

Jim Doyle
Governor

Karen E. Timberlake
Secretary



State of Wisconsin
Department of Health Services

DIVISION OF QUALITY ASSURANCE

1 WEST WILSON STREET
P O BOX 2969
MADISON WI 53701-2969

Telephone: 608-266-8481
FAX: 608-267-0352
TTY: 888-241-9432
dhs.wisconsin.gov

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DQA Memo 09-040

Supersedes memos 99-013, 00-082 and 03-008

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From: Cremear Mims, Director
Bureau of Health Services

cc: Otis Woods, Administrator
Division of Quality Assurance

For All Facilities Performing Tests on Human Specimens: CLIA Requirements

Under the authority of Section 353 of the Public Health Service Act, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) require **all facilities performing tests on human specimens to be certified to perform these tests.** The regulations that implemented CLIA became effective September 1, 1992.

These regulations also apply to testing performed in facilities without conventional laboratories, such as care and service residential facilities, ambulances, health fairs, home health agencies, pharmacies, end stage renal dialysis facilities, etc.

Collection of blood or other specimens does **not** require CLIA certification. **Testing specimens is regulated and requires a CLIA certificate.**

If employees of a facility, or individuals contracted by the facility, perform testing on human specimens, the facility must have a CLIA certificate. There are four types of CLIA certificates: Certificate of Waiver, Certificate for Provider Performed Microscopy Procedures, Certificate of Compliance, and Certificate of Accreditation. Testing performed in residential health care settings is generally included in the tests allowable under the Certificate of Waiver, e.g., whole blood glucose testing or occult blood testing (stool or gastric).

For questions regarding alcohol and other laboratories, analysts, and the Clinical Laboratory Improvement Amendments (CLIA), you may e-mail the Division of Quality Assurance via dhswebmaildqa@wisconsin.gov or phone (608) 261-0653.

CLIA applications (form CMS 116) are also available via the federal CLIA site at <http://cms.hhs.gov/clia/>.