First Breathalyzer Test to Diagnose COVID-19
The first test that uses breath samples to diagnose COVID-19 recently received Emergency Use Authorization from the FDA.

The InspectorIR COVID-19 Breathalyzer, which uses an instrument about the size of a piece of carry-on luggage—a “chemical-lab-in-a-box,” as its developer describes it—can provide results within 3 minutes, according to the FDA. Testing with the device is performed by specially trained operators under the supervision of a health care professional licensed to prescribe tests in physicians’ offices, hospitals, and mobile testing sites.

A study involving 2409 people, only some with COVID-19 symptoms, validated the performance of the testing device. In the study, the breathalyzer correctly identified 91.2% of positive samples and 99.3% of negative samples, according to the FDA, which noted that a follow-up clinical study found the test performed with similar sensitivity with the Omicron variant.

The breathalyzer uses gas chromatography–mass spectrometry to detect volatile organic compounds (VOCs) in exhaled breath that are associated with SARS-CoV-2 infection, according to the FDA. When those VOCs are detected, the test result should be confirmed with a molecular test. Negative test results from the breathalyzer don’t rule out SARS-CoV-2 infection and should be considered in the context of the patient’s recent exposures, history, and symptoms consistent with COVID-19, FDA officials noted.

Developer InspectorIR Systems, located in Frisco, Texas, expects to produce 100 instruments per week, each of which can evaluate 160 breath samples per day, according to the FDA.

More Diversity in Clinical Trials
The FDA recently issued a new draft guidance for industry about improving the enrollment of clinical trial participants from underrepresented racial and ethnic populations, many of whom are part of medically underserved communities.

“Individuals from these populations are frequently underrepresented in biomed-ical research despite having a disproportionate disease burden for certain diseases,” the guidance noted.

The new guidance expands on a 2016 guidance that outlined how to collect and present race and ethnicity data in submissions to the FDA.

When drawing up a diversity plan for clinical trials, sponsors should begin by assessing data that may indicate the potential for a medical product to have a different safety profile or level of effectiveness depending on patients’ race or ethnicity, the FDA said.

For drug development, the agency strongly encourages gathering pharmacokinetic, pharmacodynamic, and pharmacogenomic data from a diverse population, according to the guidance. For device development, phenotypic, anatomical, biological, and other relevant factors that could affect device performance across a diverse population should be collected, according to the FDA.

Although the guidance focuses specifically on racial and ethnic minorities, the FDA said, the agency advises sponsors of investigational medical products to seek diversity as defined by other demographic factors such as sex, gender identity, age, pregnancy and lactation status, and the presence of certain clinical characteristics, such as multiple comorbidities.

“The US population has become increasingly diverse, and ensuring meaningful representation of racial and ethnic minorities in clinical trials for regulated medical products is fundamental to public health,” FDA Commissioner Robert Califf, MD, said in a statement.

Websites Selling Controlled Drugs Without a Prescription
The FDA and the US Drug Enforcement Administration (DEA) recently issued joint warning letters to the operators of 2 websites illegally selling amphetamine drug products marketed as Adderall, a Schedule II stimulant, without a prescription.

“The illegal sale of prescription drug stimulants online puts Americans at risk and contributes to potential abuse, misuse, and overdose,” FDA Commissioner Robert Califf, MD, said in a statement. “These particular types of online pharmacies also undermine our efforts to help consumers safely purchase legitimate prescription medicines over the internet.”

The warning letters were sent to Kupapharm.com and Premiumlightssupplier.com. Consumers who have unused drugs purchased from these websites should dispose of them and buy prescription drugs online only from state-licensed pharmacies, according to the FDA.

Selling misbranded amphetamine drug products violates the Federal Food, Drug, and Cosmetic Act, the warning letters note. And failing to register with the DEA violates the Ryan Haight Online Pharmacy Act, which sets requirements for dispensing controlled substances via the internet.

“Consumers cannot trust the safety or legitimacy of pills sold on unaccredited sites,” DEA Administrator Anne Milgram, JD, said in the statement. “DEA strongly urges anyone seeking controlled medications to obtain a prescription from a trusted medical professional and have it dispensed by a licensed pharmacy.”

The combination of dextroamphetamine and amphetamine is approved for the treatment of attention-deficit/hyperactivity disorder and narcolepsy. However, healthy adults use the drug off-label because they think it increases alertness. — Rita Rubin, MA

Note: Source references are available through embedded hyperlinks in the article text online.