

# CLIA Certificate Requirements

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## WHAT IS CLIA?

Clinical Laboratory Improvement Amendments (CLIA) of 1988 are federal regulatory standards that apply to all clinical labs which perform tests on humans (except for clinical trials and basic research). CLIA sets standards for clinical laboratory testing to ensure the accuracy, reliability and timeliness of test results regardless of where the test was performed. All facilities that perform such tests must be certified by CLIA.

## DOES WIC REQUIRE A CLIA CERTIFICATE?

Yes. CLIA applies to WIC clinics because we perform a “finger stick” to test hemoglobin levels. However, because the procedure used in WIC is relatively simple and low-risk, WIC qualifies for a **Certificate of Waiver**. Certificates are issued by Centers for Medicare and Medicaid Services (CMS), cost \$248, and are good for 2 years. In Minnesota, they are issued through the CLIA Program, in the Health Regulations Division in MDH.

Generally, a Certificate is required for each clinic location, however, there are some exceptions, including government public health and non-profits.

- If your county Public Health Department, or Tribal equivalent, holds a CLIA Certificate, the WIC program clinics could/should be included on the certificate, and your WIC program **would not need** to obtain a separate certificate.
- If your WIC program is not included on your agency’s certificate, it can be added, using [CLIA Form CMS-116](#), and filling out Section V. to identify multiple sites.

Most MN WIC Programs are covered by their organizations. If you have questions, please contact your State WIC Consultant.

## Reference – Complete Listing of Hyperlinks

[CLIA Form CMS-116 \(https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms116.pdf#:~:text=The%20CLIA%20application%20%28Form%20CMS-116%29%20collects%20information%20about,and%20to%20fulfill%20the%20statutory%20requirements%20for%20CLIA.\)](https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms116.pdf#:~:text=The%20CLIA%20application%20%28Form%20CMS-116%29%20collects%20information%20about,and%20to%20fulfill%20the%20statutory%20requirements%20for%20CLIA.)

*Minnesota Department of Health - WIC Program, 625 Robert St N, PO BOX 64975, ST PAUL MN 55164-0975; 1-800-657-3942, [health.wic@state.mn.us](mailto:health.wic@state.mn.us), [www.health.state.mn.us](http://www.health.state.mn.us); to obtain this information in a different format, call: 1-800-657-3942.*

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