BinaxNOW Antigen Test for COVID-19

On August 26, 2020, the Abbott Company's BinaxNOW COVID-19 Ag Card antigen test was granted Emergency Use Authorization (EUA) by the FDA. This is the fourth rapid antigen test for COVID-19 that has been given an EUA. The other 3 antigen tests and their date of EUA:

Sofia SARS Ag FIA (*Quidel*) – 5/8/2020

BD Veritor System for Rapid Detection of SARS-CoV-2 (*Becton Dickinson*) – 7/2/2020

LumiraDx SARS-CoV-2 Ag Test (*LumiraDx Group*) – 8/18/2020

Unlike the first 3 antigen tests released, the BinaxNOW test does not require an instrument to be read. It is a lateral flow immunoassay that may be used for the qualitative detection of SARS-CoV-2 nucleocapsid antigen from a nasal swab within the first 7 days of symptom onset. According to the company that produced the test, it is inexpensive (about $5 per test), easy to use (does not require a trained laboratory technician), and is designed specifically for point-of-care testing. The company plans to produce 50 million tests per month by October. Some important features of this new test:

- Accuracy as compared to a real-time PCR test showed 97.1% positive agreement (sensitivity) and 98.5% negative agreement (specificity).
- The test is only authorized for use within 7 days of symptom onset
- Results are available within 15 minutes
- It is CLIA-waived (as are the other 3 antigen tests)
- It is designed for point-of-care testing, and specimens must be tested within 1 hour of collection
- Testing for cross-reactivity with 3 human coronaviruses (OC43, 229E, and NL63), as well as many other common respiratory pathogens, was negative. The test will probably react positive with SARS- CoV-1. Cross reactivity with MERS-CoV and human coronavirus HKU1 is unlikely, but cannot be ruled out.
- Probably the biggest advantage of this test is that it does not require an instrument for reading it.
- The test is designed to be used with a smartphone app called NAVICA if so desired (but not required). This app gives patients their test results in a digital format.

For more information on the BinaxNOW COVID-19 Ag Card, go to the following link:

https://www.abbott.com/BinaxNOW-Test-NAVICA-App.html

The BinaxNOW COVID-19 Ag Card package insert (Information for Users) may be found here:

https://www.fda.gov/media/141570/download

For information on all currently authorized antigen tests, go to the following link:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen