COLLEGE of AMERICAN PATHOLOGISTS

FDA LDT Rule: Corrective Action and Removal Reporting

College of American Pathologists

January 9, 2025

Today's Presenters

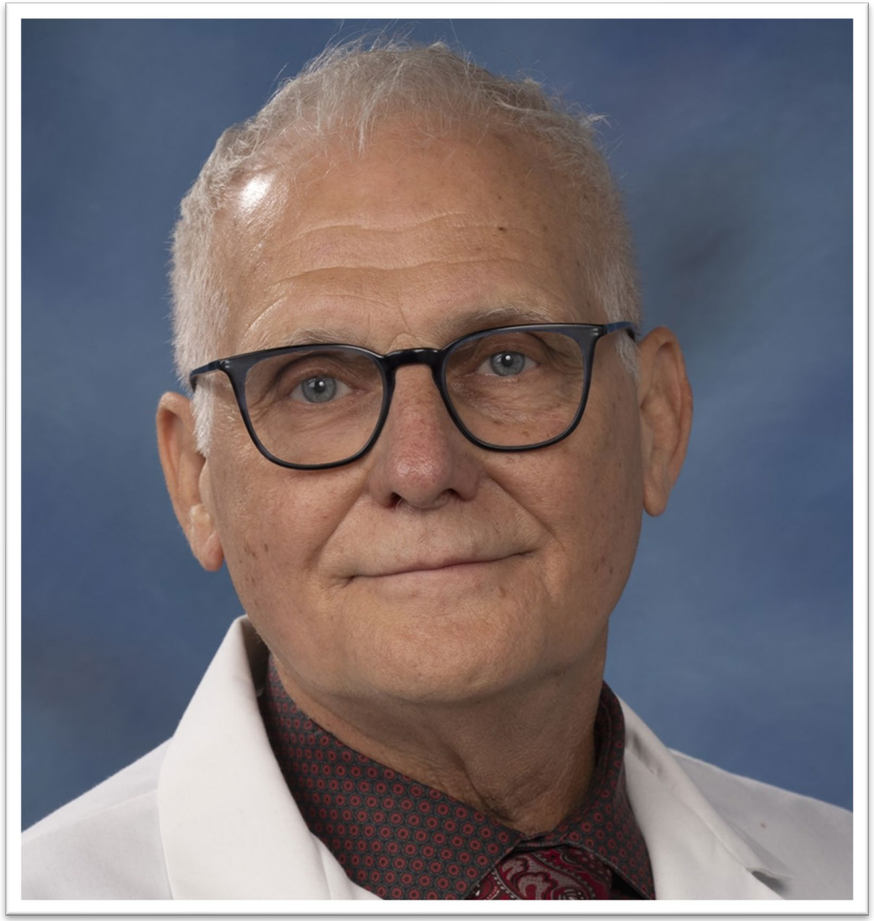
Bobbi S. Pritt, MD, FCAP

- Board-certified in anatomic, clinical pathology and microbiology
- Professor of laboratory medicine and pathology at Mayo Clinic, Rochester, MN; Chair of the clinical medical microbiology division
- Earned her medical degree at the University of Vermont Larner College of Medicine; residency at UVMC; fellowship in clinical microbiology at Mayo Clinic College of Medicine
- Producer of the podcast "Answers from the Lab."
- Awarded Mayo Clinic's 2018 Distinguished Educator Award, CAP Excellence in Teaching award, and CAP Distinguished Patient Care award
- Chair of CAP's Council on Scientific Affairs

Today’s Presenters

Earle S. Collum, MD, FCAP

- Board-certified in anatomic and clinical pathology
- Serves as medical director for LabCorp's Center for Esoteric Testing West and its Phoenix and Denver regional laboratories
- Earned his medical degree from the Medical University of South Carolina and completed his residency at Yale-New Haven Medical Center
- Former medical director of pathology and laboratory medicine at St. Joseph’s Hospital and Medical Center in Phoenix, Arizona
- Performed over 300 laboratory inspections and facilitated 20 Inspector Training Seminars
- Chair, CAP's Council on Accreditation
- CAP Lifetime Achievement Award recipient



