FDA authorizes COVID-19 breathalyzer test

April 15, 2022—The FDA issued an emergency use authorization to InspectIR Systems for its InspectIR COVID-19 Breathalyzer test. The InspectIR COVID-19 Breathalyzer uses gas chromatography–mass spectrometry to separate and identify chemical mixtures and rapidly detect five volatile organic compounds associated with SARS-CoV-2 infection in exhaled breath. Results are available in less than three minutes.

The FDA authorized the test to be performed in environments where the patient specimen is both collected and analyzed, such as doctor's offices, hospitals, and mobile testing sites by a qualified, trained operator under the supervision of a health care provider licensed or authorized by state law to prescribe tests.

In a study of 2,409 people, including those with and without symptoms, the test was shown to have 91.2 percent sensitivity and 99.3 percent specificity. Positive test results should be confirmed with a molecular test.