



Statement to the Clinical Laboratory Improvement Advisory Committee

By the

American Association for Laboratory Accreditation (A2LA)

November 7, 2024

The American Association for Laboratory Accreditation (A2LA) appreciates the opportunity to provide comments to the Clinical Laboratory Improvement Advisory Committee (CLIA) for your consideration.

A2LA has been offering accreditation services for over forty-five years. We currently hold Centers for Medicare and Medicaid Services Deemed-Status and the International Laboratory Accreditation Cooperation (ILAC) Recognition to provide clinical laboratory accreditation. A2LA is the only accreditation organization in the world to achieve and maintain both of these formal recognitions.

Over the years, A2LA has performed thousands of remote assessments in different capacities and has gained valuable knowledge of the remote assessment process. We wish to highlight some points for your consideration that may make virtual competency assessments more widely accepted.

A primary objective when performing a remote assessment is that the assessment is held to the same level of rigor as an in-person assessment. A2LA uses resources provided by ILAC in order to help us meet this objective.

A2LA considers if an assessment activity is a candidate for a remote assessment, by first ensuring that the laboratory is eligible for a remote assessment by following the remote assessment policy which includes conducting a risk assessment. A risk assessment is an important tool that should be included in a laboratory's policy and/or procedures for a virtual competency assessment. A risk assessment is the overall process of risk identification, risk analysis, and risk evaluation (according to ISO 31073:2023) and is initiated early in the planning stages. The concept of a risk assessment should be applied to competency assessments in order to determine if a virtual competency assessment is viable.

For example, for an accreditation organization conducting a survey, A2LA considers these factors in a risk assessment: previous survey technique (remote or in person), number and nature of previous findings, depth of previous survey observations, laboratory scope, and laboratory resource changes from previous survey. Likewise, the risk assessment factors for competency assessments may include technique for previous competency assessments, environmental conditions, outcomes/findings from previous competency assessments, external survey results for that area and severity of findings, proficiency testing results, and staff turnover. Another factor that needs to be considered is if there are areas of the laboratory in which the testing would not be able to be easily observed due to internet connectivity issues or the lack of visibility of the testing personnel, facilities and/or instruments. An additional factor one needs to consider is the media that the laboratory records are maintained - electronically or paper, and how readily are they available for review. This may lead to a higher risk of the competency assessment not being held to the same standard as an in-person assessment. With a higher risk identified, the

laboratory may decide that an in-person competency assessment is a better option than a virtual competency assessment. Alternatively, if the laboratory considers this to be a lower risk, the laboratory will need to develop a mechanism to share necessary records prior to the virtual competency assessment occurring. This may significantly increase the amount of preparation and overall time in which a competency assessment occurs.

A2LA encourages the committee to consider these topics as CLIAC continues to evaluate the use of virtual competency assessments.

Thank you for allowing A2LA the opportunity to provide comments on this matter and consider us as a resource if additional information is required.