Today's Presenters

Deeona Gaskin, JD, MPH

- Partner at the law firm of Sidley Austin LLP in Food, Drug, and Medical Device Group
- Former Associate Chief Counsel at FDA
- Earned her law degree at the Harvard Law School and her Master in Public Health at the Harvard T.H. Chan School of Public Health
- Advises medical device and in vitro diagnostic (IVD) manufacturers regarding various regulatory and compliance issues, including complaints, medical device reporting (MDRs), corrections and removals (recalls)
- Provides strategic guidance regarding FDA's new LDT rule

Stage 1

- **May 6, 2025**
- Compliance with medical device reporting, correction and removal reporting, and quality system requirements for complaints.

Reminder

Step 1 should be an analysis of whether and how the new LDT rule applies to your LDT(s)

Applicability differs based on:

- Intended uses (e.g., compliance not expected for public health surveillance tests, forensic tests, or “1976 type LDTs”)
- Intended users (e.g., for “direct-to-consumer” tests, donor screening tests, and blood typing tests, compliance expected now)

The list of LDTs used to comply with COM.40830 can be used to help the lab register their LDTs, although it’s not required until May 6, 2026

Agenda

- Define and review the stage 1 FDA requirements for medical device corrections and removal reporting
- Discuss examples that are applicable to laboratories as manufacturers
- Identify actions that laboratories can do now to prepare

Key Terms and Concepts

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- Manufacturer: “any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures.” 21 C.F.R. § 806.2(h)
- This term includes product developers: “The term includes any person who: . . . Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications.” 21 C.F.R. § 806.2(h)(2))
- Labs with LDTs are considered manufacturers under the new FDA rule

Key Terms and Concepts

Complaint: “any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.”

21 C.F.R. § 820.3(b)

Key Terms and Concepts

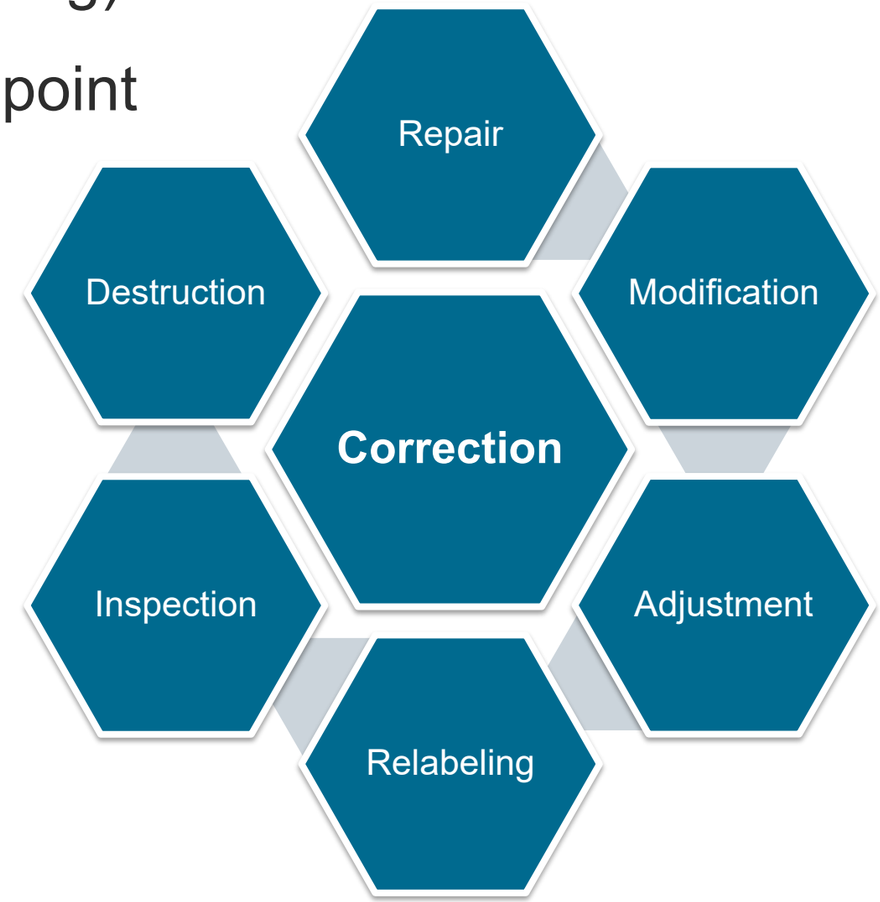
Medical Device Report: Reports to FDA submitted when manufacturers "become aware" of an event that "reasonably suggests" that one of the marketed devices (*i.e.*, tests) "[m]ay have caused or contributed to a death or serious injury"

