# Cristales and Nguyen in Med Device Online: A Closer Look at FDA's Controversial Rule on Laboratory Developed Tests

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Haynes Boone Associates Kayla Cristales and Luke Nguyen authored an article for *Med Device Online* exploring the FDA's recently issued Final Rule changing the Agency's longstanding enforcement policy on Laboratory Developed Tests (LDTs).

Read an excerpt below.

FDA's recent issuance of a final rule (the "rule") on laboratory developed tests (LDTs) ended the agency's long-standing policy of exercising enforcement discretion with regard to medical device regulations that would, otherwise, apply to any labs that prepare and/or market LDTs. The rule is also a clear indication of FDA's final answer to the question of whether it has the authority to regulate LDTs under the Food, Drug, and Cosmetic Act (the FD&C Act). Spoiler alert: It's "yes." Unsurprisingly, given the well documented back-and-forth between FDA and industry on this very issue over the last three decades, the rule was immediately met with lawsuits from industry stakeholders challenging FDA's authority to regulate LDTs, which the lawsuits contend (among other things), do not fall within the FD&C Act's definition of "device." Congressional opposition to FDA's enforcement of the rule and an incoming presidential administration promising to overhaul FDA policies viewed as unduly restrictive have contributed to industry uncertainty regarding the rule's viability. Nonetheless, unless/until something changes, the rule is effective. Potentially affected stakeholders should, thus, understand what the rule requires (and when), how it applies to them, what steps are required to comply by the applicable deadlines, and the likely associated costs, as well as the potential risks of noncompliance.

**How Did FDA Regulate LDTs Before The New Rule?**
In vitro diagnostics (IVDs) are clinical tests performed on samples taken from the human body, which are generally classified — and regulated — as medical devices under the FD&C Act. LDTs are a subset of IVDs that are (1) intended for clinical use and (2) designed, manufactured, and used within a single CLIA-certified laboratory. Prior to the rule, FDA exercised enforcement discretion with regard to all LDTs and all otherwise applicable device regulations.

**What Does The Rule Require?**
FDA's new framework phases out enforcement discretion for applicable LDTs in five stages, with specified carveouts for certain categories of tests (discussed further below).

To read the full article from *Med Device Online*, click here.