

## Missouri's BinaxNOW Antigen Testing Program for K-12 Institutions

Updated December 17, 2020

(Look for this icon  throughout the document to view the most recent updates.)

The federal government has prioritized public and private K-12 districts/schools to receive Abbott's BinaxNOW rapid antigen test kits to test school personnel and students for COVID-19. The Missouri Department of Elementary and Secondary Education (DESE) strongly believes that these rapid antigen tests will be instrumental in both opening schools and keeping schools open so onsite education can safely be delivered to as many students as possible. The Centers for Disease Control and Prevention (CDC) provides [additional information on antigen testing here](#).

The Abbott BinaxNOW test is a minimally invasive anterior nasal swab test. The test must be administered by a trained health professional (e.g. nurse or doctor), and yields results in just 15 minutes without any additional equipment. The Missouri Department of Health and Senior Services (DHSS) has established statewide orders enabling school-based RNs and LPNs, or their designee, to administer the test at the point-of-care (See Appendix B).

The CDC offers [considerations](#) for ways in which schools can help protect students and staff and slow the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19). [Testing to diagnose COVID-19](#) is one component of a comprehensive response strategy and should be used in conjunction with [promoting behaviors that reduce spread](#), [maintaining healthy environments](#), [maintaining healthy operations](#), and [preparing for when someone gets sick](#). CDC also offers [Interim Considerations for Testing for K-12 School Administrators and Public Health Officials](#) based on what is currently known about COVID-19 as of October 11, 2020. Schools should carry out these strategies in a way that protects privacy and confidentiality, consistent with applicable laws and regulations. In addition to state and local laws, regulations and guidance, school administrators should follow guidance from the [Equal Employment Opportunity Commission](#) when offering COVID-19 testing to school personnel. Schools also should follow guidance from the U.S. Department of Education on the [Family Educational Rights](#)

[and Privacy Act \(FERPA\)](#) and its applicability to students and COVID-19 [contact tracing](#) and testing.

## Test Site Obligations

Public and private PK-12 districts/schools that wish to receive BinaxNOW tests to administer at school must first complete the [online application here](#). The application requests the following information:

- Student enrollment and number of staff members
- Number of tests desired, if less than the maximum allocation
- Primary point of contact
- Testing locations, including building names and addresses
- Health care professionals who will administer the tests and their professional license numbers
- Shipping address for receiving the test kits
- Affirmation that the district/school meets the requirements for receiving the BinaxNOW test kits

DESE will notify districts/schools when their application is approved. **For questions about the online application process, please email [communications@dese.mo.gov](mailto:communications@dese.mo.gov).**

If your district/school does not have a health professional available to administer the BinaxNOW test onsite, please contact Marjorie Cole, State School Nurse Consultant at [Marjorie.Cole@health.mo.gov](mailto:Marjorie.Cole@health.mo.gov). Districts/schools may choose to work with an outside entity, such as a local public health agency or medical clinic, to administer the BinaxNOW tests for their staff and students, as long as these entities meet requirements (i.e., training, CLIA waiver, reporting, etc.) set forth for BinaxNOW testing.

To participate, schools must agree to meet the following conditions:

### ***Prior to Using BinaxNOW Tests:***

- The district/school has medical personnel available to administer the tests.
- Testing personnel will complete the required training and [training documentation](#) as outlined in this guidance document prior to administering any BinaxNOW tests.
- The district/school is able to receive the tests in one central location and potentially store the maximum amount of tests requested.
- The district/school will follow the electronic reporting process.
- The district/school will agree to use the tests only for testing symptomatic individuals (students or school personnel) and asymptomatic students or staff on or after seven full days of quarantine to determine eligibility for release from quarantine..

- The district/school has a process in-place for disposal of infectious waste created through the testing process.

***Ongoing BinaxNOW Testing Program Requirements:***

- Testing personnel will adhere to the written Instructions for Use (IFU) provided by the manufacturer in the test package insert.
- The district/school will ensure DHSS has up-to-date information on test administrators and testing locations.
- The district/school will abide by the infectious waste disposal criteria.
- The district/school will have all individuals being tested, or his/her parent/guardian, sign an authorization for testing.
- Test sites must submit all required data elements to DHSS at within 24 hours of conducting tests.
- Test sites must retain documentation related to this testing program for at least two years.

