

COVID-19

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

Updates

Test to Stay protocols for close contacts

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).

School testing gives communities, schools, and families added assurance that schools can open and remain 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 four primary reasons:

- 1. Persons with symptoms of COVID-19, regardless of vaccination status.
- 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,
- 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. Regular screening 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). Fully vaccinated individuals should also be tested if they have symptoms of COVID-19 or after exposure to someone with COVID-19. Vaccinated individuals with symptoms should immediately self-isolate and test. Vaccinated individuals who have been exposed to a confirmed or probable case of COVID-19 are not considered close contacts and may remain in school, do not need to self-isolate, but should seek testing 5-7 days after exposure. In addition, during outbreak situations, fully vaccinated persons with suspect exposures should be tested according to the LHD's recommended outbreak testing cadence. 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 <u>CDC</u>.

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 strongly recommended for students for schools in outbreak status, and required for unvaccinated school personnel who are included in the outbreak definition established by public health authorities. Outbreak status is currently 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 schoolassociated 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. A "core group" includes but is not limited to extracurricular activity, cohort group, classroom, sports team, performing arts group, before/after school care, etc. IDPH recommends schools acquire parental consent for student testing at the beginning of the school year to accommodate outbreak testing should the need arise. Schools must conduct twice weekly testing of unvaccinated school personnel who are included in the outbreak definition established by public health authorities. Additionally, schools should conduct twice weekly testing of unvaccinated students targeted to the impacted classroom(s), grade(s), extracurricular participants, or entire student body, depending on the circumstances, unless the local health department 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 http://dph.illinois.gov/testing.

Additionally, SHIELD Illinois may be deployed to a school setting by completing this interest form: https://bit.ly/interestedSHIELD. 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/interestedSHIELD. However, prioritization of outbreak testing will be given to districts with weekly student screening programs. Schools can also utilize BinaxNOW rapid antigen testing for their 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.

The state of Illinois has made testing for students available free of charge to all schools in Illinois through SHIELD Illinois. Those interested in establishing a K-12 testing program using the SHIELD Illinois saliva test should complete this interest form: https://bit.ly/interestedSHIELD. Note: SHIELD Illinois is also able to offer BinaxNOW rapid antigen testing along with its weekly saliva testing program. Those interested in implementing a K-12 testing program using the BinaxNOW rapid antigen test should email dph.antigentesting@illinois.gov. (See the IDPH Interim Guidance on Testing for COVID-19 in Community Settings and Schools for complete information on testing.)

<u>Surveillance testing</u> 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 exclusion 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. <u>Viral tests</u>, 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 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

Executive Order 2021-24 (as amended by Executive Order 2021-25) requires schools to exclude unvaccinated students and school personnel who are identified as close contacts to a confirmed or probable case of COVID-19, except that schools may use Test to Stay procedures if the close contact and the confirmed or probable case were consistently masked during the entire exposure period. CDC defines a close contact as an individual not fully vaccinated against COVID-19 who was within 6 feet of an infected person for a cumulative total of 15 minutes or more over a 24-hour period. A student who was within 3-6 feet of a confirmed or probable case in a classroom setting is not considered a close contact if both confirmed case or probable case and close contact were consistently masked for the entire exposure period. Individuals who are fully vaccinated or who tested positive for COVID-19 within prior 90 days and are currently asymptomatic are not considered close contacts.

To protect in-person learning, close contacts in circumstances where both the case and the contact where consistently and correctly masked, as required by Executive Order 2021-18,

may remain in school through Test to Stay protocols, as has been documented by the CDC.¹ IDPH requires that schools test close contacts on days one, three, five, and seven from date of exposure with a NAAT viral test (such as a PCR or, preferably, a rapid antigen or PCR test with Emergency Use Authorization (EUA)) and that close contacts be permitted to remain in the classroom as long as the results are negative. Rapid antigen or PCR tests (e.g., BinaxNOW) may be most appropriate for Test to Stay given the short turnaround time for results. Testing must be conducted in school and, preferably, should be performed at the start of the school day before entering the classroom. It is recommended, but not required, that schools using Test to Stay participate in weekly screening testing, as described above in the Screening Testing section.

Local health departments have the authority to assess high-risk exposures and order a traditional quarantine without the option for Test to Stay. Students who violate Test to Stay rules or are not tested as requested by their school and LHD will revert to normal exclusion requirements.

Participation Requirements:

- Test to Stay is only applicable when both the COVID-19 case and close contact were engaged in consistent and correct use of well-fitting masks, regardless of vaccination status, as required by Executive Order 2021-18.
- Test to Stay may be used for any indoor exposure, with the exception of household exposures, for both students and staff who are not fully vaccinated.
- The individual must be able to maintain physical distancing as much as possible, and masking at all times (indoors and outdoors) during the testing period.
- Students or staff who are not fully vaccinated and engaged in Test to Stay after an
 exposure may participate in extracurricular activities as long as they remain consistently
 and correctly masked and physically distanced for the full testing period. Students
 should not participate in sports competition.
- Test to Stay 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, excluded from school, and the local health department notified.

Testing Cadence for Test to Stay:

 IDPH requires that schools test close contacts on days one, three, five, and seven from date of exposure by a PCR or rapid Emergency Use Authorization (EUA)-approved viral test and that close contacts be permitted to remain in the classroom as long as the results are negative.

