HOW TO GET CERTIFICATION FOR IN-SCHOOL COVID-19 TESTING

WHAT IS CLIA? WHY WOULD MY SCHOOL NEED A CLIA CERTIFICATE?

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 are federal regulatory standards that ensure patient laboratory test results are accurate, reliable, and timely. CLIA applies to testing performed on humans, including testing performed in schools.

A school, school district, county or state needs a CLIA certificate to perform on-site COVID-19 testing. This certificate shows that a school meets CLIA quality and safety requirements to follow test manufacturers’ instructions and provide accurate results.

WHICH CLIA CERTIFICATE DOES MY SCHOOL NEED?

On-site COVID-19 tests generally require schools to get a Certificate of Waiver. These tests are generally of low complexity and therefore most schools would only need a Certificate of Waiver.

A Certificate of Waiver costs $180. If a school continues to perform testing and pays the certificate fee, the certificate will be automatically renewed every 2 years. CMS recommends keeping a copy of the CLIA certificate on file at each school nurse’s office or on-site testing location.

HOW DOES A SCHOOL APPLY FOR A CLIA CERTIFICATE?

A school can follow the quick start guide and complete the CMS-116 Application to get a CLIA certification. Completed forms should be sent to the State survey agency for the school’s state.

DOES THE GOVERNMENT INSPECT SCHOOLS FOR CLIA COMPLIANCE?

A facility that holds a CLIA Certificate of Waiver is not usually inspected, but it can be if a complaint is received. CLIA inspectors can make in-person visits to schools and other facilities to make sure they meet CLIA requirements. Please refer to the How To Obtain A Certificate of Waiver brochure for additional information.

During the COVID-19 public health emergency, inspectors will also ensure schools and other facilities are reporting COVID-19 test results as required. Generally, CMS is recommending that the inspections related to test reporting be done remotely, if possible.

For questions related to COVID-19 testing in schools, please email LabExcellence@cms.hhs.gov.