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Clinical Bulletin

December 1, 2020

Subject: FDA Authorizes Use of First at Home COVID-19 Test Kit

On November 17, 2020, the U.S. Food and Drug Administration (FDA) has authorized the first COVID-19 diagnostic test to be used at home.[1] The Lucira™ COVID-19 All-In-One Test Kit is a single use kit intended to detect the novel coronavirus SARS-CoV-2 and provide rapid results.[2]

This test, which uses self-collected nasal swabs, is authorized for at home use in persons 14 years and older who are suspected of having COVID-19. The test may also be used in all ages when the specimen is collected by health care provider at a point of care facility such as a doctor's office, hospital, or urgent care. Although the emergency use authorization (EUA) is for at home use, a health care professional must first prescribe the Lucira test.

According package insert, the Lucira COVID-19 All-In-One Test Kit achieved a 94% positive percent agreement and a 98% negative percent agreement when compared to an FDA authorized high sensitivity SARS-CoV-2 test.[2] The test takes about 30 minutes and an indicator light will note a positive or negative result. Individuals with positive tests should self-isolate and seek additional care from their health care provider. Negative results do not necessarily preclude SARS-CoV-2 infection, and those persons with negative tests should consult their health care provider.

The Lucira COVID-19 All-In-One Test Kit will initially only be available to patients served by Sutter Health in Northern California and the Cleveland Clinic Florida in Miami-Ft. Lauderdale. Availability nationwide is expected in spring 2021.[3]

First Script will continue to monitor this situation and provide additional updates where relevant.

Should specific questions or concerns arise, or for more information, please contact your Account Manager, Account Pharmacist or email us at askthepharmacist@cvty.us.com.

References:

1. Commissioner, Office of the. "Coronavirus (COVID-19) Update: FDA Authorizes First COVID-19 Test for Self-Testing at Home." *FDA*, 17 Nov. 2020, www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-test-self-testing-home. Accessed 25 Nov. 2020.
2. Lucira Health, Inc. [website]. Available at: https://www.lucirahealth.com/. Accessed on November 25, 2020.
3. Lucira Health, Inc. [website]. Lucira News Release. FDA Authorizes First Prescription At Home Molecular Test for COVID-19 Lucira Health test provides lab-quality result in 30 minutes or less from home. November 18, 2020. Available at: https://2nyvwd1bf4ct4f787m3leist-wpengine.netdna-ssl.com/wp-content/uploads/2020/11/FDA-Authorizes-First-Prescription-At-Home-Molecular-Test-for-COVID-19-released-20201118.pdf. Accessed on November 25, 2020.