

Preserving Access to Lab Developed Testing

Laboratory developed tests (LDTs) are proprietary tests that clinical labs create for in-house use when a commercial test does not exist or is not appropriate for a particular application or patient population. For example, a lab may develop an LDT to monitor a rare disease or screen for a new designer drug.

LDTs are regulated by the Centers for Medicare and Medicaid Services (CMS) through the Clinical Laboratory Improvement Amendments (CLIA).

Under CLIA, laboratories are required to validate LDTs and adhere to strict quality control and proficiency standards.

LDTs are at the cutting edge of clinical laboratory science and play a vital role in providing quality healthcare in the face of patients' changing medical needs.

CLIA provides robust safeguards; nonetheless, there have been recent efforts to supersede CMS authority and create a duplicative regulatory structure for LDTs within the Food and Drug Administration (FDA).

The Verifying Accurate, Leading-edge IVCT Diagnostics (VALID) Act, introduced in the 118th Congress by Representatives Larry Bucshon and Dianne DeGette, **failed to gain support in Congress due to the significant concerns raised by stakeholders across the medical community.**



The FDA's new proposed rule to regulate LDTs is an attempt to circumvent Congress by unilaterally placing these tests under its authority. This would create a dual, expensive, and potentially contradictory regulatory environment for clinical laboratories, eliminating most labs' ability to perform laboratory developed tests and drastically limiting patients' access to critical laboratory test results.

LDT Reform Belongs where Congress Originally Intended: CLIA

"ADLM advocates for a balanced, evidence-based approach to regulating laboratory developed tests. We must identify what problems we are trying to fix and correct them without hindering scientific advancement or limiting patient access to these innovative, often life-saving tests. We urge the FDA to join us in working within the current regulatory system to advance patient care and prioritize health equity"

- Octavia Peck Palmer, PhD
President, Association for Diagnostics & Laboratory Medicine (formerly AACC)

Our Position:

- CLIA should remain the mechanism for regulating LDTs.
- Duplicative federal regulation will hinder the development of new tests.
- Expanded oversight will force some labs to stop performing LDTs thereby limiting patient access to testing services.

For more information, please contact:

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