

The Verifying Accurate, Leading-edge IVCT Development (VALID) Act

In vitro clinical tests (IVCTs) are tests that Americans rely on to help get a diagnosis of a disease or condition. These tests use human samples, such as blood or tissue, to inform patient care. Rapidly occurring innovation in the diagnostic field holds great promise for improving health care for Americans. While diagnostic test results are critical factors in making health care decisions, ambiguous regulation creates future of innovation and patient care uncertainty.

The Food and Drug Administration (FDA) does not currently have a specific process tailored to diagnostic test review, resulting in developers submitting product review through the broader medical device pathway, which does not account for the unique characteristics of IVCTs. A single laboratory may manufacture or use a subset of IVCTs, known as Laboratory Developed Tests (LDTs); those laboratories are already subject to the Clinical Laboratory Improvement Amendments of 1988 and are regulated by the Centers for Medicare & Medicaid Services. LDTs must meet certain lab operation and procedure requirements, but FDA medical device requirements are different and more relevant to IVCT manufacturers and devices. As the number and complexity of IVCTs increases, FDA should have risk-based IVCT evaluation tools to ensure accurate health care information and high-quality patient care.

The VALID Act establishes a comprehensive, risk-based framework to regulate IVCTs, including LDTs and tests that would go through FDA review as a medical device today. Under this framework, FDA would review a diagnostic test's analytical and clinical validity, regardless of the setting where was created. The VALID Act would require FDA to prioritize the tests that present the highest patient risk while encouraging innovation for all categories of IVCTs.

The VALID Act aims to protect patients and accelerate innovation through:

- ***Establishing a risk-based framework, focusing FDA resources on cutting-edge diagnostics.*** Under the VALID Act, FDA would be authorized to prioritize regulatory efforts based on risk level and patient benefit through high-risk test premarket review, a streamlined technology certification pathway, certain lower-risk test exemptions, and modification review of tests that could expose patients to serious harm in the event of inaccurate results. This legislation would grandfather in diagnostic tests available today, exempting them from premarket review.
- ***Building on the success of the breakthrough designations at FDA.*** This bill would establish a program to expedite IVCT development that addresses unmet needs for patients, like those with rare diseases, building on the successful breakthrough designations for medical devices and drugs.
- ***Balancing the pace of innovation with regulatory reform.*** This bill would establish a technology certification process where IVCT developers could receive certification to bring non-high-risk tests to market if they are within the same representative IVCT scope of approval so that FDA would not have to repeatedly review tests in the same category. This pathway would exempt tests from premarket review and ensures that developers could continue innovation within parameters that protect patients.
- ***Improving transparency and understanding of the IVCT market in the long-term.*** The VALID Act includes provisions that would strengthen FDA's authority to understand the current diagnostic test landscape available to Americans and oversee IVCTs once they are available for clinical use, including newly available public information on the types of tests available to Americans, labeling, postmarket monitoring and reporting, and quality and design requirements.