pennsylvania
DEPARTMENT OF HEALTH

November 22, 2020

COVID-19 Laboratory Testing
Frequently Asked Questions

Q1: Can an employer or school purchase point of care (POC) tests to test their staff and/or students?
A1: Yes, the Pennsylvania Department of Health (DOH) does not regulate who can **purchase** tests, but, all COVID-19 tests must be **performed** by a laboratory or entity that has (1) a Pennsylvania Clinical Laboratory Permit issued by the DOH Bureau of Laboratories (BOL) and (2) a Clinical Laboratory Improvement Amendments (CLIA) Certificate issued by the Centers for Medicare & Medicaid Services (CMS).

Q2: What is a CLIA Certificate?
A2: CMS regulates all laboratory testing performed on human specimens for diagnostic, prevention, or treatment purposes. If a facility performs testing for these purposes, they must apply for and obtain a CLIA Certificate. There are four types of CLIA Certificates:

- Certificate of Waiver – laboratories performing only waived tests
- Certificate of Provider-Performed Microscopy Procedures – laboratories performing limited provider-performed microscopy procedures
- Certificate of Compliance – laboratories performing nonwaived or moderate and/or high complexity tests
- Certificate of Accreditation – laboratories that are accredited by a private accreditation organization approved by CMS. These laboratories perform nonwaived or moderate and/or high complexity tests.

Q3: How do I know if a test in considered waived or moderate/high complexity?
A3: The U.S. Food & Drug Administration (FDA) reviews and approves all clinical laboratory tests for use. As a part of that review, FDA will assign the test complexity. FDA maintains a CLIA Database where you can search for specific tests to determine their assigned test complexity. The FDA also has a page which lists all COVID-19 tests that have been issued an Emergency Use Authorization (EUA).

Q4: How much does a Pennsylvania Clinical Laboratory Permit and CLIA Certificate cost and where and how do I apply?
A4: There is a $100 filing fee to apply for a State Laboratory Permit. The Pennsylvania Clinical Laboratory Permit Application for In-State Laboratories can be found on DOH's website here.

The CLIA Application for Certification can be found on the CMS website here. CMS will bill the laboratory separately once the application has been processed. CLIA fees vary depending on the type of certificate and/or the annual volume of testing performed.

When applying, the following items must be mailed to the Bureau of Laboratories, PO Box 500, Exton, PA 19341:

- A completed and signed PA Clinical Laboratory Permit Application;
- A check or money order for $100, payable to the "Pennsylvania Department of Health;"

- A completed and signed CLIA Application (this application must indicate the type of COVID-19 test that will be administered); and
- Copies of the laboratory director's qualifications (including a copy of the director's current PA medical license and CV).

For additional information, please see Understanding Clinical Laboratory Regulations in Pennsylvania.

For any additional questions, you can email RA-DHPACLIA@pa.gov.

Q5: What are the minimum qualifications in Pennsylvania for a director of a laboratory applying for a Pennsylvania Clinical Laboratory Permit and CLIA Certificate?
A5: An individual serving as a director of a clinical laboratory must hold a doctor of science degree or its equivalent in the basic sciences of chemistry, biology or microbiology or a doctoral degree in public health, medicine, osteopathy, pharmacy, dentistry, or veterinary medicine from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Pennsylvania Department of Education. In addition, the individual must have had two years' experience in a laboratory acceptable to DOH or be certified by the American Board of Pathology, American Osteopathic Board of Pathology, American Board of Microbiology, American Board of Bioanalysis, American Board of Clinical Chemistry, or other national accrediting board in laboratory specialties acceptable to DOH. The qualifications for a director of a laboratory can be found in Pennsylvania's regulations governing Clinical Laboratories. Please note, CLIA has additional, more stringent requirements for an individual serving as the director of a laboratory performing moderate and/or high complexity testing.

Q6: Can a laboratory director oversee more than one laboratory?
A6: Under the regulation at 28 Pa. Code § 5.22(f), no person may act as a director of more than two clinical laboratories. However, the DOH BOL does grant exceptions to this regulation on a case-by-case basis. If the exception request is approved, then there is no limit on the number of CLIA-waived laboratories a laboratory director may oversee. However, a laboratory director can oversee no more than five moderate/high complexity laboratories as per the CLIA requirements under §493.1407 of Title 42.

