Enlyte

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

December 1, 2020
2 MIN READ

On November 17, 2020, the US Food and Drug Administration has authorized the first COVID-19 diagnostic test to be used at home. 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.

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 a 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 to the 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. 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 healthcare provider. Negative results do not necessarily preclude SARS-CoV-2 infection, and those persons with negative tests should consult their healthcare 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.

Mitchell Pharmacy Solutions will continue to monitor this situation and provide additional updates where relevant.

©2022 Mitchell International, Inc. and Genex Services, LLC. All rights reserved.

mitchell | genex | coventry