

# BinaxNOW Professional Testing Information

## 2021-2022 SCHOOL COVID-19 TESTING PROGRAM

9/8/2021

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### Description of the test

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. Results are available within 15 minutes of processing. In order to use this test, schools must have an Ordering Provider. MDH is providing a standing order for schools that do not have an alternative option. In addition, schools will need to apply for and obtain a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver, as regulated by the Centers for Medicare and Medicaid Services (CMS) in order to administer the test. The Minnesota Department of Health (MDH) has received a limited supply of BinaxNOW Professional through a grant from the U.S. Department of Health and Human Services (HHS). These tests are available for schools at no cost.

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### Considerations for use

- This type of test should be considered when rapid results are needed.
- A medical provider is required to order the test. Refer to the “Logistics and roles” section of this document for more information, including how MDH can provide a medical provider if needed by the school.
- CLIA requires that those administering the test are properly trained to conduct the test, interpret the test results, and understand necessary quality controls.
- Adults who are administering the test to people should understand and implement Standard Precautions for infection prevention, including the proper use of personal protection equipment (PPE) as needed for the situation.
  - [CDC: Standard and Transmission-Based Precautions \(www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/overview/#standard-based-precautions\)](https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/overview/#standard-based-precautions)
  - [OSHA: COVID-19 Healthcare Emergency Temporary Standard \(ETS\) \(www.osha.gov/coronavirus/ets\)](https://www.osha.gov/coronavirus/ets)
- The person administering the test will be able to see the test results and must complete training through Abbott Laboratories. See “Legal and consent” and “Results” sections below for more information.

- [BinaNOW™ COVID-19 Ag Card and NAVICA™ App Set-Up and Training \(www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html\)](http://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html)
- Additional technology is needed. The free NAVICA app needs to be installed on a school-issued mobile device to get test results. The app is available on commercial application platforms.<sup>1</sup>
  - [NAVICA on the App Store \(https://apps.apple.com/us/app/navica/id1527297235\)](https://apps.apple.com/us/app/navica/id1527297235)
  - [NAVICA - Apps on Google Play \(https://play.google.com/store/apps/details?id=com.abbott.ardx.navica.consumer.prod\)](https://play.google.com/store/apps/details?id=com.abbott.ardx.navica.consumer.prod)
- BinaxNOW is recommended to be used for people who are symptomatic. Refer to the Centers for Disease Control and Prevention's (CDC) [Antigen Test Algorithm for Community Settings \(www.cdc.gov/coronavirus/2019-ncov/lab/resources/Antigen\\_Testing\\_Algorithm\\_CommunitySettings.pdf\)](http://www.cdc.gov/coronavirus/2019-ncov/lab/resources/Antigen_Testing_Algorithm_CommunitySettings.pdf).
- BinaxNOW can also be used for testing an asymptomatic person in a community. Refer to [CDC: Interim Guidance for Antigen Testing for SARS-CoV-2 \(www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html\)](http://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html).
- Adults must test children 2 years of age and older. Refer to the FDA fact sheet: [BinaxNOW™ COVID-19 Ag Card Instructions for Use \(www.fda.gov/media/141570/download\)](http://www.fda.gov/media/141570/download).
- When there is a positive test result, families should notify the school and schools should follow MDH and CDC quarantine guidance: [Best Practice Recommendations for COVID-19 Prevention in Schools for the 2021-22 School Year \(www.health.state.mn.us/diseases/coronavirus/schools/schoolrecs.pdf\)](http://www.health.state.mn.us/diseases/coronavirus/schools/schoolrecs.pdf).
- When a person is symptomatic **and** there is a negative test result, a confirmatory lab-based COVID-19 test is highly recommended. Schools can use the following CDC guidance to inform decisions around re-testing, isolation, and quarantine: [Antigen Test Algorithm for Community Settings \(www.cdc.gov/coronavirus/2019-ncov/lab/resources/Antigen\\_Testing\\_Algorithm\\_CommunitySettings.pdf\)](http://www.cdc.gov/coronavirus/2019-ncov/lab/resources/Antigen_Testing_Algorithm_CommunitySettings.pdf). The student or staff can be referred to their health care provider for further testing or if the school has Cue, Vault, or any other molecular test available, one can be administered for verification.
- If a student or staff member develops symptoms during the school day, a BinaxNOW rapid test is a way to find out if COVID-19 is present. Schools interested in this option should keep a supply of tests available for quick deployment as needed. Even if the person tests negative, people with symptoms of illness should be sent home until symptoms improve and they have been fever-free for 24 hours. The CDC recommends that people who are symptomatic but get a negative test should get another test to confirm the results.
- Information on test accuracy and any risks or side effects is available in the manufacturer's instructions. Refer to the FDA fact sheet: [BinaxNOW™ COVID-19 Ag Card Instructions for Use \(www.fda.gov/media/141570/download\)](http://www.fda.gov/media/141570/download).

