

CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE
Statement on Efforts to Address the CLIA Top 10 Laboratory Deficiencies

November 8, 2023

Ladies and Gentlemen,

I am Dr. Barb Jones, CEO of the Clinical and Laboratory Standards Institute (CLSI). On behalf of CLSI, I would like to thank the Clinical Laboratory Improvement Advisory Committee (CLIAC) for allowing me to present our remarks regarding **Efforts to Address the CLIA Top 10 Laboratory Deficiencies**.

CLSI is the only global, accredited, nonprofit standards development organization (SDO) in the field of laboratory medicine. As an accredited SDO serving a diverse laboratory constituency including industry, government, and health systems and professionals, CLSI itself must meet rigorous requirements to develop our standards and guidelines through a highly structured, open, and inclusive voluntary consensus process, that balances stakeholder participation, expertise, and perspectives. Since its inception in 1967, CLSI has been the voice of the laboratory medicine professionals who have given generously of their time and expertise for the advancement of quality clinical and laboratory practices and improved patient outcomes.

CLIA's assessment of laboratory deficiencies demonstrates that despite the incredible efforts of accreditors and federal and state agencies, laboratories continue to struggle with understanding how to implement the requirements of CLIA regulations. CLSI has published over 40 comprehensive documents and education tools that, when implemented, can mitigate these deficiencies. These guidelines, tools, and education products represent the accumulated experience and expertise of the leading subject matter experts in their fields who voluntarily share their knowledge and leadership to support the development of global best practices. The standards are not simply a record of processes and procedures, but are the best tools available to laboratory directors for bringing the expertise of these leading professionals in laboratory medicine directly into their facilities.

CLSI works closely with accreditors, public health entities, and government regulators around the country and the world to ensure that we are providing laboratories with the guidance they need to put this expertise to use effectively. Through crosswalks that match requirements and regulations to the appropriate CLSI guidance, as well as gap analysis and method evaluation navigation tools, we are delivering on our mission to develop and also to promote quality laboratory practices. We know from talking with laboratorians and accreditors, that laboratories that know and use CLSI standards are better prepared for and have more success navigating audits and assessments.

CLSI works collaboratively with many stakeholders to further these efforts, but we can do more. We are constantly working to make our standards more accessible and usable for laboratories and testing facilities in different settings, and with differing levels of complexity. In addition, we are focusing more effort on providing implementation guidance and training, and will continue to expand that effort as much as we are able with limited resources.

I would like to ask CLIAAC to consider how we can work together to encourage the utilization of these critically important standards and tools. The Office of Management and Budget (OMB) Circular A-119 (Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities) directs federal agencies to participate in standards-setting bodies and to adopt voluntary consensus standards when possible. We believe the spirit of this directive can also be applied by encouraging laboratories to use these relevant standards that provide guidance for how to meet federal regulations or requirements. We welcome any opportunity to work collaboratively with laboratories, public health organizations, regulators, and accreditors, to provide guidance for laboratories and testing sites on the implementation of consensus standards and to deliver the best possible patient care.

Thank you,



Barb Jones, PhD
Chief Executive Officer