

A blue-tinted photograph of laboratory equipment, including a microscope, several Erlenmeyer flasks, and test tubes, arranged on a lab bench.

CLIA Information for Ohio Schools



What is CLIA?

CLIA is an acronym for [Clinical Laboratory Improvement Amendments](#). This national program is managed by Centers for Medicare & Medicaid Services (CMS) working with state partners. “The objective of the CLIA program is to ensure quality laboratory testing.” At the Ohio Department of Health (ODH), “the [Laboratory Certification Program](#) works to ensure Ohioans receive accurate, cost-effective clinical laboratory testing as a part of their health care. Clinical laboratory testing directly or indirectly affects every Ohio resident from pre-cradle to grave.”

What is considered a laboratory under CLIA?

The ODH Laboratory Certification Program “monitors more than 13,400 clinical laboratories located in ambulances, ambulatory surgical centers, ancillary test sites, assisted living facilities, blood banks, community clinics, comprehensive outpatient rehab facilities, end stage renal disease dialysis facilities, federally qualified health centers, health fairs, health maintenance organizations, home health agencies, hospice facilities, hospitals, independent laboratories, industrial facilities, insurance facilities, intermediate care facilities for individuals with developmental disabilities, mobile laboratories, pharmacies, physicians’ offices, plasmapheresis centers, prisons, public health laboratories, rural health clinics, **schools/student health services**, skilled nursing facilities, tissue banks, and universities.”

What laboratory tests done in schools fall under CLIA?

Ohio schools serve students with a wide variety of health needs. Some students come to school with diabetes, for example. The typical student with diabetes will need to conduct blood sugar/glucose testing during the school day and may need to do a urine test for ketones on occasion. Both of these are considered laboratory tests under CLIA.

Does my school need to have a CLIA certificate?

“CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. [CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing.](#)”

While your school must comply with CLIA requirements, you may be eligible for a CLIA Certificate of Waiver.



What is a CLIA Certificate of Waiver?

If your school only performs laboratory tests that are considered waived tests, you may apply for a Certificate of Waiver.

[“NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.”](#)

What are waived tests?

“As defined by CLIA, waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.” [The Food and Drug Administration \(FDA\) determines which tests meet these criteria](#) when it reviews manufacturer’s applications for test system waiver.” For a list of waived tests sorted by name, visit the FDA website at: CLIA – [Currently Waived Analytes](#).

Some waived tests currently on the list that are commonly conducted in schools includes:

- [GLUCOSE MONITORING DEVICES \(PRESCRIPTION USE ONLY\).](#)
- [GLUCOSE.](#)
- [KETONE, URINE.](#)
- [URINE QUALITATIVE DIPSTICK KETONE.](#)

What must we do if we conduct waived tests?

“For waived testing, CLIA requires that you:

- Enroll in the CLIA program by obtaining a certificate;
- Pay the certificate fee every two years;
- Follow the manufacturer’s instructions for the waived tests you are performing; and
- Notify your State Agency of any changes in ownership, name, address or Laboratory Director within 30 days, or if you wish to add tests that are more complex.”

How do you obtain a CLIA Certificate of Waiver?


Instructions on how to obtain CLIA Certificates of Waiver may be found on [online](#). You must complete the [application](#). In Ohio, the Ohio Department of Health manages the CLIA program; you may contact them by [email](#) with questions.

After your Certificate of Waiver is processed and approved, CMS will invoice you for the \$248 fee. The Certificate of Waiver must be renewed on a biennial basis.

Once a Certificate of Waiver is received, you may only conduct laboratory tests in the [waived category](#).

Do we need one Certificate of Waiver for each school, or can we get one for the whole district?

There are several considerations regarding the decision to get one CLIA Certificate of Waiver for the entire school district versus getting one per school building.



Certainly, it is typically less expensive to get one per district rather than one per building. In order to qualify for a multi-site CLIA certificate, you must meet one the exceptions listed below:

- “If your testing location changes, such as with **mobile units** providing laboratory testing, health screening fairs, or other temporary testing locations, the testing may be covered under the certificate of the designated primary site or home base, using its address.
- “If you are performing limited public health testing, you may file a single application to cover multiple locations. Limited public health testing is defined as not-for-profit or Federal, State or local government laboratories that engage in limited testing (not more than a combination of 15 moderately complex* or waived tests per certificate).”

What is a Director?

When applying for a CLIA Certificate of Waiver, a laboratory director must be identified. There are no particular qualifications to be listed as the “laboratory director.” The person listed is attesting that they are responsible for the training and supervision of school staff performing the testing and that the manufacturer’s instructions for the waived test are being followed. Resources such as the CDC’s [Ready? Set? Test!](#) Can be used to support correct testing techniques. [Free online training](#) is also available.

Responsibilities for the person identified as the [laboratory director](#), is responsible for the overall operation and administration of the laboratory. Other activities include ensuring:

- The laboratory develops and uses a quality system approach to testing.
- The physical and environmental conditions of the lab are adequate and appropriate for the testing.
- The employee environment is safe from physical, chemical, and biological hazards and safety and biohazard requirements.
- A sufficient number of educated and trained staff are employed.
- All new test procedures are reviewed.
- There is effective communication in place.
- Notification of the Ohio Department of Health of any change in laboratory director.
- The laboratory is customer-focused.

References

[Laboratory Director Responsibilities.](#)

[Ohio Department of Health CLIA website.](#)

[CLIA Application for Certification.](#)

[How to obtain a CLIA Certificate of Waiver.](#)

Moran, V., Buktas, M. (2022). [Laboratory Testing in the School Setting: Are You CLIA Compliant?](#)

Journal of School Nursing. National Association of School Nurses.

[Ready? Set? Test!](#) Booklet.

[Ready? Set? Test!](#) Training.