PCG Laboratory News

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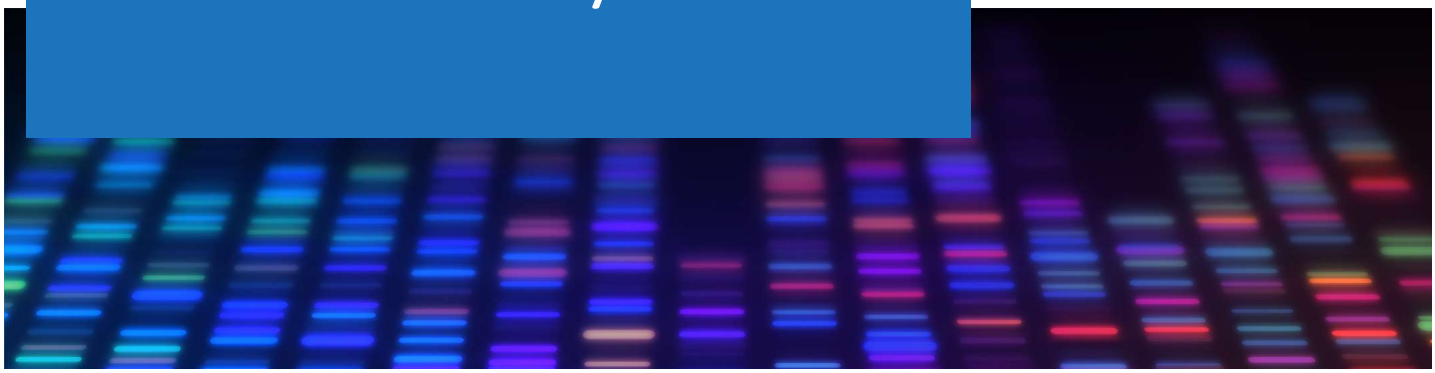


PREPARING FOR LDT CHANGES

The FDA published the Final Rule for Laboratory Developed Tests (LDT) on May 6, 2024, bringing several regulatory changes to hospital and clinical laboratories.

The FDA plans to "phase out" enforcement discretion that has been in place for decades, increasing regulatory oversight for LDT. For decades, the FDA has chosen not to enforce regulations related to LDT. Most laboratories will be impacted by this change to the Final Rule. The process to phase out will occur over the next 4 years via five stages.

Laboratories should act now, as the first stage (Stage I) of regulations goes into effect on May 6, 2025. LDTs in use prior to May 6, 2024, will be exempt from full regulation, if the LDT isn't significantly modified after May 6, 2024.

Stage I requirements include Medical Device Reporting (21 CFR 803), Correction and Removal Reporting (21 CFR 806), and Complaint Handling (21 CFR 820.198). Each LDT performed is expected to comply with these regulations by May 6, 2025.

FDA LDT FINAL RULE KEY DATES

STAGE	EFFECTIVE DATE	DESCRIPTION
Stage 1	May 6, 2025	**Adverse Event Reporting** (21 CFR pt. 803), **Reporting of Corrections and Removals** (21 CFR pt. 806), and **Complaint Files** (21 CFR 820.198)
Stage 2	May 6, 2026	**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)
Stage 3	May 6, 2027	**Quality System Requirements Other than Complaint Files** (21 CFR pt. 820 other than 21 CFR 820.198)
Stage 4	November 6, 2027	**Pre-Market Review - High Risk** (21 CFR pt. 807, subpt. E; 21 CFR pt. 860, subpt. D; 21 CFR 814; 21 CFR pt. 601)
Stage 5	May 6, 2028	**Pre-Market Review - Mod-Low Risk** (21 CFR pt. 807, subpt. E; 21 CFR pt. 860, subpt. D; 21 CFR 814; 21 CFR pt. 601)

Source: https://www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests; Accessed 12 June 2024

Need help complying with the new FDA Final Rule?
Contact PCG today at mbiskup@purchaseconsultinggroup.com

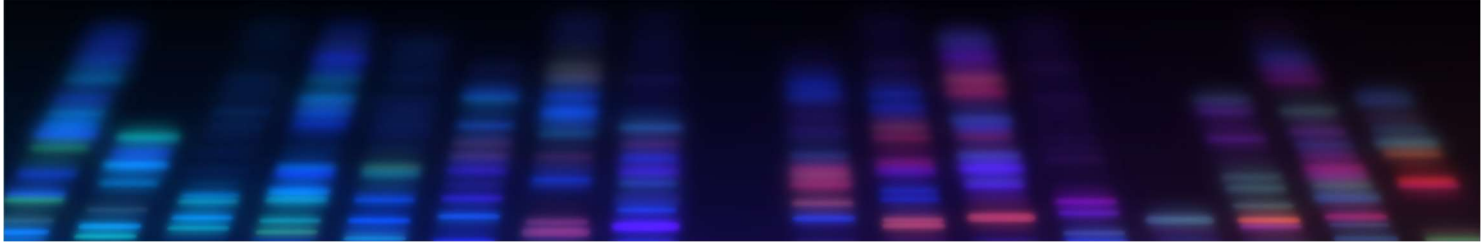
WHAT IS A LABORATORY DEVELOPED TEST (LDT)?

Body fluid chemistries are among the tests considered to be an LDT.

According to the FDA, LDTs are laboratory tests designed for clinical use that have not previously been approved by the FDA. This includes FDA approved tests that have been modified or run "off label." A common example of a modified LDT is body fluid chemistry.

The FDA considers the laboratory as a "manufacturer" of that LDT and is now regulated similar to other manufacturers by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The FDA's goal with this change is to assure LDTs are safe and effective for patients.



WHAT SHOULD WE DO?

Ignoring the LDT Final Rule will not make it go away!

Ignoring the regulation change will place your laboratory at risk for violating federal law. Waiting and hoping for a court injunction to stop the regulation may be the equivalent to lottery tickets as a retirement plan. Laboratories should prepare today!

Among initial steps to take, laboratories should create a running list of LDTs currently in use. Include whether the test was in use prior to May 6, 2024. For these LDTs, start preparing for Stage I requirements. LDTs developed after May 6, 2024, are subject to full regulation, including 510 (k) or Pre-Market Review, which carry significant financial costs.

Next, review package inserts for your reagents and evaluate what tests have been FDA approved and what specimen types are FDA approved. Determine whether the assay is for "adult use only" making pediatric use "off label, and therefore an LDT.

Finally, educate yourself about the changes to the regulation. The FDA provides an excellent place to start. Type "FDA LDT" into your Internet search browser or visit the FDA's website at https://www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests as a place to start.

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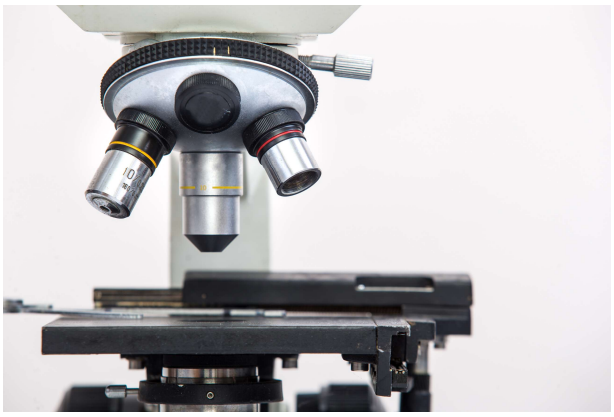

Purchase Consulting Group, LLC
Braintree MA 02184

mbiskup@purchaseconsultinggroup.com
https://labconsultingpartners.com/