Please read the following information carefully for additional information about participation in the Missouri BinaxNOW K-12 Testing Program.

**Information about Abbott's BinaxNOW Rapid Antigen Test Kits**

The [Abbott BinaxNOW rapid antigen test](#) is intended for qualitative detection of protein antigen from SARS CoV-2 in individuals suspected of COVID-19 within the first seven days of symptom onset. This U.S. Food and Drug Administration (FDA) authorized diagnostic test does not require any instrumentation to test the samples and instead determines a COVID-19 negative or positive result using a test card. To conduct the test, health professionals insert a swab into the anterior nasal cavity. **For technical usage questions about the BinaxNOW™ test, contact Abbott technical support directly at [ts.scr@abbott.com](mailto:ts.scr@abbott.com) or 1-800-257-9525.**

**Waiver to Perform Laboratory Testing**

The [Emergency Use Authorization](#) supports testing in point-of-care settings operating under a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation. Any site that performs laboratory testing must follow applicable regulatory requirements including federal, state, and local mandates for testing, as well as requirements for the safety and confidentiality of personal information. Use of this authorized test is limited to CLIA certified laboratories. DHSS has established a process whereby health professionals within districts/schools can administer the BinaxNOW test under a centralized CLIA Certificate of Waiver. Districts/schools will provide DHSS' BinaxNOW Lab

Director with information needed for complying with the CLIA waiver through the application process.

Districts/schools **must notify the Missouri BinaxNOW Lab Director with any changes made to the information provided** in the initial DESE application, including changes in staff or locations for administering the tests. **For questions about CLIA requirements and notifications of changes, email Russ Drury at [Russ.Drury@health.mo.gov](mailto:Russ.Drury@health.mo.gov).**

## **Public Readiness and Emergency Preparedness Act (PREP Act)**

The [Public Readiness and Emergency Preparedness Act \(PREP Act\)](#) added new legal authorities to the Public Health Service (PHS) Act to provide liability immunity related to the manufacture, testing, development, distribution, administration, and use of medical countermeasures against chemical, biological, radiological, and nuclear agents of terrorism, epidemics, and pandemics. It also added authority to establish a program to compensate eligible individuals who suffer injuries from administration or use of products covered by the PREP Act's immunity provisions.

On August 31, 2020, the U.S. Department of Health and Human Services, through the Assistant Secretary for Health, extended coverage under the PREP Act to licensed health-care practitioners prescribing or administering point-of-care COVID-19 tests, using anterior nares specimen collection or self-collection, for screening in congregate facilities across the Nation. Enhancing the safety of nursing homes, assisted-living facilities, long-term-care facilities, and other facilities where people congregate to receive care or education or to work is critical for our Nation's response to the COVID-19 pandemic. Using COVID-19 tests to screen for infections is a key part of that effort. PREP Act coverage encompasses licensed health-care practitioners prescribing or administering FDA-authorized COVID-19 tests.

More information about the PREP Act can be found at the following links:

<https://www.hhs.gov/sites/default/files/prep-act-coverage-for-screening-in-congregate-settings.pdf>

<https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx>

<https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf>

## **Test Inventory and Personal Protective Equipment (PPE)**

Missouri is receiving incremental shipments of the BinaxNOW test kits. Districts/schools that choose to participate in the testing program will receive incremental shipments of tests likely not to exceed the total number of personnel and students within the district/school.

Districts/schools may request a smaller number of tests through the application process if they so choose. You may also view the [K-12 Antigen Testing Program map/visualization](#) that shows participating districts/schools, how many tests each institution requested and the status of the statewide shipments.

The district/school must select a centralized location for receipt of the test kits. Test kits, packed 40 in a box, must be stored at 35.6° to 86°F and used by the expiration date listed on the packaging. Districts/schools must have the capacity to store the maximum number of tests requested. The district/school is responsible for distributing test kits to schools/buildings within the district/school; however only whole cases should be distributed to testing locations to ensure the control test remains with the box it is assigned. If additional test kits become available, DESE will send notification of a process to provide further inventory to districts/schools. For further questions about test allocation or to change your allocation, email [Communications@dese.mo.gov](mailto:Communications@dese.mo.gov).

