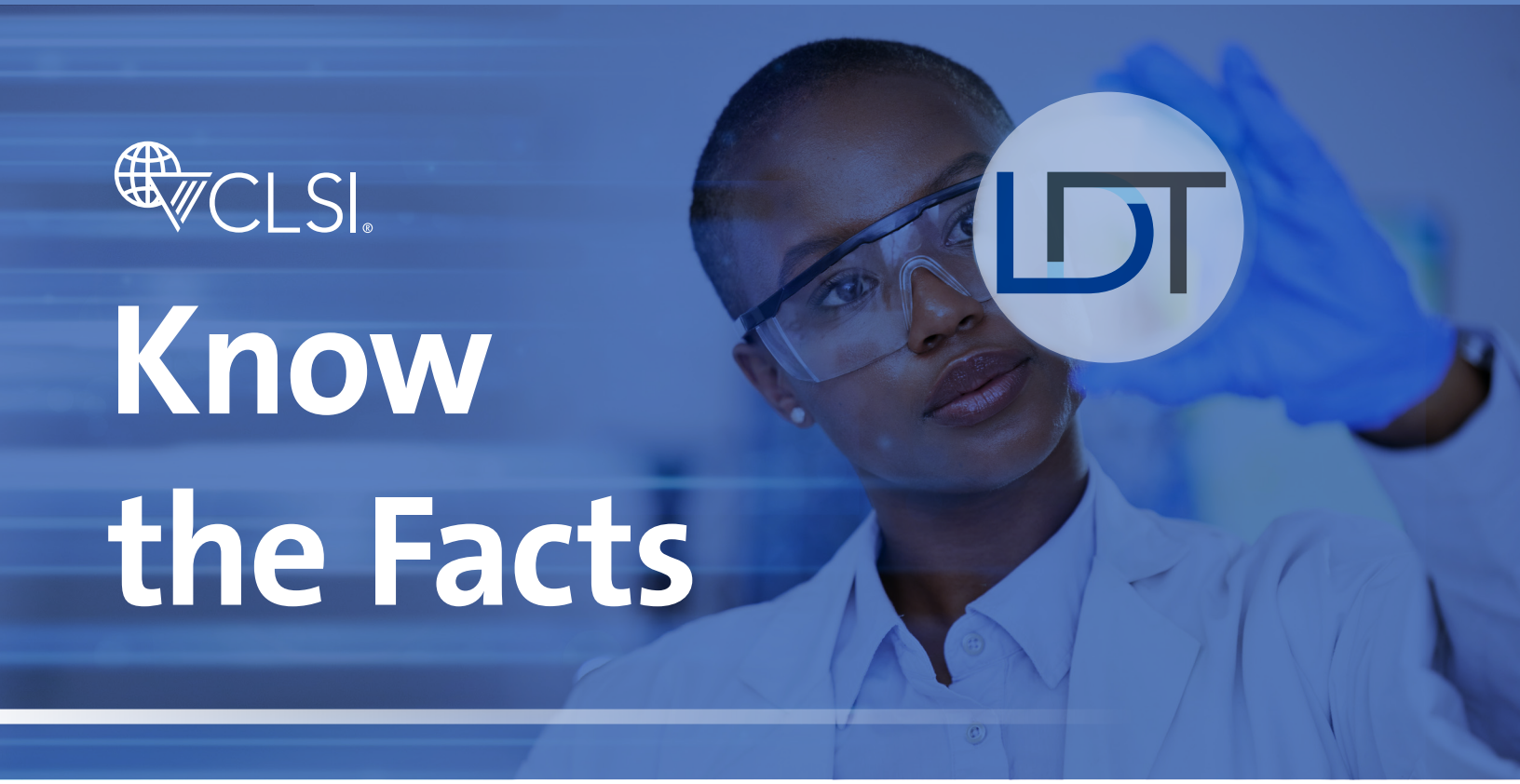

Know the Facts

FDA LDT Final Rule Implementation Fact Sheet

- The FDA asserts that *in vitro* diagnostics (IVDs) devices are medical devices, including when a laboratory is the manufacturer of an IVD device. In this rule, laboratories that develop their own tests, or modify an existing approved test, are referred to as "device manufacturers" and are subject to FDA review.
- The FDA ruling on LDTs went into effect May 2024 and the requirements will be phased in stages beginning May 2025 through May 2028.
- The FDA has identified LDT categories subject to enforcement policies with limited exceptions regarding meeting the requirements. This continued "enforcement discretion" means that the FDA is generally not enforcing requirements except as follows:
  - For LDTs approved or conditionally approved by the New York State Clinical Laboratory Evaluation Program (NYS CLEP) and certain modified versions of another manufacturer's 510(k) cleared or De Novo authorized test, **only Stages 1, 2, and 3 are required.**
  - For LDTs manufactured and performed by a laboratory integrated within a health care system to meet an unmet need of patients receiving care within the same health care system and for LDTs that were first marketed before May 6, 2024, **only Stages 1, 2, and the Stage 3 Quality System Requirements (QSRs) for Records (21 CFR 820, Subpart M) are required**.

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Toll Free (US): 877.447.1888 | P: +1.610.688.0100 | F: +1.610.688.0700 | E: customerservice@clsi.org

Phase Out Stages and Requirements

1 Stage 1

Beginning May 6, 2025, **all laboratories are required** to do the following:

1. Report any adverse events where the LDT caused, or is likely to contribute to, serious injury or death. These events will need to be reported using the FDA's electronic portal (eMDR).
2. Establish procedures for receiving, reviewing, and evaluating complaints; determine if reportable; and maintain complaint files.
3. Report complaints to FDA that are related specifically to the LDT test method or performance. Laboratories are **not required** to report complaints related to laboratory operations that are not related to the method or device.

2 Stage 2

Beginning May 6, 2026, **all laboratories are required** to do the following:

1. Register as a device manufacturer and list information on all LDTs in a public database. There will be a user fee, and registration is required using the FDA's electronic registration portal. The FDA has not provided guidance on this yet.
