptoms.

The InspectIR COVID-19 Breathalyzer uses a technique called gas chromatography gas mass-spectrometry (GC-MS) to separate and identify chemical mixtures and rapidly detect five Volatile Organic Compounds (VOCs) associated with SARS-CoV-2 infection in exhaled breath.

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