Laboratory Developed Tests: Frequently Asked Questions

This page provides answers to frequently asked questions (FAQs) related to laboratory developed tests (LDTs) (/medical-devices/in-vitro-diagnostics/laboratory-developed-tests).

Q: What is a laboratory developed test (LDT)?

Laboratory developed tests, or LDTs, are in vitro diagnostic products (IVDs) (/medical-devices/products-and-medical-procedures/in-vitro-diagnostics) that are intended for clinical use and designed, manufactured, and used within a single clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meets the regulatory requirements under CLIA to perform high complexity testing.

IVDs are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. IVDs are intended for use in the collection, preparation, and examination of specimens taken from the human body, such as blood, saliva, or tissue. IVDs, including LDTs, can be used to measure or detect substances or analytes in the body, such as proteins, glucose, cholesterol, or DNA, to provide information about a patient's health, including to diagnose, monitor, or determine treatment for diseases and conditions.

Q: How does the FDA's final rule for LDTs help to assure IVDs offered as LDTs are safe and effective?

The final rule, including the phaseout policy described in the preamble to the final rule, is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance. The FDA is phasing out the general enforcement discretion approach for LDTs so that IVDs manufactured by laboratories will generally fall under the same enforcement approach as other IVDs.

Compliance with device requirements under the FD&C Act will help assure IVDs offered as LDTs are appropriately safe and effective and put patients in a better position to have confidence in IVDs regardless of where they are manufactured. Device requirements include, among others:

- adverse event reporting,
- establishment registration,
- device listing,
- labeling requirements,
- investigational use requirements,
- quality system requirements, and
- premarket review.

Q: Does the FDA's LDT final rule apply to future LDTs only or does it also apply to all LDTs currently in use?

The LDT final rule amends the FDA's regulations to make explicit that IVDs are devices under the FD&C Act including when the manufacturer of the IVD is a laboratory. This amendment is not specific to certain types of LDTs, but rather relates to all IVDs manufactured by laboratories. In addition, the preamble to the LDT final rule describes a tailored phaseout policy under which the FDA will provide greater oversight of IVDs offered as LDTs through a phaseout of its general enforcement discretion approach for LDTs over the course of four years. The phaseout policy includes targeted enforcement discretion policies for specific categories of IVDs, including policies for currently marketed IVDs offered as LDTs and LDTs for unmet needs under certain circumstances.

As described in the preamble to the final rule (https://www.federalregister.gov/d/2024-08935), the FDA intends to exercise enforcement discretion with respect to premarket review and most Quality System (QS) requirements for currently marketed IVDs offered as LDTs that were first marketed before the LDT final rule issued. Additionally, as described in the preamble to the final

rule, the FDA intends to exercise enforcement discretion with respect to premarket review and most QS requirements for LDTs manufactured and performed by a laboratory integrated within a health care system to meet an unmet need of patients receiving care within the same health care system. FDA expects compliance with other device requirements for IVDs falling within these policies.

Q: Will patients have access to critical tests given FDA's greater oversight of LDTs?

The phaseout policy is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance. The targeted enforcement discretion policies described in the preamble to the LDT final rule for certain categories of IVDs, such as the policies for IVDs marketed at the time of issuance of the final rule and LDTs for unmet needs, for example, will help to facilitate patient and health care professionals' access to certain IVDs.

Q: How can the FDA's oversight of LDTs help facilitate innovative advances?

The FDA believes that by applying the same general oversight approach to laboratories and non-laboratories that manufacture IVDs, the FDA will reduce regulatory uncertainty, which will give stakeholders more stability, clarity, and confidence, and facilitate investment in the development of innovative IVDs.

Q: Why does the final rule include enforcement discretion policies for certain categories of IVDs?

FDA is phasing out its general enforcement discretion approach to help assure the safety and effectiveness of IVDs offered as LDTs. As discussed in the preamble to the final rule (https://www.federalregister.gov/d/2024-08935), FDA recognizes the role that laboratory-manufactured tests play in modern healthcare, the effect that the Agency's longstanding enforcement discretion approach for LDTs has had on the market, and the presence of other expert regulatory bodies. FDA's phaseout of the general enforcement discretion approach and targeted enforcement discretion policies balance the important public health considerations at issue (for a comprehensive discussion of those considerations, please refer to section III.B of the preamble to the final rule, as well as the discussions of the various enforcement discretion policies throughout the preamble to the rule).