2. Submit certain labeling information to the FDA, including performance information and a supporting validation summary; this rule is what is meant by "labeling your device" or "meeting labeling requirements." This information can be made available to clinicians and/or patients with the test report.

3 Stage 3

Beginning May 6, 2027, **all laboratories are required** to do the following:

1. Meet the Quality System Regulations (QSRs). Most Clinical Laboratory Improvement Amendments (CLIA) laboratories already meet such as recordkeeping, management controls, audits, etc.; however, there will be new requirements like device master files, and acceptance procedures. CLSI will provide education on meeting these requirements before the required implementation date.

Phase Out Stages and Requirements

4 Stage 4

Beginning November 6, 2027, **laboratories that are developing LDTs not included in enforcement categories with limited exceptions are required to:**

1. Submit a Premarket Approval application for high-risk (Class III) LDTs. High-risk means there is no predicate device, and the device poses a significant risk of illness or injury. Most LDTs are **NOT** high-risk, and this requirement will not affect most LDT developers.

5 Stage 5

Beginning May 6, 2028, **laboratories that are developing LDTs not included in enforcement categories with limited exceptions are required to:**

1. Apply for premarket review for moderate-risk (Class II) and low-risk (Class I) LDTs. Most low-risk LDTs are exempt from premarket review.
   - Submissions include a 510(k) for LDTs with a predicate device and De Novo for LDTs that have no predicate device but whose risk is lower than high-risk.

There are LDTs that are completely exempted from requirements, including:

- **"1976-Type LDTs":** Tests using manual techniques and components marketed for clinical use, which are designed, manufactured, and used within a single CLIA laboratory certified to perform high-complexity testing
- **Human Leukocyte Antigen (HLA) Tests for Transplantation:** LDTs used for organ, stem cell, and tissue transplantation.
- **Forensic Tests:** LDTs used only for law enforcement purposes
- **Department of Defense (DoD) and Department of Veterans Affairs (VHA) LDTs:** LDTs manufactured and performed within the DoD or VHA and only used for patients being treated within the DoD or VHA.
- **Tests for public health emergencies, potential emergencies, or material threats** under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C) are outside the scope of the FDA's LDT Final Rule phaseout policy.

CLSI

CLSI is committed to providing guidance, tools, and resources to help laboratories meet the new FDA LDT requirements. To explore more of CLSI's resources related to LDTs, visit:

- LDT Foundations webinar series
- Method Navigator tool
- LDT landing page