BinaxNOW Professional Testing Information

6/9/2022

Test description

BinaxNOW professional is an individual, diagnostic, rapid COVID-19 antigen test recommended for symptomatic people and may also be used for screening testing when testing is conducted frequently. The test uses a nasal swab, control swabs, and test cards. No testing instrument is needed. The test administrator adds extraction reagent and inserts the swab into the card after collection. Results are available within 15 minutes of processing. The provider can expect to see one purple control line on the card if the result is negative, and one purple control line plus one additional purple line if the result is positive.

Test sites must have an ordering provider to obtain this test. In addition, test sites must operate under a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver, certificate of compliance, or certificate of accreditation to administer BinaxNOW professional tests. This resource describes how to apply for a CLIA certificate of waiver or, for eligible test sites, request to use the MDH-issued CLIA certificate of waiver.

MDH has a limited supply of BinaxNOW professional tests. As available, these tests will be provided to approved test sites at no cost.

Considerations for use

Test sites must agree to and meet several core requirements to receive the BinaxNOW professional tests.

General information

- BinaxNOW professional tests must be administered according to the requirements in the manufacturer’s instructions and the applicable FDA emergency use authorization (refer to the vendor information section below for these resources).
- Test sites should also implement testing programs in accordance with MDH and Centers for Disease Control and Prevention (CDC) guidance.
- BinaxNOW professional tests may be used when rapid results are needed.
- BinaxNOW professional tests are recommended to be used for people who are symptomatic.
- The person administering the test will receive test results, which are available within 15 minutes.
- The person administering the test must report the test result to the person upon receiving the result.
Test sites are strongly encouraged to advise people who test positive to follow MDH general isolation guidance or the relevant setting-specific guidance. General isolation guidance is at If you test positive or have symptoms (www.health.state.mn.us/diseases/coronavirus/sick.html#positive).

Even if a test result is negative additional measures (e.g., testing, isolation) may be recommended, depending on the setting where the patient lives, works, or attends. Refer to setting specific guidance for additional details at Guidance Library: COVID-19 (www.health.state.mn.us/diseases/coronavirus/guidance.html).

BinaxNOW professional tests can also be used for serial testing an asymptomatic person in a community setting. For additional details, refer to CDC: Guidance for Antigen Testing for SARS-CoV-2 (www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html). The information is under the section, Serial Testing When Using Antigen Tests.

Training

Test sites must review and follow all applicable standards in the test manufacturer instructions, available below. For test sites using the MDH statewide CLIA waiver, a person administering the test must complete the BinaxNOW online training modules referenced in the MDH CLIA Waiver COVID-19 Testing Acknowledgement (www.health.state.mn.us/diseases/coronavirus/hcp/cliawaiver.pdf). Training, FAQs, and support from Abbott Laboratories is 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).

CLIA requirements

- Test sites must operate under a Clinical Laboratory Improvement Amendment (CLIA) certificate of waiver, certificate of compliance, or certificate of accreditation to order and conduct the BinaxNOW professional test.
- Many organizations have two options to obtain CLIA certification.
  - First, any organization may apply for and obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver from the Centers for Medicare and Medicaid Services (CMS).
  - Second, eligible organizations may submit a request for MDH to use one of the statewide MDH CLIA certificates of waiver. More detail about eligibility, requirements, and limitations and requests for these statewide certifications are available below.

Individual test site CLIA certificate of waiver

- Some organizations may have an existing CLIA waiver that can be used to administer the BinaxNOW professional test.
- Organizations that are not eligible for the statewide CLIA certifications must obtain their own CLIA certificate of waiver.
- Test sites can learn more about the CLIA certificate of waiver application process at Minnesota Clinical Laboratory Improvement Amendment (CLIA) (www.health.state.mn.us/facilities/regulation/clia/index.html).
  - For questions about CLIA, contact health.clia@state.mn.us or call 651-201-4120.
  - CLIA application forms may be submitted to health.clia@state.mn.us. Once the form is submitted, it takes MDH approximately three days to process the application. Once MDH processes the application, test sites may choose to receive instructions to pay online with a credit card ($180 every two years) or to wait two to three weeks to receive an invoice in the mail. While this entire process takes about four to six weeks, testing may begin as soon as the test site has been assigned a CLIA certificate of waiver number, which is typically issued in approximately three days after MDH receives the application.

