

ORDER OF THE SECRETARY OF HEALTH REQUIRING ALL PERSONS SUBMITTING,  
PERFORMING OR RECEIVING RESULTS OF AN ANTIGEN TEST FOR SARS-CoV-2

The 2019 novel coronavirus (COVID-19) is a contagious disease that spreads rapidly from person to person throughout 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 sickened 49 individuals in this Commonwealth with an illness now known as Multisystem Inflammatory Syndrome in Children (MIS-C). As of October 13, 2020, there have been 174,646 cases and 8,384 deaths in this Commonwealth caused by the still present and ongoing pandemic.

Earlier in the pandemic, I issued an order directing life-sustaining businesses to institute mitigation measures to protect the safety of employees and customers. *Order of the Secretary of the Pennsylvania Department of Health Directing Public Health Safety Measures for Businesses Permitted to Maintain In-person Operations*, dated April 15, 2020. The Department of Health (Department) also issued guidance to health care providers in the form of Health Care Alerts (HANs) regarding isolation and quarantine, intended to allow for the continuation of life-sustaining health care services in the midst of the pandemic. Now, with the measured reopening of the Commonwealth, the *Order of the Governor Regarding the Closure of All Businesses That Are Not Life Sustaining*, dated March 19, 2020, *as amended*, and my *Order Regarding the Closure of all Businesses That Are Not Life Sustaining*, dated March 19, 2020, *as amended*, have been suspended. The pandemic continues to spread, however, 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 ensure that participation in those activities contributes as little as possible to endangering the people of the Commonwealth.

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 of 1955 ("the Act") 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). Particularly, the Department of Health 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.

To slow the spread of COVID-19, the Department and Pennsylvania health care providers and practitioners utilize point-of-care antigen tests to allow for testing in circumstances where quick results can inform the response to the disease, for example, in congregate care settings like nursing

homes and prisons. The Department has received and expects to continue to receive shipments of point-of-care antigen tests from the federal government for these purposes, some of which may be destined for use by entities providing health care services who are not typically responsible for reporting disease test results. In fact, some health care providers, practitioners, or other entities may already have received these antigen tests. While some, for example, university and college student health centers, will be required by federal and state laboratory regulations to have or partner with traditional reporting entities, *i.e.*, laboratories, in order to provide this testing, the Department is utilizing this Order to reinforce already existing reporting requirements, particularly for those who have not routinely reported cases under the Act and regulations. COVID-19 is a reportable disease pursuant to the Act and the regulations promulgated thereunder. 35 P.S. §§ 521.2 and 521.4; see also 28 Pa. Code §§ 27.3, 27.4, 27.21a and 27.22.

Accordingly, on this day, October 13, 2020, in order to prevent and control the spread of disease, I hereby order:

Section 1: Definitions:

- A. *Health care practitioner*--An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board.
- B. *Health care provider*--An individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), the Commonwealth, or a political subdivision, or instrumentality (including a municipal corporation or authority) thereof, that operates a health care facility.
- C. *Clinical laboratory*--A laboratory for which a permit has been issued to operate as a clinical laboratory under the Clinical Laboratory Act ([35 P. S. §§ 2151--2165](#)).

Section 2. Reporting of Antigen Test Results

- A. A health care practitioner or health care provider, that is submitting a specimen for antigen testing, performing antigen testing or receiving the result of an antigen test is required to:
  - i. When submitting to a laboratory for processing, include with the specimen all of the information required by the Department in HAN 495 (relating to providing demographic variables as part of laboratory submission forms).
  - ii. Report all antigen test results in accordance with the law and the direction of the Department as defined in HAN 531

(relating to guidance for reporting point of care SARS-CoV-2 test results).

- B. A clinical laboratory that is performing antigen tests shall report all test results in accordance with the law and the direction of the Department.

Section 3. Effective Date and Duration:

This Order is effective at 12:01 a.m. on October 15, 2020 and will remain in effect until further notice.

A handwritten signature in black ink, appearing to read "RLV MD".

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Rachel L. Levine, MD

Secretary of Health