The DHSS recognizes that school health professionals may lack adequate PPE needed for administering the BinaxNOW tests. The first shipment of test kits will include a small amount of PPE to meet immediate needs. If needed, schools/districts may [order additional PPE from the State of Missouri here](#).

### Training Requirements

It is very important that testing staff administer the test correctly in order to assure the highest confidence in the test results. The [BinaxNOW test training video](#), produced by the test manufacturer, provides a detailed step-by-step guide to the test process. All testing staff must watch the overview video and modules one through four before performing tests on individuals. Test kits will not be sent until confirmation of training completion is provided. All health professionals administering the BinaxNOW rapid antigen tests through this program must provide documentation of training to the BinaxNOW Lab Director, Russ Drury through this [link](#). **For questions about clinical training, districts/schools may email Marjorie Cole at [Marjorie.Cole@health.mo.gov](mailto:Marjorie.Cole@health.mo.gov) or Russ Drury at [Russ.Drury@health.mo.gov](mailto:Russ.Drury@health.mo.gov).**

### Use of BinaxNOW Tests

The Emergency Authorization for Use for the Abbott BinaxNOW antigen test is for testing of [symptomatic](#) individuals within seven days of symptom onset. DESE and DHSS encourages districts/schools to first use the tests for symptomatic school personnel, knowing workforce shortages are currently a key challenge in continuing to provide onsite education. School nurses, or their designees, administering minimally invasive nasal swabs for students and staff members fits within the scope of practice for school nurses, based on documented education, experience, skill, training, knowledge, and/or competency.



Due to CDC adding additional options for quarantine recommendations, Missouri is authorizing schools/districts participating in the BinaxNOW project to use the BinaxNOW test to test ASYMPTOMATIC close contacts on or after quarantine day 7, if the local jurisdiction is utilizing the new quarantine options. If the person's result is negative, they may end their quarantine period. Additionally, monitoring should continue throughout the full 14 days and if a symptom develops, the individual must immediately isolate and contact a public health authority or health

care provider. Please see the standing order in Appendix B for more information about asymptomatic testing.

### **Point-of-Care Requirements**

When students or personnel receiving a BinaxNOW test are suspected to have COVID-19, they should be isolated from others. Health professionals should administer this test in a space other than the school health office. The testing location should:

- Have facilities and/or products for proper hand hygiene (e.g. alcohol-based hand cleanser).
- Have appropriate waste disposal within arm's length from the patient.

### **Materials Needed**

Test administration requires the following resources:

- PPE for the health professional using contact and droplet precautions.  
Recommended PPE includes gown, surgical mask, protective eyewear and gloves, as well as hand hygiene products. [Additional PPE guidance can be reviewed here.](#)  
Districts/schools can request the PPE necessary to administer these tests safely from the state.
- BinaxNOW Ag test kit.
- Copy of consent (parental or staff).
- [Patient educational materials to provide information about the test and interpreting results.](#)
- Infectious waste bags for discarding used testing materials and PPE.

### **Consent for Testing**

Test administrators should obtain written consent for anyone they test. For those under age 18, a parent or guardian should provide written consent. A sample consent form is provided in Appendix C, but districts/schools should modify this form to meet the needs of their agency. Participating districts/schools should maintain record of signed consent forms for two years. For questions obtaining consent, the district/school should consult their legal counsel.

### **Evaluating the Results of Rapid Antigen Testing**

Health professionals administering the BinaxNOW tests should consult the [BinaxNOW COVID-19 Ag Care Procedure Card](#) for determining the test results. Rapid antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest. A positive test is diagnostic for COVID-19. People testing positive shall be instructed on [isolation requirements](#).

Individuals with negative test results, but who are showing possible COVID-19 symptoms, should be encouraged to follow-up with their health care provider. People showing symptoms of illness, but test negative for COVID-19 should be encouraged to stay home until their

symptoms have resolved, following the organization's policy for illness. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposure history and the presence of clinical signs and symptoms consistent with COVID-19.

