2/26/2021

Interim Guidance on Rapid Point-Of-Care Testing for COVID-19 in Community Settings and Schools

PURPOSE

This guidance addresses use of rapid 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 is released in conjunction with the state's distribution of Abbott BinaxNOW tests to local health departments, schools, and other settings. The BinaxNOW test is one of several rapid POC antigen tests available and in use right now. This guidance is also applicable to other types of FDA-approved tests as described below. This guidance also reflects newly released Center for Disease Control and Prevention (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.
2. Persons who are determined to be close contact with someone with recent COVID-19 infection.
3. All staff and students/participants with possible exposure in the context of outbreak settings.
4. Where the risk of transmission is high to moderate, screening of staff and/or students/participants can be used 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 of teachers and staff should be prioritized over students in any sampling strategy, and older students prioritized over younger students. Testing for people who have recovered from a SARS-CoV-2 infection may resume testing after 90 days from symptom onset or previous positive test. Isolation and contact tracing should begin immediately when positives are identified as detailed in the COVID-19 Interim Exclusion Guidance. Effectiveness of entry testing or universal testing in reducing virus transmission is not known, but may be helpful when students are returning to school after a long break where travel or attending gatherings may occur, e.g., winter break.

BACKGROUND

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

Diagnostic testing for SARS-CoV-2, the virus that causes COVID-19, is intended to identify current infection at the individual level and is 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.

Screening testing for SARS-CoV-2 is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission.

Any laboratory or facility that performs diagnostic or screening testing must have a Clinical Laboratory Improvement Amendments (CLIA) certificate and meet all requirements to perform testing. A CLIA certificate is required to report or to provide any of the following diagnostic testing information from your screening testing: Negative, Positive, Inconclusive, or Presumptive Positive, a result 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 U.S. Currently approved FDA EUAs can be found on FDA's website.

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 cannot be used for individual decision-making. 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 your surveillance testing: 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 the Real-Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), the rapid POC molecular test, and the POC antigen test, are approved or authorized by the FDA and are recommended to **diagnose current COVID-19 infection**. The RT-PCR molecular test is the "gold standard" for clinical diagnostic detection of SARS-CoV-2. Rapid POC molecular and POC antigen tests, including the Binax NOW, usually provide more rapid results than the RT-PCR, but have a higher probability of missing an active infection. Therefore, it may be necessary to confirm a

rapid POC antigen or rapid POC molecular test result with a RT-PCR test, especially if the result of the rapid POC test is inconsistent with the clinical perspective, i.e., a negative antigen test on a symptomatic individual or on 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. Rapid 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, rapid 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. The CDC does **not** currently recommend using antibody testing as the sole basis for diagnosing current infection or disproving a positive by viral testing. Depending on when someone was infected and the timing of the test, the test may not find antibodies in someone with a current COVID-19 infection. In addition, it is not currently proven whether a positive antibody test indicates protection against future SARS-CoV-2 infection; therefore, antibody tests should **not** be used at this time to determine if someone is immune.

HOW TO IMPLEMENT 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, rapid 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 the 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, rapid 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 rapid 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 rapid antigen or rapid molecular tests, 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. The process simply involves completing and submitting a 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, 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.

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 point of contact 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 report all positive test results to their local health department (LHD).
- If you have questions, please 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 RT-PCR test may be needed in certain situations as described below in the enclosed table: Guidance for Interpreting Viral Test Results for SARS-CoV-2.**

- **POC testing for persons with symptoms (diagnostic - not screening).** The intended use of currently available rapid 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 **rapid POC test is negative**, a **confirmatory RT-PCR test 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 RT-PCR test. Recommendations for confirmatory testing are subject to change based on findings.

POC testing for asymptomatic persons (outbreak response or routine screening). Data is limited to guide the use of rapid POC tests to screen asymptomatic persons to detect COVID-19 infection; therefore, testing of asymptomatic individuals may be recommended when an outbreak is declared to identify

additional positives due to widespread exposures or as part of routine screening of classrooms, groups, or teams to detect unsuspected COVID-19 infection.

Guidance for Interpreting Viral Test Results for SARS-CoV-2

Test Modality	Symptomatic		Asymptomatic with HIGH index of suspicion[1]		Asymptomatic with LOW index of suspicion[2]	
	POS	NEG	POS	NEG	POS	NEG
RT-PCR	Positive	Negative	Positive	Negative	Positive	Negative
POC-Ag/Molecular	Presumptive positive[3]	Possible false negative[4]	Presumptive positive[3]	Possible false negative[4]	Possible false positive[5]	Presumptive negative[3]

[1]Known exposure to a case of COVID-19 in last 14 days; resident/visitor/staff in a congregate living/work setting in outbreak status; lives in an area with moderate/high community transmission (contact your local health department for details on your community's transmission status); or has history of travel to area with high community transmission in the past 14 days.

[2]No known exposure; resident/visitor/staff in a congregate living/work setting with no COVID-19 cases in last 14 days; lives in an area with low community transmission (contact your local health department for details on your community's transmission status); or no history of travel to an area with high community transmission in the past 14 days.

[3]No confirmatory testing is recommended in response to this POC testing result.

[4]Perform confirmatory RT-PCR on new specimen collected within 48 hours of the previous test if the individual is a close contact to a confirmed case within 14 days or part of an ongoing outbreak or under the clinical discretion of ordering provider and/or as advised by the local health department due to community transmission levels.

[5]Consider performing confirmatory RT-PCR on new specimen collected within 48 hours of the previous test if the individual is NOT a close contact to a confirmed case within 14 days, NOT part of an ongoing outbreak or under the clinical discretion of ordering provider, and/or as advised by the local health department due to ongoing community transmission.

Contact: Questions regarding COVID-19 testing in schools can be directed to: DPH.COVIDSchool@Illinois.gov