# The Regulation of Laboratory-Developed Tests

## AAMC Position

The AAMC affirms that it is essential for laboratory-developed tests (LDTs) to be accurate and clinically valid in their use as diagnostics informing treatment decisions for patients. However, we share our academic medical center (AMC), teaching hospital, and physician faculty's concerns that the **regulation of LDTs by the U.S. Food and Drug Administration (FDA) as proposed in the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022 and incorporated into the Senate Health, Education, Labor, and Pensions (HELP) Committee's FDA Safety and Landmark Advancements (FDASLA) Act would interfere with delivering innovative, cutting-edge medical care, negatively impact patients, and mire the development of critical new tests in a costly and laborious regulatory process.** The AAMC joined over 100 stakeholders in a June 16 letter reiterating these concerns, and sent its own letter on June 2.

As the AAMC has consistently communicated, AMCs, teaching hospitals, and the faculty physicians that are performing LDTs every day on the front line of patient care are best able to determine the best way to treat patients with important information gleaned from clinically validated, well-proven, and carefully tailored diagnostic tests. The FDA should be working in concert with academic medicine to encourage safe innovation in patient care, not stifle it.

As the regulation of in vitro clinical tests is debated in Congress, the AAMC is engaged with many stakeholders and continues to advocate to allow for the valuable and critical use of LDTs in the practice of medicine. With the input of many AAMC-member institutions who are deeply engaged in the development and provision of LDTs for the benefit of patients across the nation, the AAMC has identified key issues that must be addressed in any proposed or implemented regulation of LDTs.

## Key Messages for Congress's Consideration of the VALID Act as Part of the FDASLA

### *Differentiating Academic Medical Center Clinical Labs*

Clinical labs in AMCs have several unique characteristics that differentiate them from other types of labs that develop and manufacture LDTs, or in vitro clinical tests. These factors were a large part of why the FDA was comfortable with the development and provision of LDTs in AMCs without FDA regulation for many years. Any revised regulatory framework must include as one goal a recognition that an overly burdensome system to review LDTs could greatly slow the rate of clinical innovation that is critical to keeping our health care system at the forefront of discovery, providing quality care to patients, and responding quickly to emerging public health risks. The extensive time commitment and the economic impact of institutional compliance with the proposed new regulatory framework for currently administered and newly developed LDTs would be untenable, given the time and cost of guiding even a single test through the FDA premarket approval process. This cost would necessarily lead to institutional decisions that could limit patient access to innovative and targeted diagnostic tests.

Key characteristics of academic clinical laboratories (ACLs):

- The ACLs is an integrated and integral aspect of an academic institution, which provides direct patient medical care.
- The primary role of the lab is to provide testing and interpretation for the benefit of the patients and clinicians in an affiliated hospital or academic health center as a part of the treatment decision-making process.
- ACLs have been certified by the Centers for Medicare & Medicaid Services through the CLIA (Clinical Laboratory Improvement Amendments) program to conduct high-complexity tests.

## Requests

Given AMC labs integration of the test development and administration into the continuum of patient care, the many other safeguards for patients that such labs are already subject to, and the FDA's retention of the ability to investigate and remove any test from the market regardless of the entity that develops it, **we urge Congress to exempt these "academic clinical laboratories" from the revised oversight framework presented in the FDASLA**. Short of that, lessening the burden on academic labs by addressing several provisions in the FDASLA would make these new regulations less likely to decrease the number of available tests for patient care and potentially negatively impact patients' health.

The most onerous and resource-intensive aspects of the FDASLA could be diminished without increased risk to patients or access to care by making the following changes applicable only to labs that are designated as "academic clinical laboratories" (ACLs):

- Exclude ACLs from the requirement to proactively list all tests that are to be grandfathered under [§587]. Instead, such labs should be prepared to present evidence of use of the test prior to enactment should a question arise about whether a test was properly included in this exemption.
- Have every test developed by an ACL be designated as low-risk and not subject to the additional requirements for high-risk tests [§587(9)]. This would acknowledge the risk-mitigating factors that arise from additional oversight, expertise, and integration into clinical care that ACLs demonstrate, aspects that are wholly different from commercial or reference labs.
- When a test is grandfathered, exempt from premarket review through a technology certification, or approved through premarket review if that test is developed and administered by an ACL, any changes to the type of specimen used for the test would not be considered a modification which would cause it to be treated as a new test [§587C(a)(6)].
- Expand custom/low volume tests exempt categories to include <100 tests annually (instead of five).

## Additional Background

For many years, the development and provision of LDTs in the context of clinical care was deemed by the FDA and by academic labs to be different enough from the tests provided by commercial labs to not require additional oversight and regulation. In October 2014, the FDA released draft guidance on proposed oversight of LDTs, and in vitro diagnostic tests, both of which are designed and used by a single laboratory. The LDTs offered by clinical labs at academic medical centers were not regulated by the FDA through the existing device regulations, but many would have been subject to this regulatory oversight under the proposed guidance and subsequent proposed legislation. According to the FDA, the purpose of the revised framework was to give the FDA oversight of LDTs "based on risk to patients rather than whether they were made by a conventional manufacturer or a single laboratory." In this structure, LDTs designated as higher-risk, including companion diagnostics and LDTs used to inform treatment decisions, would be reviewed by the FDA through the existing pre-market review process used for devices. The FDA proposed to continue to use its enforcement discretion and not require the same process for certain LDTs, including those deemed to be low-risk and those used for rare diseases.

In response to concerns raised by the academic medicine community and other stakeholders, the FDA did not finalize the draft guidance, and subsequently Congress drafted and introduced several versions of proposed legislation to require FDA oversight of LDTs, with the most recent bill, the VALID Act, being incorporated into the Senate HELP Committee's draft FDA user fee reauthorization text, the FDASLA Act of 2022.

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