

National Independent Laboratory Association
VALID Act
Talking Points

- My name is [redacted] and I am [redacted] at [Laboratory] in [state]. I am also a member of the National Independent Laboratory Association, or NILA.
- NILA represents community and regional independent laboratories that serve a wide variety of patient populations, many of which are not served by larger independent clinical laboratories. This includes rural areas, underserved urban areas, and nursing home populations.
- I am [writing/calling] with concerns about the VALID Act, which is included in Senate legislation to reauthorize FDA user fee programs. As Congress moves to extend FDA user fees before the end of the fiscal year, I ask you to ensure that the VALID Act is not included in final legislation or added to any end of the year legislative package.
- The VALID Act creates costly and duplicative review and registration requirements on LDTs, which will burden independent laboratories and limit patient access to critical diagnostic testing.
- Like my laboratory, many NILA members use laboratory-developed tests, or LDTs, to provide expansive test menus for providers and patients-particularly of tests for which there are not adequate tests kits on the commercial market.
- [Provide and explain an example that impacts your laboratory, some prompts are below]
 - LDTs have been invaluable in detecting emerging synthetic fentanyl's fueling the ongoing opioid epidemic. LDTs allow labs to respond immediately to the new and novel threats posed by these substances, facilitating both the emergency treatment of patients and swift public health response.
 - Labs have developed LDTs to detect more than 400 different allergens, most of which are not available from IVD manufacturers.
 - Testing required for organ transplant requires the use of LDTs.
- Overly burdensome and costly requirements will lead to laboratories dropping these types of tests from their menus, leaving patients and physicians without access. In its current form, the VALID Act would be catastrophic to the independent laboratory industry, which has already suffered damage from reimbursement cuts under the Protecting Access to Medicare Act and which made significant investments to respond to the COVID-19 pandemic.
- If the VALID act cannot be removed from pending legislation, NILA has recommendations that could help lower the burden of proposed registration requirements. Could I follow up to connect you with NILA and share those recommendations with you?