84% of Survey Respondents Believe the FDA's Proposed Rule to Regulate Lab-Developed Tests Will Hurt Their Laboratories. Patient Access to Testing Is a Major Concern.

In October 2023, the FDA released a proposed rule to regulate laboratory-developed tests (LDTs) as medical devices. About 6,700 public comments were submitted during the open comment period. To better understand how laboratorians perceive the proposed rule, ARUP Laboratories conducted a survey of the clinical laboratory community. Most respondents identified as lab managers, lab supervisors, lab directors, lab employees, medical directors, pathologists, physicians, clinicians, or PhD scientists.

Support for FDA Proposal

Yes **8.2%**

No **71.6%**

Don't know **13.7%**

No opinion **6.6%**

Of 503 respondents, only 8% support the FDA's proposed rule.

Negatively Impacted by Rule

Yes **83.9%**

No **3.4%**

Don't know **12.7%**

Of respondents whose laboratories perform LDTs, nearly 84% believe the rule will negatively impact their laboratories.

Remove Tests From Menu

Yes **60.9%**

No **5.9%**

Don't know **33.2%**

The majority of laboratories believe they will have to remove tests from their menus.

ARUP CLIENTS

More than 50% of the nation's:

- University medical centers
- Pediatric hospitals
- Teaching hospitals

ABOUT ARUP

- Provides diagnostic testing services for hospitals in all 50 states
- Processes 70,000 specimens per day
- Impacts healthcare diagnoses of 17 million patients annually

EXAMPLES OF LDTS

- Newborn toxicology testing with mass spectrometry
- Rare disease testing
- Genetic testing

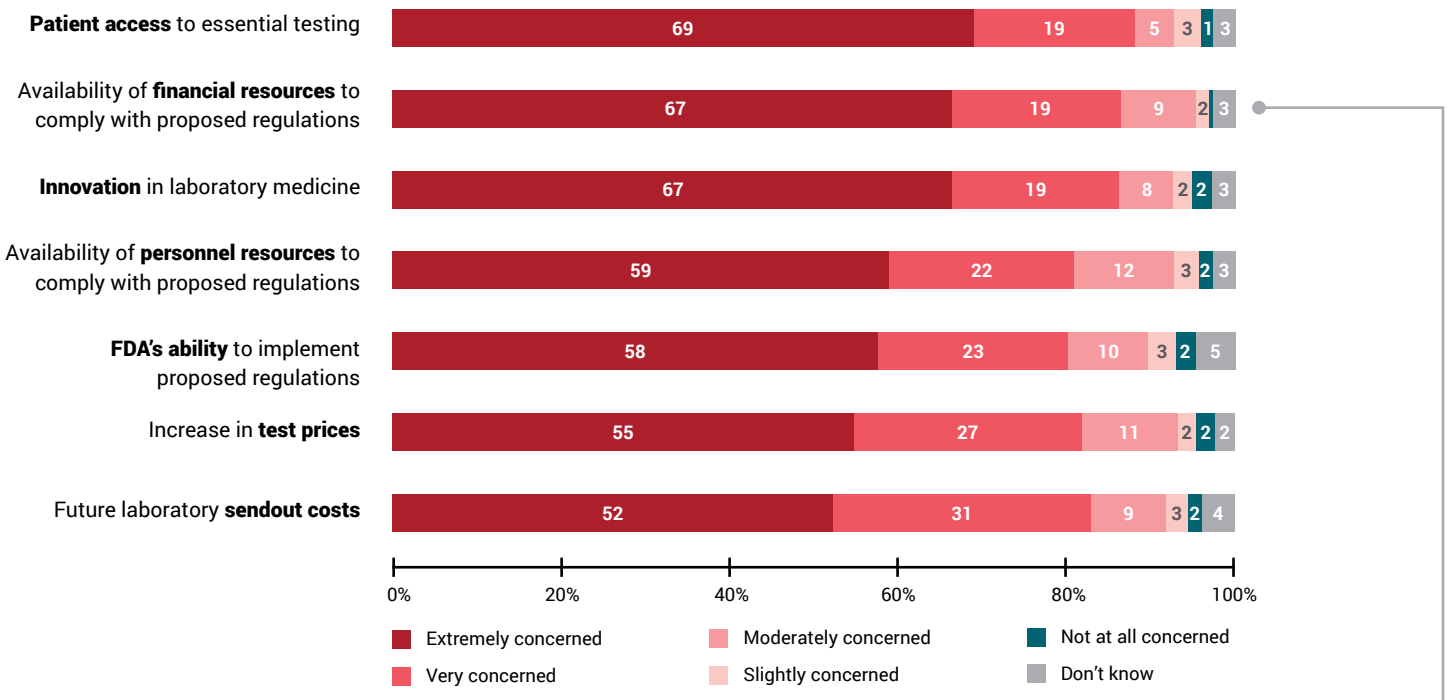
SEE : ARUP's survey results
READ: ARUP's formal public comment, industry/partner resources, FDA announcement
WATCH: ARUP's chief medical officer and compliance officer discuss the proposed rule and its impact on patient safety, test availability, and innovation.
aruplab.com/fda-ldt

ARUP® LABORATORIES

"This survey shows there is profound concern within the clinical laboratory community regarding the proposed rule and its impact on laboratories and patient care. If labs cannot afford to comply with the regulations, they will have to discontinue essential tests, and that harms patients."

Jonathan Genzen, MD, PhD, ARUP's chief medical officer and senior director of governmental affairs

88% of respondents expressed strong concern regarding the proposed rule and patient access to essential testing.



Only 3% reported having sufficient financial resources to pay FDA user fees.

ARUP has urged the FDA to withdraw the proposed rule and encouraged the Department of Health and Human Services, which oversees the FDA, to work with the Centers for Medicare and Medicaid Services, legislators, and the clinical laboratory community to determine how to better address LDT oversight.

ARUP® LABORATORIES