MDH statewide CLIA certificate of waiver

MDH has a statewide CLIA certificate of waiver for schools and other settings to use the BinaxNOW professional test. Eligible organizations include:

- Child care organizations
- Correctional facilities (e.g., jails, juvenile detention centers)
- Institutions of higher education
- K-12 schools
- Local and tribal public health organizations
- Long-term care organizations, including group homes
- Shelters

Eligible organizations are encouraged to assess their own needs to determine whether to use the statewide certification or to obtain their own CLIA certificate of waiver.

More information for organizations that elect to use MDH CLIA certificates of waiver is at MDH Statewide Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver for COVID-19 Testing (www.health.state.mn.us/diseases/coronavirus/hcp/clia.html).

- In general, organizations must send an email to health.test.help@state.mn.us to request approval to use the statewide certifications. The request must include a completed MDH CLIA Waiver COVID-19 Testing Acknowledgment (www.health.state.mn.us/diseases/coronavirus/hcp/cliawaiver.pdf).

Ordering provider requirements

An ordering medical provider is required to order the test. Most test sites will need to partner with their own provider or an outside health care provider to order the tests.

Schools that are unable to work with a provider may use the Minnesota state medical director standing order by submitting a request to COVIDTesting.MDE@state.mn.us. If the standing order is used, schools are strongly encouraged to tell those who are tested to follow up with their primary care provider if they have questions or test positive for COVID-19. The standing order is only for the purpose of ordering tests and the Minnesota state medical director cannot provide follow-up care or consultation. The standing order is in effect for all K-12 schools that meet the criteria described in this order, until rescinded or until July 31, 2022, whichever is sooner.

Skilled nursing or assisted living facilities that do not have access to an ordering provider also may use a standing order from the Minnesota state medical director by submitting a request to seoc.covid.testing@state.mn.us. If the standing order is used, those who are tested are strongly encouraged to follow up with their primary care provider if they have questions or test positive for COVID-19. The standing order is only for the purpose of ordering tests and the Minnesota state medical director cannot provide follow-up care or coordination. The current standing order is effective through June 30, 2022.
Preparing the test area

- The area chosen for testing should provide enough room to safely administer the test, offer privacy, and have surfaces that can hold testing materials and it include convenient methods to dispose of test material (use biohazard bags).
- Disinfect surfaces within 6 feet of the specimen collection and handling area at these times: before testing begins each day; between each specimen collection; at least hourly during testing; when visibly soiled, in the event of a specimen spill or splash; and at the end of every testing day.

Use of personal protective equipment

- Test sites must follow any personal protective equipment (PPE) requirements in the manufacturer instructions and in the applicable FDA emergency use authorization.
- Test sites should ensure that adults administering the test understand and implement appropriate infection prevention measures, including the proper use of PPE for the tasks they are performing. For example, personnel collecting specimens or working within 6 feet of someone suspected to be infected with SARS-CoV-2 should maintain proper infection control and use recommended PPE, which could include an N95 respirator or higher-level respirator (or face mask if a respirator is not available), eye protection, gloves, and a lab coat or gown. For more detailed information on standard and transmission-based infection prevention precautions, visit CDC: Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the COVID-19 Pandemic (www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html).
- Depending on the setting, federal or state law may also impose PPE requirements. For example, the Occupational Health and Safety Administration may impose standards relating to the use of respirators, depending on whether respirators are mandatory, voluntary, or employer-distributed.
  - You may also contact:
    Minnesota OSHA Workplace Safety Consultation
    651-284-5060 or 800-657-3776
  - For general information and resources on the use of PPE, PPE training, and respiratory protection programs in K-12 schools, visit Recommendations for Infection Prevention and Control Practices for Delivering Direct Student Support Services (www.health.state.mn.us/diseases/coronavirus/schools/directsupport.pdf).

Technology needs and considerations

- Additional technology is recommended for the administrator of the test. If used, the free NAVICA Administrator app1 must be installed on a test-site-issued mobile device. Personal devices may not be used.

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1 Reference to any specific commercial products, process, or service by trade name, trademark, manufacturer, or otherwise, does not constitute or imply its endorsement, recommendation, or favoring by the State.
Test sites should ensure the most up-to-date app is installed. Information on training and using the app is listed below, under vendor information. The app is available on commercial application platforms.

- **App store preview - NAVICA** (apps.apple.com/us/app/navica/id1527297235)

- The person administering the test, which may be a staff person or outside provider, will be able to see the test results. MDH recommends against storing health information in the app directly. Refer to the legal and consent section below.

**Test performance and technical considerations**

- Information on test accuracy and any risks or side effects is available in the manufacturer instructions. Refer to the FDA fact sheet *BinaxNOW™ COVID-19 Ag Card Instructions for Use* (www.fda.gov/media/141570/download).
- If there are technical difficulties when using the BinaxNOW professional test, test sites should contact the vendor for further guidance.