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<sup>1</sup> 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.

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## Logistics and roles

- A CLIA Certificate of Waiver is **required** to order and conduct the BinaxNOW Professional tests. Schools can learn more about the application process on [Minnesota Clinical Laboratory Improvement Amendment \(CLIA\) \(www.health.state.mn.us/facilities/regulation/clia/index.html\)](http://www.health.state.mn.us/facilities/regulation/clia/index.html).
  - For questions on CLIA: [health.clia@state.mn.us](mailto:health.clia@state.mn.us) or 651-201-4120.
  - Individual school sites will apply for a CLIA waiver.
  - CLIA application forms can be submitted to [health.clia@state.mn.us](mailto: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, schools can be sent instructions to pay online with a credit card (\$180 every two years) or schools can wait two to three weeks to receive an invoice in the mail. The entire process takes about four to six weeks.
  - Additional information about waived testing can be found in the [Ready? Set? Test! Patient Testing is Important. Get the right results. \(www.cdc.gov/labquality/images/waived-tests/RST-Booklet\\_Dec-2019.pdf\)](http://www.cdc.gov/labquality/images/waived-tests/RST-Booklet_Dec-2019.pdf) booklet developed by CDC and CMS.
- An Ordering Provider is required to order the tests. You will need to partner with your school health clinic or an outside health care provider for this.
- **Schools that are unable to work with a provider may use a standing order from the Minnesota State Medical Director standing order.** They may obtain it by requesting it at the following e-mail: [COVIDTesting.MDE@state.mn.us](mailto: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 or a school medical professional 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.
- Ordering requires a lead time of at least two weeks.
- Nasal swab needs to be collected by the nurse or other trained staff member for anyone under the age of 18. The nurse or trained staff member must have their competency-evaluated by a health care provider or registered nurse before administering the test.
  - Required training: [BinaNOW™ COVID-19 Ag Card and NAVICA™ App Set-Up and Training \(www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html\)](http://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html).

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## Results

- The person administering the test will receive test results, which are typically available within 15 minutes.
- The person administering the test must report the test result to the individual upon receiving the result. The test administrator may choose to report test results directly, by email, or by phone. Refer to the “Legal and consent” section below—the test administrator must ensure compliance with any applicable laws governing data privacy and health records, consulting with legal counsel as necessary.
- When there is a positive test result, the person administering the test and the tested individual should follow MDH/CDC quarantine guidance found on [Recommended COVID-19 Decision Tree for People in Schools, Youth Programs, and Child Care Programs \(www.health.state.mn.us/diseases/coronavirus/schools/exguide.pdf\)](http://www.health.state.mn.us/diseases/coronavirus/schools/exguide.pdf).

