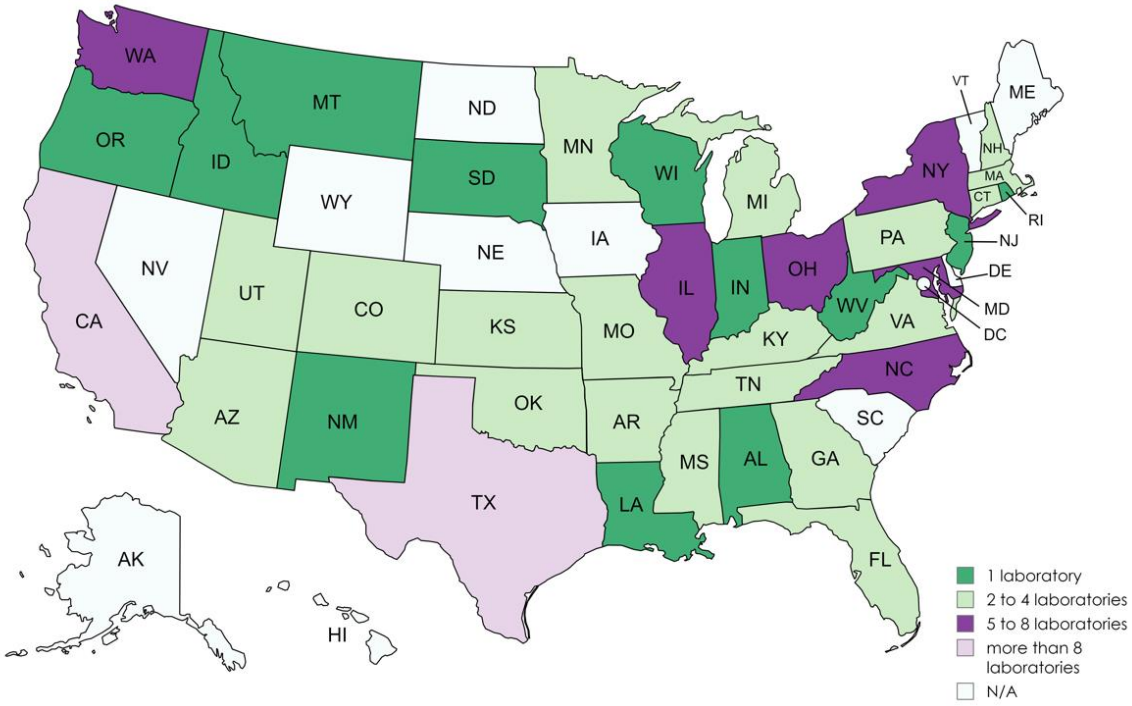
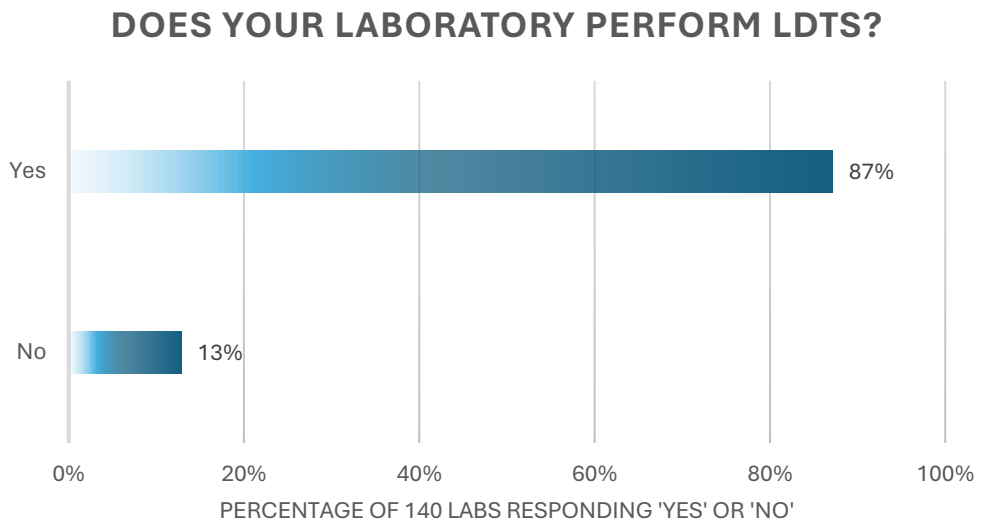
ADLM Member Feedback: Assessing Responses to FDA's Proposed LDT Regulation Survey



