



**Laboratory-  
Developed Test**



## What is a Laboratory-Developed Test under the FDA?

The U.S. Food and Drug Administration (FDA) defines a Laboratory-Developed Test (LDT) as an in vitro diagnostic medical device (IVD) intended for clinical use and designed, manufactured, and used within a single clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meets the regulatory requirements under CLIA to perform high complexity testing.

Key points to classify an IVD as an LDT under the FDA definition:

**Developed and used within a single clinical laboratory**

The test must be designed, manufactured, and used exclusively within a single laboratory. It is not commercially distributed or shared outside the lab, which distinguishes it from commercial IVDs.

**CLIA-certified laboratory**

The lab must be certified under the Clinical Laboratory Improvement Amendments (CLIA) and authorized to perform high complexity testing. This ensures regulatory oversight of lab operations.

**Intended for clinical use**

The test is intended for clinical decision-making (e.g., diagnosis, monitoring or prognosis), not solely for research or non-medical purposes.

## Regulation of LDTs in the FDA: Historical Overview and Controversy

- **Origins of LDTs:**
  - Initially developed by individual laboratories to address specific or local healthcare needs (e.g., rare diseases, unique patient populations).
  - Performed manually with FDA-compliant components and interpreted by physicians within the same institution.
  - Due to their limited scope, the FDA historically exercised enforcement discretion and did not fully apply IVD regulations.



- **Evolution of LDTs:**

- Modern LDTs are high-tech, high-volume tests often used nationwide.
- Commonly developed by large laboratory corporations and used for serious conditions (e.g., cancer, heart disease).
- Frequently rely on complex instruments, software, and components not legally marketed for clinical use.
- Typically performed outside the patient’s healthcare setting.

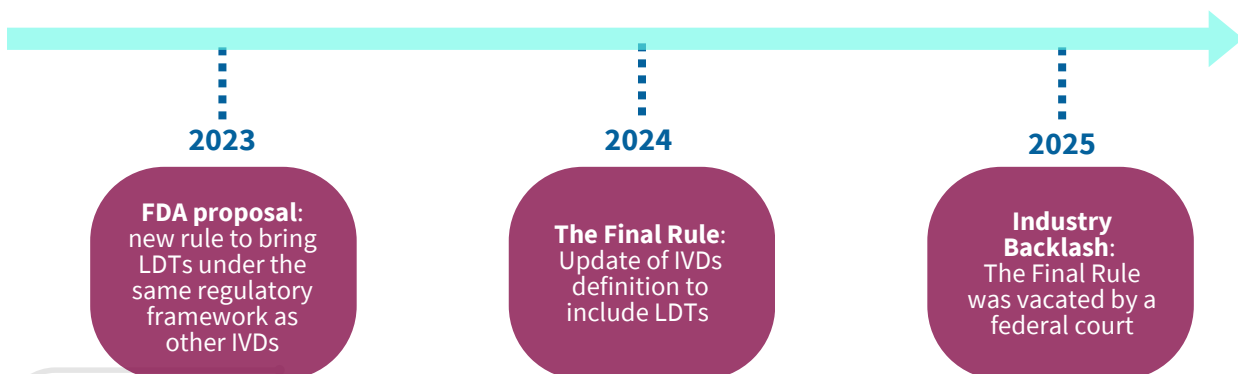
As a result of this evolution in the testing landscape, the FDA has long recognized the need for a change in the Agency's general enforcement discretion approach for LDTs. In 2023 and with the goal to improve patient safety by ensuring LDTs meet quality, performance, and transparency standards, the FDA proposed a new rule to bring LDTs under the same regulatory framework as other IVDs.

- **The Final Rule (2024)** adopted a single amendment: it updated the definition of *in vitro diagnostic (IVD) products* to make clear that IVDs developed and used by clinical laboratories are still considered **medical devices** under the **Federal Food, Drug, and Cosmetic Act (FFDCA)** (21 C.F.R. §809.3). The amended definition proposed was as follows (change in bold):

*“In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, **including when the manufacturer of these products is a laboratory.**”*

Approval of the Final Rule (2024) would have required:

- Premarket review for high-risk LDTs.
- Post-market controls.
- Compliance with Quality System Regulation.