For questions regarding possible control measures for persons who test negative but have recent exposures and symptoms of COVID-19, please contact your local public health agency. Districts/schools conducting COVID-19 testing may also wish to review [School Reporting of a Positive or Suspected COVID-19 Student or Employee](#) guidance previously shared with districts/schools. Contact your local public health agency for questions regarding case investigation, contact tracing, and other public health control measures following a positive result.

**For technical usage questions about the BinaxNOW™ test, contact Abbott directly at [ts.scr@abbott.com](mailto:ts.scr@abbott.com) or 1-800-257-9525.**

## **Disposal of Testing Materials**

All components of the BinaxNOW test kit, as well as gloves used by persons administering the test and any grossly contaminated PPE, should be discarded as infectious waste according to Missouri regulatory requirements. Other medical waste (i.e. trash, such as test packaging and PPE that is not grossly contaminated) coming from facilities testing for COVID-19 is no different than waste coming from facilities without COVID19 patients. CDC's guidance states that management of such medical waste should be performed in accordance with routine procedures. There is no evidence to suggest that such waste needs any additional disinfection. [Read further waste management information from the CDC here.](#)

Hiring a [Missouri Licensed Infectious Waste Transporter](#) is strongly recommended to assist with this process and ensure the infectious waste is packaged, transported, disposed of, and tracked appropriately. You should ensure the licensed infectious waste transporter provides containers/packaging to you so that the waste handling will comply with regulatory requirements. A [statewide contract for infectious waste pick-up and disposal](#) is available to all public schools through the [Cooperative Procurement Program](#). (Any facility is welcome to contact the company on statewide contract but the contract price is not guaranteed.) Infectious wastes should be kept secure in appropriate containers until pick-up occurs, which should be scheduled at an interval to minimize accumulation of multiple full containers. The DHSS estimates that a couple hundred used test kits and gloves may fit in a single standard 4.5 cubic foot box. Find more information about waste management options in the fact sheet [Infectious Waste Management, Transport and Disposal in Missouri here.](#)



Recommended waste disposal plan steps:

1. Contact and contract with a licensed infectious waste transporter for pick-up and disposal of infectious wastes. (A statewide contract is available.)
2. Get appropriate packaging materials from the contractor for each location that the tests will be administered.
3. Work with the contractor on an appropriate pick-up schedule based on the number of tests the site anticipates using, the size of containers provided, number of testing locations, and any other facility-specific factors.

**For questions about infectious waste disposal, please email Jonathan Garoutte at [Jonathan.Garoutte@health.mo.gov](mailto:Jonathan.Garoutte@health.mo.gov).**

### **Documentation and Reporting of BinaxNOW Test Results**

By administering BinaxNOW tests, a facility is acting as a laboratory. Laboratories are required to submit all COVID-19 test results (positive/negative/other) for tests performed in their facility to the State of Missouri. The facility is also acting as the provider. Providers are required to submit case reports to DHSS.

Facilities, including K-12 schools, which administer point-of-care tests may report the necessary information for **both** the laboratory report **and** the case report on a single comma separated values (CSV) file, which is a format-free version of a spreadsheet. Required data fields include facility information, patient demographics, lab results (both positive and negative) and basic information about symptoms. The CSV file is then uploaded to a Secure File Transfer Protocol (SFTP) site, and is auto-ingested into the state's disease monitoring platform, known as EpiTrax. This information is then immediately accessible to local and state health authorities.

To successfully submit test results through SFTP, testing sites will need:

- One person and at least one or two back-ups trained to submit data
- Reporting template from DHSS
- Access to a computer/laptop with Microsoft Excel or an alternative application that can work with Excel files
- Access to the Internet
- User name and password for the secure upload site

There are four onboarding steps to complete laboratory/case reporting. This is a high-touch process that involves several intricate steps.

**Step 1:** Once DESE approves the district's/school's application for participation in the BinaxNOW testing project, the district/school will need to identify a designated reporter and at least one back-up data submitter for the entire district; each individual school within the



district should not report results individually. The district/school must provide the contact information for their designated reporter to DHSS [here](#).

