STAY SAFE MN

BinaxNOW™ Description and Provider Instructions to Distribute to Priority Populations

ABBOTT BINAXNOW™ COVID-19 AG CARD TEST

11/24/2020

What is the Abbott BinaxNOW™ COVID-19 test?

The test is a rapid antigen test, not a molecular (PCR) test. The kits include 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 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, 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 days of symptom onset. Use of these tests should be reserved for instances where a positive result would direct immediate clinical decisions or infection control measures.

Why should we use this test?

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

Why is Minnesota distributing this test?

Minnesota is receiving BinaxNOW™ tests directly from the federal government. The U.S. Department of Health and Human Services is also sending tests directly to long-term care and assisted living. BinaxNOW™ received a BinaxNOW™ COVID-19 Ag Card Letter of Authorization (www.fda.gov/media/141567/download) from the Food and Drug Administration. The test does not require instrumentation and it delivers COVID-19 test results in 15 minutes or less. MDH guidance

describes the conditions for receiving and using the state-distributed BinaxNOW™ test and is effective as of Nov. 15, 2020. It may be updated as scientific data and needs evolve.

Background on Abbott BinaxNOW™ COVID-19 Ag Card

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

According to the manufacturer's instructions for use (see BinaxNOW™ COVID-19 Ag CARD [www.fda.gov/media/141570/download]), the BinaxNOW™ test should have a total agreement of 97%, compared to RT-PCR testing. A pilot evaluation was completed comparing the BinaxNOW™ test with RT-PCR. Results showed that BinaxNOW™ had a sensitivity of 84%, which means for every 100 infected individuals tested, 16 would be false negative, and a specificity of 99%, which means for every 100 infected individuals tested, one would be a false positive.

Less is known about the efficacy of its use in asymptomatic people. The current FDA Emergency Use Authorization (EUA) for the BinaxNOW™ test was granted based on testing of 102 adults with acute COVID-19 symptoms. MDH is working with health care research partners and other states to gather evidence on the performance of the test and to understand the appropriate uses with asymptomatic populations.

Guidance for using the BinaxNOW™ test

- Facilities may use the BinaxNow™ test on people who exhibit symptoms suggestive of COVID-19 infection within seven days of onset of symptoms.
- Results evaluation:
  - 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 (i.e., health care) or if symptoms continue to get worse.

For more guidance, please refer to CDC: Interim Guidance for Rapid Antigen Testing for SARS-CoV-2 (www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html).

See Information for Providers Requesting Abbott BinaxNOW™ Antigen Tests (www.health.state.mn.us/diseases/coronavirus/hcp/binaxnow.html) learn more or to request tests.

Distribution priorities and how tests will be distributed

MDH anticipates receiving up to 1.6 million BinaxNOW™ tests from the federal government. Distribution priorities are to health care, pharmacies, and long-term care facilities that agree to distribute the tests to the following symptomatic populations:

- Infant – 18 years of age
- 18-35 years of age
- Essential workers
- High-risk settings, such as long-term care, corrections, etc.

Since demand may exceed 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.

If you are a health care provider that meets the Requirements of Sites Administering BinaxNOW™ listed below and agree to administer the BinaxNOW™ test to symptomatic priority populations, you can request a biweekly shipment of tests from the Minnesota Department of Health (MDH).

The tests are provided at no cost to you. The testing supplies provided by the Minnesota Department of Health 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.

See Information for Providers Requesting Abbott BinaxNOW™ Antigen Tests (www.health.state.mn.us/diseases/coronavirus/hcp/binaxnow.html) to learn more or request tests from MDH.

Questions? E-mail: health.test.help@state.mn.us.

Resources from Abbott:

For any questions about the BinaxNOW™ COVID-19 Ag Card or NAVICA™, call the Abbott Technical Services Team at 800-257-9525 from 7 a.m. to 7 p.m. Monday-Friday or email ts.scr@abbott.com.

Training:
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)

Product inserts:
BinaxNOW™ COVID-19 Ag CARD (www.fda.gov/media/141570/download)

Requirements of sites administering BinaxNOW™ tests

Sites must agree to and meet several core requirements in order to receive the BinaxNow™ tests.

- The facility agrees to use the tests in accordance with MDH guidance, including the priority populations, as laid out in this document, which may be updated based on evolving information.
- The facility has either a valid Clinical Laboratory Improvement Amendment (CLIA) certificate of waiver, certificate of compliance, or certificate of accreditation.
- The facility is not currently receiving BinaxNOW™ tests directly from the federal government and will let MDH know if it starts to receive them directly from the federal government, OR if the long-term care or assisted living facility is receiving tests, but needs additional allocation to meet testing needs.
- The facility can appropriately manage biohazard waste disposal.
- The facility has a provider able to order and administer BinaxNOW™ tests (MD, PA, NP), 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).
- The facility must report BinaxNOW™ test results and other required data to MDH and follow data reporting requirements and instructions, as 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.
- The facility will support publicity of test availability at your site(s) to key stakeholder groups that work with priority populations, such as local schools.

Reporting data to MDH

All COVID-19 test results performed using BinaxNOW™ inside your facility must be reported 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.

Publicizing test availability

Once MDH has confirmed that tests will be made available to your site(s), MDH will publicize this information with key stakeholders, such as higher education clinics, health care providers, and child care, as well as through other forums.

Frequently asked questions

How should results be reported to the patient?

Refer to the instructions for use (see BinaxNOW™ COVID-19 Ag CARD [www.fda.gov/media/141570/download]) for proper reporting language. Negative test results should be considered presumptive and continued isolation is required.

What information can I give the patient?

Providers should provide the BinaxNOW™ COVID-19 Ag CARD (www.fda.gov/media/141570/download) fact sheet. Patient fact sheets are also provided with each BinaxNOW™ kit and can be distributed as needed.

What personal protective equipment is required?

Test administration requires the following personal protective equipment:

- Personal protective equipment for health professionals using contact and droplet precautions. This includes gown, surgical mask, protective eyewear, and gloves as well as hand hygiene products.

A safe place is needed to complete the test. We recommend that all tests are completed in a setting that can be decontaminated between tests and when a positive test is detected, to reduce possibility of cross contamination. When a test is complete, dispose of it in a biohazard bag.

What is the appropriate billing?

Please refer to the Centers for Medicare & Medicaid Services (CMS) frequently asked questions for the most up-to-date information: HHS: COVID-19 Rapid Point-Of-Care Test Distribution (www.hhs.gov/coronavirus/testing/rapid-test-distribution/index.html).

CMS released information to help states, nursing facilities, and other providers better understand the sources of Medicare and Medicaid coverage and payment for COVID-19 testing, including a flow chart detailing testing coverage for nursing facility residents:

- Medicare Payment for COVID-19 Viral Testing (www.cms.gov/files/document/covid-medicare-payment-covid-19-viral-testing-flow-chart.pdf)

Minnesota Department of Health | health.mn.gov | 651-201-5000
625 Robert Street North PO Box 64975, St. Paul, MN 55164-0975

Contact health.communications@state.mn.us to request an alternate format.