¹ Lanier, W. A., Babitz, K. D., Collingwood, A., Graul, M. F., Dickson, S., Cunningham, L., Dunn, A. C., MacKellar, D., & Hersh, A. L. (2021, May 28). COVID-19 testing to sustain in-person instruction and extracurricular activities in high schools – Utah, November 2020-March 2021. *Morbidity and Mortality Weekly Report*, 70(21), 785-791. http://dx.doi.org/10.15585/mmwr.mm7021e2

- IDPH recommends that maximum possible testing cadence as an alternative to exclusion. However, if the close contact is identified five days or more from the date of exposure, adjust testing accordingly, ideally on days five and seven after the last exposure.
- Every effort should be made to accommodate testing on weekends and holidays, however, if testing in the outlined cadence is not possible, students should be tested at the earliest possible opportunity (e.g., first thing on Monday morning before attending classes).
- Close contacts should be identified on or before day 5 after exposure so that at least two tests are performed for Test to Stay. If the close contact is identified five days or more from the date of exposure, adjust testing accordingly, ideally on days five and seven after the last exposure.
- Testing should be performed on site at the school, and preferably should be performed at the start of the school day.

Documentation:

 At the conclusion of the Test to Stay period, the school should notify the local health department that the individual has successfully completed testing and remained negative.

See the <u>Test To Stay flowchart</u> at the end of this document.

Regardless of when an individual return to school, daily symptom monitoring should continue through calendar day 14 after the exposure. If any symptoms develop, the individual should immediately self-isolate and contact their local health department or health care provider to report their symptoms. The local health department can provide guidance on how to safely quarantine and isolate within the household.

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 for return to school or 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 exclusion or quarantine. The robustness and durability of immunity following natural infection remain unknown. The Schools and LHD may allow return to school or an exemption from quarantine, respectively, 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 return to school, 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 <u>CLIA</u> 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 <u>form</u> 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 <u>infection control</u>, 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 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 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 <u>Control of Communicable Disease Code</u>, 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

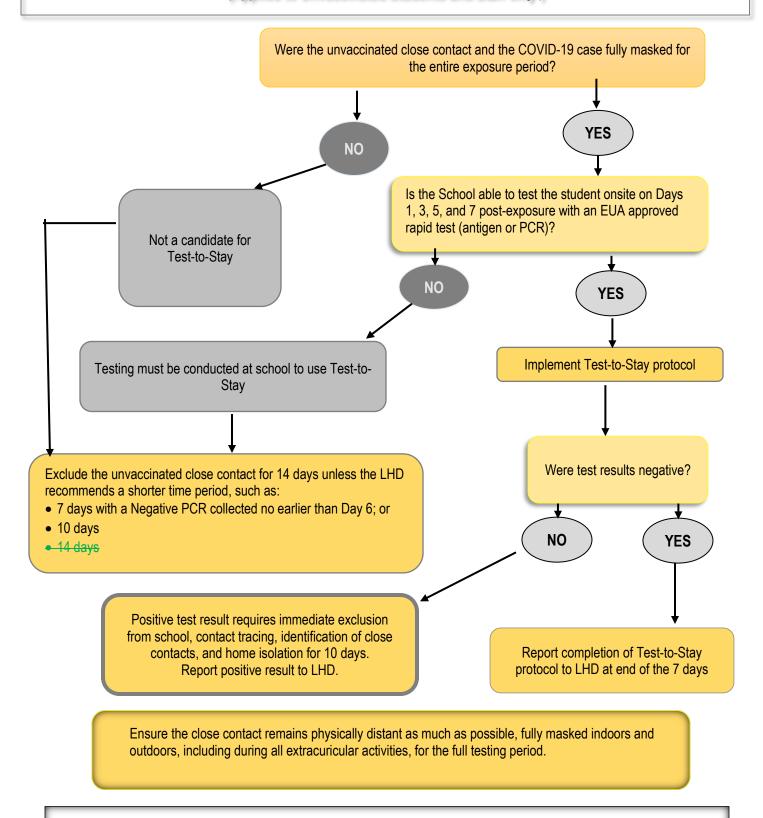
Results from COVID-19 POC onsite testing, as well as testing performed at other locations, should be interpreted based upon the test sensitivity and specificity, whether the individual being tested has symptoms, and the level of transmission in the community. A confirmatory Nucleic Acid Amplification 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 excluding a confirmed or probable case and close contacts from school. 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 (follow Situation #1 and Situation #3 from the School Exclusion Protocols) and should not be discounted or deemed a false positive if the symptomatic person later receives a negative result from a PCR test. 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 <u>updated CDC guidance</u> 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 <u>asymptomatic</u> persons (outbreak response or screening testing). Antigen tests can be used for testing during outbreaks or screening testing in highrisk <u>settings</u> in which repeat testing could quickly identify persons with a SARS-CoV-2 infection to initiate exclusion, 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 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 Situation #1 and Situation #3 from the School Exclusion Protocols.

• 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 a high pretest probability for a positive test, 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 exclusion 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 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.

Test -to-Stay Protocol Flow Chart 10/18/2021 (Applies to Unvaccinated Students and Staff only¹)



1 Fully vaccinated persons are not considered close contacts so would not need to be enrolled in Test -to-Stay protocol. However, fully vaccinated persons who have close contact to a confirmed case should test 5 to 7 days after close contact.