- The data submitter does not have to be the school nurse or medical professional administering the test – or the point-of-contact for your testing program. Ideally, the district will select someone that has more experience working with spreadsheets that will be comfortable submitting this data.
- The on-boarding team suggests having two or three individuals trained to submit this data for the district/school. The 24-hour reporting requirement means that someone needs to be ready to fill in if the primary data submitter is sick, out of the office, etc., while also maintaining confidentiality in accordance with [HIPPA](#), [ADA](#), [FERPA](#), and other applicable laws and regulations (see more K-12 testing information from the CDC [here](#)).

**Step 2:** Staff involved in **recording and reporting** test results need to watch the [COVID-19 Electronic Lab Reporting Video for K-12 and Higher Education](#). It is helpful to have the [DHSS formatted template](#) and the [Electronic COVID-19 Lab Reporting Submission Instructions](#) on hand when reviewing the training.

**Step 3:** Upon completion of Step 2, an onboarding team member will reach out to the data submitter to provide the MOFTP credentials (to be used to access the SFTP site) and:

- A CSV Excel file to facilitate seamless reporting into EpiTrax, DHSS' disease surveillance system
- Electronic COVID-19 Laboratory Reporting Submission Instructions to walk through the process for submitting files via SFTP

**Step 4:** At this point, the district/school may start testing and submitting the data within 24 hours of administering tests. DHSS will review the data. Properly formatted data ingests directly into EpiTrax, where DHSS and local public health agencies document and track case investigation activities. If there are problems with the data, the DHSS Onboarding Team will reach out to you and work through those for resubmission.

The information must be formatted exactly how the template shows; the slightest variation will cause an issue with how the CSV file is auto-ingested into EpiTrax. DHSS team members will review the data that is submitted and contact the district/school reporter to address any errors in the data entry. Uploading this CSV file to the SFTP site within 24 hours fulfills the requirement to submit your district's/school's results within that timeframe, but it is important to note that your district/schools is not fully compliant until you have helped to resolve any errors in the data, its formatting, etc. Data reporters for each district/school should keep note of those errors as DHSS team members address them and work to avoid similar errors moving forward.

DHSS has assembled a team to assist you in this ongoing effort. Ryan Marsch and the DHSS Onboarding Team ([ELR@health.mo.gov](mailto:ELR@health.mo.gov)) will be your primary contacts if you have questions about formatting your Excel files or how the process works. State School Nurse Consultant Marjorie Cole ([Marjorie.Cole@health.mo.gov](mailto:Marjorie.Cole@health.mo.gov)) and Barbara Spaw ([Barbara.Spaw@health.mo.gov](mailto:Barbara.Spaw@health.mo.gov)) from DHSS are also available to answer questions. Please note that there are over 1,000 facilities that may receive some type of point-of-care test, so there may be some delay in the onboarding process.

### **Antigen Testing Program Dashboard and Test Usage Data**



If you have not already done so, DESE and DHSS encourage each district/school to review the [K-12 Antigen Testing Program dashboard/visualization](#), which is linked within the Antigen Testing section of the [DESE COVID-19 webpage](#). This interactive tool allows anyone to review all participating sites, as well as how many tests the site requested and how many tests were shipped to date. Shipping information is updated daily.

The dashboard also provides the usage data for each participating district/school. This data is added weekly (typically Wed.-Fri.). DESE and DHSS encourage each district/school to regularly review their usage data and cross-reference it with the records/inventory you are tracking locally. If there is a large discrepancy between what the dashboard reflects and your records, please contact [ELR@health.mo.gov](mailto:ELR@health.mo.gov) to resolve this issue. Again, please note the usage data is added to the dashboard weekly, so that would likely be the cause of any minor differences between the dashboard and your records.

### **Test Inventory and Future Shipments**



DESE and DHSS will send additional test kits when the dashboard usage data reflects that the district/school has used at least 75% of the original test inventory received. Supply of inventory is being tightly controlled to minimize overstocking due to the short timeframe for use of the test kits. The expiration date for some test kits is as early as March. Once a district/school reaches 75% of inventory used, a DESE/DHSS representative will contact the antigen testing program point-of-contact to determine if additional tests are needed and how best to move forward.

