FDA authorizes direct-to-consumer COVID-19 test kit

January 2021—The FDA authorized the first COVID-19 direct-to-consumer test system—LabCorp's Pixel COVID-19 Test Home Collection Kit, for use by any person 18 years and older without a prescription.

The kit can be purchased online or in a store without a prescription and allows a person to self-collect a nasal swab sample at home and then send the sample to LabCorp for testing. Positive or invalid test results are delivered to the user by phone call from a health care provider. Negative test results are delivered via email or online portal.

"This is the first kit for consumers to self-collect a nasal sample for COVID-19 in their home that does not require a prescription," Jeff Shuren, MD, JD, director of the FDA's Center for Devices and Radiological Health, said in a press statement from the agency. "While many home collection kits can be prescribed with a simple online questionnaire, this newly authorized direct-to-consumer collection kit removes that step from the process, allowing anyone to collect their sample and send it to the lab for processing."

The test is intended to enable users to access information about their COVID-19 infection status that could then aid in determining if quarantine is appropriate and to assist with health care decisions after speaking with a health care professional.

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