**Specimen collection**

- Adults must test children 2 years of age and older. Refer to the FDA fact sheet *BinaxNOW™ COVID-19 Ag Card Instructions for Use* (www.fda.gov/media/141570/download).
- MDH recommends that people administering tests are competency evaluated by a registered nurse or health care provider before administering a test. **Note:** This competency evaluation is required for organizations that use the Minnesota state medical director standing order.

**Reporting results**

- Reporting cases and test results relating to infectious diseases is a vital step in controlling and preventing the spread of communicable disease. Test sites have two different COVID-19 reporting obligations under federal and state law.
  - **Test results:** Test sites must report positive *BinaxNOW professional test results* through one of the methods identified at [COVID-19 Test Reporting Requirements](https://www.health.state.mn.us/diseases/coronavirus/hcp/reportlab.html). All organizations that report through MDH RePortal must use the specific BinaxNOW professional spreadsheet template available at [MDH COVID-19 Test Reporting Spreadsheet ABN - for Abbott BinaxNOW COVID-19 Ag Card](https://www.health.state.mn.us/diseases/coronavirus/hcp/ltcantigenabn.xlsx). For templates and guidance specific to schools and child care, visit [COVID-19 Testing in K-12 Schools and Child Care](https://www.health.state.mn.us/diseases/coronavirus/schools/testing.html#report).
  - **Cases:** Minnesota law also requires reports of cases of infectious disease, including COVID-19, regardless of whether the case was identified on-site or elsewhere (e.g., at home test, external test site, provider diagnosis, etc.). Refer to [Reportable Disease Rule](https://www.health.state.mn.us/diseases/reportable/rule/index.html) for more information.
Legal and consent

- The State of Minnesota makes no representations or warranties, express or implied, regarding these tests, including the use, condition, and effectiveness of tests or the accuracy of test results. People ordering and taking tests accept the tests as-is and assume all risks associated with the test. The State of Minnesota assumes no responsibility for actual, consequential, incidental, special, or exemplary damages resulting from, caused by, or associated with any test.

- The person administering the test must ensure that the person taking a test has given informed consent to take the test. The person should work with a parent or guardian as necessary to ensure they understand and fully complete any informed consent requirements.

- Test sites must determine how to manage consent. This includes ensuring each person being tested completes the necessary informed consent and may include consent to sharing information with the test administrator and, if applicable, test sites before the test is performed.

- Test sites may be subject to federal and state laws and are responsible for complying with all applicable legal obligations, including those that govern data privacy and health records.

- Test sites are strongly encouraged to consult with legal counsel. The State of Minnesota cannot provide legal advice to test sites and this document should not be relied on as legal advice.

- These tests are available to approved test sites at no cost.

Vendor information

For any questions pertaining to the BinaxNOW COVID-19 Ag Card or NAVICA, please contact the Abbott Technical Services Team at 800-257-9525, between 7 a.m. and 7 p.m. Monday-Friday, or email ts.scr@abbott.com.

Training

More information on Abbot Laboratories’ BinaxNOW professional test, including training, FAQs, and support, is 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).

BinaxNOW professional test resources

Before administering the BinaxNOW professional test, it is critical that test sites and all staff involved in administering the test understand the following information:


- FDA Instructions for use: BinaxNOW™ COVID-19 Ag Card - Instructions for Use (PDF) (www.fda.gov/media/141570/download).


- FDA Fact sheet for patients: BinaxNOW™ COVID-19 Ag Card - Fact Sheet for Patients (PDF) (www.fda.gov/media/141569/download).
**How to order tests**

- An ordering provider and a CLIA certificate of waiver number is required for each test to place your order. Orders received without this information will not be processed. Refer to the CLIA requirements section above for information on obtaining an ordering provider or a CLIA certificate of waiver number.

- Ordering requires a lead time of at least two weeks.

- Order BinaxNOW professional tests at [Information for Organizations Requesting Abbott BinaxNOW COVID-19 Ag Card](www.health.state.mn.us/diseases/coronavirus/hcp/binaxnow.html) (order form is near the bottom of the page).

- These tests come in boxes of 40 tests per box.

- Minnesota has a limited supply of BinaxNOW professional tests available for test sites.

- The BinaxNOW tests you receive may have a printed expiration date on the box that is past the current date (expired). These tests have had their expiration date extended by the FDA. Documentation will be sent with your order confirmation.

**For more information**

For more information on BinaxNOW professional tests, contact: health.test.help@state.mn.us.