



For Immediate Release

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National Independent Laboratory Association (NILA) and American Association of Bioanalysts (AAB) Respond to FDA’s Release of Final Rule on Laboratory Developed Tests (LDTs)

The National Independent Laboratory Association (NILA) and the American Association of Bioanalysts (AAB) expressed deep concern today over the Food and Drug Administration’s (FDA) newly finalized rule on Laboratory Developed Tests (LDTs). The rule ends the FDA’s longstanding practice of enforcement discretion of LDTs, integrating them into the regulatory framework applicable to in vitro diagnostic products (IVDs).

NILA and AAB remain opposed to the approach taken by the FDA to regulate LDTs as IVDs. LDTs are fundamentally distinct from manufactured IVDs and should not be subject to the same regulatory process. The unique and essential role LDTs play in health care and public health—identifying emergent infectious diseases, tracking new substances in the opioid crisis, and providing critical clinical data to health care providers—cannot be overstated. LDTs are developed, validated and used within a specific laboratory by skilled laboratory professionals and are tailored to meet pressing and unique health needs that often cannot be addressed with existing IVD test kits.

“FDA finalizing this rule poses significant risks to the patients our members serve,” said Mark Birenbaum, PhD, executive director of AAB and NILA. “Many of our member laboratories have told us they will be forced to cut their test menus, and some might even close their doors—significantly limiting patient access to essential tests that simply aren’t available in the form of FDA-approved test kits,” Birenbaum stated.

NILA and AAB urged the FDA to reconsider its approach in [formal comments submitted to the agency on December 4, 2023](#), and reiterated this position in a meeting with the Office of Information and Regulatory Affairs in a meeting on April 15, 2024.

NILA and AAB call for an urgent dialogue with policymakers to explore a viable regulatory framework that recognizes the unique nature of LDTs and prioritizes patient access to essential diagnostics.

About NILA and AAB NILA represents community, regional, and specialty clinical laboratories across the U.S., providing essential testing services to diverse patient populations. AAB, established in 1956, includes clinical laboratory professionals dedicated to supporting community and specialty laboratories in delivering critical diagnostic services.