Montana Department of Public Health and Human Services

BinaxNOW Antigen Testing Program for Educational Institutions

Background

The federal government has prioritized K-12 schools, colleges and universities to receive Abbott's BinaxNOW rapid antigen test kits to test symptomatic school personnel and students for COVID-19. The Abbott BinaxNOW test is a minimally invasive anterior nasal swab test. The test should be administered by, or under the direction of, trained medical staff, and yields results in just 15 minutes without any additional equipment.

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). In settings where resources allow, 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.

Valuable guidance on testing in schools can be found at CDC's Interim Considerations for Testing for K-12 School Administrators and Public Health Officials and 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 2 and Privacy Act (FERPA) and its applicability to students and COVID-19 contact tracing and testing.

When this test might be performed

Schools can play an important role in assisting public health officials in identifying teachers, staff, or students who have COVID-19 symptoms or who had recent close contact (within 6 feet for a total of 15 minutes or more) with someone with COVID-19. If the school is experiencing an outbreak, the school should immediately notify public health officials and collaborate to facilitate increased testing and contact tracing, as necessary. School administrators working in close collaboration with public health officials might choose to test students, teachers, or staff for purposes of surveillance, diagnosis, screening, or in the context of an outbreak and public health consultation.

School-based testing may be considered, when resources allow, for:

- People in a school setting who show signs or symptoms consistent with COVID-19 while at school.
- Schools in a community where public health officials are recommending expanded testing on a voluntary basis including testing of a sample of asymptomatic individuals, especially in areas of moderate to high community transmission.

Learn more about what to do when a student becomes sick at school:
https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/student-becomes-sick-diagnosis-flowchart.html

Test Site Obligations

To participate in the BinaxNOW testing program, facilities must agree to meet the following conditions:

Prior to Using BinaxNOW Tests:

- The facility has medical personnel available to oversee staff responsible for conducting 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 facility is able to receive the tests in one central location and store tests received.
- The facility will complete the electronic reporting on-boarding process described elsewhere in the packet.
- The facility will agree to use the tests only for testing **symptomatic individuals** (students or school personnel). Deviations from this protocol may be made based on consultation with DPHHS.
- The facility 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 facility will ensure DPHHS has up-to-date information on test administrators and testing locations.
- The facility will abide by the infectious waste disposal criteria.
- The facility will get permission from parents/guardians of individuals being tested
- Test sites must submit all required data elements to DPHHS at least every 24 hours.
- Test sites must retain documentation related to this testing program for at least two years.

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, trained staff inserts a swab into the anterior nasal cavity of patient or instructs and oversees self-collection by patient.

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. Facilities are encouraged to work with their local clinics or laboratories. In the event that an agreement cannot be reached, DPHHS has established a process whereby health professionals within facilities can administer the BinaxNOW test under a centralized CLIA Certificate of Waiver. Facilities will provide DPHHS with information needed for complying with the CLIA waiver through the application process.

Facilities operating under the DPHHS CLIA-waiver must notify DPHHS with any changes made to the information provided in the initial application, including changes in staff administering the tests and/or changes in locations administering the BinaxNOW tests.

Test Inventory and Personal Protective Equipment (PPE)

Montana is receiving incremental shipments of the BinaxNOW test kits. Initial distribution is allocated based on enrollment. Facilities may request a smaller number of tests through the application process if they so choose. Facilities that choose to participate in the testing program will receive additional tests upon request.

The facilities 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. Facilities must have the capacity to store the maximum number of tests requested. If distributed, the facility is responsible for distributing test kits to schools/buildings within the facility; 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, DPHHS will send notification of a process to provide further inventory to facilities.

Depending on testing method used (see materials needed), DPHHS 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, along with information for ordering additional PPE to administer the tests safely.

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 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.

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. DPHHS encourages facilities 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.

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 include gown, surgical mask, protective eyewear and gloves, as well as hand hygiene products. Additional PPE guidance can be reviewed here.
    - For healthcare providers who are observing patient self-collection of nasal (anterior nares) samples, so are therefore handling specimens, but are not directly involved in collection and not working within 6 feet of the patient:
        - Follow Standard Precautions
        - Gloves are recommended. Note that healthcare personnel are recommended to wear a form of source control (facemask or cloth face covering) at all times while in the healthcare facility.
        - PPE use can be minimized through patient self-collection while the healthcare provider maintains at least 6 feet of separation.
- Districts/schools can request the PPE necessary to administer these tests safely from the state.
- BinaxNOW Ag test kit.

- Timer.
- 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 consent for anyone they test. For those under age 18, a parent or guardian should provide consent for the minor. For questions obtaining consent, the district/school should consult their legal counsel.

Evaluating the Results of Rapid Antigen Testing

Staff 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. A **positive test** is diagnostic for COVID-19. People testing positive shall be instructed on isolation requirements.
B. 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 exposures, 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.

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 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 COVID-19 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.

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 Montana. The facility is also acting as the provider. Providers are required to immediately report all positive test results to the local public health department.

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. Required data fields include facility information, patient demographics, lab results (both positive and negative) and basic information about symptoms.

How to proceed:

1. **Register** your facility at the link below:
   https://PHEP.formstack.com/forms/binaxnow_montana_registration
   Note: If you are unable to partner with a local clinic or laboratory, please select that you do not have a CLIA-waiver and complete additional onboarding steps as outlined in the form.

2. Once registered, you can **order supplies** here:
   https://phep.formstack.com/forms/testing_supplies_request
   Note: test kits will not we shipped until onboarding has been completed and quantities are allocated on school enrollment and availability

3. All tests conducted must be **reported** at this secure site:
   https://montanagovernment-aijle.formstack.com/forms/covid19_lab_test_result_survey
   Remember, any positive test results must be reported to your local health department immediately.

For any additional question, please contact the Communicable Disease Epidemiology Section at

406-444-0273