21 C.F.R. § 803.3

What is a Correction?

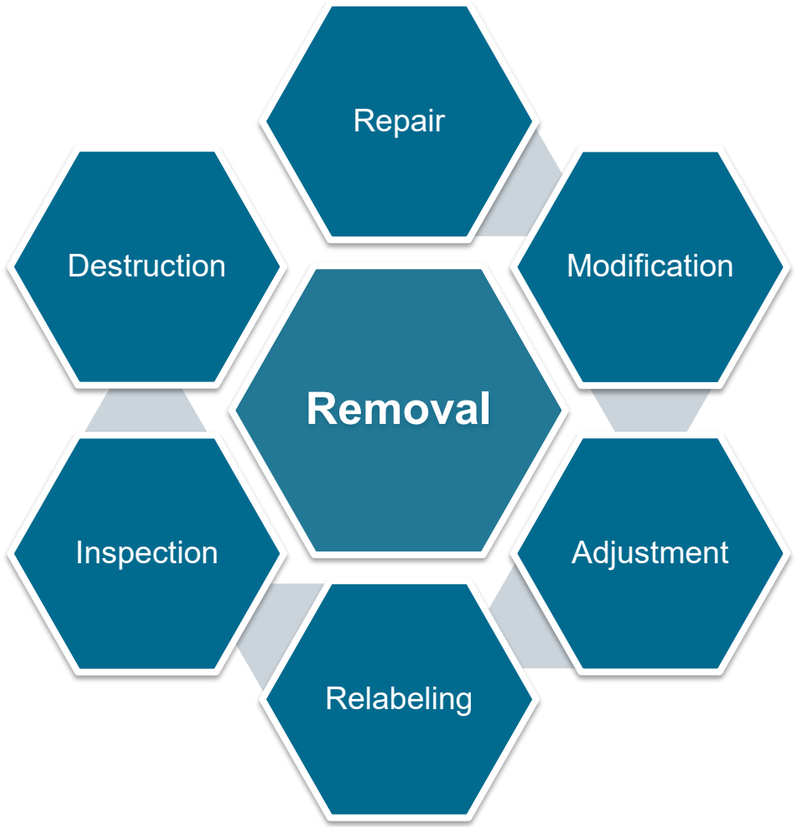
"the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device **without its physical removal** from its point of use to some other location."

21 C.F.R. § 806.2(d) (emphasis added)



What is a Removal?

- “the **physical removal** of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.” 21 C.F.R. § 806.2(j) (emphasis added)
- “retirement of the test” or “no longer in use”



When would it be considered a recall?

- When it is a correction or removal by a lab of a device (test) “that the Food and Drug Administration **considers to be in violation of the laws** it administers and **against which the agency would initiate legal action**, e.g., seizure. *Recall* does not include a market withdrawal or a stock recovery.”

21 C.F.R. § 7.3(g) (emphasis added)

Corrections and Removals: Reporting Requirements

21 C.F.R. Part 806 – Reports of Corrections and Removals

- Device manufacturers (such as labs) are required to:
  - Report promptly to FDA certain actions concerning device corrections and removals
  - Submit report within 10-working days of initiating the correction/removal
  - Maintain records of all corrections and removals regardless of whether they are reported to FDA

When to report corrections / removals to FDA?

