COVID-19 Update: FDA authorizes first diagnostic test where results can be read directly from testing card

Today, the U.S. Food and Drug Administration issued an emergency use authorization for the first antigen test where results can be read directly from the testing card, a similar design to some pregnancy tests. This simple design is fast and efficient for healthcare providers and patients and does not need the use of an analyzer.

“This new COVID-19 antigen test is an important addition to available tests because the results can be read in minutes, right off the testing card. This means people will know if they have the virus in almost real-time. Due to its simpler design and the large number of tests the company anticipates making in the coming months, this new antigen test is an important advancement in our fight against the pandemic,” said Jeff Shuren, M.D., J.D., director of the FDA’s Center for Devices and Radiological Health.

HOW IT WORKS:

A healthcare provider swabs the patient’s nose and twirls that sample on a test card with a testing reagent added. After waiting 15 minutes, the healthcare provider reads the results directly from the testing card. One line indicates a negative result; two lines indicate a positive result.

WHERE IT CAN BE USED:

This test could be used at point-of-care settings, like a

doctor’s office, emergency room or some schools. This test has been authorized for use in patients suspected of COVID-19 by their healthcare provider within seven days of symptom onset. Given the simple nature of this test, it is likely that these tests could be made broadly available. According to the test manufacturer, Abbott, it plans to make up to 50 million tests available monthly in the U.S. at the beginning of October 2020.

TEST DETAILS:

In general, antigen tests are very specific, but are not as sensitive as molecular tests. Due to the potential for decreased sensitivity compared to molecular assays, negative results from an antigen test may need to be confirmed with a molecular test prior to making treatment decisions. Negative results from an antigen test should be considered in the context of clinical observations, patient history and epidemiological information.

The emergency use authorization was issued to Abbott Diagnostics Scarborough, Inc for its BinaxNOW COVID-19 Ag Card.

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.