

FAQs for Laboratories Licensure

Q. What do the letters “CLIA” stand for?

A. “CLIA” stands for the Clinical Laboratory Improvement Amendments Act of 1988. CLIA is a federal regulatory program that monitors the quality of laboratory testing.

Q. Why do I need a State license and a CLIA certificate if I do not have a “laboratory”?

A. Any site where one or more laboratory procedures are performed on patient specimens requires appropriate licensing and certification even if it is only one procedure, done one time per year.

Q. Why do I need two “licenses”, one for the state and another for CLIA?

A. Under Maryland regulations, COMAR Title 10, Subtitle 10, a State license is required if a testing site performs clinical laboratory tests. A site must also meet certain federal operating requirements under 42 CFR Part 493, including having a CLIA certificate.

Q. Why do I need a certificate if I only perform waived tests?

A. A waiver is a level of certification that is issued by the federal government. Waived tests are simple, one-step tests. If a laboratory makes an error while performing a waived test, the patient’s life would not be in serious immediate jeopardy; however, the federal government is still concerned about the quality of all laboratory testing. Therefore, you would need a Certificate of Waiver to perform these tests.

Q. Why am I being billed by CLIA if my current certificate expires a year from now?

A. CLIA typically sends 3 bills, 60 days apart. This timing ensures that the renewal process is complete (including a survey if required) before the current certificate expires, thus avoiding termination from the CLIA program.

Q. Why haven’t I received my certificate from CLIA if I paid my bill several months ago?

A. The federal government usually mails a new certificate approximately 30 days before the current certificate expires. See the previous question.

Q. How can I renew my certificate if I have not received a renewal notice from CLIA?

A. CLIA does not send renewal notices. They only send bills. Any changes to the list of tests performed must be sent to the Office of Health Care Quality.

Q. How long is a CLIA certificate valid?

A. A CLIA certificate is valid for 2 years.

Q. Why have I received a renewal from the Office of Health Care Quality, Laboratory Licensing Unit and my CLIA certificate is not due for renewal?

A. The Office of Health Care Quality is the State licensing agency and CLIA is the Federal regulatory program.

Q. How much does a State license and CLIA certificate cost?

A. The cost of your license and certificate is based on two factors: the types of tests that you perform and the number of tests that you perform each year. You must submit a completed application for a State license and an initial application fee. You will receive separate bills for your State license and CLIA certificate.

Q. Where can I get help concerning laboratory licensure and certification in Maryland?

A. Laboratory Licensure Program

Main number 410-402-8025

Toll-free 877-402-8202

Fax 410-402-8213

Q. Do I need a Maryland permit if my tissue bank is located in another state?

A. Yes. Under Maryland regulations, COMAR Title 10, Subtitle 50, a Maryland State license is required for any Tissue Bank, in-state or out-of-state, that provides a service to a person in Maryland.

Q. Do I need a separate permit if the hospital in which my tissue bank is located in has a license for the laboratory?

A. That depends on whether the tissue bank is being directed by the same person that is designated as the Director of the hospital's laboratory. Tissue banks are sometimes part of the operating room and are directed by a person other than the Director listed on the hospital's laboratory license. If the Director of the hospital laboratory is not actively taking part in the direction of the tissue bank, a second permit must be issued to the person who is directing the tissue bank. This person, of course, must meet all of the requirements that are listed in the regulations for tissue bank directors.

Q. Do I need a permit if I have not yet started testing patient samples?

A. No. A laboratory may establish its facilities and its policies and procedures before applying for a laboratory permit. A provisional permit is obtained before patient testing begins. However, a provisional permit cannot be renewed after 180 days. A successful survey of the laboratory must take place before the permit expires. A survey cannot be performed until patient testing is occurring. So applying for a provisional permit when the laboratory facilities, and policies and procedures are not yet in place can result in the provisional permit expiring prior to the conclusion of a successful survey. The entire application process then comes to a halt with the expiration of the provisional permit.

Q. Do I need a permit to hold cholesterol screenings at public places such as a shopping mall, church or place of business?

A. Yes. Once the laboratory has the permit it needs to complete a Cholesterol Site Approval Request for each screening event. Then, the site approval is displayed in a public place at the testing site throughout the testing event. Such events are periodically surveyed by the Office of Health Care Quality to ensure compliance.