COVID-19 Update: FDA authorizes first COVID-19 test for self-testing at home

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the first COVID-19 diagnostic test for self-testing at home and that provides rapid results. The Lucira COVID-19 All-In-One Test Kit is a molecular (real-time loop mediated amplification reaction) single use test that is intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19.

“The FDA continues to demonstrate its unprecedented speed in response to the pandemic. While COVID-19 diagnostic tests have been authorized for at-home collection, this is the first that can be fully self-administered and provide results at home. This new testing option is an important diagnostic advancement to address the pandemic and reduce the public burden of disease transmission,” said FDA Commissioner Stephen M. Hahn, M.D. “Today’s action underscores the FDA’s ongoing commitment to expand access to COVID-19 testing.”

The Lucira COVID-19 All-In-One Test Kit test has been authorized for home use with self-collected nasal swab samples in individuals age 14 and older who are suspected of COVID-19 by their health care provider. It is also authorized for use in point-of-care (POC) settings (e.g., doctor’s offices, hospitals, urgent care centers and emergency rooms) for all ages but samples must be collected by a healthcare provider when the test is used at the POC to test individuals younger than 14 years old. The test is currently authorized for prescription use only.

The test works by swirling the self-collected sample swab in a vial that is then placed in the test unit. In 30 minutes or

less, the results can be read directly from the test unit's light-up display that shows whether a person is positive or negative for the SARS-CoV-2 virus. Positive results indicate the presence of SARS-CoV-2. Individuals with positive results should self-isolate and seek additional care from their health care provider. Individuals who test negative and experience COVID-like symptoms should follow up with their health care provider as negative results do not preclude an individual from SARS-CoV-2 infection.

"Today's authorization for a complete at-home test is a significant step toward FDA's nationwide response to COVID-19. A test that can be fully administered entirely outside of a lab or healthcare setting has always been a major priority for the FDA to address the pandemic. Now, more Americans who may have COVID-19 will be able to take immediate action, based on their results, to protect themselves and those around them," said Jeff Shuren, M.D., J.D., director of FDA's Center for Devices and Radiological Health. "We look forward to proactively working with test developers to support the availability of more at-home test options."

An important component to successful at-home testing is the ability to efficiently track and monitor results. As noted in this EUA, prescribing health care providers are required to report all test results they receive from individuals who use the test to their relevant public health authorities in accordance with local, state and federal requirements. Lucira Health, the test manufacturer, has also developed box labeling, quick reference instructions and health care provider instructions to assist with reporting.

Diagnostic testing remains one of the pillars of our nation's response to COVID-19. The FDA continues its public health commitment to pursue new approaches that help make critical tests available to more Americans through EUA authority.

The FDA, an agency within the U.S. Department of Health and

Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.