CLIA: Clinical Laboratory Improvement Amendments of 1988
School System Compliance

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 require anyone performing even **one** test, including waived procedures, on ". . . 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 be subject to CLIA and to register for a CLIA certificate. As a result, all institutions providing any lab procedures are required to obtain this certificate as evidence of assuring compliance with federally monitored guidelines for safe, accurate laboratory procedures. Medically ordered student procedures, such as finger sticks for blood sugar, are defined as laboratory procedures, even when using the student's equipment.

In order to avoid the requirement to comply with all laboratory regulations under CLIA, school systems providing staff to assist students with lab procedures, that have been identified as eligible to be 'waived' and are based on a physician's order, must obtain an appropriate CLIA Certificate of Waiver. The school system should identify an individual to oversee CLIA compliance for all defined services in the school. An LEA will pay an application fee for a Certificate of Waiver that will cover the school system. School Based Health Centers and/or telehealth services are separate entities and individual determinations must be made related to what is needed to maintain CLIA compliance.

Lab procedures included in the CLIA waiver category that are commonly done in schools include urine ketone testing, blood glucose monitoring and COVID-19 rapid antigen tests. These procedures are considered to be inherently accurate and risk free to the patient.

The requirements of the waiver process and the ongoing monitoring are outlined in the following information:

- Apply for a Certificate of Waiver from the North Carolina Division of Facility Services for the school district.
- Pay the certificate of waiver fee every two years.
- Follow the manufacturer's instructions for the waived tests that are performed.
- Notify the State Agency of any changes in ownership, name, address, or 'Laboratory Director' within 30 days, OR, to add tests.
    - Implementation of COVID-19 rapid antigen testing requires an entity to have a current and up to date CLIA certificate of waiver which may require submitting an updated application that includes the specific waived test name/manufacturer of the rapid test on Form CMS-116.
    - A school district may partner with an entity that has a CLIA certificate that can be extended to include the district or school.
    - DHSR Compliance Consultants are available to assist. Forms and contact information are available at the link below.

Resources for more information:

https://info.ncdhhs.gov/dhsr/ahc/clia/index.html

- NC DHHS, NC Division of Health Care Service Regulation- CLIA contact information

https://www.cdc.gov/hiv/testing/nonclinical/clia.html

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- How to obtain a CLIA certificate of waiver.

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf

- Brochure about how to obtain a certificate of waiver.

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf

- This link provides the most current list of waived tests.