

Laboratories are regulated by the Centers for Medicare and Medicaid Services (CMS) through the Clinical Laboratory Improvement Amendments (CLIA). Under CLIA, labs must validate the tests they perform and adhere to strict quality control and proficiency standards.

Originally enacted in 1988, discussions regarding if or how CLIA should be modernized have periodically occurred over the years. AACC has been actively engaged in these policy debates and has articulated several positions regarding laboratory developed tests (LDTs), Certificate of Waiver (CoW) testing sites, and personnel qualifications:

Regulation of Laboratory Developed Tests

- CLIA should be updated to require laboratories to demonstrate that LDTs are clinically valid for use in medical decisions.
- AACC encourages CMS to credential third-party organizations to review a laboratory's clinical validation data for LDTs.
- AACC urges CMS and its deemed accrediting organizations to ensure that CLIA inspection teams include individuals with specialized method expertise to evaluate LDTs.
- AACC urges CMS to redefine the definition of LDTs to exclude modified tests that do not significantly alter the clinical claims.

Certificate of Waiver Testing

- CMS should resume its CoW Laboratory Project and annually inspect a minimum of two percent of waived laboratories – covering a representative cross-section of decentralized testing sites.
- CoW laboratories should document the quality and reliability of their test results (e.g., through participation in proficiency testing).
- CoW laboratories should continually assure their personnel are properly supervised and trained to consistently and reliably perform clinical laboratory tests necessary for the provision of quality patient care.

Personnel Qualifications

- CMS should not equate a bachelor's degree in nursing as equivalent to a bachelor's degree in the biological sciences under CLIA.
- Alternative pathways—aside from holding a bachelor's degree in biological sciences—should be created (e.g., defined laboratory curriculum, competency exams, certification) for individuals to qualify as testing personnel.
- CMS should retain its current requirements for high complexity laboratory directors

AACC has developed a series of position statements regarding the modernization of CLIA that can be viewed on the association's website.

Position Statements:

- Modernization of CLIA: Laboratory Developed Tests (LDTs)
- Modernization of CLIA: Certificate of Waiver Sites
- Modernization of CLIA: Moderate and High Complexity Testing

For more information, please contact:

Vince Stine, PhD
Senior Director,
Government & Global Affairs
vstine@aacc.org

Evan Fortman
Government Affairs Specialist
efortman@aacc.org