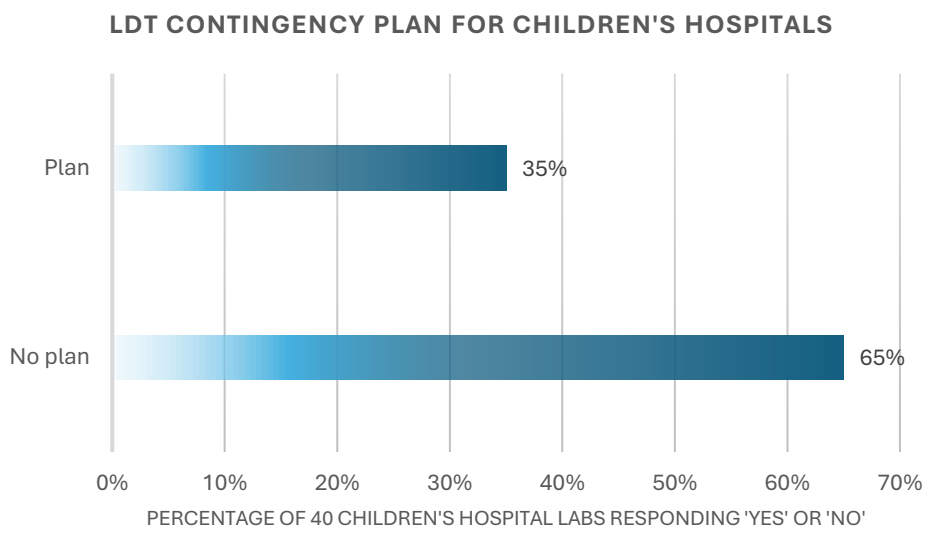
Results and Interpretations

Number of responding laboratories:
140 US-based laboratories

Q1. Does your laboratory perform laboratory developed tests (LDTs)?



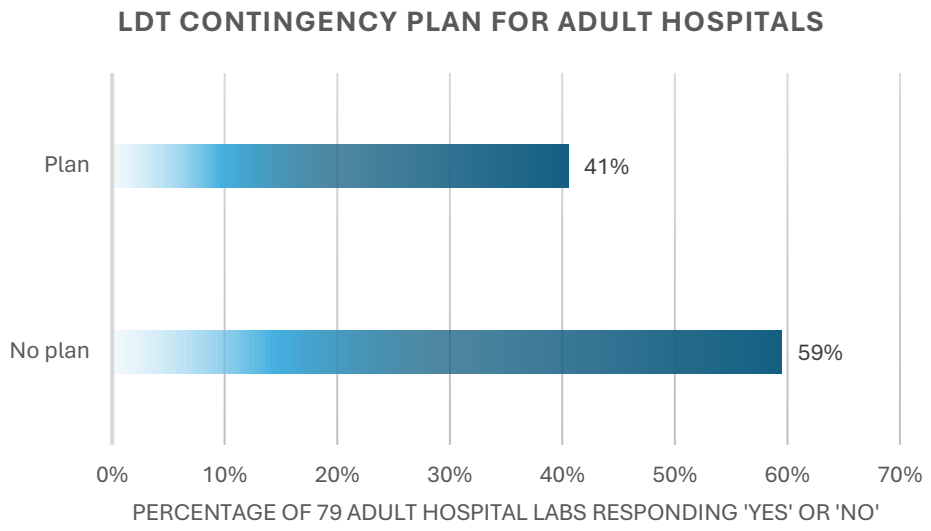
Q2. For children's hospitals, do you have a plan for LDTs if the FDA rule is enacted?