- When there is a negative test result, a confirmatory lab-based COVID test is highly recommended. Even if the test result is negative, students and staff with symptoms of illness should be sent home until symptoms improve and they have been fever free for 24 hours. If symptoms persist, families are encouraged to connect with health care provider or seek another testing opportunity.
- Results and case reporting requirements:
  - Schools must report lab results (positive and negative) and cases to MDH. Reporting of cases of infectious diseases and related conditions is a vital step in controlling and preventing the spread of communicable disease. By law a number of infectious diseases must be reported to the Minnesota Department of Health; this includes cases, suspected cases, and carriers. [Minnesota Rule 4605.7050 \(www.revisor.mn.gov/rules/4605.7050/\)](http://www.revisor.mn.gov/rules/4605.7050/).
  - Refer to [Reporting COVID-19 Test Results for Schools: Cue and BinaxNOW Professional \(www.health.state.mn.us/diseases/coronavirus/schools/reportcb.pdf\)](http://www.health.state.mn.us/diseases/coronavirus/schools/reportcb.pdf) for required reporting instructions. This information will also be provided when schools order BinaxNOW Professional tests so they know how to report test result information to MDH.
  - Cases of COVID-19 [caused by SARS-CoV-2] are reportable under the Minnesota Disease Reporting rule. Schools are mandated reporters under 4605.7070 specifically: [Minnesota Rule 4605.7070 \(www.revisor.mn.gov/rules/4605.7070/\)](http://www.revisor.mn.gov/rules/4605.7070/).
  - More information on reporting communicable diseases to the Minnesota Department of Health can be found at [Reportable Disease Rule \(www.health.state.mn.us/diseases/reportable/rule/index.html\)](http://www.health.state.mn.us/diseases/reportable/rule/index.html).

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## 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. The persons ordering and taking a test accept the test “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.
- Individual schools and school districts 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, the school or school district before the test is performed.
- **Schools are strongly encouraged to consult with legal counsel. The State of Minnesota cannot provide legal advice to schools or districts and this document should not be relied on as legal advice.**
- Schools may be subject to federal and state laws that govern student and healthcare data, which may include the Minnesota Government Data Practices Act. Different schools may have different federal and state obligations, including those that apply to student and health data.
- Minnesota Statutes, Section 13.04, Subdivision 2 requires those subject to the Minnesota Government Data Practices Act to provide a “Tennessee Warning” containing specific information before collecting private or confidential data concerning individuals

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## Cost

The Minnesota Department of Health (MDH) has received a limited supply of BinaxNOW Professional tests through a grant from the U.S. Department of Health and Human Services (HHS). These tests are available for schools at no cost to schools or families.

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## Vendor information

More information on Abbot Laboratories' BinaxNOW Professional test, including training, FAQs, and support, can be found at [BinaNOW™ COVID-19 Ag Card and NAVICA™ App Set-Up and Training \(www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html\)](http://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html).

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## How to order tests

Order BinaxNOW Professional test materials:

- **Note:** you will need an Ordering Provider and CLIA Certificate of Waiver number for each school to place your order. Orders received without this information will not be processed. Refer to “Logistics and roles” section above.
- **Order form:** [Abbott BinaxNOW Test Request Form \(two-week supply\) \(https://redcap.health.state.mn.us/redcap/surveys/?s=WL9N3NLT4L\)](https://redcap.health.state.mn.us/redcap/surveys/?s=WL9N3NLT4L)
- **Note:** these tests come in boxes of 40 tests per box.

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## Receipt of tests

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.

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## For more information

For any questions pertaining to the BinaxNOW COVID-19 Ag Card or NAVICA, please contact the Abbott Technical Services Team at 1-800-257-9525 between 8 a.m. and 8 p.m. EST Monday-Friday or email [ts.scr@abbott.com](mailto:ts.scr@abbott.com).



Minnesota Department of Health | [health.mn.gov](http://health.mn.gov) | 651-201-5000  
625 Robert Street North PO Box 64975, St. Paul, MN 55164-0975

Contact [health.communications@state.mn.us](mailto:health.communications@state.mn.us) to request an alternate format.