

## Steps to implement rapid antigen BinaxNOW testing in Montana K-12 schools:

1. Prior to implementing a screening/testing program consult with your local health department, who can assist you with developing a plan on what to do when you have a positive case.
2. You can **order COVID-19 testing supplies here:**  
[https://phep.formstack.com/forms/testing\\_supplies\\_request](https://phep.formstack.com/forms/testing_supplies_request)
3. Please watch the training module first. A training module on the BinaxNOW test is available (10 min). Every operator should watch this before conducting a test:  
<https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html> (watch modules 1-4)
4. Currently, under the Emergency Use Authorization, the BinaxNOW (rapid antigen) COVID-19 test can be operated under a [CLIA-waiver](#), which is a laboratory requirement. Under Clinical Laboratory Improvement Act (CLIA), a laboratory is defined as a facility that performs applicable testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings. To make sure this test is conducted properly, staff is trained, and tests are reported to meet the federal, state and CLIA requirements, we need to verify that we ship to locations that either have their own CLIA-waiver or have them register under ours, assuring us those requirements will be met. If you currently have CLIA waiver through a clinical partner that waiver can be used for this testing. If you do not currently have a CLIA waiver, contact DPHHS.
5. Next, register your facility at the link below:  
**[https://PHEP.formstack.com/forms/binaxnow\\_montana\\_registration](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. Schools have generally onboarded under the DPHHS waiver.*
6. Facilities must **report** all tests conducted to an electronic reporting system determined by the department. Additional information about the reporting system will be made available to participants. *Positive test results must be reported to your local health department immediately.*

*Here are the reporting references:*

*Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires “every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19” to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS)*

**[37.114.201 \[nam10.safelinks.protection.outlook.com\]](#) REPORTERS**

*(1) With the exceptions noted in (3), (4), and (5), any person, including a physician, dentist, nurse, medical examiner, other health care practitioner, administrator of a health care facility or laboratory, public or private school administrator, or laboratory professional who knows or has reason to believe that a case exists of a reportable disease or condition defined in ARM [37.114.203 \[nam10.safelinks.protection.outlook.com\]](#) must immediately report to the local health officer the information specified in ARM [37.114.205 \[nam10.safelinks.protection.outlook.com\]](#)(1) and (2).*