**Industry Backlash:** The FDA’s attempt to regulate LDTs as medical devices faced strong resistance from across the clinical laboratory industry. Critics warned of higher costs, reduced innovation, and limited access to essential tests. Additionally, many challenged the FDA’s legal authority, asserting that LDTs are clinical services, not commercial products, and therefore fall outside the scope of device regulation under the FDCA. This led to legal challenges and pushback from Congress, prompting the FDA to pause implementation of the Final Rule.

**Current Regulatory Situation:** As of now, LDTs remain largely unregulated by the FDA. Following intense industry opposition and legal challenges, a federal court vacated the Final Rule in 2025, ruling that the FDA had exceeded its statutory authority. As a result, LDTs continue to operate under enforcement discretion, and their regulatory future remains uncertain and subject to ongoing debate.

## EU Comparison: In-House IVDs under the EU Regulation 2017/746 (IVDR)

In the European Union, in-house IVDs are the analogue to LDTs.

According to the IVDR, an in-house IVD refers to a device manufactured and used only within a health institution, and not transferred to another legal entity. These devices are exempt from many IVDR requirements (e.g., CE marking), provided certain conditions are met. These key conditions are described in Article 5 (5), and include:



The device is not transferred to another legal entity



Manufacturing and use are carried out under an appropriate quality management system (e.g., ISO 15189)



The health institution justifies that the needs of the patient cannot be met by an equivalent CE-marked device available on the market



The institution must comply with relevant General Safety and Performance Requirements (GSPRs)



Certain documentation, declarations, and transparency obligations must be fulfilled

Importantly, certification by a notified body is not required; however, appropriate documentation and justification must be maintained.



Aspect	LDTs under FDA	In-House IVDs under IVDR
<b>Commercial use</b>	Not commercially distributed	Not transferred to other legal entities
<b>Internal use only</b>	Yes	Yes
<b>Quality system</b>	CLIA requirements	Must comply with appropriate QMS (in accordance with EN ISO 15189)
<b>Notified Body</b>	Not needed	Not needed
<b>Regulatory Status</b>	Historically, regulated under FDA enforcement discretion; Final Rule vacated 2025	Exempt from CE marking if conditions in IVDR Article 5(5) are met
<b>Legal Classification</b>	Not classified as a medical device (currently under debate)	Considered IVDs, but allowed for in-house use
<b>Performance Requirements</b>	Not always formally assessed	Must meet General Safety and Performance Requirements (GSPRs)
<b>Transparency</b>	Historically, only limited requirements apply	Documentation must be available upon request



## Conclusion

While both LDTs and in-house IVDs are internally developed diagnostics used within healthcare institutions, their regulatory approaches differ significantly. In the EU, in-house IVDs are explicitly addressed under the IVDR (Article 5(5)), which permits their use under specific conditions, including adherence to a quality management system and compliance with safety and performance requirements.

In contrast, in the U.S., LDTs have traditionally operated under FDA enforcement discretion and are regulated primarily under CLIA. Although the FDA issued a Final Rule in 2024 to increase oversight, the rule was vacated by a federal court in 2025, leaving LDTs outside formal FDA regulation for the time being. The future of LDT oversight in the U.S. remains uncertain and subject to ongoing legal and policy debate.

## References:

- [Food and Drug Administration. \(2023, October 3\). Medical Devices; Laboratory Developed Tests \(Proposed Rule\). Federal Register, 88 FR 68006.](#)
- [U.S. Food and Drug Administration. \(n.d.\). Definitions and General Oversight: Laboratory Developed Tests FAQs.](#)
- [Regulation \(EU\) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices \(EUR-Lex – Regulation \(EU\) 2017/746\).](#)

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