American Proficiency Institute

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Statement to the

Clinical Laboratory Improvement Advisory Committee

from the

American Proficiency Institute

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Thank you for this opportunity to address the Clinical Laboratory Improvement Advisory Committee on the issue of emerging technologies and the clinical laboratory.

The American Proficiency Institute (API) is one of the nation's largest proficiency testing providers, serving over 20,000 laboratories. Widely accepted, API clinical proficiency testing programs are approved by CMS, The Joint Commission, COLA, and all state health departments. The College of American Pathologists also accepts most analytes for its Laboratory Accreditation Program. Established in 1991, API was granted ISO/IEC 17043 accreditation for operating proficiency testing schemes in 2018 after an examination of its quality systems, statistical methods, reporting and interpretation. Our comments focus on the use of proficiency testing in the changing clinical laboratory landscape.

As CLIAC considers how to address emerging technologies in the clinical laboratory, it is noteworthy that updates to proficiency testing regulations, as related to analytes and acceptable performance, were proposed only several months ago. Once finalized, these modernizations will be the first significant updates to proficiency testing in over 25 years. This may speak well to the endurance of the objectivity and necessity of proficiency testing. It may also unveil concerns with how we as the clinical laboratory community are able to adapt to a changing technological landscape.

Proficiency testing is essential to the clinical laboratory. In the 2016 *Molecular Microbiology* chapter, "Proficiency Testing and External Quality Assessment for Molecular Microbiology," author Roberta Madej, PhD quotes laboratory pioneer, F. William Sunderman, MD, "There can be no more important task for the director of a clinical laboratory than to assess the precision and accuracy of the analytical procedures under his/her supervision." In Clinical Chemistry in 1992, Dr. Sunderman wrote, "Since the introduction of proficiency testing in the late 1940s, dramatic improvement in laboratory performance has been demonstrated."

While the benefits may be evident, the way forward is less clear. Proficiency testing is used to identify errors in the analysis and interpretation of an assay as well as assess overall laboratory performance. While proficiency testing programs are available for some next generation sequencing testing, it is not widespread. The pace of moving metagenomics from the research bench to the clinical laboratory is accelerating, but the quality assessment tools needed to confirm accuracy are not in sync with this pace.

Microbiome testing provides another example where more standardization of operating procedures, including proficiency testing, would help to address the wide variation in current testing results before this field moves further into the clinical diagnostic setting.

We offer three suggestions for the CLIAC emerging technologies task force to consider:

First, the proposed rule from the Centers for Medicare and Medicaid Services (CMS-3355-P) would require proficiency testing programs to have a minimum of 10 laboratory participants before offering any proficiency testing analyte. This draws concerns with implementation and practicality, especially in light of emerging technologies.

Proficiency testing providers need to offer new modules to accommodate changes in instrumentation and availability of sample materials. Providers commit to purchase samples well ahead of shipment dates and will not always know how many laboratories will enroll. Sometimes new modules are slow to grow, or some analytes hover around 10 participants. If alternatives are not available, laboratories may still find the modules a useful source of samples and comparison data that would otherwise be difficult to obtain. Qualitative challenges should be able to be graded with fewer than 10 participants and can be graded based on reference values. Understanding these issues, the proposed rule should permit flexibility between the agency and the proficiency testing provider before approval is withdrawn. CLIAC should recommend the same.

Second, support for efforts to standardize methods for new technologies is needed. Qualitative demands will become more complex for the clinical laboratory. Clinical laboratories operate best with uniform standards for analysis. Proficiency testing is an important component of these standards.

Third, communication is essential. Whether CLIAC meetings, forums on clinical independent diagnostics, or metagenomic conferences, proficiency testing providers should have a seat at the program. This will allow proficiency testing providers to prepare for emerging technologies that will require their metrological services in the not too distance future.

If you have questions or need additional information regarding clinical proficiency testing, please contact Daniel C. Edson, President, American Proficiency Institute.