STAY SAFE MN

Abbot BinaxNOW™ COVID-19 AG Card Test

DESCRIPTION AND PROVIDER INSTRUCTIONS FOR DISTRIBUTION TO INSTITUTES OF HIGHER EDUCATION

2/24/2021

This guidance describes the state-distributed BinaxNOW™ test and the conditions for receiving and using the test. This document is effective as of Feb. 24, 2020. It may be updated as scientific data and needs evolve.

Go to Information for Providers Requesting Abbott BinaxNOW™ Antigen Tests (www.health.state.mn.us/diseases/coronavirus/hcp/binaxnow.html) to learn more about BinaxNOW™ or to request tests. For answers to specific questions, email: health.test.help@state.mn.us.

What is the BinaxNOW™ test?

The BinaxNOW™ test is a rapid antigen test, not a molecular (PCR) test. The test comes in a kit that includes nasal swabs, control swabs, and test cards. No instrument is needed. The medical professional adds extraction reagent and inserts the swab into the card after specimen collection. In 15 minutes, the provider can expect to see one purple control line on the card if the result is negative, and one purple control line and one additional purple line if the result is positive.

Per its Emergency Use Authorization (EUA) from the United States Food and Drug Administration (FDA), the BinaxNOW™ test is intended for the qualitative detection of antigen from COVID-19 in direct nasal swabs from people that present with symptoms of COVID-19 within the first seven (7) days of symptom onset. As described in greater detail below, institutes of higher education may also use these tests as a tool to screen their student and staff population to identify and isolate **asymptomatic** COVID-19 positive people.

Why and when should we use this test?

This test allows for a rapid test result for **symptomatic** people. A quick positive test allows for more rapid medical intervention and may influence a person's behavior to immediately follow prevailing isolation guidelines.

The federal government has also endorsed the use of diagnostic tests (including rapid antigen tests) for screening **asymptomatic** people in environments "where people congregate to receive care or education or to work" – including institutes of higher education. While asymptomatic screening is an "off-label" use, several federal agencies have issued guidance on screening asymptomatic people and removed barriers and potential liabilities associated with these "off-label" uses.[1]

BinaxNOW™ tests may be useful when used at least two times per week as a screening tool to detect infections in asymptomatic people. If used as a one-time screening effort (e.g., for students returning to campus), **institutes of higher education must be aware that because of the lower sensitivity of this test, it is likely positive patients will be missed.** Further, higher education should consider the FDA recommendations for health care providers using SARS-CoV 2 diagnostic tests for screening asymptomatic patients (see FDA COVID-19 Test Uses: FAQs on Testing for SARS-CoV-2 (www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-uses-faqs-testing-sars-cov-2).

For additional recommendations on testing, screening, and outbreak response in institutes of higher education (including screening of asymptomatic people), refer to CDC: Testing, Screening, and Outbreak Response for Institutions of Higher Education (IHEs) (www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/ihe-testing.html).

Why is Minnesota distributing this test to institutes of higher education?

Minnesota is receiving BinaxNOW™ tests directly from the federal government, which has directed states to use the tests in the way they deem appropriate, which for many states includes supporting in-person education. BinaxNOW™ received emergency use authorization from the FDA and can be a useful tool for institutes of higher education because it does not require instrumentation and delivers COVID-19 test results in 15 minutes or less.

[1] For example, the Centers for Medicare & Medicaid Services will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency, under Clinical Laboratory Improvement Amendments (CLIA) for the use of antigen tests for asymptomatic people: CMS: Updated CLIA SARS-CoV-2 Molecular and Antigen Point of Care Test Enforcement Discretion (www.cms.gov/files/document/clia-sars-cov-2-point-care-test-enforcement-discretion.pdf). In addition, the U.S. Department of Health and Human Services has provided Public Readiness and Emergency Preparedness Act (PREP) coverage for any qualified practitioner testing asymptomatic people in congregate settings, including educational settings: HHS: Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities (www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf).

Reliability and risks of the BinaxNOW™ test

According to the manufacturer's instructions for use (FDA: BinaxNOW™ COVID-19 Ag Card (www.fda.gov/media/141570/download), the BinaxNOW™ test should match results of RT-PCR testing 97% of the time. A pilot evaluation was completed comparing the BinaxNOW™ test with RT-PCR on symptomatic patients. Results showed that BinaxNOW™ had a sensitivity of 84%, which means for every 100 infected people tested, 16 will be false negative. In addition, the test had a specificity of 99%, which means for every 100 infected people tested, 1 will be a false positive.

Less is known about the efficacy of its use in asymptomatic people and institutes of higher education must be aware that there may be increased risks of incorrect results when using BinaxNOW™ on asymptomatic people. The current FDA emergency use authorization for the BinaxNOW™ test was granted based on testing of 102 adults with acute COVID-19 symptoms. A CDC Morbidity and Mortality Weekly Report evaluating a similar antigen test to the BinaxNOW™ indicated antigen test sensitivity is much lower (41.2% in this example) when used for screening of asymptomatic people (see CDC: Performance of an Antigen-Based Test for Asymptomatic and Symptomatic SARS-CoV-2 Testing at Two University Campuses (www.cdc.gov/mmwr/volumes/69/wr/mm695152a3.htm). The Minnesota Department of Health (MDH) is working with health care research partners and other states to gather more evidence on the performance of the test and to understand the appropriate uses with asymptomatic people.