If your district/school has not reached 75% usage by the end of January or early February, DESE and DHSS will begin considering how the state may recoup the test inventory in order to redistribute it to another entity (i.e. long-term care facilities, hospitals, etc.) to use prior to the date the test expires. The State must be good stewards of these valuable resources and ensure they are used. If DESE/DHSS needs to recoup tests from your district/school, a DESE/DHSS representative will contact you to make those arrangements. If that occurs, DESE and DHSS will do our best to replenish your inventory as quickly as possible so you have tests on hand throughout the school year, but, as always, cannot make any guarantees during this ever-evolving pandemic.

## Appendix A Quick Reference Resources

Topic	Name	Contact Information
Application, Test Allotment and Shipments	DESE Communications	<a href="mailto:Comunications@dese.mo.gov">Comunications@dese.mo.gov</a>
Electronic Reporting of Test Results	DHSS Electronic Reporting On-boarding Team	<a href="mailto:ELR@health.mo.gov">ELR@health.mo.gov</a>
Waiver to Perform Laboratory Testing (CLIA)	Russ Drury	<a href="mailto:Russ.Drury@health.mo.gov">Russ.Drury@health.mo.gov</a>
Infectious Waste Disposal	Jonathan Garoutte	<a href="mailto:Jonathan.Garoutte@health.mo.gov">Jonathan.Garoutte@health.mo.gov</a>
Positive Case Reporting	John Bos Craig Highfill	<a href="mailto:John.Bos@health.mo.gov">John.Bos@health.mo.gov</a> <a href="mailto:Craig.Highfill@health.mo.gov">Craig.Highfill@health.mo.gov</a>
Clinical Training	Marjorie Cole	<a href="mailto:Marjorie.Cole@health.mo.gov">Marjorie.Cole@health.mo.gov</a>

### Helpful Documents for the BinaxNOW COVID-19 Test Kit

Available materials include:

BinaxNOW COVID-19 Ag Healthcare Provider Fact Sheet (English)

BinaxNOW COVID-19 Ag Patient Fact Sheet (English and Spanish)

BinaxNOW COVID-19 Ag Procedure Card (English)

BinaxNOW COVID-19 Ag Card Package Insert (English)

[CDC's Interim Considerations for Testing for K-12 School Administrators and Public Health Officials](#)

## Appendix B Standing Orders

Standing Order for:

*BinaxNOW* Abbott Rapid Antigen Testing for COVID-19

### Purpose

To reduce transmission of the SARS-CoV-2 virus in the school community by using the BinaxNOW COVID-19 Ag Card to identify cases of COVID-19. Test to be administered to test symptomatic staff members and students from any public or private school that serves Grades Pre-K – 12, or any higher education institution in Missouri who meet at least one of the criteria listed below.

- Any new cough, difficulty breathing, loss of taste/smell, fever ( $\geq 100.4^{\circ}\text{F}$ ), congestion/runny nose, nausea/vomiting/diarrhea, sore throat, headache, myalgia.

### Policy

This standing order authorizes any Registered Professional Nurse or Licensed Practical Nurse who is licensed by the Missouri State Board of Nursing or has a privilege to practice in the State of Missouri from another compact state to test symptomatic staff members and students from any public or private school that serves Grades Pre-K – 12, or any higher education institution in Missouri with the BinaxNOW rapid antigen test. After receiving documented training, the designee of any aforementioned RN or LPN may also administer this test.

### Procedure

1. Evaluate students and staff with the above criteria for symptoms of COVID-19
2. Provide Abbott Fact Sheet For Patients
3. Offer opportunity for questions
4. Ensure permission has been obtained
5. Administer the test pursuant to the Product Insert and Procedure Card
6. Document
  - a. Date, time, location of test
  - b. Name, title, and professional license number of person administering the test
  - c. Name of test and manufacturer lot and number
  - d. Results of the test
  - e. Presenting symptoms
  - f. Verification of signed consent form
7. After completing the required initial onboarding process established by the Missouri Department of Health and Senior Services ("DHSS"), submit the required data and all test results via secure file transfer protocol in accordance with the procedure specified by DHSS within twenty-four hours of each test's administration
8. In the event of a positive test result, immediately notify the designated point of contact at the local health authority in order for contact tracing to begin and appropriate control measures to be established pursuant to the statewide Order issued by DHSS on August 7, 2020.

