Abbott’s 15-minute COVID-19 antigen test gets EUA

September 2020—The FDA has issued emergency use authorization for Abbott’s BinaxNow COVID-19 Ag Card rapid test for the detection of COVID-19 infection.

The test is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals suspected of having COVID-19 by a health care provider within the first seven days of symptom onset. A health care provider collects a patient’s sample using a nasal swab and then twirls the sample on a test card, about the size of a credit card, with a testing reagent added. Results are read directly from the testing card after 15 minutes. No instrumentation is required. The test has demonstrated a sensitivity of 97.1 percent and a specificity of 98.5 percent.

Abbott will sell the BinaxNow test for $5 and plans to make up to 50 million tests available monthly in the U.S. at the beginning of October. The company is also offering a free mobile app, Navica, that will allow people to display their results when entering a facility that requires proof of testing.

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