

Know As You Go:

Pilot Program of Point-of-Care SARS-CoV-2 Antigen Screening Testing in Delaware Schools

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Introduction

In Delaware, the first case of coronavirus disease 2019 (COVID-19) was identified on March 11, 2020 and the first death attributed to COVID-19 occurred on March 26, 2020. As of March 5, 2021, 88,891 cases were diagnosed and 1,492 Delawareans died due to complications associated with COVID-19. Since the first case was announced, Delaware moved rapidly to institute statewide mitigation and suppression strategies to limit effects on the populace and health infrastructure, including widespread access to testing and sweeping public restrictions such as school and business closings and stay-at-home orders. Public schools were closed by executive order on March 13th, 2020. On March 24, 2020, private schools closed with the State's stay-at-home order.

Since then, the Delaware Department of Education (DDOE), in close collaboration with the Division of Public Health (DPH), provided extensive guidance to help schools reopen safely and to provide in-person instruction to the greatest extent possible. The guidance was crafted to prioritize the health and safety of students and staff while maintaining the goal of providing a high-quality, equitable education for all Delaware learners. Data continue to demonstrate that while the risk remains low for sustained, person-to-person transmission in schools when mitigation strategies are implemented consistently; emerging data suggest that students face significant risks resulting from the disruption caused by school closures, including but not limited to learning loss, increases in adverse mental health outcomes for youth, dropout risk, lack of access to nutritious meals, and potential safety concerns such as abuse or neglect.¹⁻⁶

With this in mind, DDOE's *Returning to School Guidance*⁷ was designed to:

- Be a general framework for districts and charters, allowing flexibility for each district and charter to meet its community's unique needs;
- Help districts/charters, families/caregivers, and staff understand and articulate risks and benefits, which are inherent and inevitable when reopening schools during a pandemic;
- Reflect the best available evidence, science, and best practices in both education and public health, with required flexibility as new evidence and best practices have shifted recommendations and guidance; and

- Leverage the cooperation and coordination of students, staff, families/caregivers, and the community with the goal of creating and maintaining safe, healthy, and supportive learning environments.

The guidance outlines specific mitigation strategies for districts, school buildings, and classrooms that, in combination, are designed to reduce the risk of transmission of COVID-19. These strategies include ensuring physical distancing, required use of face coverings for all who are able to wear them, cleaning and disinfection practices, access to handwashing facilities and supplies or sanitizer, proper ventilation, and cohorting of students as possible. These strategies were codified in Governor John Carney’s Twenty-Seventh Modification to the Emergency Order and guidance from the Delaware Division of Public Health, which required that all schools, public and private, comply with these practices. The guidance emphasizes that these mitigation strategies are intended to be layered to work optimally; no one strategy is sufficient alone.

To complement these strategies in schools, Delaware offered accessible community polymerase chain reaction (PCR) testing statewide for symptomatic and asymptomatic individuals. From the beginning of the school year, all teachers and school staff in the state have had access to routine PCR at-home testing, as well as community testing sites as needed. This broad use of community testing has allowed DPH to identify and isolate positive cases, as well as conduct contact tracing and quarantine close contacts. In schools, DPH collaborated with school nurses, present in every public school (14 Del.C., Ch.13, §1310) and many private, parochial, and independent schools, to identify and isolate positive cases that were potentially contagious in the school environment, as well as to conduct contact tracing of school exposures of close contacts. DPH and DDOE also worked closely with dedicated “COVID coordinators” – personnel appointed within schools and districts as subject matter experts and points of communication regarding COVID recommendations and mitigation measures. Despite such interventions, testing results often took several days to be returned, with positive individuals in the school environment in the interim.

Building on this critical linkage between DPH, school nurses, and DDOE, schools in Delaware scaled up the use of SARS-CoV-2 antigen tests, which are relatively inexpensive and can be used at the point-of-care in schools. In addition to the benefit of rapid response in the general school environment, antigen testing offered an added level of protection in classroom environments where students were not able to consistently employ mitigation strategies, such as young children or students with special needs unable to wear face coverings and who require close contact with staff. Currently authorized devices can return results in approximately 15 minutes, providing schools another critical mitigation strategy to more quickly respond and limit potential transmission.