This order and procedure shall remain in effect until rescinded or until June 30, 2021.

MO DHSS Director, Randall Williams MD, FACOG



10/15/2020

Title

Print Name

Signature

Date

**Standing Order for:****Administer BinaxNOW Rapid Antigen Test****Purpose**

To enable communities the opportunity to implement additional quarantine options in an effort to increase compliance with quarantine recommendations through use of the BinaxNOW COVID-19 Ag Card to test ASYMPTOMATIC individuals on or after seven full days of quarantine to determine eligibility for release from quarantine.

The BinaxNOW rapid antigen card may be used to test asymptomatic staff members and students from any public or private school that serves grades Pre-K – 12, or any higher education institution in Missouri who is considered a close contact of an individual with SARS-CoV-2, and has remained in quarantine for seven full days without symptoms of SARS-CoV-2. Symptoms are a new cough, difficulty breathing, loss of taste or smell, fever ( $\geq 100.4^{\circ}\text{F}$ ), congestion/runny nose, nausea/vomiting/diarrhea, sore throat, headache, and myalgia.

**Policy**

This standing order authorizes any Registered Professional Nurse or Licensed Practical Nurse who is licensed by the Missouri State Board of Nursing or has a privilege to practice in the State of Missouri from another compact state to test asymptomatic staff members and students from any public or private school that serves grades Pre-K – 12, or any higher education institution in Missouri with the BinaxNOW rapid antigen test. After receiving documented training, the designee of any aforementioned RN or LPN may also administer this test.

**Procedure**

1. Evaluate students and staff with the above criteria for symptoms of COVID-19 in the past seven days
2. Calculate the number of days of quarantine to assure that testing is on or after seven full days of quarantine
3. Provide Abbott Fact Sheet For Patients
4. Offer opportunity for questions
5. Ensure permission has been obtained
6. Administer the test pursuant to the Product Insert and Procedure Card
7. Document
  - a. Date, time, location of test
  - b. Name, title, and professional license number of person administering the test
  - c. Name of test and manufacturer lot and number
  - d. Results of the test
  - e. Presenting symptoms
  - f. Verification of signed consent form

8. Submit the required data and all test results via secure file transfer protocol in accordance with the procedure specified by the Missouri Department of Health and Senior Services (DHSS) within twenty-four hours of each test's administration
9. In the event of a positive test result, immediately notify the designated point of contact at the local health authority in order for contact tracing to begin as soon as possible and appropriate control measures to be established pursuant to the statewide Order issued by DHSS on November 30, 2020.
10. In the event of a negative test result, symptom monitoring should continue throughout the full 14 days and if a symptom develops, the individual must immediately isolate and contact a public health authority or healthcare provider

This order and procedure shall remain in effect until rescinded or until June 30, 2021.



---

Randall W. Williams, MD, FACOG,  
Director Missouri Department of Health and Senior Services

December 16, 2020

---

Date

## Appendix C Sample Consent Forms

### BinaxNOW COVID-19 Antigen Testing for Symptomatic Patients

#### Voluntary Testing Consent & Acknowledgement Form for \_\_\_\_\_ School District

Enclosed with this form is a notice entitled "School Reporting of a Positive or Suspected COVID-19 Student or Employee." If that notice is not enclosed, it can be located at the following hyperlink: <https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/pdf/school-covid-reporting.pdf>

BinaxNOW is an antigen test that detects the presence of the SARS-CoV-2, which is the virus that causes a COVID-19 infection, in about fifteen (15) minutes. The specimen for the test is collected via nasal swab. This test is completely voluntary and will not ever be administered unless this form is signed. As stated in the above notice, a positive result of this test will be immediately reported to the Local Public Health Agency ("LPHA") so that it can begin contact tracing and instituting appropriate disease control measures. The LPHA solely manages these efforts. Additionally, all test results will be shared with the Department of Health and Senior Services pursuant to state regulation.