- For actions taken to:
  - “reduce a risk to health posed by the device” or
  - “remedy a violation” that may present a risk to health
- A risk to health is defined as:
  - “A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death;” or
  - “That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.”

21 C.F.R. Part 806

Notification to the FDA

Should include, for example:

- Report number
- Name, address, telephone of laboratory
- Names and intended use of product
- Reason for correction/removal, any injury
- Actions taken
- Quantity of product distributed
- Distribution dates
- Copy of related communications

Records of Corrections/Removals

- Manufacturers are required to keep records of corrections/removals and provide FDA access to records and reports
- Reports submitted to the FDA are available for public disclosure (but with redactions, such as for trade secret and confidential commercial information and for privacy)

What are the Exemptions?

- Certain actions are exempt from correction and removal reporting
  - When reported to FDA in an MDR; or
  - Not initiated to reduce a risk to health and
  - Not initiated to remedy violation that may present a risk to health

Records for Corrections/Removals not Reported

- Retain the following for correction/removals of devices (e.g., lab tests) that are not required to be reported to the FDA
  - Name
  - Model
  - Description of events
  - Justification for not reporting correction/removal to FDA
  - Copy of all communications related to correction/removal

FDA Recalls

FDA Recall Classification

- FDA classifies recalls
- A recall can be Class I, Class II, or Class III
- Risk-based classification where Class I is the highest risk

FDA Recall Classification

Class 1

- “situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.”

  21 C.F.R. § 7.3(m)(1)

FDA Recall Classification

Class 2

- “a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.”

