



The VALID Act is Carefully Tailored to Ensure Continued Access to Tests Offered by Academic Medical Centers and other Laboratories

Over the course of several years, the authors of the VALID Act engaged in substantive and longstanding deliberations with a wide variety of stakeholders, resulting in a carefully honed package that evolved significantly from the earlier versions of the legislation. A core consideration in the legislation is to ensure that the level of regulatory oversight for in vitro clinical tests is based on risk. In developing a comprehensive system for all in vitro clinical tests, VALID actually lowers the regulatory burden on many in vitro clinical tests, and provides an oversight framework that exempts *significantly more* tests from premarket review than current law. In doing so, VALID also ensures that clinically important tests offered by laboratories will continue to be available, and that laboratories, particularly those affiliated with academic medical centers and other hospitals, will have ample time and opportunity to adapt to this new regulatory framework.

The VALID Act incorporates a wide variety of accommodations to ensure continued access to tests offered by academic medical centers and other laboratories:

- Many tests offered by academic medical centers (AMCs) will be completely exempt from FDA premarket review:
 - *All tests that have already been offered before VALID is enacted ("grandfathered tests")*: this will ensure continued availability of all tests currently offered by AMCs that have been validated and are reliable.
 - *Grandfathered tests that are modified*: VALID also allows AMCs even to make certain modifications to their grandfathered tests that might otherwise require FDA review.
 - *Tests that are already classified by FDA as either low-risk, or exempt from 510(k) review*: Many tests developed by AMCs would be exempt from review based on their risk level and intended use, based on existing exempt classifications.
 - *Tests for unmet needs*: VALID expands the current criteria for humanitarian tests, for which AMCs frequently develop their own tests,



- and makes these tests for unmet need exempt from any premarket review.
- *VALID also exempts low-volume tests, custom tests, manual tests, public health surveillance testing, and testing performed for law enforcement or forensic purposes.*
 - *VALID exempts general laboratory equipment and laboratory operations.*
- VALID eases regulatory burdens on all in vitro clinical tests and offers a gradual transition for laboratory developed tests:
 - *Extended Transition Period:* Laboratory tests first offered over the next five years will receive a transition period to submit an application (if the test is even subject to application requirements) until *after* VALID takes effect. Furthermore, any laboratory test that has been approved by the New York Department of Health will receive an *additional* two or five years before having to submit an application.
 - *Leveraging CLIA Oversight:* VALID avoids duplication with CLIA in numerous respects, particularly with regard to test design and quality requirements. VALID explicitly avoids duplication of regulations and guidance under CLIA and does not apply to laboratory operations.
 - *Pro-Innovation Reforms:* VALID's technology certification approach and change protocols will mean that many tests and changes to tests that currently go through FDA review will be *exempt* from premarket review. Under technology certification in particular, an academic medical center or other developer would submit *one test* for review and based on showing their validation methods, could then *offer dozens of tests* using the same test platform or even a different platform.
 - *Allowances for first of a kind tests:* Academic medical centers are sometimes the source of novel tests. Under VALID, even a "first of a kind" test could potentially be offered, via technology certification, *without FDA review*.
 - *Expansion of accredited person review:* Laboratories would rely heavily on third party review for tests that actually require a premarket application. VALID significantly improves the third party review program as it currently exists for devices, in a manner that will prevent FDA from engaging in unnecessary "re-reviews."
 - *Discretionary exemptions:* Under VALID, FDA also has authority to grant discretionary exemptions for in vitro clinical tests.



- *Improved regulatory definitions:* VALID employs risk-based definitions that are tailored to in vitro clinical tests rather than therapeutic devices. Moreover, to avoid the risk that they might be misapplied, VALID contains statutory protections to ensure that tests that are low-risk under current law, or moderate risk under current law, will remain so and will not be “up-classified.”