Highlighted Comments:

- *No equivalent FDA approved tests*
- *The tests I do are very complex and low-volume and are for patients with rare immune and genetic diseases. I am not sure that we can afford to submit for PMA as the cost will be prohibitive to the hospital and the patient. So, I am frankly at a loss at what to do if the rule is enacted.*
- *We do not currently have a plan as to what we will do if the FDA rule is enacted.*
- *We have a ballpark plan, but need to know exactly how the FDA is planning to roll this out and what details we need to focus on. A standard LDT study isn't hard, but an FDA pre-market submission is new territory for us.*

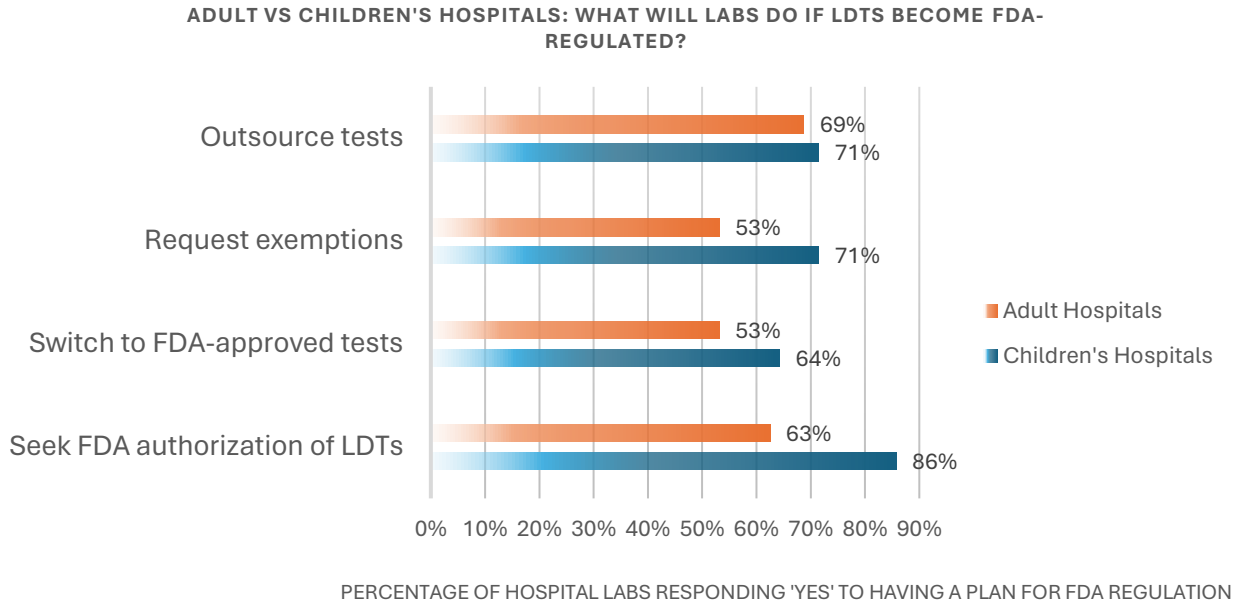
Q3. For adult hospitals, do you have a plan for LDTs if the FDA rule is enacted?



Highlighted Comments:

- *Not sure if we could afford filing for FDA approval.*
- *This is an abrupt change in an age-old process governed under CLIA. Nobody is "ready" for such a change.*
- *This is being discussed, but no conclusion yet because the stake is very high for the hospitals and the patients. Any non-current LDT process will result in a significant financial burden on our hospital system which is under a lot of financial pressure due to the staff shortage and recovery from COVID.*
- *Too expensive*
- *We are a genetics laboratory. There are no FDA approved tests for our entire menu. We would have to re-evaluate offering these services.*
- *We will likely need to abandon LTD's.*

Q4. If you answered "Yes" to Q4 or Q5, please select from the list below those changes you are considering:



Q5. What are your major concerns regarding the FDA's proposed regulation of LDTs?

