COLLEGE of AMERICAN PATHOLOGISTS

FDA Oversight of LDTs Phase 1 Requirements (Starting May 6, 2025)

MEDICAL DEVICE ADVERSE EVENT REPORTING

Laboratories must report certain device-related adverse events and product problems to the FDA.

- FDA Resource: Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities

CORRECTION AND REMOVAL

Required to make a report to the FDA of any correction or removal of a medical device(s) if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health.

- FDA Resource: Recalls, Corrections and Removals (Devices)

QUALITY SYSTEM FOR COMPLAINTS REQUIREMENTS

- Maintain complaint files.
- Designate a formal complaint handling unit.
- Establish and maintain procedures for receiving, reviewing, and evaluating complaints.

Full Phases of FDA Oversight of LDTs

	STAGE 1	STAGE 2	STAGE 3	STAGES 4 & 5
Category of IVD/LDT	Adverse Event Reporting (21 CFR pt. 803) Reporting of Corrections and Removals (21 CFR pt. 806) Complaint Files (21 CFR 820.198)	Requirements Not Covered In Other Stages, Including: Establishment Registration & Device Listing (21 CFR pts. 607, 807 subpts. A-D) Labeling (21 CFR pts. 801, 809) Investigational Use Requirements (21 CFR pt. 812)	Quality System Requirements Other than Complaint Files (21 CFR pt. 820 other than 21 CFR 820.198)	Premarket Review (21 CFR pt. 807, subpt. E; 21 CFR pt. 860, subpt. D; 21 CFR 814; 21 CFR pt. 601)
LDTs for unmet needs by labs integrated in the health care system treating the patient	compliance generally expected beginning May 6, 2025	compliance generally expected beginning May 6, 2026	compliance with 21 CFR 820.180-820.186 generally expected beginning May 6, 2027; compliance generally not expected with other QS requirements (except for complaint files)	compliance generally not expected

Source: US Food and Drug Administration (FDA)

	STAGE 1	STAGE 2	STAGE 3	STAGES 4 & 5
Currently marketed IVDs offered as LDTs first marketed prior to rule publication date and not modified beyond scope described FDA rule	compliance generally expected beginning May 6, 2025	compliance generally expected beginning May 6, 2026	compliance with 21 CFR 820.180-820.186 generally expected beginning May 6, 2027; compliance generally not expected with other QS requirements (except for complaint files)	compliance generally not expected
Nonmolecular antisera LDTs for rare red blood cell antigens	compliance generally expected beginning May 6, 2025	compliance generally expected beginning May 6, 2026	compliance with 21 CFR 820.180-820.186 generally expected beginning May 6, 2027; compliance generally not expected with other QS requirements (except for complaint files)	compliance generally not expected
LDTs approved by NYS Clinical Laboratory Evaluation Program (CLEP)	compliance generally expected beginning May 6, 2025	compliance generally expected beginning May 6, 2026	compliance generally expected beginning May 6, 2027	compliance generally not expected
Modified version of another manufacturer's 510(k) cleared or De Novo authorized test	compliance generally expected beginning May 6, 2025	compliance generally expected beginning May 6, 2026	compliance generally expected beginning May 6, 2027	compliance generally not expected
IVDs offered as LDTs within scope of phaseout policy, but that do not fall within a targeted enforcement discretion policy summarized above	compliance generally expected beginning May 6, 2025	compliance generally expected beginning May 6, 2025	compliance generally expected beginning May 6, 2025	compliance generally expected beginning November 6, 2027 for high-risk tests compliance generally expected beginning May 6, 2028 for moderate-risk and low-risk tests
1976-type LDTs	compliance generally not expected	compliance generally not expected	compliance generally not expected	compliance generally not expected
HLA tests for transplantation	compliance generally not expected	compliance generally not expected	compliance generally not expected	compliance generally not expected
Forensic tests	compliance generally not expected	compliance generally not expected	compliance generally not expected	compliance generally not expected
Department of Defense and Veterans Health Administration LDTs	compliance generally not expected	compliance generally not expected	compliance generally not expected	compliance generally not expected