BinaxNOW is currently only able to be administered to individuals suffering from symptoms consistent with an infection of COVID-19. A negative test result, however, may indicate that those symptoms are actually the result of a common cold, allergies, or a different illness. If symptoms consistent with an infection of COVID-19 develop or persist after a negative test result, consult with a health care provider or the appropriate LPHA to determine the best course of action.

Except as required by law, test results and testing information will be kept confidential by the school district, LPHA, and Department of Health and Senior Services.

Completing and signing this form serves as consent for the test to be performed on the named individual and is also an acknowledgment of the above statements as well as the content of the enclosed notice entitled "School Reporting of a Positive or Suspected COVID-19 Student or Employee." Upon request, this completed and signed form should be provided to the appropriate school district personnel.

#### CONSENT & ACKNOWLEDGMENT

Print name of person to be tested: \_\_\_\_\_

Status of person to be tested (circle): student      employee      other \_\_\_\_\_ (explain)

Print parent / guardian name (if applicable): \_\_\_\_\_

Date: \_\_\_\_\_

Signature of person tested or parent / guardian: \_\_\_\_\_

#### DISTRICT USE:

Received by (name) \_\_\_\_\_ on (date) \_\_\_\_\_

Place of test administration: \_\_\_\_\_ on (date) \_\_\_\_\_



## BinaxNOW COVID-19 Antigen Testing for Shortened Quarantine Period Following Exposure to Covid-19

### Voluntary Testing Consent & Acknowledgement Form for \_\_\_\_\_ School District

Enclosed with this form is a notice entitled "School Reporting of a Positive or Suspected COVID-19

Student or Employee." If that notice is not enclosed, it can be located at

<https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/pdf/school-covid-reporting.pdf>

BinaxNOW is an antigen test that detects the presence of the SARS-CoV-2, which is the virus that causes a COVID-19 infection, in about fifteen (15) minutes. The specimen for the test is collected via nasal swab. This test is completely voluntary and will not ever be administered unless this form is signed. As stated in the above notice, a positive result of this test will be immediately reported to the Local Public Health Agency ("LPHA") so that it can begin contact tracing and instituting appropriate disease control measures. The LPHA solely manages these efforts. Additionally, all test results will be shared with the Department of Health and Senior Services pursuant to state regulation.

BinaxNOW tests can be administered to individuals in quarantine after an exposure to a positive individual for the purposes of "testing out of quarantine". The individual must have been in quarantine for seven full days without symptoms for the purposes of "testing out of quarantine" to be able to return to work or school.

A negative test result may indicate no infection; however, if symptoms consistent with an infection of COVID-19 develop after a negative test result, the individual must self-isolate immediately and consult with a health care provider, or the appropriate LPHA to determine the best course of action. Individuals testing out of quarantine after seven days should employ mitigation practices, including wearing a mask if social distancing is not possible until the 14<sup>th</sup> day of quarantine is completed.

Except as required by law, test results and testing information will be kept confidential by the school district, LPHA, and Department of Health and Senior Services.

**Completing and signing this form serves as consent for the test to be performed on the named individual and is also an acknowledgment of the above statements as well as the content of the enclosed notice entitled "School Reporting of a Positive or Suspected COVID-19 Student or Employee." Upon request, this completed and signed form should be provided to the appropriate school district personnel.**

### CONSENT & ACKNOWLEDGMENT

Print name of person to be tested: \_\_\_\_\_

DOB: \_\_\_\_\_ Gender: \_\_\_\_\_ Ethnicity: \_\_\_\_\_ Race: \_\_\_\_\_

Full Address:

\_\_\_\_\_  
\_\_\_\_\_ Phone number:

\_\_\_\_\_  
\_Date quarantine began\_\_\_\_\_

Symptom history: \_\_\_\_\_

Status of person to be tested (circle): student   employee   other \_\_\_\_\_ (explain) Print

parent / guardian name (if applicable): \_\_\_\_\_

Date: \_\_\_\_\_

Signature of person tested or parent / guardian: \_\_\_\_\_

**DISTRICT USE:**

Received by (name) \_\_\_\_\_ on (date) \_\_\_\_\_

Place of test administration: \_\_\_\_\_ on (date) \_\_\_\_\_

**Results of test**-----