American Proficiency Institute

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October 27, 2014

Burton W. Wilcke, Jr., PhD
Chair
Clinical Laboratory Improvement Advisory Committee
Centers for Disease Control and Prevention
1600 Clifton Road, Mailstop F-11
Atlanta, GA 30333

Dear Dr. Wilcke:

The Clinical Laboratory Improvement Advisory Committee (CLIAC) issued recommendations for revising proficiency testing (PT) requirements back in September 2010. The American Proficiency Institute (API), along with other proficiency testing providers, the government, and other interested parties, actively participated in the CLIAC Proficiency Testing Work Group in an effort to review and update proficiency testing requirements for clinical laboratories. I am writing to inquire formally about the status of those recommendations and subsequent work efforts.

As mentioned, the CLIAC PT Work Group, as well as the full CLIAC, deliberated on a variety of PT issues. These issues included:

- Issuing a defined list of analytes for which PT is required, which may be updated easily;
- Maintaining five PT challenges, three times per year as the requirement;
- Using the factors of PT availability, test volume, clinical relevance, scientific basis, and cost to determine if a PT analyte should be required;
- Requiring PT for laboratories that perform susceptibility and/or resistance testing in all microbiology subspecialties;
- Allowing a two-year phase-in period for implementation of required PT after analytes are added to the list;
- Periodic review of grading criteria for all analytes that require PT for continued clinical relevance;
- Retaining peer grouping as a component of the grading criteria, when appropriate;
- Increasing PT challenges for antimicrobial susceptibility testing and/or resistance testing to two challenges per event for a total of six challenges per year in bacteriology (including one Gram-negative and one Gram-positive organism in each event);
- Requiring PT for direct antigen testing for all microbiology subspecialties;
- In microbiology PT grading, retaining the five required challenges per event and 80% consensus;
- Additional recommendations addressing performance monitoring, mixed cultures, Gram stain PT, matrix effects, and other topics were made.

In early 2013, the Department of Health and Human Services requested that PT providers simulate scoring actual PT results using a set of proposed acceptance limits derived by the Centers for Disease Control and Prevention. API performed the simulation using retrospective, actual data from the 2012 proficiency testing year. API fast-tracked this significant undertaking, performed the simulation and produced a subsequent report by August 2013. We have not yet received feedback on this activity.

API is one of the largest proficiency testing providers in the world, serving over 19,000 laboratories. We understand that CLIAC acts in an advisory capacity to HHS and its recommendations are not binding. Similarly, we recognize that the agencies tasked with overseeing CLIA must navigate the regulatory process. However, it has been over four years since the CLIAC recommendations were issued. Already, the private sector is making changes in lieu of more definitive CLIA activity. For example, one laboratory accreditation program now requires certain "non-scored" analytes to be tested at five samples, three times per year.

In light of the significant work and deliberations from CLIAC, its Work Group and others, I respectfully request a detailed update on the status of the CLIAC recommendations on PT.

Thank you for your time and consideration.

Sincerely,

/Dan Edson

Daniel C. Edson
President