



## 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 impact offering of LDTs and subsequent consequences for patient care.
- Lab equity is an important aspect in our response to the proposed rule. To fully articulate this, ASM clinical microbiology staff is meeting with directors who serve populations that are at the highest risk for impact by the proposed ruling. This includes Indigenous American, pediatrics, immunocompromised/transplant, travelers, LGBTQIA+ and other underserved patient populations including those in

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 organizations to engage in conversations about the issue with House and Senate offices given the Congressional interest in this issue and previous legislative proposals. We have provided [a letter template](#) for members to communicate concerns about FDA's proposed action to lawmakers.
- ASM will submit a formal response to the FDA by the deadline of Dec. 4, 2023. FDA denied ASM's and other organizations' requests for an extension to the comment period.

### **3. Is ASM working with other organizations?**

ASM regularly works with other stakeholders in the community on this issue and others. Partners include, but are not limited to, Infectious Diseases Society of America (IDSA), Association for Molecular Pathology (AMP), Association for Diagnostic & Laboratory Medicine (ADLM), College of American Pathologists (CAP), American Clinical Laboratory Association (ACLA), and the National Independent Laboratory Association (NILA). For example, ASM partnered recently with IDSA on [a letter](#) to the White House Office of Management and Budget.

### **4. Did ASM request an extension to the 60-day comment period?**

ASM, along with dozens of other organizations, submitted a request for an additional 60-day extension. This request was denied by the FDA.

### **5. What assays will be grandfathered?**

As the rule stands at this time, no microbiology assays are grandfathered.

### **6. If I modify an FDA-approved assay in any way, would this modified assay be considered an LDT and be subject to the proposed regulation?**

Yes, any modification of an FDA-approved assay makes the assay an LDT and would fall under the new proposed rule. Modifications to commercial FDA-approved assays would be considered "remanufactures" and be put through the approval process.

Examples of modifications include, but are not limited to, changes in:

- Specimen source
- Swab type, collection device, transport media
- Approved patient population (e.g., age, sex assigned at birth, immune status, symptom status)
- Incubation time
- Breakpoints (e.g., using CLSI breakpoints instead of FDA breakpoints)

### **7. What exemptions are included in this rule?**

The only current exemptions are for organ-transplant-associated human leukocyte antigen (HLA) testing, and surveillance for public health, where screening is not documented in the

individual's medical record. "Pre-1976"-type tests also are not subject to the proposed rule.

**8. My lab does screening that is reported in the patient chart and to the clinical team. Is this exempt?**

No, if the results are reported in any way back to the clinical team or in the patient chart, this is considered an LDT and not surveillance in the proposed rule.

**9. Does this proposed rule need to go through Congress? Can Congress stop this?**

The short answer is no. The long answer is a little more complicated.

Federal regulations of this type do not require federal approval. They do need to:

- a. Follow the federal rulemaking process. There is no reason to believe that FDA is not following this process.
- b. The agency must have the authority to initiate the regulation. Some have questioned whether FDA has the authority to regulate LDTs as "Medical Devices," which is what this rule proposes to do. However, such a challenge will require legal action, which cannot take place until a final rule is published.

As a practical matter, Congressional intervention would likely take the form of enacting the VALID Act. That legislation would establish a specific process for regulating LDTs, as opposed to treating them as "medical devices". However, it also contains a number of potentially problematic provisions. ASM and its partners are continuing to work on addressing concerns, recognizing that this may be a viable alternative to the proposed rule. Congress has many pressing priorities and legislation to regulate LDTs is not at the top of the list at a time when rulemaking is moving ahead.

There are several other ways that Congress could stop the rule from taking effect (invoking the Congressional Review Act, denying appropriations to implement the rule, CLIA modernization as an alternative). We do not anticipate that any of these are viable at this time. With this in mind, ASM is focused on responding to the proposed rule that is before us while continuing to engage with Capitol Hill on constructive ways to address the concerns raised in the proposed rule.

**10. When will this rule take effect?**

After the comment period ends, FDA is required to read and consider every comment. FDA then can issue a final rule, which may or may not change due to public comment. The final rule becomes effective 60 days following publication in the [Federal Register](#).

**11. If my lab has testing that is approved by New York State (NYS), does this ruling still apply to us?**

Yes, in its current form, NYS and equivalent bodies are not exempt. Those performing testing approved by NYS will still need to submit their LDTs for FDA approval. The FDA proposed rule is asking for feedback regarding recognizing NYS. If you would like to comment on this, please share your experience and rationale with the ASM Advocacy team at [advocacy@asmusa.org](mailto:advocacy@asmusa.org).

**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.