



JB Pritzker, Governor

Amaal V.E. Tokars, Acting Director

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Interim Guidance on Testing for COVID-19 in Community Settings and Schools

Updates (shown in red)

- Update to Test to Stay protocols to allow home testing and unobserved testing.
- Align with updated CDC guidance

Purpose

This guidance addresses COVID-19 testing options using U.S. Food and Drug Administration (FDA)-approved testing for schools and other community settings, and is consistent with the Centers for Disease Control and Prevention ([CDC guidance on testing strategies for COVID-19 prevention in K-12 schools](#)).

School testing gives communities, schools, and families added assurance that schools can stay open safely for all students. By identifying infections early, testing helps keep COVID-19 transmission low and students in school for in-person learning, sports, and extracurricular activities. Screening testing is likely to be most feasible in larger settings and for older children and adolescents. Testing is performed for five primary reasons:

1. Testing of persons with symptoms of COVID-19, regardless of vaccination status.
2. Testing of persons who are determined to be close contacts to someone with active COVID-19 infection.
3. Testing of staff and students/participants with possible exposure in the context of outbreak settings.
4. Screening of staff and/or students/participants, **especially at medium and high COVID-19 Community Levels**, as a strategy to identify asymptomatic positives.
5. Weekly screening of staff not fully vaccinated is required under [Executive Order 2021-22, Section 3](#).

Testing used for screening purposes to identify new, asymptomatic positives can be an effective mitigation strategy, especially in areas with **medium to high community levels**. **Many people with COVID-19, especially children and teens, are asymptomatic but can still spread the virus.** Regular testing helps find people who have the virus before it can spread to others or cause outbreak. Regular testing also means parents or guardians are notified if their child tests positive, allowing them to plan for treatment and take steps to protect the rest of the family from COVID-19. Testing is important for those that have symptoms of COVID-19 or who have

been exposed to someone with COVID-19, regardless of vaccination status. Individuals with COVID-19 symptoms should immediately self-isolate and test. If they test positive, they should isolate at home. In addition, during outbreak situations, persons with suspect exposures, regardless of vaccination status, should be tested according to the Local Health Department's recommended outbreak testing cadence. Also, those working in health care settings should be tested according to infection control guidance from the CDC.

In general, PCR testing for people who are asymptomatic and have recovered from a SARS-CoV-2 infection is not recommended if they are within 90 days from symptom onset or previous positive test, but testing should resume once the 90 days has passed. For those developing COVID-19-like symptoms within 90 days of past infection, antigen testing is recommended to rule out COVID-19 due to the residual risk with PCR testing or referred to their primary care provider to rule out other etiologies. If the ill student/staff tests negative or another etiology is diagnosed, the case can return to school when symptoms are improving and fever free for 24 hours without use of fever reducing medications.

BACKGROUND

It's important to first understand the difference between diagnostic testing and screening, as defined by the CDC.

Diagnostic tests for SARS-CoV-2, the virus that causes COVID-19, are intended to identify current infections at the individual level and are performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2. Current CDC recommendations are to test five days after exposure.

Outbreak testing is strongly recommended for staff and students in schools in outbreak status. As established by the Council of State and Territorial Epidemiologists (CSTE), a school-associated outbreak is defined as multiple cases comprising at least 10% of students, teachers, or staff, within a specified core group OR at least three cases within a specified core group meeting criteria for a probable or confirmed school-associated COVID-19 case with symptom onset or positive test result within 14 days of each other; who were not identified as close contacts of each other in another setting (i.e., household) outside of the school setting; AND epidemiologically linked in the school setting or a school-sanctioned extracurricular activity.¹ According to CSTE, a "core group" includes, but is not limited to, an extracurricular activity, cohort group, classroom, sports team, performing arts group, before/after school care, etc. IDPH recommends schools acquire parental consent for student testing in advance to accommodate outbreak testing should the need arise. Schools must conduct twice weekly testing of school personnel who are not fully vaccinated and linked to an outbreak. Additionally,

¹ Council of State and Territorial Epidemiologists. (2021, August 6). *Standardized COVID-19 K-12 school surveillance guidance for classification of clusters and outbreaks*. Retrieved from <https://preparedness.cste.org/wp-content/uploads/2021/08/CSTE-Standardized-COVID-19-K-12-School-Surveillance-Guidance-for-Classification-of-Clusters-and-Outbreaks.pdf>

schools should conduct twice weekly testing of students linked to the impacted classroom(s), grade(s), extracurricular participants, or entire student body, depending on the circumstances, unless the local health department recommends otherwise. Students who have been identified as part of an outbreak should not participate in extracurricular activities unless participating in outbreak testing. Testing should continue until the school has gone one incubation period, or 10 days, without identifying any new cases. If testing is not already in place for screening, schools should make plans to deploy outbreak testing when needed. A listing of Illinois community-based testing sites is available at <https://dph.illinois.gov/covid19/testing.html>.

