

NM Department of Health
ELC-Reopening of Schools Abbott BinaxNOW COVID-19 Ag Testing Program
Statement of Assurances

To reduce transmission of COVID-19 and to support in-person instruction, the New Mexico Department of Health (NM DOH) is making the point of care Abbott BinaxNOW COVID-19 Ag testing available to districts and schools at no cost through the end of the 2021-2022 school year. This will include extended and summer school. Schools and districts must submit an application at the link provided by NM DOH to receive services.

Point of care test are diagnostic tests performed at the place where a specimen is collected, and they provide results within minutes rather than hours. If a school conducts a point of care test, a CLIA Certificate of Waiver is required for every site the CLIA waived test is being conducted. Rapid point-of-care tests provide results within minutes (depending on the test) and are used to detect SARS-CoV-2 infections. For more information about point of care test: [Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing | CDC](#).

The Abbott BinaxNOW COVID-19 Ag test is a point of care **rapid antigen test**. Antigen tests are commonly used in the diagnosis of respiratory viruses. The U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for antigen tests that can identify SARS-CoV-2.

Antigen tests are relatively inexpensive, and most tests return results in approximately 15–30 minutes. Antigen tests for SARS-CoV-2 are generally less sensitive than polymerase chain reaction (PCR) for detecting the presence of viral nucleic acid.

The clinical performance of a rapid antigen test is best if the person is tested when their viral load is generally highest and used best in symptomatic people and within a certain number of days since symptom onset, antigen tests are used frequently on people who are symptomatic. Antigen tests also may be informative in screening and surveillance to assist in a rapid response. Results of rapid antigen yield the schools ability to assist in rapid response and immediate isolation.

No COVID-19 test is perfect and the rapid antigen test may produce false Notwithstanding the results of any rapid antigen test, participating schools and districts are to encourage members of the school population to consult their individual health care providers if they have signs or symptoms of COVID-19 or otherwise believe they have been exposed to COVID-19. In the event of a negative test result in a student or staff member that is symptomatic, a PCR based test will be required to confirm or rule out the result of the rapid antigen test.

The participating school or district will coordinate training and ordering from the Abbott Corporation or by the NM DOH once application is received

To support the effective administration of this program as well as the safe and effective administration of the rapid antigen BinaxNOW COVID -19 Ag test program , the NM DOH seek assurances from [Applicant district/school] before authorizing access to the Abbott Corporation’s training and ordering services.

For access to the Abbott BinaxNOW COVID-19 Ag program, [Applicant district/school] (“Applicant”) must agree to the following:

Consent and Privacy

Applicant will follow Abbott’s BinaxNOW COVID-19 Ag testing program guidance and procedure and will use only Abbott’s BinaxNOW COVID-19 Ag consent form. The school will be responsible for the distribution of the consent and collection of the consent form(s) prior to test administration from students’ parents/guardians, teachers, staff, and any other person participating in the Abbott’s BinaxNOW COVID-19 Ag testing program.

Applicant will protect the privacy of individuals participating in the Abbott’s BinaxNOW COVID-19 Ag program, maintain and archive records per New Mexico Statute.

Testing Protocols

Staff and students with consent may use the Abbott’s BinaxNOW COVID-19 Ag to participate in the testing of symptomatic students/staff, student/staff screening and staff surveillance. The testing may be conducted for screening and surveillance purposes once per week regardless of vaccination status. It is **recommended** that 25 percent of student population be screened every week with the pooled method of COVID-19 screening. Applicant must follow all requirements for surveillance testing per the NM Public Health Order or NM PED toolkit. Results from the Abbott’s BinaxNOW COVID-19 Ag screening can be used to meet requirements for NM educational staff surveillance.

Applicant will have plans and written protocols in place for contact tracing, home quarantine, and reporting for all positive test result from the pooled testing screening an at a minimum follow the NM PED Toolkit. For staff or students requesting diagnostic (symptomatic) COVID -19 testing due to COVID-19 like symptoms or COVID -19 exposure, the Abbott’s BinaxNOW COVID-19 Ag may be used; however, other options perhaps would be better suited for this situation.

Isolation, Quarantine, and Contact Tracing

If a positive test result from the Abbott’s BinaxNOW COVID-19 Ag test, the Applicant must have in a school isolation space, appropriate protocols to ensure individuals stay home from school until it is safe to return, follow NM DOH isolation and quarantine protocols, and conduct additional contact tracing if necessary, and to report to NM DOH positive individual diagnostic

test results within 24 hours using Simple Reports.

Training, Compliance, Product Ordering and Shipping

Applicant will communicate with teachers, staff, students, and families about this program on an ongoing basis and coordinate training to be provided by the Abbott's BinaxNOW COVID-19 Ag test. Applicant will work with the NM DOH and be assigned to the Abbott Corporation for training or given Abbott links by the NM DOH. To order test, the Applicant will order directly from Abbott Corporation using order forms found on the NM DOH ELC-Reopening of Schools web page. Once the Abbott Corporation receives order form, Abbott will drop ship to the school or school districts address listed on the order form.

Platform Terms & Conditions

Applicant acknowledges the requirement, for itself and its authorized users, to comply with the following Terms & Conditions of engagement for the Abbott's BinaxNOW COVID-19 Ag test:

- I. Confidentiality.** Applicant will hold any data or information, including personally identifiable information, in strict confidence and will protect the same with at least the same degree of care with which School protects its own similar confidential information, which protections shall follow applicable laws, rules and regulations, including, without limitation, those related to privacy and personal information.
- II. Representation/Warranty.** Applicant represents, warrants, and covenants that it has and will have the legal authority and all rights and consents necessary to provide the data and information it provides under these Terms & Conditions for the purposes described therein, including, without limitation, any consents as required under this Statement of Assurances.
- III. Reporting:** *Schools and school districts are required to report all results within 24 hours to the NM DOH using Simple Reports, and to follow requirements for reporting authorized by the NM PED.*

Superintendents, charter school leaders, and executive directors: please complete the information and sign below to affirm that you make the above-listed assurances.

Name of District or School

Superintendent/Executive Director Name

Phone Number

Date

Signature

If you are submitting as a district or an organization with multiple schools, please list all individual schools on behalf of which you are submitting this Statement of Assurances:

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