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FDA approves first self-testing at home kit for COVID-19

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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 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.