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FDA's Latest on Emergency Diagnostics and a No-Frills Rescission of the LDT Rule

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On Tuesday, September 23, 2025, FDA published guidance titled "Consideration of Enforcement Policies for In Vitro Diagnostic Tests During a Section 564 Declared Emergency." The guidance, a draft of which was published on May 6, 2024, specifies the factors that FDA intends to assess in deciding whether to issue an enforcement discretion policy with regard to in vitro diagnostics (IVD) manufacturers offering unapproved IVDs, among other devices, during a declared emergency. These factors include:

- *Public health need*. FDA would consider the testing needs presented by the declared emergency, including an analysis of the authorized or approved tests available and the time sensitivity of the testing needs. The time sensitivity would be dependent on a variety of factors, including the transmissibility of the disease in question, as well as its morbidity and mortality.
- *Benefits and risks.* This analysis would weigh the benefits of expedient access to testing (e.g., infection control) against the risks of using an unapproved or unauthorized test (e.g., risk of false result).
- *Alternatives*. FDA will consider whether alternative approved or authorized IVDs might be used to diagnose the disease or condition and whether there is sufficient manufacturing capacity for these tests to meet the demand, among other factors.
- *Mitigations*. FDA noted that it intends to consider manufacturer experience and participation in a government evaluation program such as the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) Tech program's Independent Test Assessment Program (ITAP), along with other factors.

FDA noted that it would consider the public health needs as well as the risks and benefits of the use of unapproved or unauthorized IVDs periodically during the declared emergency and that it would adjust its policy of enforcement discretion depending on the outcome of that analysis.

This follows the agency's publication of a final rule on September 19th, revising the definition of IVD devices to reflect the United States District Court for the Eastern District of Texas' final judgment in *American Clinical Laboratory Association et al., v. FDA*. In that case, the District Court vacated and set aside a rule that would have formally brought laboratory developed tests under FDA oversight (the LDT Rule). The rule published last week restores the definition of IVD devices to its pre-LDT Rule language (*see* 21 C.F.R. § 809.3(a)). While this simple rescission rule restores the regulations to their previous wording, it does not address how FDA interprets the court's decision, which did not provide clear guidance on what, precisely, falls within the types of laboratory tests that fall outside the statutory device definition.

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