American Proficiency Institute

Innovative Solutions. Technical Excellence.

1159 Business Park Drive, Traverse City, MI 49686
800-333-0958 / FAX: 231-941-7287
api-pt.com

Statement to the Clinical Laboratory Improvement Advisory Committee
September 1-2, 2010

The American Proficiency Institute (API) applauds the Clinical Laboratory Improvement Advisory Committee (CLIAC) for addressing issues related to proficiency testing for clinical laboratories. Daniel C. Edson, API President, participated on the CLIAC Proficiency Testing Work Group. In his estimation, one of the most important aspects of the work group was the discussion and collaboration among proficiency testing providers, the government, and other interested parties.

API is one of the largest proficiency testing providers in the world serving over 16,000 laboratories. API offers innovative solutions and technical excellence for the proficiency testing needs of hospital laboratories, physician offices, clinics, and point-of-care testing sites. As CLIAC deliberates on a variety of proficiency testing issues, API offers below comments and suggestions on a select few.

Addition of Regulated Analytes

We strongly encourage CLIAC to recommend the development of a more rapid process for incorporating regulated analytes under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

It is important to distinguish between regulated and unregulated analytes. Some health systems and accrediting agencies are requiring proficiency testing for unregulated analytes. On the surface, it may appear that more proficiency testing is positive, no matter how it is achieved. The problem is that for proficiency testing providers, while we may be able to comply in developing programs for certain unregulated analytes, the demand for the product will be low. Since comparison against same instruments and methods will also be low, the statistical relevance of the results may be weak.

Ultimately, proficiency testing should be required of all tests for which proficiency testing products are available. However, it is important to determine the appropriate process for adding – and in some cases – deleting proficiency testing for specific tests. For example, a phase-in process for adding proficiency testing will assist laboratories and proficiency testing providers alike in accommodating the additional volume.

There should also be a process in place to determine what analytes to add or delete from the PT menu. CLIAC may want to consider recommending processes similar to the public forum used at the Centers for Medicare and Medicaid Services (CMS) to determine pricing for new CPT codes under the clinical laboratory fee schedule, or encourage biannual meetings of all proficiency testing providers and representatives from CMS, the Centers for Disease Control and Prevention, and the Food and Drug Administration for frank and open conversations using sample data and agreed-upon criteria.

Microbiology Proficiency Testing and the Small Laboratory

Last year, API concluded a five-year study of the ability of clinical laboratories to identify *E. coli* O157:H7 in proficiency testing samples. In 2003, our study found that 30% of laboratory participants failed to detect the E. coli strain even though they were explicitly instructed to test for the organism. Reexamining laboratories in 2008, 85.3% of laboratories were able to detect the *E. coli* strain, a remarkable improvement. API made several recommendations for continuing to improve the accuracy of these laboratories, including following CDC screening recommendations and including these guidelines in accreditation survey checklists.

Using examples such as this one, some urge an increase in the number of samples per test event (e.g., increasing susceptibility testing from 1 sample to 2 samples). While some larger laboratories might benefit from this change, smaller laboratories may find this increase too burdensome. Ultimately, it may not even be necessary. We hope CLIAC considers the cost-benefit of such a change to smaller laboratories and their patient populations before making a recommendation in this area.

Overall

Thank you for the opportunity to submit these initial comments to you. While API has not yet been asked to review the final work group product, we look forward to providing additional input when appropriate. The American Proficiency Institute looks forward to continuing to share with you data from our studies and experience from our years in the proficiency testing field.

Sincerely,

/DAN EDSON

Daniel C. Edson
President