Antigen Testing Background

Antigen tests for SARS-CoV-2 are generally less sensitive than nucleic acid viral tests that use PCR for detection. Proper interpretation of antigen test results is important for accurate clinical management of patients with suspected COVID-19, or for identification of potentially infected persons when used for screening.

The sensitivity of rapid antigen tests is generally lower than PCR. The first two antigen tests that have received Food and Drug Administration (FDA) Emergency Use Authorizations (EUAs) demonstrate sensitivity of 84% and 97% compared to PCR. Studies have shown that antigen levels in some patients who have been symptomatic for more than five days may drop below the

limit of detection of the test. Scant data are available regarding performance in asymptomatic individuals.

The specificity of rapid antigen tests is generally as high as PCR – the first two antigen tests that received FDA EUAs reported specificity of 100%– which means that false positive results are unlikely. While all published datasets reflect specificities of 100%, cases of false positives have been reported—it is unclear at this time whether these incidents represent actual false positives, contamination, or test performance failure (false positives are a known phenomenon when certain transport media [e.g. Remel M4 or M4RT] are used). Positive and negative predictive values of all in-vitro diagnostic tests vary depending upon the pretest probability of the patient being tested. Pretest probability is impacted by the prevalence of the target infection in the community, as well as the clinical context of the recipient of the test.

Definition of Screening Testing

Screening testing for SARS-CoV-2 is intended to help identify infected persons who are asymptomatic (asymptomatic carriers) 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. Examples of screening include testing in congregate settings, such as a long-term care facility or a correctional facility, a workplace testing its employees, or a school testing its students, faculty, and staff.

Use of Antigen Tests for Screening Testing

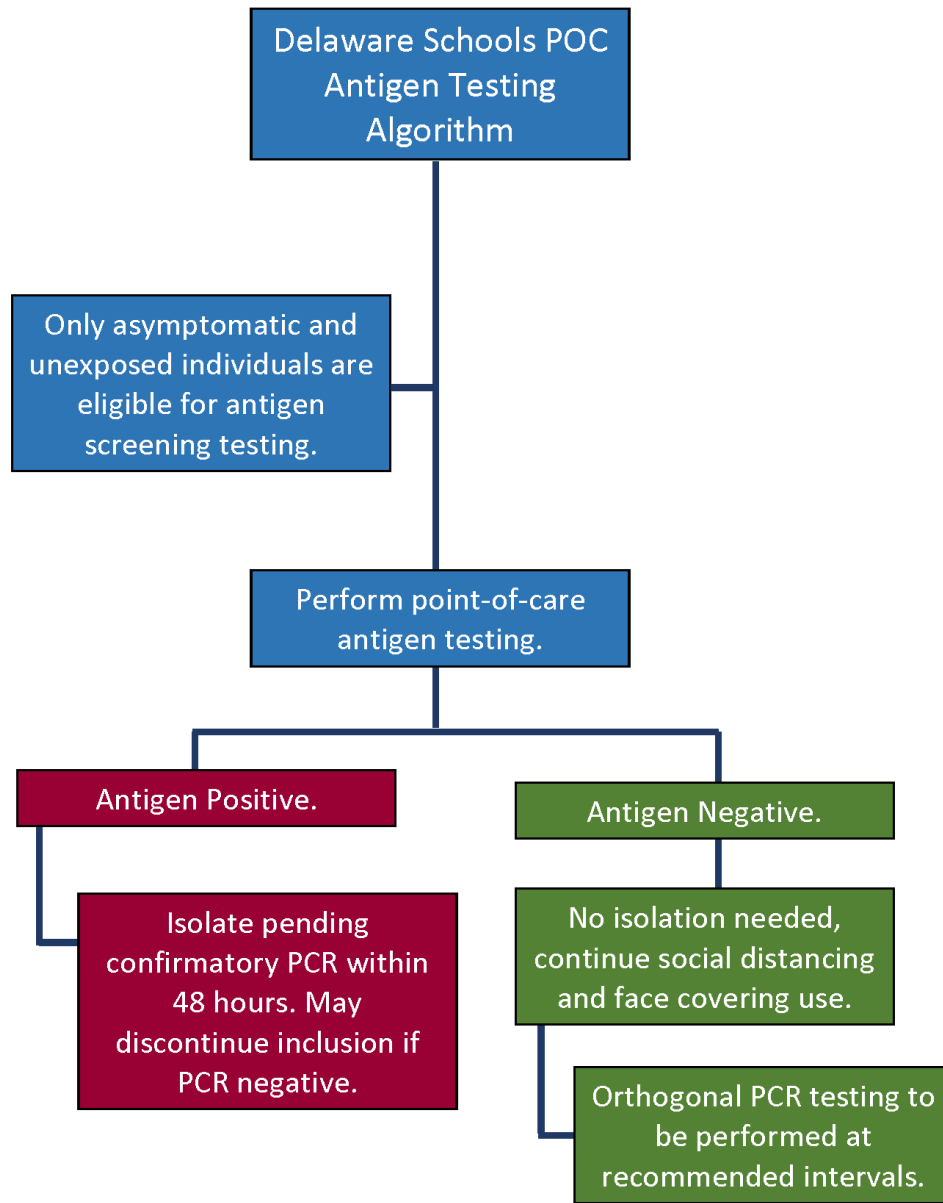
Modeling studies have convincingly demonstrated that point-of-care or self-administered surveillance tests with fast turnaround time or frequent testing have high epidemiological value, and can attenuate surges of infection in highly congregate settings, such as military bases and centers of education.⁸ Universal high-frequency testing holds significant promise in stopping the spread of disease.⁹ In testing of asymptomatic individuals, however, community prevalence significantly influences test utility.