We received >110 individual responses from our member participants. While unable to include all comments here, we have grouped the major concerns regarding the FDA's proposed regulation of Laboratory Developed Tests (LDTs) into the following five main categories:

1. **Impact on Patient Care and Access**: Concerns about decreased access to diagnostic testing, particularly for rural and disadvantaged populations, as well as potential delays in patient care due to increased regulatory burdens and the new need to send out specimens for testing.
    a. *Delayed clinical care due to having to discontinue in-house testing.*
    b. *Not providing result(s) in a timely manner for patient care when samples are sent out to a reference lab. Not being able to perform testing if reference labs are not able to get FDA approval for their testing.*
    c. *Limiting access to testing for rural and disadvantaged populations*
    d. *Decreased access and worse turnaround times for important LDTs - Substantial cost increases for LDTs that are critical for diagnosis.*
    e. *There are many: 1) High cost, each FDA submission costs greater than $1M and $2M by the time all the applicable studies are completed. 2) FDA staffing's inability to move quickly. The timing it will take for the FDA to review all the submissions they will be flooded with make the approval process take years. 3) Overall, this will stifle innovation and barriers to clinical labs trying to solve diagnostic testing challenges.*

2. **Financial and Operational Burden**: Worries about the financial and operational burden on laboratories, including the cost of FDA submissions, the expense of conducting additional clinical testing to introduce new tests, and the concern that labs will shut down or discontinue certain tests due to the increased cost and regulatory burden.
    a. *The cost and effort required to seek FDA authorization for current LDTs is likely above and beyond what we will be able to do. Patient care will therefore definitely suffer if we have to send tests out to reference labs.*
    b. Cost and Compliance

3. **Innovation and Development**: Concerns exist that heightened regulation may impede innovation and the advancement of new tests, especially for rare or complex diseases. There are also worries regarding the ability of labs to adjust methods to align with market and usage trends.
    a. *The rule will curtail developing new tests and the use of many tests already in use and critical to patient care.*
    b. *Patterns of drug abuse vary over time and geography. Laboratories must be able to respond quickly new drugs (analytes) and incorporate them into their testing regime. Viral outbreaks and mutations vary over time. Laboratories must be able to incorporate new analytes & biomarkers (examples: SARS-CoV-2, Zika Virus, C. auris, Monkeypox, Avian Bird Flu, etc.) into their testing regimes quickly.*
    c. *There are no FDA replacements for some of our tests and many FDA-approved tests require modifications making them LDTs, especially for the pediatric population.*
    d. *Our ability to provide customers/patients with cutting edge laboratory tests.*

4. **FDA Expertise and Oversight**: Doubts about the FDA's expertise and ability to review complex LDTs, as well as concerns about the FDA's capacity to handle the anticipated volume of LDT submissions and the potential for arbitrary review processes.
    a. *FDA lacks appropriate knowledge and experience regulating clinical labs performing LDTs. Patient care is going to be negatively impacted.*
    b. *The FDA has not considered who will develop and validate high complexity, low-volume tests for patients with rare diseases, the associated cost to academic medical centers and patients. Also, the FDA has no expertise in reviewing high complexity immune testing, and thus any such review will be arbitrary. There is no current evidence to indicate that FDA review provides additional quality and safety.*
    c. *1) I don't believe FDA has expertise to review the complex LDTs; 2) many labs do not have financial resources and personnel to do the FDA submission; 3) lengthy and costly review process will hinder innovation. Hospital based clinical labs choose to run an LDT is usually because no FDA cleared test available, or the FDA-approved test is really bad, such as whole blood lead testing.*

5. **Quality and Safety**: Questions about the actual benefit of increased regulation in terms of improving the quality and safety of LDTs, as well as concerns about the potential negative impact on clinical laboratories and their ability to respond to emerging infectious diseases.