

Order of the Acting Secretary of the Pennsylvania Department of Health Authorizing COVID-19 Diagnostic Rapid Antigen Testing in K-12 Schools

The 2019 novel coronavirus (COVID-19) is a contagious disease that is spreading rapidly from person to person in the world, the United States, and this Commonwealth. COVID-19 can be transmitted from any person who is infected, even if they have no symptoms. Additionally, exposure is possible by touching a surface or object that has the virus on it and then touching one's mouth, nose, or eyes. Symptoms of COVID-19 may include fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea. Older adults and people who have serious chronic medical conditions are at a higher risk for serious illness. Illness in children and young adults has become more common as the face of the pandemic continues to change. There have been 1,300,368 cases and 28,235 deaths in this Commonwealth caused by the still present and ongoing pandemic.

The Department of Health (Department) has the authority to take any disease control measure appropriate to protect the public from the spread of infectious disease. *See* 35 P.S. § 521.5; 71 P.S. §§ 532(a), and 1403(a); 28 Pa. Code § 27.60. COVID-19 is a threat to the public's health, for which the Secretary of Health may order general control measures, including, but not limited to, closure, isolation, and quarantine. This authority is granted to the Secretary of Health pursuant to Pennsylvania law. *See* section 5 of the Disease Prevention and Control Law, 35 P.S. § 521.5; sections 2102(a) and 2106 of the Administrative Code of 1929, 71 P.S. §§ 532(a), and 536; and the Department of Health's regulations at 28 Pa. Code §§ 27.60-27.68 (relating to disease control measures; isolation; quarantine; movement of persons subject to isolation or quarantine; and release from isolation and quarantine).

Expanding access to diagnostic rapid antigen testing is a disease control measure that is appropriate to protect the public from the further spread of COVID-19. To reduce transmission of COVID-19 and to support in-person classroom instruction, the Department's Authorized Vendor will provide Authorized Tests for diagnostic rapid antigen testing to any School that chooses to complete and submit a Statement of Assurances and become an Authorized School for participation in COVID-19 diagnostic rapid antigen testing. Authorized Schools will be provided by the Department and the Department's Authorized Vendor with the necessary tools and information to implement COVID-19 diagnostic rapid antigen testing. This Order is limited to diagnostic rapid antigen testing and is intended to authorize schools to use DOH's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver and exempt them from state laboratory regulatory requirements for the diagnostic rapid antigen testing option only.

By increasing the availability of diagnostic rapid antigen testing in schools, students and staff from communities across the Commonwealth will be able to better contain the spread of COVID-19 and participate in important public health surveillance efforts which will support the safety of the community and provide continuous information on the spread of disease.

Accordingly, on this day, August 31, 2021, to prevent and control the spread of disease, I hereby order:

Section 1: Definitions

For purposes of this Order, the listed terms have the following meanings:

“Authorized School”: any School that completes and submits a Statement of Assurances to the Department and opts in for COVID-19 diagnostic rapid antigen testing. This definition excludes schools located in Philadelphia County.

“Authorized Test”: point of care diagnostic rapid antigen test for SARS-CoV-2 authorized by the Food and Drug Administration (FDA) and distributed to an Authorized School by the Department’s Authorized Vendor.

“Authorized Vendor”: an entity approved by the Department to offer COVID-19 diagnostic testing support services in Authorized Schools.

“Department”: the Department of Health of this Commonwealth.

“School”: any public or non-public pre-K-12 school, charter school, career and technical center (CTCs), or intermediate unit (IU). This definition excludes schools located in Philadelphia County.

Section 2: Submission of Statement of Assurances

- A. Before a School is authorized to obtain Authorized Tests and perform diagnostic rapid antigen testing pursuant to this Order, the School must complete and submit a Statement of Assurances to the Department. The required Statement of Assurances is attached to this Order as Appendix A and is hereby incorporated by reference.
- B. The Statement of Assurances must be completed and signed by an individual authorized to bind the School to the terms outlined in the Statement of Assurances, such as the superintendent or executive director.
- C. A completed Statement of Assurances must be submitted to the Department at RA-DHK12COVIDTEST@pa.gov.
- D. Upon submission and receipt of the completed Statement of Assurances, the School will be deemed an Authorized School, unless otherwise notified by the Department in writing that the Statement needs to be revised.

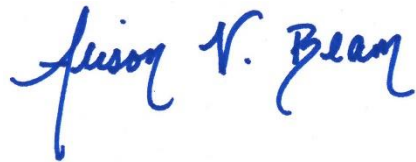
Section 3: Additional Requirements

- A. Authorized Schools must comply with all requirements set forth in the Statement of Assurances.

- B. Authorized Schools must utilize the Authorized Vendor's portal to report all individual diagnostic rapid antigen test results within 24 hours of an Authorized Test being performed.
- C. Through submission of a Statement of Assurances and compliance with this Order, Authorized Schools are eligible to participate as a temporary testing site, pursuant to 42 CFR § 493.55(b)(2), under the Department's CLIA Certificate of Waiver. This will allow Authorized Schools to perform diagnostic rapid antigen testing using Authorized Tests on-site, without needing to apply for a separate CLIA Certificate of Waiver and State Laboratory Permit.
- D. Only Authorized Schools, together with the Authorized Vendor, may administer Authorized Tests pursuant to this Order. Schools that do not complete and submit a Statement of Assurances to the Department must obtain a CLIA Certificate and State Laboratory Permit to conduct diagnostic testing.

Section 4: Effective Date and Duration

This Order shall take effect immediately and shall remain in effect until further notice.



Alison V. Beam,
Acting Secretary of Health