Implementation

DPH, in partnership with DDOE, schools, and school districts throughout the State of Delaware, identified point-of-care lateral flow immunoassays (“rapid antigen tests”) as useful diagnostic tools for COVID-19, and subsequently developed guidance for use and implementation of such tests within the school setting. DPH and DDOE implemented a process to readily identify asymptomatic students in the school setting to keep the community safe and healthy, as well as to better understand the prevalence of asymptomatic children and adolescents in the community.

Beginning in December of 2020, schools throughout the state were given access to rapid antigen testing platforms that had been purchased by DPH (BD Veritor) or provided by the federal government (Abbott BinaxNOW). A physician’s standing order for testing was provided by DPH, and a multidisciplinary workgroup comprised of representatives from DPH, DDOE, and the education community collaborated to develop guidance for school rapid antigen testing implementation, including a test interpretation algorithm (see Figure 1), information regarding certifications and licensure, permission forms for testing, and web-based training.¹⁰

Figure 1. Delaware schools antigen testing algorithm



Uptake and implementation across schools and school districts was brisk, with more than two dozen educational settings beginning antigen testing as of February 1, 2021, with heterogeneous implementation across locations reflective of the unique landscape and needs of each educational

setting. Many schools opted to introduce students and families to the process through initial drive-through testing events, where parents could assist students with self-swabbing techniques and witness test performance to gain confidence and insight into the testing process. Sites developed testing processes that best suited their students and facilities. For example, many schools had students perform and process tests shortly after school arrival and prior to entrance into the educational environment. Other districts opted for a “classroom service” model, placing testing equipment on a mobile cart within hallways and moving between classrooms to test small groups of students at a time. Nearly all students performed self-swabbing, though assistance could be rendered by testing personnel if needed. In the first three months of testing, 13 schools and districts throughout Delaware performed 3,739 tests, of which 16 (0.43%) were positive. All positive antigen tests were subsequently confirmed positive by PCR.

Challenges and Lessons Learned

Implementation of the *Know As You Go* antigen screening program faced a number of challenges and lessons learned during development and operationalization. Early on, clear guidance regarding obtaining parental consent for and addressing legal requirements surrounding testing became paramount, and DDOE collaborated closely with legal counsel from the Delaware Department of Justice (DOJ) to ensure compliance. Additionally, continuous feedback from all stakeholders allowed for program improvement and sustainability, and involvement of school nurses as on-site technical experts was quickly identified to play a critical role in enhancing communication and engaging all participants in testing.

Staffing showed itself to be the greatest challenge throughout program implementation. Staff are needed for testing supervision and performance, as well as documentation and state-mandated results reporting. Automated reporting processes were identified as a critical area for staffing improvement.

Conclusion

Studies have convincingly demonstrated that high-frequency point-of-care antigen testing has high epidemiological value, and can attenuate surges of infection in highly congregate settings such as schools. Delaware’s schools have demonstrated how an antigen testing program can be easily and successfully integrated into school operations to help protect against COVID-19 infection within educational settings.

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