

USET Tribal Epidemiology Center

Recommendations for Tribal Consideration

USET TEC COVID-19 Guidance 2020-010: BinaxNOW Antigen Test for COVID-19



Background

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 three 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

The Indian Health Service (IHS) has been provided with 300,000 BinaxNOW COVID-19 tests intended for use within Tribal communities.

BinaxNOW Test

Unlike the first three antigen tests that were 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 seven days of symptom onset. According to Abbott, the test 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. By October, Abbott plans to produce 50 million tests per month.

BinaxNOW Test Performance

- 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 three 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 three 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.
- 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.

Recommendations

The major advantages of the BinaxNOW are:

1. the rapid time of the test (15 minutes);
2. the fact that it is CLIA-waived and can be used as a point-of-care test; and
3. the high degree of sensitivity and specificity among symptomatic patients.

This test has not been tested on known asymptomatic patients, therefore the test accuracy among this cohort is unknown. Due to this consideration and the current limited supply of tests, the USET TEC does not recommend BinaxNOW tests for community testing.

- Read more about the [BinaxNOW](#) test and the [BinaxNOW COVID-19 Ag Card package insert](#) (Information for Users).
- The FDA has [information on all currently authorized antigen tests](#).

The USET Tribal Epidemiology Center (TEC) is charged under the Indian Health Care Improvement Act with providing epidemiologic and public health support to federally recognized Tribal Nations in the Nashville Area. The USET TEC is a designated public health authority.