

The FDA believes that all patients deserve to have access to accurate and reliable tests regardless of where they are made. While laboratory developed tests (LDTs) play an important role in our healthcare system, the FDA is very concerned about problematic LDTs currently used in the U.S. that might not provide patients with accurate and reliable results. A legislative solution offers the opportunity to create a modern framework specifically tailored to in vitro clinical tests.

VALID remains one of the FDA's top legislative priorities for reauthorization of the Pandemic and All-Hazards Preparedness Act. A modern oversight framework that is specifically tailored to assuring tests work is critical to position ourselves for the future – whether it is preparing for the next pandemic or realizing the full potential of diagnostic innovation. The past few years have highlighted the critical need for a modern regulatory framework that strikes the appropriate balance to promote innovation while also ensuring patients have access to accurate and reliable diagnostics. Patients and providers in the U.S. want and deserve assurances that the in vitro clinical tests used in their health care decision-making are accurate and reliable, regardless of where they are made. The FDA stands ready to continue working with Congress on diagnostic testing reform. However, given problems we have seen with some LDTs, we are pursuing an administrative solution under our current statutory authority.