

Preserving Access to Laboratory Developed Tests

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).

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.

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



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 116th Congress by Representatives Larry Bucshon (R-IN) and Dianne DeGette (D-CO) would increase the administrative burden and costs on labs performing LDTs without improving patient care. It is expected to be reintroduced in the 117th Congress shortly.

While the increase in the number and complexity of LDTs may warrant a fresh assessment of how they are regulated, any changes should be evidence-based and take place within the existing CLIA oversight structure.

The implications of FDA regulation have been recently demonstrated by the agency's involvement in LDT oversight during the early days of the COVID-19 pandemic. The slow rollout of COVID-19 tests that resulted from FDA inserting itself into the process underscores the fact that imposing additional federal requirements on clinical laboratories can stifle innovation and limit patient access to testing.

In May, Sen. Rand Paul introduced S.1666 the Verified Innovative Testing in American Laboratories (VITAL) Act, which would codify current federal regulations that place oversight of LDTs under the purview of CLIA. AACC supports the VITAL Act.

AACC holds the following positions regarding the appropriate oversight of LDTs:

- 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.

VITAL is needed to protect labs from costly, unwarranted FDA oversight. The slow federal response to expand access to COVID-19 tests is a real-world case study in the devastating effects of the FDA's attempts to over-regulate LDTs.