Q7: Does a laboratory director need to be present in the laboratory every day?
A7: The regulation at 28 Pa. Code § 5.22(g) requires that a director be present for a reasonable period of each working day in each laboratory for which they are a director. However, DOH realizes that this may not be realistic in some situations. In those situations, the laboratory director must be able to get to the laboratory quickly if there is a problem; therefore, the laboratory director should be within reasonable commuting distance to the laboratory. The DOH BOL may ask for a written statement from the director asking how the director will ensure that he or she is able to meet this requirement, provide oversight of the laboratory in his or her absence, or both. This is handled on a case-by-case basis.

Q8: What if a laboratory needs to change something on an existing State Laboratory Permit and CLIA Certificate?
A8: A Change of Status Form must be submitted to the DOH BOL if any changes need to be made, including:

- Change of laboratory director
- Change of address
- Change of laboratory name
- Change of ownership

- Change of federal tax ID number
- Change of State Laboratory Permit type
- Change of CLIA Certificate type
- Change of test menu
- Laboratory is closing or discontinuing all clinical testing

The laboratory will be notified in writing once the change(s) have been approved.

Q9: Does a laboratory need to complete a Change of Status Form to add additional test kits/instruments to the test menu?
A9: If the laboratory has already been approved to perform COVID-19 testing using a CLIA-waived test and the laboratory wants to add another type of CLIA-waived COVID-19 test, a Change of Status Form does not need to be submitted. However, if the laboratory has been approved to perform COVID-19 testing using a CLIA-waived test and wants to add testing that is moderate or high complexity, a Change of Status Form must be submitted.

Q10: Can an employer or school purchase tests directly and then engage with a CLIA-certified laboratory to perform the testing?
A10: Based on communication from CMS, an entity, such as an employer or school, has the ability to "partner" with a laboratory with the appropriate CLIA Certificate type. That laboratory would need to agree to have technical oversight and assume liability for the testing performed at a temporary testing site.

A temporary testing site is an entity that is not at a fixed or permanent location at which laboratory testing is performed at various intervals of time. Records, files, and other documents relating to that temporary testing site are kept at the primary site of the laboratory or the laboratory's home base. The equipment, supplies, and reagents are not kept at the temporary testing site. For example, a health care entity that provides screening tests at various locations on different days at different times is a temporary testing site. The equipment, staff and supplies are transported to the testing site on the day of testing prior to patient arrival.

In addition, the director of the partnering laboratory is responsible for compliance with all applicable laws and regulations, including:

- That all tests are ordered by a health care practitioner licensed to practice in Pennsylvania (28 Pa. Code § 5.41(a));
- That each test is validated as required by CLIA requirements;
- That all personnel meet personnel qualifications for the complexity of tests performed (the personnel are listed on the laboratory's CMS-209 Form);
- That all personnel were appropriately trained prior to testing patient specimens;
- That Quality Control is performed and recorded as required;
- That lot numbers of reagents/tests can be related to patient results; and
- That results are reported as required and that all results are reported into PA-NEDSS.

The partnering laboratory must submit a revised CLIA application, updating Section V of the application (Multiple Sites) to indicate that their existing certificate will cover additional temporary testing locations. In addition, the CLIA-certified facility must apply for a permit to conduct screenings at the site.

If testing materials are maintained at the testing site, or tests are performed by staff not employed by the CLIA-certified laboratory, that facility or building is a permanent laboratory location and both a PA Laboratory Permit and CLIA Certificate would be required to perform testing.

Q11: Could a physician's office with a CLIA certified laboratory hire additional licensed professionals to accommodate the need/demand for temporary site testing at multiple different employers or schools?
A11: CLIA does not impose a limit on the number of laboratory personnel a clinical laboratory may employ.

Q12: Is any licensed health care professional permitted to perform the test for the employer or school, or must the health care professional be affiliated with a CLIA-certified or CLIA-waived laboratory?
A12: *Regarding specimen collection*: There are no personnel requirements under the Pennsylvania Clinical Laboratory Act for health care professionals who only collect specimens and send them to a licensed and certified laboratory for testing.

Regarding the testing of the specimen: The employer or school must be appropriately licensed and certified if the testing is occurring at the worksite or school. If testing is being conducted under the auspices of a "partner" laboratory at a temporary testing location as indicated above, the health care professionals performing the testing must be affiliated with the CLIA-certified laboratory.