



Laboratory Testing Certification Requirements for Schools and Colleges

Wisconsin Department of Health Services / Division of Quality Assurance
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Purpose

Schools and colleges are required to obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate to perform laboratory testing. Examples of laboratory testing that may be performed in an educational setting are SARS-COV-2 (COVID-19), blood glucose, rapid Streptococcus A, etc. All laboratory testing must be performed in a CLIA certified setting. Providers found to be performing such testing without a CLIA certificate are in violation of the federal CLIA regulations and subject to possible federal enforcement actions.

Requirements

The definition of “Laboratory” at 42 CFR §493.2 means a facility that examines materials derived from the human body for the purpose of providing diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances in the human body. Therefore, any entity or facility performing testing and/or screening where the test results are used for the purpose of referring, offering, or making available to the test subjects treatment or a diagnosis, must obtain an appropriate CLIA certificate.

CLIA Certificate of Waiver

If you would like to perform laboratory testing please submit your Center for Medicare and Medicaid Services (CMS)-116 CLIA application to DHSDQACLIA@dhs.wisconsin.gov. The application fee for a Certificate of Waiver is a \$180 biennial fee and the invoice will be sent directly from CMS.

Resources

CMS Laboratory Quick Start Guide: <https://www.cms.gov/files/document/laboratory-quick-start-guide-cms-clia-certification.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>

State Agency CLIA Program Contact Information

Application or testing questions may be sent to DHSDQACLIA@dhs.wisconsin.gov or call 608-261-0654.