FDA'S LDT RULES

Reference Guides

These guides were created to help clinical labs:

- **Understand the key aspects of the FDA Final Rule for LDTs.**
- **Learn about the phaseout policy and timeline.**
- **Identify the types of tests included and excluded from the rule.**
- **See the implications of the rule for clinical laboratories.**

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Who is ELITech? At ELITech, we are leaders in providing innovative diagnostic solutions to laboratories around the world. With decades of experience in the industry, our mission is to empower labs with the tools and knowledge they need to deliver accurate, reliable, and timely diagnostics. We are committed to supporting our partners through every regulatory change, ensuring that patient care remains at the forefront of everything we do.

Phase-Out Timeline

Effective Date:
July 5, 2024

STAGE 1:
Medical device reporting, correction and removal reporting, & complaint file

May 6, 2025

STAGE 3:
Quality System requirements, design controls, purchasing controls, acceptance activities, corrective and preventative actions, records requirements

May 6, 2027

May 6, 2025 → **2026** → **2027**

MDUFA VI:
Negotiations begin

Late 2025-2026

STAGE 2:
Registration & listing, labeling, IDE

May 6, 2026

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Phase-Out Timeline

MDUFA VI:
Performance goals and fees go into effect

October 1, 2027

STAGE 5:
Premarket review required for all moderate and low risk IVD's; third party review allowed.

May 6, 2028

2027

2028

STAGE 4:
Premarket approval required for high-risk IVD's

November 6, 2027

For Stage 4 and 5, if completed application submitted, IVD may remain on market while FDA completes review.

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Continued Enforcement Discretion

What stages apply to you?

CATEGORY OF TEST	STAGE 1 MDR, Correction & Removal Reporting, etc.	STAGE 2 Registration & Listing, Labeling	STAGE 3 QSR	STAGES 4 & 5 Premarket Review
LDTs Approved by the NYS CLEP Includes LDTs that are approved, conditionally approved, or within an approved exemption from full technical documentation	Required	Required	Required	**EXEMPT**
LDTs for unmet needs used in an integrated healthcare system	Required	Required	**EXEMPT**	**EXEMPT**
Currently marketed LDTs (Prior to May 6, 2024)	Required	Required	**EXEMPT**	**EXEMPT**
Non-molecular antisera LDTs for rare red blood cell antigens	Required	Required	**EXEMPT**	**EXEMPT**

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