PCG Laboratory News

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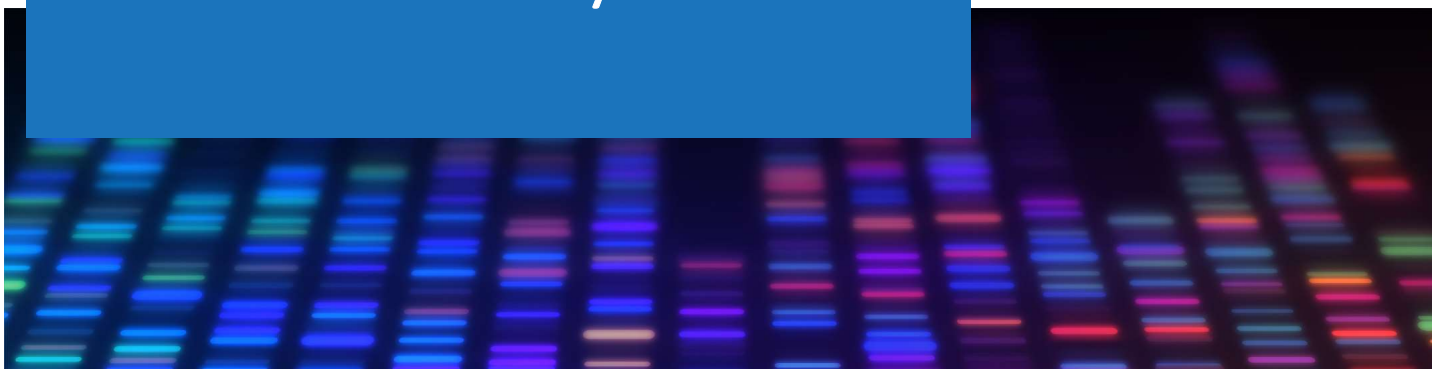

LDT REGULATIONS CARRY COST

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

Any laboratory that maintains complaint files as required under 21 CFR 820.198 for LDTs is required by law to register annually with the FDA and pay an annual fee (Stage 2). In 2024, the **registration fee is $7,653** per location. This will apply to almost all laboratories with an LDT, except Department of Defense (DoD) and Veteran's Affairs (VA).

Laboratories will need to plan and include these expenses as part of Stage 2 budgets (May 2026).

There are other fees to consider if your LDT requires a 510(k) (Stage 5), De Novo (Stage 5), or PMA (Stage 4) submission. The fees are charged per test submission.

510(k) Standard Fee - $21,760

De Novo Standard Fee - $145,068

PMA Standard Fee - $483,560.

Small business fee rates are available for those that qualify.

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

HOW PCG HELPS LABS

We are laboratorians!

Our lab-experienced consultants offer the following services:

- Operational and Strategic Consulting
- Benchmarking (Labor and non-Labor)
- Labor and Productivity Analysis
- Consolidation Feasibility Analysis
- Operations Assessments
- Inspection Readiness (CAP, TJC, NYS)
- Interim Management
- Leadership Mentoring

STAGE 1 – COMPLAINT FILES

Prompt attention and documentation of complaints is required!

According to 21 CFR 820.198 of the Code of Federal Regulations (CFR), a complaint is any written, electronic, or oral communication that alleges deficiencies in a medical device after it has been released for distribution. These deficiencies can relate to the device's identity, quality, durability, reliability, safety, effectiveness, or performance.

The first step for laboratories will be to officially designate an individual or team ("formally designated unit (FDU)") to promptly handle and document all complaints.

The second step will be developing policies and procedures to handle complaints related to LDTs.

Upon receipt of a complaint, the FDU will determine whether an investigation is necessary. Even if no investigation is necessary, the FDU must document the reason and who is responsible.

The FDU will also determine whether the complaint is significant and needs to be reported to the FDA (21 CFR 803).

(1) Whether the device failed to meet specifications;

(2) Whether the device was being used for treatment or diagnosis; and

(3) The relationship, if any, of the device to the reported incident or adverse event.

Stage 1 requirements are effective May 6, 2025.

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