Additionally, SHIELD Illinois may be deployed to a school setting as part of outbreak response. Schools can request assistance with outbreak testing by completing this interest form: <https://tinyurl.com/2p88t48c>. Deployment is dependent on availability. For schools partnering with SHIELD Illinois for weekly student screening, outbreak testing is included in the testing program. For districts without weekly student screening, outbreak-only testing through SHIELD Illinois is available by completing this interest form: <https://bit.ly/3mMejKH>. However, prioritization of outbreak testing will be given to districts with weekly student screening programs.

Screening tests for SARS-CoV-2 are intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening tests are performed to identify persons who may be contagious so that measures can be taken to prevent further transmission. Schools or organizations using SHIELD or another test provider to conduct end-to-end diagnostic or screening tests do not need to obtain a CLIA waiver directly; the provider will instead be responsible for obtaining a CLIA waiver. Schools that directly administer diagnostic or screening tests require a Clinical Laboratory Improvement Amendments ([CLIA](#)) certificate and a provider order signed by a medical professional. A CLIA certificate and provider order are required to report/provide any of the following diagnostic testing information from your screening program: Negative, Positive, Inconclusive, or Presumptive Positive results of Clinical Significance, or a result of Potential Clinical Significance. Assays and test systems used for COVID-19 diagnostic or screening testing must have received an emergency use authorization (EUA) from the FDA. Currently [approved EUAs](#) can be found on the FDA website. A COVID-19 diagnostic/screening test performed by a CLIA certified laboratory does not need to have an EUA. A certified lab may use a lab developed test (LDT) for COVID-19 screening without having FDA EUA.

The updated [CDC school guidance](#) aligns with [Community Levels](#) for recommendations for testing. Community levels can help schools and local health departments, as well as individuals, make decisions based on their local context and their unique needs. When communities are at a “high” and “medium” levels, the CDC recommends screening testing to keeping classrooms open for in-person learning. At all Community Levels, schools should ensure access to diagnostic testing for symptomatic persons and those exposed. Schools should also consider implementing screening testing for high-risk activities such as indoor sports and extracurricular activities, when students are returning from breaks, and for those serving students who are at

high risk for getting very sick with COVID-19. For staff who are not fully vaccinated, weekly testing is required regardless of community levels.

The state of Illinois has made testing for students available free of charge to all schools through SHIELD Illinois throughout the 2022-2023 school year. Public schools interested in establishing a K-12 testing program using the SHIELD Illinois saliva test should complete an interest form (<https://bit.ly/interestedSHIELD>). SHIELD Illinois is also able to offer rapid antigen test results tracking in conjunction with its weekly saliva testing program. Private schools have the option of testing with SHIELD or the Midwest Coordination Center (<https://testedandprotected.org/interest.html>). All schools should sign up by July 15, 2022 to better assure testing is in place for the start of school in the fall.

The FDA has granted an EUA to several tests for “unobserved” collection, [including the SHIELD Illinois saliva test](#). Unlike observed testing where school or third-party staff monitor specimen collection, unobserved collection can be administered at home under the observation of an adult. School districts that participate in SHIELD testing will be required to continue offering on-site testing to students unable to complete screening testing at home. Unobserved testing will be allowed for outbreak testing and for collection of specimens for school personnel not fully vaccinated.

[Surveillance testing](#) for SARS-CoV-2 is intended to monitor community or population-level outbreak of disease, or to characterize the incidence and prevalence of disease. Surveillance testing is performed on de-identified specimens and, thus, results are not linked to individuals. Surveillance testing does not require a lab to be CLIA certified. Without a CLIA certificate, a lab can NOT report or provide any of the following diagnostic testing information from surveillance testing with the following categories/statements: Negative, Positive, Inconclusive, Presumptive Positive, a result of Clinical Significance, or a result of Potential Clinical Significance. If the test is positive, this can delay procedures for notification and other mitigation measures. For this reason, IDPH does not recommend schools utilize surveillance testing.