As discussed in the preamble to the final rule, for example, we included an enforcement discretion policy for currently marketed IVDs offered as LDTs in consideration of concerns that expecting compliance with full quality system and premarket review requirements for such IVDs could lead to the loss of access to safe and effective IVDs on which patients currently rely. We also included an enforcement discretion policy for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system in consideration of concerns that expecting full compliance with FDA requirements could lead to loss of access to such LDTs for which laboratories cannot recoup the costs of compliance. FDA has also adopted enforcement discretion policies that recognize the regulatory role that certain other Federal and State entities play.

Q: What does the FDA consider to be an unmet need for purposes of the unmet need enforcement discretion policy in the preamble to the final rule?

As described in the preamble to the final rule (https://www.federalregister.gov/d/2024-08935), 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. 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. Examples of LDTs for unmet needs are:

- An LDT that is intended for cytogenetic analysis of certain genes and chromosomes associated with rare diseases or conditions, certain metals testing, viral load monitoring for some transplant-associated viruses, or diagnosis of certain mosquito- and tick-borne-diseases, where there is no FDA-authorized IVD for the disease/condition *(rare disease or condition);*
- An LDT to accommodate an alternative specimen type that is infrequently tested when the specimen type required for the FDA-authorized IVD is not and cannot be made available *(variation from the indications for use of an FDA-authorized IVD);*
- An LDT for use on pediatric patients when FDA-authorized IVDs are indicated for use on adults only *(variation from the indications for use of an FDA-authorized IVD);*
- An LDT that generates results in a significantly shorter period (e.g., hours versus days) than an FDA-authorized IVD with the same indication where, due to the circumstances of the patient, the shorter time period to get results is critical for the clinical decision being made *(unique attribute needed to be added to an FDA-authorized IVD);*

- An LDT for the same indication as an FDA-authorized IVD that is offered only in another healthcare system that is not accessible to the patient and the developing laboratory will not make the IVD available outside its system *(FDA-authorized IVD is not available);* and
- An LDT for an emerging pathogen for which there is no FDA-authorized IVD and for which FDA has not identified an emergent situation *(no FDA-authorized IVD).*

In contrast, as described in the preamble to the final rule, the FDA does not consider an LDT to be for an unmet need when there is an available FDA-authorized IVD that would sufficiently meet the needs of the patient. For example, potential improvements in performance or lower cost in comparison to an FDA-authorized IVD that meets the patient's needs does not fall within this policy.

Q: What resources does the FDA plan to provide to labs to help them understand and comply with the requirements?

The FDA plans to hold educational webinars, publish guidance documents, provide templates, and participate in conferences. Any IVD manufacturer can also use the FDA's Q-Submission process to discuss considerations for specific IVDs.

Q: Is there an enforcement discretion policy that applies to modifications of currently marketed IVDs offered as LDTs?

As described in the preamble to the final rule (https://www.federalregister.gov/d/2024-08935), FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements for modifications to currently marketed IVDs offered as LDTs first marketed prior to the date of issuance of the rule that do not (individually or in aggregate):

- change the indications for use of the IVD;
- alter the operating principle of the IVD (for example, changes in critical reaction components);
- include significantly different technology in the IVD (e.g., addition of artificial intelligence or machine learning to the test algorithm, a change from targeted sequencing to whole genome sequencing, a change from immunoassay to mass spectrometry, or a change from manual to automated procedures); or
- adversely change the performance or safety specifications of the IVD.

Q: I am a laboratory with an LDT. Do any enforcement discretion policies apply to my LDT?

As described in the preamble to the final rule (https://www.federalregister.gov/d/2024-08935), for IVDs offered as LDTs that were marketed on the date of issuance of the rule, the FDA generally intends to exercise enforcement discretion with respect to premarket review and QS requirements (except for requirements under 21 CFR part 820, subpart M (Records)), as long as they are not modified following the issuance of this final rule, or are modified but only in a limited way. As noted in the preamble to the final rule, this enforcement discretion policy applies only to premarket review and most QS requirements.

For other types of IVDs, please refer to the preamble to the final rule to determine whether another enforcement discretion policy applies to your IVD.

Was this helpful? Yes No