

## **CLIA Certificate of Waiver Frequently Asked Questions (revised 2/15/2022)**

### **What is a CLIA Certificate of Waiver?**

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability and timeliness of test results regardless of where or by whom the test was performed. The CLIA requirements are based on the complexity of the test and the type of laboratory where the testing is performed. Certain tests qualify for waived laboratory testing if they are “simple laboratory examinations and procedures that have an insignificant risk of erroneous error.” The Food and Drug Administration (FDA) determines which tests meet these criteria when it reviews manufacturer’s applications for test systems.

### **Do schools need CLIA Certificate of Waivers?**

Yes. School district health services are considered a “laboratory” for the purpose of CLIA, if they or school staff, are performing testing on body fluids (ex. blood, saliva, or urine) or other body materials for the purpose of providing information for the diagnosis, prevention, or treatment of disease or to make health assessments. For example, if school health personnel (registered nurse, licensed practical nurse, or unlicensed assistive personnel) are assessing students’ blood sugar levels (blood) to determine the course of action to take (insulin dosage, grams of carbohydrates to eat, modify lunch or activity schedule, etc.) then they are considered a laboratory facility performing a laboratory test. It does not matter if the student is using their own equipment to perform the test. The test result (blood glucose level) is being used to determine treatment or what to do.

### **If a school district is “contracting” nursing services via a local public health department or clinic may the district use the local public health department’s or clinic’s CLIA Certificate?**

Generally, no. Staff performing the testing would need to be employed by the “owner” of the certificate, in this case the local public health department or clinic.

CLIA certificates are not only a requirement for COVID-19 testing. CLIA Certificates of Waivers are required for other laboratory testing done in schools. If staff within the school, that are not associated with the local public health department or clinic, are performing testing (such as a health aide checking blood glucose levels) then a CLIA certificate is needed by the school. If there is not a local public health department nurse or school nurse contracted via a clinic onsite to perform all testing, then the school would need the CLIA certificate. If a local public health department or clinic contracted employee will provide all testing, at all school sites, at all times within the school district, the local public health department or clinic must obtain approval from the Department of Health Services to add the school(s) to their certificate.

### **Is the requirement for CLIA certificates new and only related to COVID?**

The need for CLIA Certificates of Waivers to perform many of the laboratory tests done in schools to manage students' chronic health conditions is not new. The use of COVID-19 testing in schools highlighted the need for such certificates. The cost of obtaining a CLIA waiver intended for COVID testing could be reimbursable with federal and state COVID funding. (<https://dpi.wi.gov/cares/governors-emergency-education-relief-geer-grant-program>). As schools apply for CLIA Certificates of Waiver it behooves them to list all the laboratory procedures/tests on the application. CLIA Certificates of Waiver must be renewed every two years.

### **If we are applying for a CLIA certificate using varying testing equipment provided by individual students, what should we list under the manufacturer's column on page 3 of the waiver? (Answer updated 2/15/2022)**

It is required to list the specific tests for which a school or district is applying for a Certificate of Waiver on the initial application. (See answer above.) All tests that the FDA has determined to qualify for waived laboratory testing may be performed if a school or district has a CLIA certificate. You may use the term "various manufacturers" on the form for testing equipment provided by individual students.

It is important to note that the regulations do require the person performing the test to follow the manufacturer's instructions. The instructions for use must be accessible and followed for each type and brand of test (i.e., brands of COVID-19 tests, brand of ketones tests, brand of glucometer) used for testing.

### **If we are provided or procure a different brand of COVID-19 test kits, do we need to resubmit our application? (New question 2/15/2022)**

No. If the federal CLIA application the school or district submitted listed specific products (such as BinaxNow) it is not necessary to resubmit or amend the application if you start using a different brand.

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### **Is there a statewide CLIA Certificate of Waiver?**

Certificate of Waivers are approved by the Center for Medicare and Medicaid Services. In Wisconsin the Department of Health Services [Division of Quality Assurance](#) is the contact for CLIA program. The Department of Public Instruction does not approve, nor hold a statewide CLIA certificate for schools. School districts may apply for one certificate for multiple schools/locations if they are not applying for more than a combination of 15 "moderate or waived complexity tests."

### **What qualifications does the laboratory director need?**

There are no particular qualifications to be listed as the “laboratory director” on the CLIA Certificate of Waiver application. 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. Laboratories with a Certificate of Waiver are not subject to a routine inspection under the CLIA Program but may be surveyed in response to a complaint or if they are performing testing that is not a waived complexity level. For further information on following manufacturer’s instructions see: <https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf>

### **Where else can I find information on CLIA certificates?**

The Department of Health Services has provided information on CLIA waivers. See [Laboratory Testing Certification Requirements for Schools and Colleges](#) for more information. Additional resources are listed below.

### **Where is the CLIA application form?**

The Application for a CLIA Certificate-Form CMS-116 is located at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How to Apply for a CLIA Certificate International Laboratories>

## **Resources**

Centers for Medicare and Medicaid Services CLIA webpage: [https://www.cms.gov/regulations-and-guidance/legislation/clia?redirect=/clia/06 how to apply for a clia certificate international laboratories.asp](https://www.cms.gov/regulations-and-guidance/legislation/clia?redirect=/clia/06%20how%20to%20apply%20for%20a%20clia%20certificate%20international%20laboratories.asp)

Centers for Medicare and Medicaid Services and Department of Health and Human Services: *How to Obtain a CLIA Certificate of Waiver* <https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf>

Center for Disease Control (CDC) guidance booklet on performing waived laboratory testing: <https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf>

Department of Health Services *What you need to know about CLIA Certification & BinaxNow Tests recorded webinar*: <https://player.vimeo.com/video/540809024>