

# CLIA Laboratory Director Forum

Facilitated By:

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# Topics for Discussion

Quick Introductions (including suggestions for discussion)

## **Possible Topics to Discuss**

- What are the most common challenges you are seeing in your lab?
- What is working in your lab? What new bright spots and wins can you share with the group?
- The number of CLIA certificates expiring (or becoming inactive) is at an all-time high and the number of new applications is at an industry low. What is behind this trend? (Is it post covid correction or part of a bigger long-term trend?)
- The FDA has announced plans to require approval of LDTs. This action seems to be a reaction to a perceived inaccuracy of LDTs compared to IVDs. Do you feel this is a fair assessment?
- Do you think high complexity labs will continue to exist once approved by FDA or will they be mod complex? What does this mean for HCLDs?
- Do you feel your lab is equipped to file a 510K? If not, how do you plan to enlist resources.
- Are the current CLIA regulatory statues sufficient for today's evolving lab testing market? If not, what is the best solution?
- Is your lab adequately staffed? If not, however, are you doing more with less?