



**Department
of Health**

Overview of COVID-19 Testing

**Office of School COVID Support
New York State Department of Health**

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Agenda

During today's presentation we will review the following:

- Types of COVID-19 testing
- Performing COVID-19 tests on-site at schools
- Abbott BinaxNow test distribution
- Performing COVID-19 tests off-site
- At home test kits

COVID-19 Testing

Screening Testing

Screening Testing: refers to the testing of asymptomatic individuals even if there is no reason to suspect infection (i.e., no known exposure/no symptoms). Results of screening tests are reported to the people whose specimens have been tested and to their healthcare providers.

Teachers and staff: Unvaccinated teachers and staff working in P-12 schools are required to undergo COVID-19 screening testing once a week when a school is operating in a geographic area identified by the Centers for Disease Control and Prevention (CDC) as having low, moderate, substantial or high transmission rates.

Students: P-12 schools are required to offer COVID-19 screening testing to unvaccinated students on a weekly basis in geographic areas identified by the CDC as having moderate, substantial, or high transmission rates.

Schools have flexibility in how they operationalize screening testing.

- Schools can perform on-site COVID-19 screening testing at schools.
- Schools can have COVID-19 screening testing performed off-site by a laboratory, Local Health Department, pharmacy or other local health care provider partner.

COVID-19 Testing

Diagnostic Testing

Diagnostic Testing: refers to the testing of symptomatic individuals or asymptomatic individuals exposed to a person with COVID-19. Results of diagnostic tests are reported to the people whose specimens have been tested and to their healthcare providers.

Schools must have the capacity to provide COVID-19 diagnostic testing, for any students, teachers or staff, who are symptomatic or have been exposed to someone with COVID-19 within the last 14 days regardless of a person's vaccination status and community level of transmission.

Schools can perform COVID-19 diagnostic testing on-site or established a process to refer a person for COVID-19 diagnostic testing.

COVID-19 Testing

Performing COVID-19 screening or diagnostic testing on-site testing at schools

If your school will be performing COVID-19 screening or diagnostic testing on-site, you are considered a laboratory and you will need to meet NYSDOH requirements for performing laboratory testing.

The type of COVID-19 testing that will be performed on-site at schools is referred to as waived testing. What is a waived COVID-19 test?

Clinical laboratory tests are assigned a level of complexity. There are three categories:

- High complexity tests
- Moderate complexity tests
- Waived tests

Waived tests are those tests that have been determined by the U.S. Food and Drug Administration (FDA) to be simple tests with insignificant risk of an erroneous result.

If a laboratory is only performing waived testing, it is not subject to more stringent regulatory requirements that laboratories performing high and moderate complexity testing must meet. Therefore, they are “waived” from the more stringent level of oversight. In general, the more complicated the test, the more stringent the requirements are for performing the tests.

COVID-19 Testing

Performing COVID-19 screening or diagnostic testing on-site testing at schools

If your school will be performing waived COVID-19 screening and/or diagnostic testing on-site, you need to be registered by the NYSDOH as a limited service laboratory (LSL).

You can become registered to perform waived COVID-19 antigen testing, waived COVID-19 molecular testing, or both. Additional information on becoming registered as an LSL can be found on the [NYSDOH Wadsworth Center web site](#).

There are numerous waived COVID-19 tests that have been authorized by the FDA :

- COVID-19 antigen tests: these tests detect the presence of a specific viral antigen. Antigens are the proteins that make up the virus.
- COVID-19 Nucleic Acid Amplification Tests (NAAT): these are also referred to as molecular tests; these tests detect one or more viral ribonucleic acid (RNA) genes. An example of a NAAT is polymerase chain reaction (PCR).

A list of FDA authorized waived COVID-19 antigen tests can be found on the [FDA's web site](#). A list of FDA authorized waived COVID-19 NAAT tests can be found on the [FDA's web site](#). To find the authorized waived tests, click on the arrow to the right of the column called “authorized setting” and look for tests that have a “W” indicating that is a waived COVID-19 test.

COVID-19 Testing

Performing COVID-19 screening or diagnostic testing on-site testing at schools

Who is allowed to perform waived COVID-19 testing?

- The testing process includes the collection of the sample and then performing the test as described in the manufacturer's instruction for use.
- Note that certain [eligible NYS licensed and registered professionals](#) have been temporarily authorized under the PREP Act to collect a sample for COVID-19 testing.
- If the testing is being performed under an LSL registration, a person who is not licensed can perform the test, read the result of a waived rapid COVID-19 test if they have been trained and competency assessed.

Are there laboratory reporting requirements for an LSL?

- Yes. An LSL is required to report COVID-19 test results within 24 hours to the NYS Electronic Laboratory Reporting System (ECLRS). Be aware that the reporting of tests results by an LSL to ECLRS is not the same as the daily school reporting requirement described in 10 NYCRR 2.9.

