

COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF HEALTH

July 31, 2020

Re: Reminder of Obligation to Report COVID-19 Test Results

Dear Laboratories:

I sincerely want to thank you again for all the work you have been doing during these unprecedented times.

Throughout this pandemic, the Commonwealth has had to deal with many challenges, including a lack of specimen collection supplies and reagents, a lack of workers to get the job done, or the stress and emotional toll that this virus has put upon many of our residents. We have also had to make many difficult decisions in trying to contain and mitigate this virus. In order to make these decisions, we need the most accurate and timely data to ensure the safety and well-being of the citizens of this Commonwealth.

All laboratories providing testing for Pennsylvania must have a Pennsylvania Clinical Laboratory Permit issued by the Department of Health, and a federal Clinical Laboratory Improvement Amendments (CLIA) certificate from the Centers for Medicare and Medicaid Services (CMS). You can find further information regarding the Pennsylvania Clinical Laboratory Act and the Clinical Laboratory Improvement Amendments here.

As we see more laboratories coming on board to assist with COVID-19 testing, we have been experiencing issues with delayed reporting or lack of reporting of COVID-19 test results to the Department of Health. I cannot express how important it is that the Department receive all COVID-19 test results within 24 hours of test completion via online key entry or electronic lab reporting (ELR). This is a requirement of state disease reporting regulations (28 Pa. Code § 27.2, Title 28, Chapter 27). Failure to comply could result in revocation of your lab's Pennsylvania Clinical Laboratory Permit, as well as civil monetary penalties for noncompliance with the Pennsylvania Clinical Laboratory Act and the Department's regulations. Faxes and other forms of paper reporting for most conditions, including COVID-19, are not permitted from laboratories. Not only is electronic reporting required, but it is an integral part to our pandemic response. In order to mitigate the spread of this virus and avoid any further statewide closures, we must have this data, and it must be as complete as possible and submitted in a timely manner.

Please ensure that your laboratory is in full compliance and is reporting all results without delay. If you have any questions regarding a lab permit, please email <u>RA-DHPACLIA@pa.gov</u>. If you have any questions regarding ELR, please email <u>ra-dhnedss@pa.gov</u>.

Many of you are already compliant with the requirements and we thank you for your timely reporting of laboratory results. We appreciate your time and dedication to ensuring Pennsylvanians are safe.

Sincerely,

Rachel L. Levine, MD Secretary of Health

Commonwealth of Pennsylvania

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