



Statement from the American Society for Clinical Pathology and the ASCP Board of Certification

The following comments provided by the American Society for Clinical Pathology (ASCP) and the ASCP Board of Certification (BOC) in response to the questions posed by the Clinical Laboratory Improvement Advisory Committee (CLIAC) in advance of its November 6-7 discussions.

Question 1. Are Bioinformaticists needed in clinical and public health laboratories? If so, what are the current roles, responsibilities, and competencies of bioinformaticists in these settings?

With regard to the competencies of bioinformaticists, ASCP and the ASCP BOC are unaware of any comprehensive data or standards that specifically address the training and competencies that should be required of bioinformaticists working in clinical laboratory settings. These standards are likely to vary depending on the tasks these individuals handle within the clinical laboratories in which they work. Moreover, some bioinformaticists have training in the laboratory sciences prior to transitioning into bioinformatics while others have academic training rooted in statistics and computer/data sciences. Though ASCP is a strong supporter of rigorous and appropriate academic and clinical training for pathologists, other physicians, and non-physician laboratory professionals, we believe more information is needed before a particular set of personnel standards could be articulated for these healthcare professionals. As a result, ASCP agrees with CLIAC that additional data on the key competencies of these healthcare professionals is needed and that a bioinformatics workforce survey should be performed. ASCP has significant experience conducting workforce surveys and stands ready to assist with such an endeavor.

Question 2: What areas exist in CLIA where specific requirements or guidance might be needed to ensure the accuracy and reliability to new and emerging laboratory technologies and nontraditional testing workflow models, including next generation sequencing, biomarker testing, metagenomics, and others?

Like all laboratory testing, ASCP and the ASCP BOC strongly believe that the accuracy and reliability of new and emerging laboratory technologies is heavily influenced by the qualifications and competencies of the laboratory professionals performing them. As a result, the ASCP and the ASCP BOC strongly support the CLIAC's Personnel Regulations Workgroup recommendations to revise the CLIA regulations. ***We call on CLIAC to urge CMS to adopt these recommendations in regulations as soon as possible.***

While CLIAC outlined a number of personnel recommendations intended to improve the quality of laboratory testing, we wish to highlight several of the recommendations here that are of particular concern to ASCP and the ASCP BOC. ***Specifically, we strongly support the recommendation, supported by the full CLIAC, that the acceptable degrees for high complexity testing personnel "should include***

chemical, biological, or medical technology/medical laboratory science.” As the Workgroup stated “the base requirement is that for individuals to qualify as laboratory personnel under CLIA, they must have the necessary coursework to provide a foundation on which to function effectively in the laboratory. The acceptable degrees referenced here are acceptable because the course of study includes the relevant coursework and therefore serve as a “surrogate” for that coursework.” We also support the removal of physical science from the list of acceptable degrees.

In line with CLIAC’s recommendations, we recommended that the CLIA personnel rules should be modified to recognize the academic achievements of other baccalaureate degreeholders, provided their degrees include *substantial* coursework in the academic sciences relevant to laboratory medicine. **Accordingly, for those individuals whose baccalaureate degree is in something other than a chemistry, biology, or medical technology/medical laboratory science, we concur with CLIAC that the CLIA rules for high complexity testing personnel should be changed to recognize an earned baccalaureate degree and at least 30 semester hours (or the equivalent) of coursework in these academic sciences.**

On the topic of clinical training and work experience, **ASCP strongly agrees that “All personnel should have experience and training in the responsibilities listed for their CLIA positions at the appropriate test complexity.”**

One of the items discussed by CLIAC was primary source verification (PSV) of earned credentials, training, and experience by personnel certification agencies, such as the ASCP Board of Certification. The ASCP BOC is an accredited certifying agency, and we verify the accuracy of every applicant’s personnel qualifications as part of the certification process, including their educational transcripts. Besides verifying the accuracy of each individual’s qualifications, ASCP’s assessments could serve as a historical record that could be utilized repeatedly during the laboratory inspection process as well as by individuals who may no longer have access to their original documentation. **As a result, we believe that clinical laboratories, laboratory personnel, laboratory inspectors, and patients would be well served by CLIAC urging CMS to develop guidance outlining the requirements and conditions necessary for accredited certifying agencies to secure CMS’s approval to serve as primary source verification organizations.**

With regard to histotechnology professionals, the ASCP and ASCP BOC strongly support the establishment of high complexity personnel standards for these vital laboratory professionals. Since the last major revisions to the CLIA rules, the processing of tissue specimens has become highly complex. *As a result, we join with the National Society for Histotechnology in urging that the CLIA rules treat the histotechnology pre-examination and examination processes as highly complex.* This would require that these services be performed in a CLIA-certified facility under the direction of a board-certified anatomic pathologist, subject to applicable proficiency testing requirements and performed only by properly trained histotechnicians and histotechnologists.

In addition, because several published studies, including by the Centers for Disease Control and Prevention, have shown that clinical laboratories staffed with higher proportions of certified personnel perform better (as demonstrated by proficiency testing results), we urge that the CLIA personnel regulations adopt a certification requirement for the performance and supervision of high complexity testing.

Moreover, ASCP and the ASCP BOC believe that genetic and genomic testing, as well as many new and emerging technologies, involves higher levels of complexity and demands unique technical knowledge

and skill compared to most other high complexity laboratory tests. ***Accordingly, we urge requiring a baccalaureate degree of individuals performing such testing.*** This will better support quality testing. While we recognize some may argue that this may raise concerns about personnel shortages, we believe that this would trigger a realignment of staff responsibilities within clinical laboratories that ultimately will better support quality testing.

In closing, ASCP urges CLIAC to echo these recommendations to CMS, specifically urging the Agency to release proposed regulations to adopt the April 2019 recommendations as soon as possible. The ASCP BOC and ASCP appreciate this opportunity to provide recommendations to CLIAC on changes to the CLIA regulations.