FDA Proposed Rule on Laboratory-Developed Tests FAQs
November 21, 2023

1. **What is ASM's official stance on this proposed rule and how will we approach our response?**
While ASM opposes the proposed rule, it is still essential to provide FDA with constructive feedback with an eye toward minimizing the harm it will cause. ASM will offer specific recommendations, focusing extensively on infectious disease (ID) testing, providing data and examples to support our position.

ASM will express support for specific provisions where possible, such as phased in registration of LDTs and severe adverse event reporting as a first step to ensure a data driven approach is taken that is informed by more comprehensive information on LDTs currently in use. ASM believes that FDA lacks the data to make informed decisions regarding test regulation and ASM, along with other stakeholders, would like to address the many requests for data within the proposal so a more meaningful approach can be taken.

ASM recommends the agency pause and use this information to propose a risk-based approach that maintains enforcement discretion for low-risk tests and better accommodates the realities of ID testing.

2. **What is ASM's process for developing a response to the proposed rule?**
ASM is taking a stepwise approach:

Member Input

- ASM formed a working group composed of members spanning various laboratory settings, including academic medical centers, children's hospitals, cancer centers, community hospitals, labs serving other hospitals, reference laboratories and public health laboratories. This group met to discuss best approaches.
- ASM's public policy and advocacy team hosted an online Town Hall on Nov. 1 for members to hear about our approach, share concerns and ask questions.

Data Gathering and Responses to Specific Elements of the Proposed Rule

- ASM is taking a data-driven approach. We conducted an LDT Utilization Survey to have members help guide our response and demonstrate with data the impacts of this proposed rule. We are now comparing the LDTs performed by labs to those FDA approved to identify gaps in targets, patient populations or sample types.
- ASM is compiling specific examples of how LDTs have positively impacted patients from members, as well as how the proposed rule will negatively impact,

low resource areas.

Facilitate Responses from Across the ID Community

- **Responses from ASM Member/Partners:** ASM has developed and shared a customizable letter template for members to craft their own response to the proposed rule that aligns with ASM's response.
- **Capitol Hill Outreach:** ASM continues to work alone and in partnership with peer

individual’s medical record. “Pre-1976"-

12. **Is there a letter I can send to FDA to express my concerns?**
ASM has developed instructions and a template to share your comments with FDA.