Regulatory Oversight of Laboratory Testing[1]
Clinical Laboratory Improvement Amendments (CLIA)

CDC Consultation on Rapid HIV Testing
September 10-11, 2002

Executive Summary

Any facility that performs examinations on human specimens is considered a laboratory. All laboratories must be certified under the Clinical Laboratory Improvements Amendments (CLIA) program, administered by the Centers for Medicare and Medicaid Services (CMS). Three types of registration certificate are issued, depending on the complexity of testing performed: high complexity, moderate complexity (with the subcategory of physician-performed microscopy), and waived. The Food and Drug Administration (FDA) categorizes the complexity of laboratory tests at the time of approval. Of the approximately 173,000 laboratories registered with CLIA, it is estimated that 1800 currently perform HIV antibody testing. Most (78%) of the registered laboratories would be ineligible to perform rapid HIV testing if it is categorized as moderately complex.

Laboratories that perform moderate- or high-complexity testing are subject to biennial inspections and must meet more stringent standards for personnel, supervision, quality assurance, and proficiency testing than laboratories that perform waived testing. Waived laboratories are not routinely inspected under CLIA. However, they must agree to allow inspections, and some states do regularly inspect waived laboratories. CLIA requires only that waived laboratories register with the program and perform tests according to the manufacturer's instructions. CLIA's technical requirements for personnel are less stringent for laboratories that perform waived testing than for those that perform moderately complex testing. However, some states set standards for both types of laboratories that are higher than the minimums required by CLIA.

Each laboratory site must obtain its own CLIA certificate, with two exceptions that could allow moderately complex rapid HIV testing in expanded settings (if other requirements for moderate complexity testing are met). Laboratories that are not at a fixed location (e.g., mobile testing units, health fair screening) can operate under the certificate of the laboratory's designated main location. Laboratories at different sites that engage in moderately complex, limited public health testing may be covered under the single certificate of a not-for-profit, federal, state, or local government laboratory. The laboratory holding the certificate would be responsible for the supervision, quality assurance, and proficiency testing required by CLIA.

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[1] Source for most of this summary: DHHS, Office of the Inspector General. *Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program.* August 2001. Report OEI-05-00-00251. Available at: http://www.hhh.gov/oigoei. Update with data current as of October 2001 from the CMS Web site available at: http://www.cms.hhs.gov/clia.

To qualify for waiver, laboratory tests either must be so simple and accurate as to render the likelihood of erroneous results negligible or must pose no reasonable risk of harm to the patient if performed incorrectly. The proposed criteria for waiver currently in effect require that the tests be foolproof and deliver results comparable to those obtained by trained laboratory technicians when the tests are performed by persons with no laboratory experience and no training who have only read the testing instructions (written at a seventh grade reading level).

Concerns about waived testing have been raised by two analyses. The Office of the Inspector General interviewed or distributed written questionnaires to 52 state agencies, and examined data from a pilot program of site visits to a small sample of waived laboratories in Ohio and Colorado. Most of the states voiced concerns that the lack of routine site visits to waived laboratories might adversely affect the quality of testing. The results of the pilot survey indicated that 30%-40% of waived laboratories could not produce a current package insert for tests they performed. However, half of these correctly followed the manufacturer's testing procedure. In Colorado, waived testing practices were also evaluated in laboratories with certificates for moderate- or high-complexity testing, and 40% evidenced the same deficiencies as laboratories with certificates of waiver. However, few similar data are available from other states, because most states do not evaluate waived testing as part of their inspections of moderate- and high- complexity laboratories.

CMS expanded the two-state pilot survey to include 270 (2.5%) waived laboratories in 8 additional states (Arizona, Idaho, Iowa, Massachusetts, Mississippi, New Mexico, New York, and Pennsylvania). Findings were similar: 32% of the labs did not have a current package insert, and 16% did not follow the manufacturer's instructions for performing waived tests. (These deficiencies are also frequently cited during inspections of moderate-and high-complexity labs.) Data from the expanded survey also demonstrated that most of the quality problems were observed in laboratories located in states that do not require licensure (i.e., those that do not provide oversight beyond that required by CLIA.) Neither the Inspector General's survey nor that conducted by CMS collected outcome data. Thus, it is not possible to determine whether the quality problems that were documented with waived testing resulted in inaccurate test results.

The Office of the Inspector General recommended several steps to improve testing at waived laboratories, including increased educational outreach, periodic self-assessment, and random surveys of some waived laboratories each year.