Two different test types are available for COVID-19: **viral** tests and **antibody** tests. [Viral tests](#), including Nucleic Acid Amplification Tests (NAATs), such as SHIELD Illinois, POC NAATs, and antigen tests, such as BinaxNOW and over the counter/[home tests](#), are approved or authorized by the FDA and are recommended to **diagnose current COVID-19 infection**. The NAAT is the “gold standard” for clinical diagnostic detection of SARS-CoV-2. POC NAATs and antigen tests, including BinaxNOW, provide more rapid results than the NAAT, but have a higher probability of missing an active infection. Therefore, it may be necessary to confirm an antigen or POC NAAT result with a laboratory based NAAT, especially if the result of the antigen or POC NAAT is inconsistent with the clinical perspective, i.e., a negative antigen test in a symptomatic individual or in a person who is a close contact to a confirmed or probable case. (Detailed information is provided below.)

The CDC recommendations for SARS-CoV-2 testing are based on what is currently known about the virus. [Information on testing for SARS-CoV-2](#) is updated as more information becomes

available. 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. They also may be informative in diagnostic testing situations in which the person has a known exposure to a confirmed or probable case of COVID-19. At this time, antigen tests for screening are most appropriately used in high-risk congregate settings in which repeat testing can quickly identify persons with a SARS-CoV-2 infection to inform infection prevention and control measures, thus preventing transmission.

Test to Stay Procedures

Test to Stay (TTS) procedures have been endorsed by the CDC for exposures occurring during the school day as an alternative to staying home. To further protect in-person learning, IDPH and the Illinois State Board of Education recommend that close contacts (persons not up to date with COVID-19 vaccination who are within six feet of a case for 15 or more minutes during a 24-hour period) occurring during the school day or during extracurricular activities may remain in school through TTS protocols. To use TTS, close contacts should test at least two times during the period between close contact notification/TTS enrollment and day 7 after exposure, with the last test occurring 5-7 days after last close contact. A close contact may remain in the classroom if test results are negative, and the person remains asymptomatic. Rapid antigen, **including home tests**, may be most appropriate for Test to Stay given the short turnaround time for results. Testing may be conducted in school **or at home**, and, preferably, should be performed before the start of the school day. Testing may also be done using SHIELD's unobserved testing. IDPH strongly recommends that schools using Test to Stay participate in weekly screening testing, as described above in the Screening Testing section, and that students participating in TTS be enrolled (consented) in weekly screening, **especially at medium to high COVID-19 Community Levels.**

Participation Requirements

- For the first five days after exposure, TTS participants should avoid social gatherings and remain at home when not at school functions during the testing period. If at any time the student tests positive or becomes symptomatic, they should be immediately isolated and sent home and the school should notify the local health department.

Testing Cadence for Test to Stay

- TTS enrollment requires that schools test close contacts at least twice during the period between close contact notification/TTS enrollment and day 7 after exposure, with the last test occurring 5-7 days after last close contact (exposure date = Day 0) by a PCR or rapid EUA-approved viral test (**including a home test**). Close contacts should be permitted to remain in the classroom as long as the results are negative, they remain asymptomatic and consistently and correctly wear a mask.

Regardless of when an individual returns to school, daily symptom monitoring should continue through calendar day 10 after the exposure. If any symptoms develop, the individual should immediately self-isolate and be tested.

Antibody tests approved or authorized by the FDA are used to **detect a past infection** with SARS-CoV-2. Antibody testing is not currently recommended to assess for immunity to COVID-19 following COVID-19 vaccination or to assess the need for vaccination in an unvaccinated person. Because vaccines induce antibodies to specific viral protein targets, post-vaccination antibody test results will be negative in persons without history of previous natural infection if the test used does not detect antibodies induced by the vaccine. Antibody testing should not be promoted as a way to be exempt as a close contact. The robustness and durability of immunity following natural infection remain unknown.

