6/2/2021

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

Updates

- Testing algorithm is updated to be consistent with the Centers for Disease Control and Prevention's (CDC) guidance.
- Guidance is provided on acceptable Nucleic Acid Amplification Tests (NAATs) for confirmatory testing.
- New guidance is provided on antibody testing and its use in quarantine assessment.
- New guidance on testing for those fully vaccinated.
- New guidance on outbreak testing.
- New quarantine exceptions for schools implementing twice weekly testing.

Purpose

This guidance addresses the use of point-of-care (POC) COVID-19 testing and screening in schools and other community settings. Four options are addressed by this SIREN: testing administered in school health-based clinics, testing onsite by other trained health care workers, testing provided in pharmacies, and POC testing in health care facilities. This guidance was originally released in conjunction with the state's distribution of Abbott BinaxNOW tests to local health departments (LHDs), schools, and other settings. The BinaxNOW test is one of several antigen tests available and in use right now. More recently, IDPH entered a partnership with SHIELD Illinois to provide weekly testing to participating schools utilizing the SHIELD Illinois saliva-based RT-PCR testing. This guidance is also applicable to other types of U.S. Food and Drug Administration (FDA)-approved tests as described below. This guidance also reflects CDC interim guidance on testing strategies in schools (December 4, 2020).

Priority testing

Testing should be prioritized as follows:

1. Persons with symptoms of COVID-19, regardless of vaccination status.
2. Unvaccinated persons who are determined to be close contacts to someone with active COVID-19 infection, and certain vaccinated persons who live or work in high density/congregate settings.
3. All staff and students/participants with possible exposure in the context of outbreak settings, with special considerations for vaccinated persons depending on the living or work setting.
4. Screening of unvaccinated staff and/or students/participants, when the risk of transmission is high to moderate, as a strategy to identify asymptomatic positives.

Testing used for screening purposes to identify new positives can be an effective mitigation strategy, especially in areas with high-to-moderate community transmission. Testing is not recommended for staff or students who are fully vaccinated (14 days from the last dose) but is recommended if the vaccinated person works or lives in high density/congregate settings (e.g., dormitory, jail, homeless shelter or food production plant). In addition, those working in health care settings should also be tested according to the CDC's guidance. Testing for people who 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. Isolation and contact tracing should begin immediately when positives are identified as detailed in the COVID-19 Interim Exclusion Guidance.

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.

Outbreak testing is recommended for schools in outbreak status (five or more cases linked epidemiologically that do not share the same household and are not listed as close contacts of each other outside the outbreak setting), similar to the approach used in workplaces and congregate settings. Implementation of outbreak testing should begin as soon as possible from the date the outbreak is declared and at least within three days. Schools should conduct twice weekly testing of unvaccinated staff and students targeted to the impacted classroom(s), grade(s), extracurricular participants, or entire student body, depending on the circumstances, unless the LHD recommends otherwise. Testing should continue until the school has gone two incubation periods, or 28 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 free testing sites is available at dph.illinois.gov. Additionally, SHIELD Illinois can be quickly deployed to a school setting by emailing Beth Heller, Senior Director of External Affairs for SHIELD, at bheller@uillinois.edu. Schools can also utilize BinaxNOW rapid antigen testing for outbreak response by emailing dph.antigentesting@illinois.gov.

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. A CLIA certificate is required to report or to 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 FDA EUAs can be found on FDA's website. A COVID-19 diagnostic/screening test performed by a CLIA certified laboratory does not have to have an EUA. A certified lab may develop a lab developed test (LDT) for COVID-19 screening without having FDA EUA.

Schools participating in the IDPH School Testing Program, using either SHIELD Illinois or Binax NOW, or schools conducting testing consistent with CDC's school testing guidance may use a modified definition of close contacts for the classroom setting only. Any schools participating in the modified quarantine/testing program must have approval from their LHD. Such schools may use a definition for classroom close contacts as those who come within 3 feet or less of a COVID-19 case for a cumulative time of 15 minutes or more within a 24-hour period. Schools should work with their LHD and contact tracing teams to determine whether the circumstances of an exposure require the use of the non-modified definition of close contact, such as breaches in masking or failure to adhere to social distancing (3 to 6 feet). Students/classrooms who do not meet the guidelines for modified close contact, should continue to adhere to the standard guidelines, which define close contacts as those within 6 feet or less of a confirmed case for 15 cumulative minutes in a 24-hour period.

Students who opt out of testing are not eligible for the modified close contact definition, as described above. Fully vaccinated students and staff are not required to quarantine or test, unless symptomatic. Schools participating in this modified close contact assessment may be asked to collect and report data on close contacts in the 3-to-6-feet range and document testing and symptom status for the entire quarantine period. Tools for reporting will be provided by IDPH.

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. To report labs that are inappropriately reporting non-approved surveillance test results to individuals or to workplaces, schools, etc., as a diagnostic criteria to be used for quarantine decision-making, please report to the IDPH Office of Health Care Regulation, Central Complaint Registry, by phoning 800-252-4343 or completing an online complaint form.

Two kinds of tests 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 Binax Now, 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 the BinaxNOW, usually provide more rapid results than the NAAT, but have a higher probability of missing an active infection. Therefore, it may be necessary to confirm a 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.

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. Although used sparingly by LHDs, positive antibody tests may be used to release someone from quarantine following an exposure as long as that person has limited or no contact with persons at high risk for severe COVID-19 illness, including older adults and persons with certain medical conditions. Antibody testing should not be promoted as a way to avoid quarantine. The robustness and durability of immunity following natural infection remain unknown. The LHD may allow an exemption from quarantine if the close contact has proof of a positive antibody test collected no more than three months before the exposure or immediately following, as long as that person is asymptomatic and remains that way for the entire 14 days post-exposure.

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 benefit of POC tests in schools and other community settings is that the results may be used to expedite isolation and quarantine requirements 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

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 particular patient.

Training and Personal Protective Equipment (PPE)
Under CLIA rules, persons who perform POC tests must be appropriately 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 doing 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, should be discarded as infectious waste.

Reporting Requirements for POC Testing
Entities that perform POC testing must report each individual positive and negative 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 a link to begin reporting. This link is unique to the entity and can be shared with other staff who will be reporting results.
- Each positive and negative test result 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.**

- **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 placing the individual in isolation and placing close contacts in quarantine. 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 be in isolation pending the result of the confirmatory NAAT test. Per updated CDC guidance released on March 28, 2021, 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 serial screening).** 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 quarantine 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

- **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.

Contact: Questions regarding COVID-19 testing in schools can be directed to DPH.COVIDSchool@Illinois.gov. Those interested in participating SHIELD Illinois can emailing Beth Heller, Senior Director of External Affairs for SHIELD, at bheller@uillinois.edu. For BinaxNOW rapid antigen testing, schools should email dph.antigentesting@illinois.gov.