Past and Current Policy Proposals

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Current Pathways for Regulation of Laboratory Tests

Laboratory Developed Testing Procedures (LDT/LDPs)

- Regulated by CMS under CLIA
- Tests that are developed and performed within single laboratory

In Vitro Diagnostic Tests (IVDs)

- Regulated by FDA
- Testing kits that are boxed, sold and shipped throughout the US
- Includes Companion diagnostics (CDx)

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Two Current Legislative Proposals:

- In 2014, FDA released guidance claiming statutory authority to regulate laboratory developed testing services
- In 2016, when FDA decided not to finalize its draft guidance conversations about LDP oversight shifted to Congress.
- Conversations have resulted in two legislative proposals:

Verifying Accurate and Leading-edge IVCT Development (VALID) Act

Verified Testing in American Laboratories (VITAL) Act

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Two Current Legislative Proposals:

Verifying Accurate and Leading-edge IVCT Development (VALID) Act

Verified Testing in American Laboratories (VITAL) Act

The VALID Act represents the FDA vision for oversight and grew out of a technical assessment completed by the agency on a previous bill that focused on LDT/LDP oversight.

The VALID Act was first introduced in 2018 and conversation around LDT/LDP oversight on the Hill has since centered around this bill.

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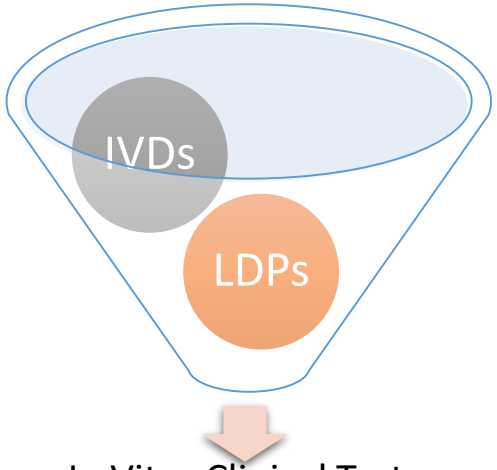
Verifying Accurate and Leading-edge IVCT Development Act (VALID)



In Vitro Clinical Tests (IVCTs)

Laboratory operations

- Creates a risk-based regulatory pathway for all diagnostics regardless of the type of laboratory that developed them. Preempts state law.
  - NYSDOH will be unable to have their own separate premarket review system, but they could act as a third party reviewer.
- A new category of product called in vitro clinical tests (IVCTs), includes **both** IVDs and LDT/LDPs would be within the jurisdiction of the device center at FDA.
- Developers could voluntarily use a technology certification pathway to exempt IVCTs that fall within scope of the certification.
- Creates a public database with information on most IVCTs in clinical use (including adverse event & corrections/removal reports). This system would also serve as the application system.

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Verifying Accurate and Leading-edge IVCT Development Act (VALID)

What happens to tests currently being offered?

- **Grandfathered LDT/LDPs:** Must comply with CLIA and FDA Special Rule.
  - Grandfathered LDT/LDPs can be modified, if modification is documented and it does not result in a new IVCT
  - Becomes a new IVCT (and requires application) if modification*:
    - Impacts analytical/clinical validity
    - Changes intended use
    - Causes IVCT to no longer comply with mitigating measures and/or other restrictions put into place by FDA
    - Impacts safety of specimen collection system

- **Cleared/approved medical devices:** Become approved IVCTs on effective date or 3 years after effective date (developer's choice).
- **IDEs:** Become investigational IVCTs on effective date
- **Instruments:** If purchased prior to enactment and does not have clearance/approval, can keep using for 5 years after enactment. After 5 year period, new IVCTs must comply with new requirements.

** Some modifications are exempt, as long as they are reported to the FDA within 60 days*

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Verifying Accurate and Leading-edge IVCT Development Act (VALID)

Other components of VALID for clinical laboratories:

- Quality Systems Requirements (QSRs)
- Label/Labelling Requirements
- Adverse Event Reporting
- Emergency Use Authorization

- VALID does not make any modernizations to CLIA!!

What would life for a clinical laboratory look like under VALID?

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Two Current Legislative Proposals:

Verifying Accurate and Leading-edge IVCT Development (VALID) Act	Verified Testing in American Laboratories (VITAL) Act

The VITAL Act is the most recent development for LDT/LDP oversight on the Hill. The VITAL Act was first introduced in 2020 and supportive stakeholders are working to call attention to the bill and develop support.

While the VALID Act re-envisions the oversight system for **BOTH** LDT/LDPs and IVDs, the VITAL Act narrowly focuses on LDT/LDP oversight.

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Verified Innovative Testing in American Laboratories (VITAL) Act of 2021

- Codifies that regulation of laboratory developed testing procedures rests within CLIA and not the FDA, **including during a public health emergency**,
- Defines LDT/LDPs as a professional medical service,
- Mandates CMS to hold a public meeting no later than 90 days after the enactment of this Act to solicit recommendations on ways to update CLIA regulations, and
- Directs the HHS Secretary to report to Senate HELP Committee and House Energy and Commerce Committee on recommendations for updating CLIA as well as provide an assessment of the availability and utilization of LDPs during COVID-19 pandemic response.

What would life for a clinical laboratory look like under VITAL?

Discussion of VALID and VITAL:

Verifying Accurate and Leading-edge IVCT Development (VALID) Act

Verified Testing in American Laboratories (VITAL) Act

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