PCG Laboratory News

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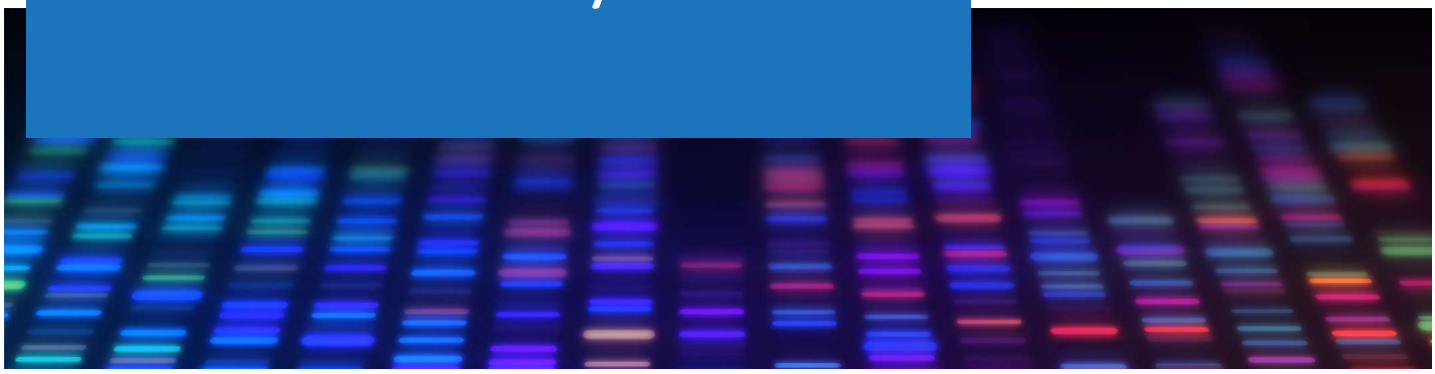


ARE MY LDT'S EXEMPT?

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 has also provided several exemptions from part or all of the regulations. The exemptions are complex, and some carry regulatory obligations as partial exemptions. A list of fully exempt laboratories and tests are provided to the right.

Despite strong opinions during the public comment period in 2023, Academic Medical Centers are *not* exempt from the FDA Final Rule.

LDTs marketed prior to May 6, 2024, are partially exempt from the regulations. This category will benefit most laboratories by avoiding the expenses and process of pre-market approval. However, the FDA warns the LDT cannot be significantly modified after May 6, 2024. Modification could include a normal upgrade of laboratory instrumentation.

It will be crucial to document the date your LDT was in use to prevent violation of federal law.

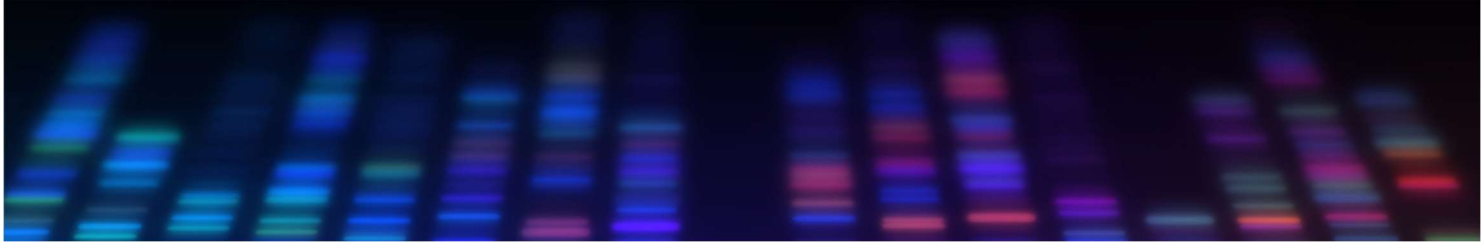
Need help complying with the new FDA Final Rule?
Contact PCG today at mbiskup@purchaseconsultinggroup.com

WHO IS EXCLUDED FROM LDT RULES?

Compliance is not expected by the FDA.

The FDA has considered the following groups and test classes *fully* excluded from enforcement of the LDT Final Rule:

- Veteran's Affairs (VA)
- Department of Defense (DoD)
- Pre-1976 manual LDTs
- HLA for transplants
- Forensic testing



WHAT IS AN UNMET NEED?

Laboratories will be challenged to thread this needle!

The Unmet Need exemption may seem to be a logical workaround for many hospital laboratories. However, the FDA has placed many restrictions on this exemption making it near impossible to use this exemption. One must read the fine print to understand the regulation and avoid violating the law.

The FDA "considers an LDT to be for an unmet need where there is no available FDA-authorized IVD that meets the patient's needs." Initially, a Lab Director may rejoice thinking a body fluid Amylase fits in this category. Not so fast… there is controversial language in the Federal Register (p. 37303) that may prevent body fluids from this exemption. The FDA is expected to provide clarity in coming months regarding this language.

Other Unmet Needs include testing for rare diseases that have no current FDA-approved tests, testing that provides results in a significantly shorter amount of time (hours vs. days), and testing that patients do not have access to.

A test will no longer qualify for the Unmet Need exemption once an FDA-approved test is available and accessible. Also, the FDA will not accept potential improvements in performance or lower cost to justify as an Unmet Need.

One must read the fine print to understand the regulation and avoid violating the law.

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FDA LDT FINAL RULE PARTIAL EXEMPTIONS

Exemption	DESCRIPTION	STAGE 1	STAGE 2	STAGE 3	STAGE 4	STAGE 5
Unmet Needs (Section V.B.3 of preamble)	No available FDA-authorized IVD that meets the patient's needs. This may be because: (1) there is no FDA-authorized IVD for the disease or condition (for example, because it is for a rare disease or condition); (2) there is an FDA-authorized IVD for the disease or condition but it is not indicated for use on the patient, or a unique attribute needs to be added to the LDT to meet the patient's needs; or (3) there is an FDA-authorized IVD but it is not available to the patient.	COMPLY	COMPLY	COMPLY (Records only)	EXEMPT	EXEMPT
Currently marketed IVDs offered as LDTs (Section V.B.3 of preamble)	LDTs currently in use (prior to May 6, 2024) and not significantly modified after May 6, 2024.	COMPLY	COMPLY	COMPLY (Records only)	EXEMPT	EXEMPT
LDTs approved by NYS CLEP (Section V.B.2 of preamble)	LDTs that are approved by, conditionally approved by, or within an approved exemption from full technical documentation under NYS CLEP.	COMPLY	COMPLY	COMPLY*	EXEMPT	EXEMPT
Nonmolecular antisera LDTs for rare RBC antigens (Section V.B.3 of preamble)	Rare antisera for transfusion medicine testing.	COMPLY	COMPLY	COMPLY (Records only)	EXEMPT	EXEMPT
Modified version of another manufacturer's 510(k) cleared or De Novo authorized test (Section V.C.4 of preamble)	Applies to modification after May 6, 2024. Modification may include specimens types not approved by FDA, any "off label" use, and instrument upgrades. The FDA is expected to clarify the definition of modified in the coming months.	COMPLY	COMPLY	COMPLY*	COMPLY	COMPLY
New LDTs or Modified LDTs after May 6, 2024	Modification may include a significant change to the process, including instrument upgrades. The FDA is expected to clarify the definition of modified in the coming months.	COMPLY	COMPLY	COMPLY	COMPLY	COMPLY

* Because these tests are LDTs, FDA generally will not expect compliance with 21 CFR Part 820 requirements other than design controls, purchasing controls, acceptance activities, CAPA, and records requirements.

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