



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

Background

This guidance addresses use of rapid point-of-care testing in schools and other community settings either when testing is being administered in school health-based clinics, onsite by trained healthcare workers, or in pharmacies or health care facilities. This guidance is being 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 point-of-care antigen tests that are available and in use right now. This guidance is also applicable to other types of tests as described below.

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 point-of-care (POC) molecular test, and the POC antigen test, are approved or authorized by the Food and Drug Administration (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 Centers for Disease Control and Prevention (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 is 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.

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 location 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.
- Process in place for disposal of infectious waste materials created through the testing process.
- Federal requirement for reporting test results (see details regarding Illinois Department of Public Health/CDC reporting below).
- 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 Clinical Laboratory Improvement Amendments ([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 Food and Drug Administration. 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 healthcare 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 healthcare provider’s order. These orders can be issued by healthcare providers on an individual basis, or healthcare 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>.

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.pocovid19registration>.
- 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 testing from 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). There are only limited data 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

¹Known 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.

²No 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.

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

⁴Perform 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.

⁵Consider 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