Montana Department of Public Health and Human Services

COVID-19 Testing Program for Educational Institutions

Background

The CDC offers considerations for ways in which K-12 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.

The Abbott BinaxNOW test is a minimally invasive anterior nasal swab test. The test should be administered by, or under the direction of, trained staff, and yields results in just 15 minutes without any additional equipment. Guidance on comprehensive prevention programs, including testing strategies and recommendations in schools can be found at CDC's Guidance for COVID-19 Prevention in K-12 Schools. A toolkit is available from CDC, including sample letters to parents, social media graphics and other FAQs.

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 with someone with COVID-19. For current contact definition consult with your local health department and review CDC guidance here. 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 (i.e., screening testing).
- Per CDC recommendation testing close contacts 3-5 days after last exposure
- In accordance with local public health policies, testing can be used to release contact from quarantine

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 designated personnel available to oversee staff responsible for conducting and reporting the tests.
- ☐ The facility will register under the DPHHS CLIA-waiver or a local clinic's CLIA-waiver and follow all associated requirements. 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 appropriately.
- ☐ The facility has a designated testing location and discards testing materials appropriately.
- ☐ 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 students, school personnel or other individuals that would have a direct impact on school operations if found infected. Deviations from this protocol may be made based on consultation with DPHHS.
- ☐ The facility has a process in-place for obtaining consent, confidential notification procedure following the test, contact tracing protocol and reporting tests to appropriate public health authorities.

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 get permission from parents/guardians of individuals being tested.
- Test sites must report 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.

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. During the registration process a valid email is required to ensure receipt of important updates to the 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, trained staff inserts a swab into the anterior nasal cavity of patient or instructs and oversees self-collection by patient.

Per Centers for Medicare & Medicaid Services (CMS), it requires facilities **where people congregate to receive education or work** with a CLIA Certificate of Waiver to follow the manufacturer's instructions (Instructions For Use) when performing laboratory testing. The FDA has granted Emergency Use Authorizations (EUA) to certain antigen tests for testing specimens from individuals who are suspected of COVID-19 by their healthcare provider **within a number of days after the onset of symptoms**, specific to each authorized test's validated performance.

CMS will **temporarily exercise enforcement** **discretion for the duration of the COVID-19 public health emergency under CLIA for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals**. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals.

Test Inventory and Personal Protective Equipment (PPE)

Facilities must order testing supplies as needed via provided electronic ordering system. 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 outside 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.

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. Each new operator must perform a test procedure using a positive and/or negative control prior to administering a test to a patient. All 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. Testing of asymptomatic persons is allowed per CMS exemptions noted above. Results must be read no earlier than 15 minutes and no later than 30 minutes after activation. It is used with self-collected direct anterior nasal (nares) swabs from individuals aged 15 years or older, or an adult collected sample from individuals aged two years or older. This test may be used to test individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. Serial testing is recommended when testing asymptomatic persons.

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 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 a limited supply of PPE necessary to administer these tests safely from the state or purchase their own.
- BinaxNOW Ag test kit.
- Timer.
- Copy of consent (parental or staff).
- Patient educational materials to provide information about the test and interpreting results.
- 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. Sample consent forms are available from the department.

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.

Evaluating the results of an antigen test for SARS-CoV-2 depends primarily on the clinical and epidemiological context of the person who has been tested (e.g., symptoms, exposure to others with COVID-19, vaccination status, previous infection status, or setting in which they live).

Review CDC's Interim Guidance for Antigen Testing for SARS-CoV-2 and consult with your local health department when to perform confirmatory testing.

Disposal of Testing Materials

All components of the BinaxNOW test kit, as well as gloves used by persons administering the test and any PPE, should be discarded according to regulatory requirements. For limited number of tests conducted in school settings, the kit components can be disposed in regular trash. However, contents need to be bagged to maintain confidentiality and minimize potential unauthorized access to test materials. Other 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 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

Federal requirements (Public Law 116-136, §18115(a)) require all COVID-19 diagnostic test results, including antibody, antigen, and PCR, to be reported daily. Per the Administrative Rules of Montana (ARM 37.114.201), any person (…) who knows or has reason to believe that a case exists of a reportable disease or condition defined in ARM 37.114.203 must immediately report to the local health officer.

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.

Please report all positive COVID-19 test results immediately to your county public health department *in addition* to reporting all test results (positive or negative) to DPHHS to comply with reporting requirements.

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 test ordered and lab results (both positive and negative) and basic information about symptoms.

Facilities must report all tests conducted to the electronic reporting system "SimpleReport" (https://simplereport.gov/) which is a federally protected CDC online platform. SimpleReport is user friendly and there are many resources available to get started. Participants should review the K-12 School Specific Guide as well as the general SimpleReport User Guide. The following links provide numerous training modules for SimpleReport.

Please note, as a federal system, a verification step for identification is required: The U.S. Citizenship and Immigration Services (USCIS) provides a list of allowable documents to meet verification. User identity is only required for the main responsible party at the facility and must only be completed once. Please allow one week of time to process identify verification.

Important links:

1. **Training** video must be completed by each operator before performing BinaxNOW tests for patients: **https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html**

2. **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.

3. Once registered, you can **order supplies** here:
   https://phep.formstack.com/forms/testing_supplies_request

4. All tests conducted must be **reported** at this secure site:
   https://simplereport.gov/ (pre-registration and identity verification required)
   Remember, any positive test results must be reported to your local health department immediately.
   Find your local health department contact information here:
   https://dphhs.mt.gov/publichealth/FCSS/countytribalhealthdepts

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

406-444-0273