



Order of the Secretary of the Pennsylvania Department of Health Authorizing the Use of Satellite Testing Locations for COVID-19

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. After a brief respite in the summer months, case counts and the number of hospitalizations have been rising throughout the Commonwealth, its surrounding states, and the world. There have been 529,335 cases and 13,392 deaths in this Commonwealth caused by the still present and ongoing pandemic.

Despite the efforts taken to date, the virus continues to spread, and taking action to prevent that spread while continuing to allow for necessary resumption of economic and social activity requires the Commonwealth to take steps to minimize the danger to Pennsylvanians as a result of participating in that activity. In response to these concerns, on November 23, 2020, the Governor and I issued new Orders intended to slow the spread of the disease. These Orders include the [Order of the Governor of the Commonwealth of Pennsylvania for Mitigation, Enforcement, and Immunity Protections, as amended](#) on December 10, 2020, my [Order for Mitigation and Enforcement](#), the Governor's [Order Directing Public School Entities in Counties with Substantial Community Transmission to Attest to Health and Safety Protocols](#), and my [Order](#) of the same name. The Governor and I also each issued a [Limited-Time Stay At Home Advisory](#). See [Limited-Time Stay At Home Advisory of the Governor of the Commonwealth of Pennsylvania](#); [Limited-Time Stay At Home Limited-Time Advisory of the Secretary of the Pennsylvania Department of Health](#). These Orders and Advisories were followed by an updated travel mitigation order issued by each of us. See [Order of The Governor of The Commonwealth Of Pennsylvania Directing Travel Mitigation](#), dated November 20, 2020; [Amended Order of the Secretary of the Pennsylvania Department of Health for Mitigation Relating to Travel](#), dated November 25, 2020. I also issued an [Updated Order Requiring Universal Face Coverings](#), dated November 17, 2020. Finally, on December 12, 2020, the Governor and I each issued limited-time orders intended to further slow the spread of the disease. See [Order of the Governor of the Commonwealth of Pennsylvania Directing Limited-Time Mitigation](#), and [Order of the Secretary of the Pennsylvania Department of Health Directing Limited-Time Targeted Mitigation](#). These limited-time mitigation orders expire on January 4, 2021.

All of these new mitigation orders were issued because of the continuing increase in the number of COVID-19 cases, the increase in hospitalizations that is beginning to make it difficult for hospitals to provide care to persons who need it, increases in the number of COVID-19 cases in long-term care



facilities, and increases in deaths Commonwealth-wide. Despite these efforts, the case numbers and number of deaths continue to rise, and the Commonwealth has seen record high case counts since the end of November.

COVID-19 is a threat to the public's health, for which the Secretary of Health may order general control measures. 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; section 2102(a) of the Administrative Code of 1929, 71 P.S. § 532(a); and the Department of Health's regulation at 28 Pa. Code § 27.60 (relating to disease control measures). Particularly, 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.

Expanding access to diagnostic and surveillance testing is a disease control measure appropriate to protect the public from the further spread of COVID-19. Surveillance testing is used to monitor community- or population-level infectious disease outbreaks. Surveillance testing can also be used to determine the effectiveness of mitigation measures and community interventions such as physical distancing.¹ Increasing the availability of rapid diagnostic and surveillance testing in schools will provide communities across the Commonwealth another tool to better contain the spread of COVID-19 and enable school staff and students to participate in important public health surveillance efforts. These efforts will support the safety of the community and provide continuous information on the spread of disease.

Accordingly, on this day, December 17, 2020, to prevent and control the spread of disease, I hereby order:

Section 1: Definitions

"Authorized Test" - Point of care diagnostic test for SARS-CoV-2 authorized by the Food and Drug Administration (FDA) and administered to students or staff of a Satellite Testing Location.

"Health care professional" - An individual licensed or certified to provide health care services in the Commonwealth and authorized by the appropriate licensing or certification board, agency, or organization to perform specimen collection and administer Authorized Tests.

"Oversight Laboratory" - A not-for-profit or local government laboratory with a valid Clinical Laboratory Improvement Amendment (CLIA) Certificate and State Laboratory Permit.

¹ Additional information on surveillance testing is available in Definitions of Diagnostic, Screening and Surveillance Testing for SARS-CoV-2, <https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html>.



“Satellite Testing Location” - A school or school administrative building where Authorized Tests may be performed, pursuant to this Order, under the supervision of an Oversight Laboratory and where testing supplies for use and Authorized Tests performed at the location may be stored.

“School” - A public and non-public pre-K-12 school, charter school, career and technical center (CTC), or intermediate unit (IU).

Section 2: Satellite Testing Location Operation Requirements

- A. An Oversight Laboratory may operate Satellite Testing Locations in the Commonwealth if all of the following conditions are met:
1. Each Satellite Testing Location has been approved as a location where testing may be performed under the Oversight Laboratory’s CLIA Certificate.
 2. The Oversight Laboratory has confirmed that each Satellite Testing Location has been approved to participate as a Satellite Testing Location by the chief school administrator and the school governing body.
 3. The Oversight Laboratory has determined that the facility of each Satellite Testing Location is suitable to operate as a Satellite Testing Location.
 4. The Oversight Laboratory has confirmed that one or more health care professionals will be on the premises of the Satellite Testing Location at all times when Authorized Tests are being offered.
 5. The Oversight Laboratory will ensure the testing supplies and Authorized Tests are stored and administered in accordance with the manufacturer’s instructions.
 6. The Oversight Laboratory has established a mechanism to provide all results of all Authorized Tests performed at all Satellite Testing Locations to the Department within 24 hours of the results being available at the Satellite Testing Location.
- B. If an Oversight Laboratory meets the conditions specified in Subsection A, prior to operating a Satellite Testing Location, the Oversight Laboratory shall provide the Department with a copy of its revised CMS-116 form which shows the name and address of all Satellite Testing Locations the Oversight Laboratory intends to operate. The Oversight Laboratory shall submit with the form a cover letter stating that the Oversight Laboratory intends to operate Satellite Testing Locations at locations identified on the form, confirming that the Oversight Laboratory has met the conditions in Subsection 2A of this Order, and including contact information for a person or persons responsible for overseeing the Satellite Testing Locations operated by the Oversight Laboratory.
- C. An Oversight Laboratory may begin to operate Satellite Testing Locations identified on its CMS-116 form upon notice to the Department under Subsection B.
- D. If an Oversight Laboratory intends to operate one or more Satellite Testing Locations at additional locations, the Oversight Laboratory must meet the conditions specified in



Subsection A and provide the information specified in Subsection B to the Department prior to operating any additional Satellite Testing Location(s).

- E. Only individuals authorized under CLIA to perform the Authorized Tests may administer the Authorized Tests.
- F. Only Authorized Tests and necessary testing supplies for Authorized Tests may be stored and administered at a Satellite Testing Location.

Section 3. Effective Date and Duration

This Order is effective at 12:01 am on December 17, 2020 and will remain in effect until further notice.

A handwritten signature in black ink, appearing to read 'RLV MD'. The signature is written in a cursive, flowing style.

Rachel Levine, MD
Secretary of Health