

# FAQs on Laboratory Developed Tests (LDT)

## ► What does this decision mean?

Laboratories developing tests solely to be used within the lab (laboratory developed tests, or LDTs) do not need to undergo pre-market review by the FDA. It is important to note, this pre-market review requirement has almost never been enforced. In the case of future pandemics, this decision will allow labs to quickly develop and utilize tests.

## ► Who made this decision?

HHS leadership asked the Office of the General Counsel (OGC) to examine the underlying authority for requiring premarket review of LDTs. The legal review concluded that FDA must issue a requirement for pre-market review by notice and comment rulemaking, or it can be required by an act of Congress.

## ► Why was this decision made at this time?

This decision was made by HHS, as part of an on-going departmental review of our response to COVID-19. HHS announced this change after the conclusion of OGC's legal review.

## ► Is this specific to LDTs testing for COVID-19?

No. This is broadly applicable to all LDTs, regardless of what they are testing for.

## ► Are LDTs now unregulated at the federal level?

No. LDTs are still regulated by the federal government, via the Department of Health and Human Services (HHS), specifically the Centers for Medicare & Medicaid Services' (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulations and the Food and Drug Administration (FDA) under the Public Health Service Act. Under CLIA, labs are required to validate a test before using it, and the lab must produce records demonstrating validation if challenged.

## ► Hasn't FDA always mandated premarket review for LDTs?

No. Although FDA has asserted the authority to do so, this requirement has in fact almost never been enforced. It was only being enforced during public health emergencies, and we are simply reverting to the same level of regulatory requirements that were in place during all other times.

## ► Did the Trump Administration remove FDA's authority to regulate COVID-19 tests?

Absolutely not. Every COVID-19 test in America is still subject to regulations at the federal level. This has no effect on ordinary commercial tests. All this did was remove the requirement that laboratories receive an EUA for LDTs that are intended for use within a single lab. The Trump Administration is merely complying with the law.



### ▶ Will this lead to low quality COVID-19 tests flooding the market?

Nothing will be flooding the market as a result of this change. LDTs, by definition, cannot be sold outside of the laboratory in which they were developed. There is no reason to believe that complying with law will have any effect on the quality of LDTs. Every COVID-19 test, including LDTs, are still regulated by the federal government.

### ▶ Is the FDA still able to regulate LDTs?

Yes. FDA is still able to regulate LDTs under the Public Health Service Act, even if they are not subject to pre-market review.

### ▶ Are COVID-19 tests that are distributed for testing required to receive FDA authorization?

Yes. Direct-to-consumer (DTC) tests are not LDTs. Any DTC test, including tests shipped by commercial labs, are still required to go through premarket review at FDA, as they are clearly medical devices under applicable statutes.

### ▶ What is the status of EUAs that have already been approved by the FDA for LDTs?

All EUAs granted under the previous requirement are unaffected by this policy announcement.

### ▶ Can FDA still issue EUAs for LDTs?

Yes. Laboratories can still voluntarily submit their LDTs to the FDA for an EUA.

### ▶ Why might a laboratory request an EUA given this announcement?

An EUA triggers PREP Act coverage which immunizes laboratories from suits for loss related to the test.