HOW TO IMPLEMENT POINT-OF-CARE (POC) TESTING

General Considerations for Performing POC Testing

Due to wide-ranging symptoms associated with COVID-19 infection and the frequency with which children are likely to display one or more of these symptoms, POC tests may be useful diagnostic tools for testing persons in the early stages of infection with SARS-CoV-2 when viral load is generally highest. The benefits of POC tests in schools and other community settings is that results may be used to expedite return to school, identify early those needing isolation and quarantine, and to inform infection prevention and control measures, thus preventing transmission. Additionally, POC testing can allow students to return to school and community members to work more quickly if their test results are negative. Entities considering implementation of POC testing should address the following prerequisites in their plans:

- Obtaining a CLIA waiver to perform the test (instructions below).
- Establishing an area/room in which POC testing will be performed.
- Designating a person(s) who will perform POC testing.
- Obtaining a provider order for the testing.
- Training for person(s) who will perform POC testing.
- Securing personal protective equipment (PPE) for person(s) who will perform POC testing.
- Putting a process in place for disposal of infectious waste materials created through the testing process.
- Complying with federal requirements for reporting test results (see details regarding Illinois Department of Public Health/CDC reporting below).
- Obtaining parental consent for POC testing of students.

Regulatory Requirements for Performing POC Testing: Clinical Laboratory Improvement Amendment (CLIA) Waiver

Any entity that conducts ***diagnostic or screening testing*** for SARS-CoV-2 with antigen or POC NAATs, including those tests conducted in school settings or for school populations, must comply with CLIA regulations. Entities that intend to conduct antigen testing must first obtain a CLIA waiver. A waiver can be obtained for tests categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result” as determined by the FDA. Entities seeking a CLIA waiver must submit this [form](#) to DPH.CLIA@illinois.gov. More

information on how to obtain a CLIA waiver can be found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf>.

Designating Personnel to Perform POC testing

Each POC test will come with requirements for training prior to administration. The FDA, in its authorization and instructions, does not require any specific qualification or license to administer the BinaxNOW test. The FDA requires that the operator using the test be “appropriately trained in performing and interpreting the results.” The state’s current recommendation is that those administering the test be any level of licensed health care professional to perform the swabbing and have proper training pursuant to any relevant state and federal guidelines and requirements, but the final determination is with the issuer of the standing order. This is primarily due to training and experience in proper [infection control](#), and use of recommended PPE. SHIELD Illinois is a laboratory-based test, so schools and facility only need to ensure that those collecting the specimen are properly trained.

Obtaining a Provider Order for POC Testing

All tests must be performed under the direction of a health care provider’s order. These orders can be issued by health care providers on an individual basis, or health care providers can issue standing orders that authorize certain trained individuals to administer the test without an order from a physician for that patient. If interested in obtaining a provider order sample template, email the IDPH Antigen Testing Team at DPH.AntigenTesting@illinois.gov and someone will share a template with you.

Training and Personal Protective Equipment (PPE)

Under CLIA rules, persons who perform POC tests must be properly trained to perform the test and must use appropriate PPE when handling samples. Recommended PPE for persons performing POC testing include fit-tested N95 respirator, face shield, gown, and gloves. Testing personnel new to CLIA-waived testing will find it useful to complete CDC’s [online training module \(continuing education available\)](#) at <https://www.cdc.gov/labtraining/training-courses/ready-set-test.html>.

Waste Disposal Requirement

Any entity performing testing must be prepared to follow proper medical waste handling and disposal guidelines. All components of the BinaxNOW test kit, as well as gloves used by persons administering the test and any grossly contaminated PPE, are considered potentially infectious medical waste (PIWM), and require disposal as hazardous waste. Based on the definition established by the Occupational Safety and Health Administration (OSHA), the state defines PIWM ([Section 1420.102](#)) to include “waste generated in connection with the diagnosis of human beings” and “specimens of body fluids and their containers.” Any waste that may be infectious to humans qualifies as PIWM and is banned from Illinois landfills unless properly treated to eliminate its infectious potential.

To assist facilities with proper handling and disposal of hazardous waste, the CDC has developed [Waste Management Guidance for SARS-CoV-2 Point-of-Care \(POC\) Testing](#). Persons

performing SARS-CoV-2 POC tests should take appropriate biosafety precautions in accordance with the manufacturer's label to ensure the safety of the individual being tested and the individual conducting the test. Consult with U.S. Environmental Protection Agency (EPA) and OSHA offices for more information and specific guidance on available services related to removal, transportation, and disposal of hazardous waste.

Reporting Requirements for POC Testing

Entities that perform POC testing must report each individual positive test result to state and local public health officials, per the Control of Communicable Disease Code, in addition to the patient/parent/guardian according to the instructions below. Anyone at the school or entity performing the testing may enter the data.