Guidance for using BinaxNOW™ test

The BinaxNOW™ test must be ordered by a health care provider, administered in a facility with a CLIA certificate or CLIA certificate of waiver, and performed by a trained CLIA-certified laboratory staff member.

Use on symptomatic people

- Facilities can use the BinaxNOW™ on people who exhibit symptoms suggestive of COVID-19 infection within seven days of onset.
- People who test positive should isolate at home for 10 days and should inform close contacts of their positive test result.
- Because of the lower sensitivity of the test, people who are symptomatic and test negative should also continue to isolate at home until symptoms resolve. Another test, by RT-PCR, is recommended for people who live or work in high-risk settings (e.g., health care, congregate living), or if symptoms continue to get worse.

Use on asymptomatic people

- Facilities may use the BinaxNOW™ for screening a group of asymptomatic people as part of a campuswide testing program.

- People who test positive should isolate at home for 10 days and should inform close contacts of their positive test result.
- Because of the low sensitivity of the test, people should be informed that a negative test does not mean they are negative for infection. It is extremely important that they continue to follow social distancing guidelines, face covering requirements, and other infection prevention measures.
- Consider following additional recommendations including:
  - FDA: FAQs on Testing for SARS-CoV-2 (www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-uses-faqs-testing-sars-cov-2).
  - CDC: Testing, Screening, and Outbreak Response for Institutions of Higher Education (IHEs) (www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/ihe-testing.html) specific to asymptomatic screening.
  - CDC: Table 1. Summary of Some Differences between NAATs and Antigen Tests (www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#table1) in the Interim Guidance for Antigen Testing for SARS-CoV-2.

Distribution priorities

If demand exceeds supply, MDH will prioritize facilities that serve high positivity rate geographies, populations at disproportionate risk, and/or where access to COVID-19 testing is otherwise limited.

How tests will be distributed

If you are a health care provider that meets the requirements described below and agree to administer the BinaxNOW™ test to **symptomatic priority populations**, you can request a **biweekly** shipment of tests from MDH. The tests are provided at no cost to you.

The testing supplies provided by MDH under this program are provided "as is." MDH makes no representations or express or implied warranty as to the condition, effectiveness, or safety of the testing supplies provided under this program. MDH shall not be liable for special, consequential, or incidental damages attributed to use of the testing supplies or kits provided under this program.

Resources from Abbott

- For any questions pertaining to the BinaxNOW™ COVID-19 Ag Card or NAVICA™, contact the Abbott technical services team between 7 a.m. and 7 p.m. CST Monday through Friday at 800-257-9525, or email ts.scr@abbott.com.
- Find training materials, videos, and additional resources at BinaxNOW™ COVID-19 AG Card and NAVICA™ App Set-Up and Training (www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html). Click on "Helpful Documents" toward the bottom of the page to download product insert, fact sheets, and more.

Requirements of sites administering BinaxNOW™ tests

Sites must agree to and meet several core requirements in order to receive the BinaxNOW™ tests:

- The facility must agree to use the tests in accordance with MDH guidance, including the priority populations described above. The guidance may be updated based on evolving information.
- The facility must have either a valid CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- The facility may not receive BinaxNOW™ tests from the state if it is receiving BinaxNOW™ tests directly from the federal government, unless the facility is a long-term care or assisted living facility and informs MDH that it needs an additional allocation to meet testing needs. The facility must agree to let MDH know if it starts to receive tests directly from the federal government.
- The facility must appropriately manage biohazard waste disposal.
- All tests must be completed in a setting that can be decontaminated between tests and when a positive test is detected, to reduce the possibility of cross contamination.
- The facility must have a provider who is able to order and administer BinaxNOW™ tests (i.e., an M.D., P.A., or N.P.), per the emergency use authorization. The facility will administer the kits to patients in a manner consistent with all manufacturer guidance, MDH health alerts, and other relevant state and federal guidelines.
- The facility must complete the BinaxNOW™ online training modules to ensure the test is used in a manner consistent with the manufacturer's instructions. That training is available at BinaxNOW™ COVID-19 AG Card and Navica™ App Set-Up and Training (www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html). **Off-label use is permitted only as specifically described in this document (i.e., asymptomatic screening).**
- The facility must report BinaxNOW™ test results and other required data to MDH and follow data reporting requirements and instructions provided by MDH.
- The facility must follow all relevant data practices and privacy requirements under state and federal law, including but not limited to the Minnesota Health Records Act, section 144.291 (www.revisor.mn.gov/statutes/cite/144.291).
- The facility must publish and provide test availability to key stakeholder groups that work with priority populations.

Reporting data to MDH

All COVID-19 test results performed using BinaxNOW™ inside your facility must be reported to MDH within 24 hours of results.

- The facility must identify a contact for reporting results to MDH when requesting tests.
- If the facility is already reporting test results to MDH using electronic lab reporting, the BinaxNOW™ test results can be included in the existing reporting to MDH.
- **Detailed reporting instructions will be sent via email with the approval of your test allocation request.**
- Facilities that are not reporting results to MDH as required will not receive additional test kits until reporting issues are resolved.