The Continuing Saga of Lab Developed Tests, Including for COVID-19 Testing



In August, the U.S. Department of Health & Human Services (HHS) **announced** that the FDA will not require premarket review of laboratory developed tests (LDTs), whether COVID-19 related or not, absent notice-and-comment rulemaking. Labs may voluntarily seek a premarket approval, 510(k) clearance, or an emergency use authorization (EUA) for their LDTs. Importantly, labs that do not obtain such FDA approval, clearance, or authorization would not be eligible for **PREP Act** coverage.

This announcement may have come as a surprise to FDA, which historically has asserted its medical device regulatory authority over LDTs while often subjecting them to enforcement discretion. Despite this HHS announcement, FDA's May 11, 2020 **Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency** remains in effect and has not been revised since the announcement. Importantly, this guidance offers two pathways for COVID-19 related LDTs – an EUA submission to FDA and the development of an LDT under the authorities of the State in which the laboratory resides, where the State takes responsibility for COVID-19 testing by labs in its State.

For FDA's latest statements on COVID-19 testing, see the **opinion piece** authored by CDRH Director Dr. Jeffrey Shuren and Dr. Timothy Stenzel, Director of the Office of Health Technology 7, In Vitro Diagnostics and Radiological Health, in the Hill.