  21 C.F.R. § 7.3(m)(2)

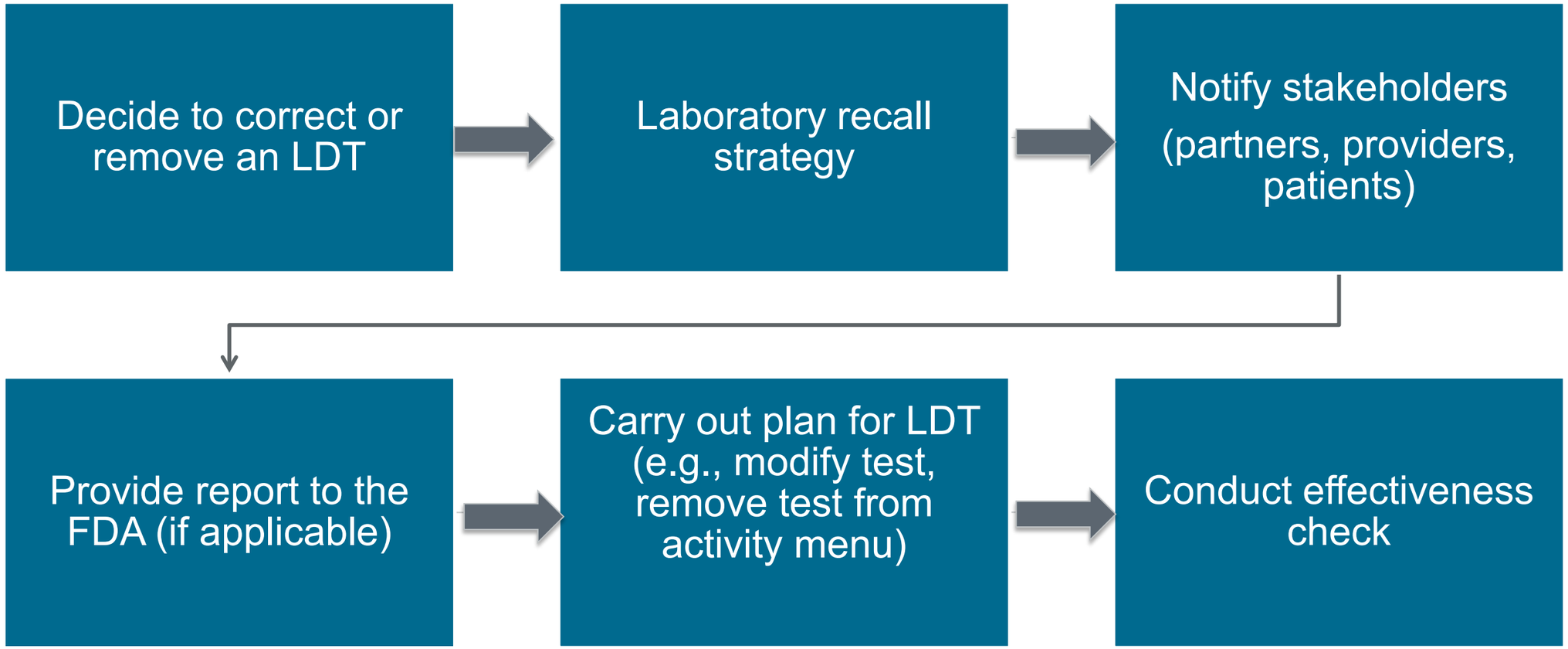
FDA Recall Classification

Class 3

- “a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.”

  21 C.F.R. § 7.3(m)(3)

Manufacturer (Lab) Recall Steps



Recall Process – Notification to Consignees (i.e. users of test)

- Communicate that the product (test) is the subject of a recall
- Outline the reason and health risk (if any)
- Provide instruction to return or correct the product
- Include a way to verify effectiveness of notification strategy

Case Discussion

Example 1

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Example 3

A laboratory developed reagent used for a test has the wrong expiry date on the label. It expired 6 months prior to the date on the label. By the time the error is identified, these reagents have already been used past expiry. An expired reagent for this test can lead to potential false positive results.

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Top 6 Takeaways

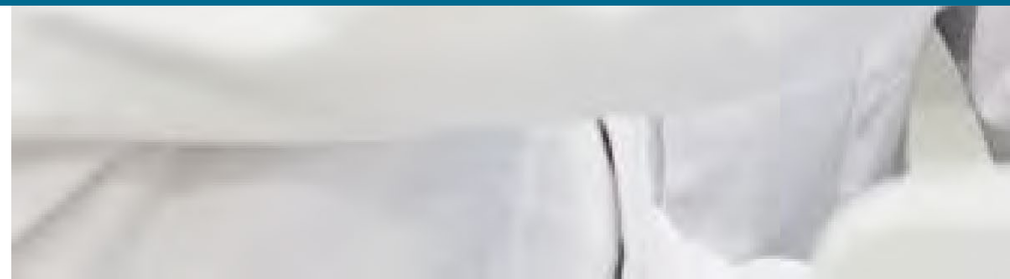
What should laboratories be doing to prepare?

- Familiarize yourself with FDA terminology and requirements
- Identify tests that are in scope of the LDT rule
- Identify individuals and departments that will be responsible for corrections and removals and determine whether additional resources are needed
- Update policies and procedures to account for the new regulations
- Prepare databases / record storage systems
- Consult with legal counsel / consultants for additional guidance

Resources

- CAP LDT Oversight web page: https://www.cap.org/advocacy/laboratory-oversight-and-regulation/laboratory-developed-test-oversight
- FDA final rule on LDTs: https://www.federalregister.gov/documents/2024/05/06/2024-08935/medical-devices-laboratory-developed-tests
- FDA regulation - Medical Devices; Report of Corrections and Removal: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-806
- FDA website guidance: https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices

Questions and Answers



Six-Part Webinar Series on LDTs

- Register for our other webinar programs:

  Understand and Prepare for the Impact of the FDA's LDT Final Rule

  - The Stage 1 Rules on Quality Systems Complaints (March 20, 2025)
  - How Enforcement Discretion Categories & Modification Rules Apply to Your LDTs (May 8, 2025)
  - Navigating FDA LDT Oversight Requirements During Public Health Emergencies (July 10, 2025)

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