- Register in IDPH's reporting system with the entities' CLIA certificate number at <https://redcap.link/dph.illinois.gov.poccovid19registration>.
- You will need your CLIA number, ordering provider, entity name, address, phone number, the type of testing platform, and the POC email and phone number.
- Once the registration has been processed, the individual who submitted the registration will receive an email with instructions and a link to register for Simple Report. In Simple Report the individual can add other authorized users who will be reporting results.
- All positive results must be reported to the IDPH system within 24 hours.
- Entities must also report all positive test results to their local health department.
- If you have questions, send an email to dph.elrresp@illinois.gov.

Considerations for Performing COVID-19 POC Testing and Interpreting Results

Results from COVID-19 POC onsite testing, as well as testing performed at other locations, should be interpreted based upon the test sensitivity and specificity, whether the individual being tested has symptoms, and the level of transmission in the community. **A confirmatory Nucleic Acid Amplification Test (NAAT) may be needed in certain situations as described below in CDC's Antigen Test Algorithm.** Tests are also affected by viral mutations. See information from the FDA about the [impact of viral mutations on COVID-19 tests](#).

- **POC testing for persons with symptoms (diagnostic - not screening).** The intended use of currently available POC testing equipment is for evaluating persons with symptoms suggestive of COVID-19. The test should be performed as soon as possible from onset and up to **seven days after symptom onset**. A positive result is considered a "**presumptive positive**," and a person with a positive test is classified as a **probable case**; therefore, positive test results should lead to immediate implementation of infection control measures, such as sending a confirmed or probable case and close contacts home to self-isolate. In most situations, a positive antigen result from a POC test for a symptomatic person does not require a confirmatory test, should be considered a probable case. If a student, teacher, or staff member has symptoms of COVID-19 and the **POC test is negative**, a **confirmatory Nucleic Acid Amplification Test (NAAT) may be needed within 48**

- hours as described below** (e.g., individual is a close contact to a confirmed case, or an outbreak is occurring in the school/facility). If indicated, the individual should self-isolate pending the result of the confirmatory NAAT test.
- According to [CDC guidance](#), only laboratory based NAATs should be used to confirm lower sensitivity tests, such as POC NAATs or antigen tests. Further, only those with EUA approval and from specimens considered optimal for detection – nasopharyngeal, nasal mid-turbinate, and anterior nasal swabs – should be used (**oral specimens are not recommended**). Recommendations for confirmatory testing are subject to change based on new findings.
 - **POC testing for asymptomatic persons (outbreak response or screening testing).** Antigen tests can be used for testing during outbreaks or screening testing in high-risk settings in which repeat testing could quickly identify persons with a SARS-CoV-2 infection to initiate isolation and identification of close contacts quickly, thus preventing transmission. In this case and especially in settings where a rapid test turnaround time is required, there is value in providing immediate results with antigen tests, even though they may have lower sensitivity than NAATs. An antigen negative result in an asymptomatic person may need confirmatory testing with a NAAT test if the person has a high likelihood of SARS-CoV-2 infection (e.g., the person has had close contact or suspected exposure to a person with COVID-19 within the last 14 days or is part of an outbreak). If the confirmatory test is positive, the person would be considered a confirmed case and schools should follow [CDC's guidance for isolation and notification of close contacts](#).
 - **CDC's Antigen Test Algorithm.** Although the CDC's algorithm is specific to antigen testing, POC molecular testing that produces presumptive positive results should follow the same algorithm. Visit the CDC's webpage, [Interim Guidance for Antigen Testing for SARS-CoV-2](#), for the most recent testing algorithm. For asymptomatic and close contacts with COVID-19 positive results by antigen or POC NAAT, clinical discretion should be used to determine if confirmation is needed. Similarly, in situations of higher pretest probability, such as when community transmission levels are high, clinical discretion should be used to determine if a positive antigen result requires confirmation. If an asymptomatic person tests positive by antigen test with no known close contact to a confirmed or suspected COVID-19 case, no linkage to an ongoing outbreak, and/or the LHD is not considering the level of community transmission to be creating a high pretest probability state, a confirmatory negative lab-based PCR collected within 48 hours could be used to determine that the first antigen test was a false positive and the individual is not infectious and isolation is not needed for case or contacts.

Contact: Questions regarding COVID-19 testing in schools can be directed to DPH.COVIDSchool@Illinois.gov. Those interested in participating in SHIELD Illinois can email Beth Heller, Senior Director of External Affairs for SHIELD, at bheller@uillinois.edu. For Midwest Coordinating Center (MCC), complete the interest form at <https://testedandprotected.org/interest.html>. For questions regarding rapid antigen testing, schools should email dph.antigentesting@illinois.gov.