Can a local health departments (LHDs) allow a school to perform waived testing under their LSL?

- Yes.

COVID-19 Testing

Abbott BinaxNow Test Distribution

NYS has been providing Abbott BinaxNow COVID-19 antigen (Binax) tests to schools and LHDs throughout the state to support testing in schools.

We are in the process of transitioning to using ELC funds to purchase Binax tests. Binax tests purchased using ELC funds will now be distributed to schools/districts operating outside of NYC. We are currently working with LHDs and BOCES to determine which schools will need Binax tests and how tests will be distributed.

Schools in NYC should contact the New York City Department of Health and Mental Hygiene for information about test kits.

COVID-19 Testing

Performing COVID-19 screening or diagnostic testing off-site

- Schools can have testing performed off-site by a laboratory, LHD, pharmacy or other local health care provider partner.
- In this scenario, people are sent to a partner for testing, or schools can arrange for a partner to conduct sample collection on-site.
- Schools may be eligible for free testing through Operation Expanded Testing, a program established by the United States Department of Health and Human Services to expand testing availability. Additional information can be found at affinitytesting.com/hhs/.

COVID-19 Testing

Performing COVID-19 screening or diagnostic testing off-site

- Schools using a laboratory to perform screening or diagnostic testing off-site need to ensure that the laboratory holds the appropriate NYS approvals to perform testing.
- Laboratories that perform high complexity NAAT are required to hold a clinical laboratory permit; to determine if a laboratory has a clinical laboratory permit, a search can be performed [here](#).
- Laboratories that only perform waived, point of care testing are required to be registered as an LSL; to determine if a laboratory has an LSL, a search can be performed [here](#).
- Some laboratories that held temporary approval to perform COVID-19 testing will be allowed to continue testing; to determine if a temporarily approved laboratory can perform COVID-19 testing, contact Covid19rapidtest@health.ny.gov.
- If you cannot determine if the laboratory is approved, contact Covid19rapidtest@health.ny.gov.

COVID-19 Testing

Performing COVID-19 screening or diagnostic testing off-site

Some laboratories offer pooled testing as an option for testing.

Pooled Testing: specimens collected from individuals are combined to create one sample that is tested using a nucleic acid amplification tests (NAAT), such as PCR. If a pooled sample is positive, each specimen in the pool is retested individually to determine which individual(s) are positive.

COVID-19 Testing

Performing COVID-19 screening or diagnostic testing off-site

Screening testing on pooled samples vs Surveillance testing on pooled samples

Screening Testing: refers to the testing of asymptomatic individuals even if there is no reason to suspect infection (i.e., no known exposure/no symptoms). Results of screening tests are reported to the people whose specimens have been tested and to their healthcare providers.

Surveillance Testing: refers to testing that is intended to monitor community- or population-level outbreaks of disease, or to characterize the incidence and prevalence of disease. The test results are not reported to the people whose specimens have been tested or their healthcare providers. Because results are not being reported, laboratories performing surveillance testing on pooled samples are not considered to be a clinical laboratory and, therefore, are not required to be approved by NYS and are not required to have their test authorized by the FDA or NYS.

Although the CDC has indicated that ELC funds can be used to fund surveillance testing on pooled samples, surveillance testing on pooled samples does not meet the requirement that schools maintain capacity to conduct screening testing.

COVID-19 Testing

At home tests

In general, there are two categories of at home tests that have been authorized by the FDA.

At home collection kit

- A sample (e.g., nasal swab or saliva) is self collected by an individual at home.
- The sample is sent to a laboratory for testing using a NAAT.

At home test kit

- A sample is self collected by an individual.
- A test kit is used to perform the testing at home.
- The FDA has authorized both at home antigen test kits and at home molecular (NAAT) test kits.

COVID-19 Testing

At home test kits

The FDA has currently authorized 3 molecular at home tests kits and 10 antigen at home test kits.

The authorizations granted by the FDA vary between the tests. For example:

- Some require a prescription, and some are available over the counter (OTC) which does not require a prescription.
- Some can be used only on symptomatic individuals, and some can be used on both symptomatic and asymptomatic individuals.
- Some are performed under the supervision of a telehealth proctor, and others are not.
- The age of the person that can self collect a sample vary between tests.
- Some have a mechanism to report the test result public health authorities and others rely on the individual to inform their healthcare provider who would report results to public health authorities.

COVID-19 Testing

At home test kits

Because at home test kits are authorized by the FDA, there is no regulatory prohibition for using at home test kits to meet the requirements for screening or diagnostic testing in schools.

However, schools, LHDs and BOCES would need to ensure that the at home test kit being used:

- meets the requirements for either screening or diagnostic testing
- be confident that the test was performed as described in the instructions for use
- be confident that the test results are accurate and reliable
- ensure that there is a mechanism to meet NYSDOH reporting requirements

Questions?

SchoolQuestionsCOVID@health.ny.gov