

## Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests

As part of HHS's ongoing department-wide review of regulatory flexibilities enacted since the start of COVID-19, the department has determined that the Food and Drug Administration ("FDA") will not require premarket review of laboratory developed tests ("LDT") absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances. Those seeking approval or clearance of, or an emergency use authorization ("EUA") for an LDT may nonetheless voluntarily submit a premarket approval application, premarket notification or an EUA request, respectively, but are not required to do so, and FDA will adjudicate those submissions. Those opting to use LDTs in their laboratories without FDA premarket review or authorization may do so with the understanding that they would not be eligible for PREP Act coverage absent approval, clearance or authorization and would remain subject to regulation by the Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, and its implementing regulations at 42 C.F.R. pt. 493. Those with an active EUA to use an LDT to detect the virus causing COVID-19 or its antibodies are unaffected by this announcement.

[Read the FAQs on Laboratory Developed Tests - PDF](#)

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