

<p style="text-align: center;">Texas WIC Health and Human Services Commission</p>

Effective June 1, 2002

Policy No. GA:16.0

**Compliance with the Clinical Laboratory
Improvement Amendments of 1988**

Purpose

To ensure that all local agencies (LAs) are in compliance with the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

Authority

42 CFR Part 353; Public Law 100-578

Policy

Each LA shall obtain appropriate CLIA certification. The CLIA Certificate or copy shall be kept on file and available for quality assurance monitoring review.

Procedures

- I. The Patient Quality Care Unit of the Health Care Quality Section of the Department of State Health Services (DSHS) shall be contacted to obtain an application and specific requirements for CLIA certification. All costs pertaining to registration and certification for CLIA are WIC allowable expenditures.
- II. A Certificate of Waiver may be obtained by LAs performing hemoglobin by copper sulfate, HemoCue Hemoglobin System, and/or spun microhematocrit tests. A certificate is valid for a maximum of two years and requires a registration and certificate fee. Laboratories with a Certificate of Waiver are not subject to routine inspections.
- III. WIC LAs not co-located with their parent agency shall apply for their own certification when the parent agency has a high complexity certification.

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- IV. WIC LAs co-located with their parent agency may obtain their own certification, with their Laboratory Director's approval, or choose to continue under the parent agency's certificate.
- V. WIC LAs that perform only waived hematocrit/hemoglobin testing may obtain their own Certificate of Waiver, with their Laboratory Director's approval, or choose to continue under the parent agency's certificate when the parent agency has a moderate complexity certification.
- VI. WIC LAs falling under their parent agency's CLIA certification are subject to any sanctions imposed on the parent agency as a result of routine inspections. If a parent agency's CLIA certification is suspended, limited or revoked and the LA operates under their parent agency's CLIA certification, the LA shall also lose its testing ability.

Guidelines

Guidelines for an application and specific requirements for CLIA certification can be found at <https://hhs.texas.gov/doing-business-hhs/provider-portals/health-care-facilities-regulation/laboratories-clinical-laboratory-improvement-amendments>.