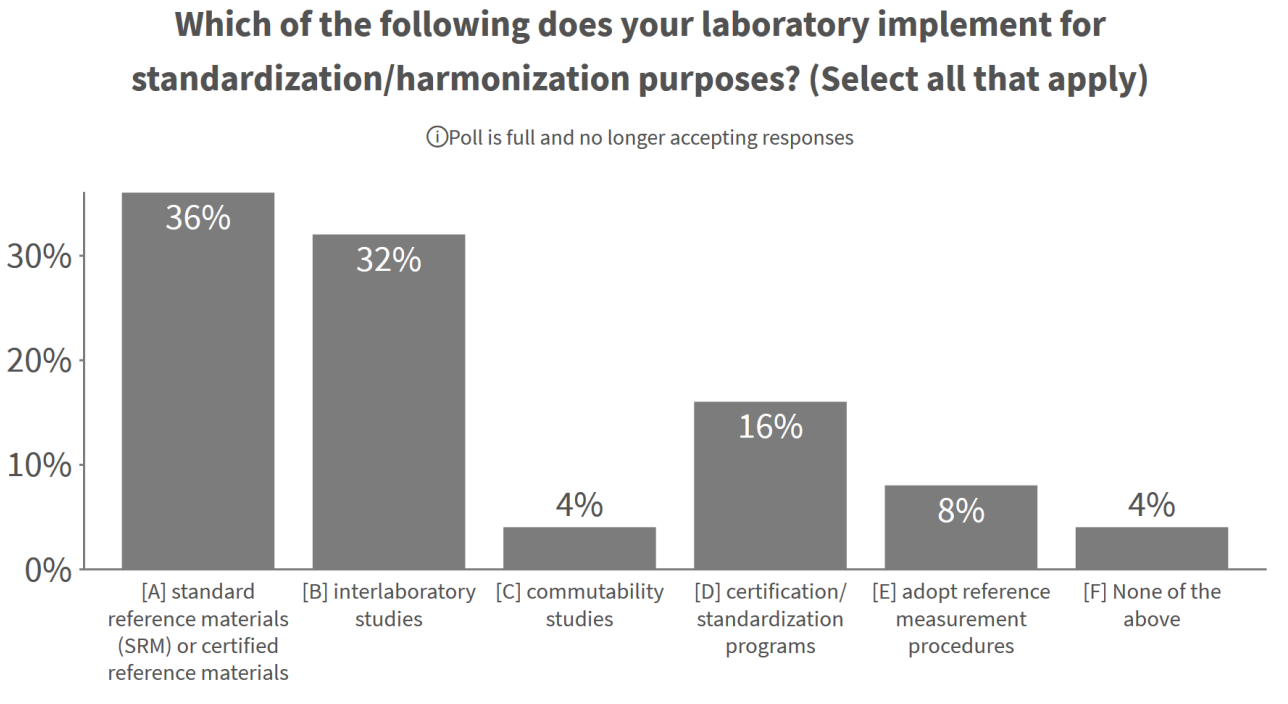
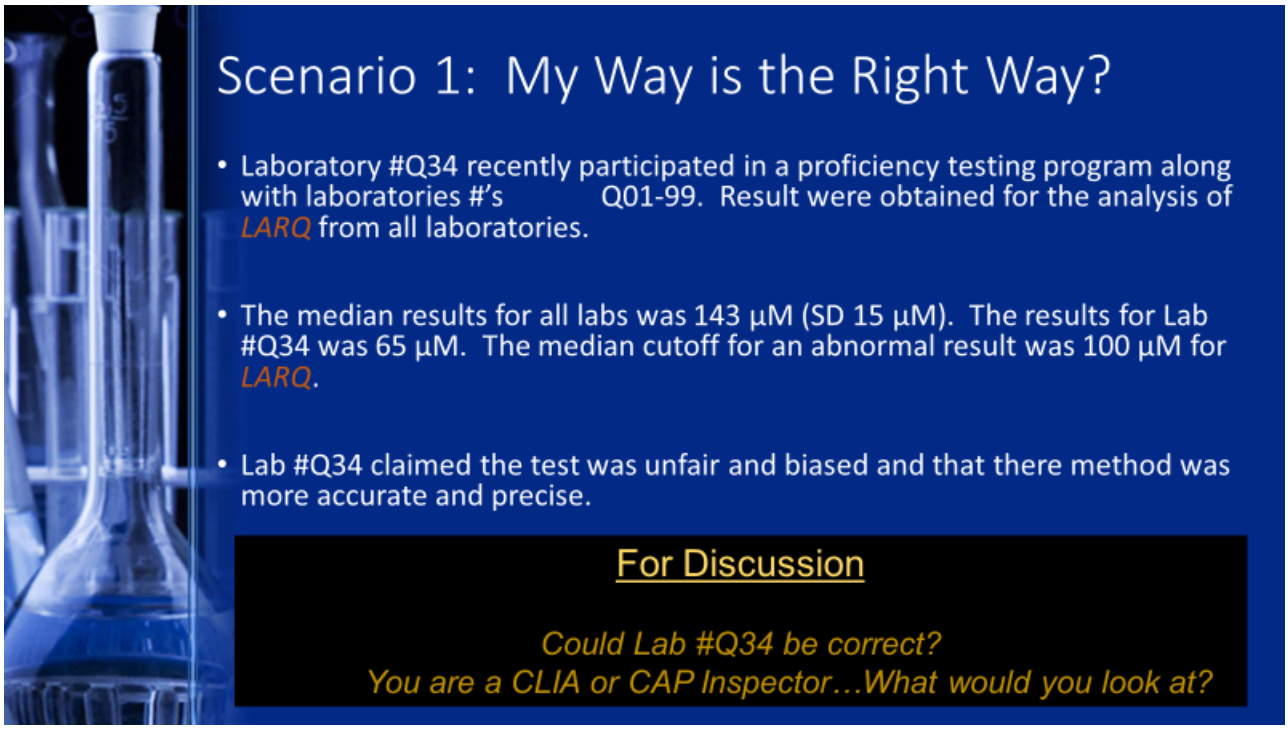
The Clinical Chemistry Workshop for the 67th ASMS Conference entitled "03 Clinical Applications: Standardization and Harmonization Efforts", was held on Wednesday, June 5th from 5:45pm-7:30pm. The workshop was organized by Clinical Chemistry Interest Group chairs, Dr. Donald Chace and Dr. Candice Z. Ulmer. The purpose of this workshop was to [1] highlight the need for harmonized results, [2] introduce ongoing standardization efforts within clinical chemistry, and [3] discuss opportunities to create and engage in commutability studies, certification programs, and clinical-based interlaboratory studies. Dr. Uliana Danilenko, coordinator for various standardization programs within the Clinical Chemistry Branch at the Centers for Disease Control and Prevention, provided a brief presentation on available CDC Clinical Standardization Programs. Danilenko highlighted new CDC accuracy-based monitoring services for clinical and research laboratories with mass spectrometric assays in addition to CDC certification services for various metabolites. Many audience members mentioned that they were previously unfamiliar with the standardization programs available at the CDC and found this presentation to be quite helpful. In addition, a presentation entitled "An Overview of Clinical SRMs (from the Organic Chemical Measurement Science Group)" was provided by Dr. Christina M. Jones, co-coordinator of the Metabolomics Quality Assurance and Quality Controls Materials Programs at the National Institute of Standards and Technology in Gaithersburg, MD. Jones explained the difference between primary/secondary standards and standard reference materials (SRMs), presented a list of all available clinical matrix SRM materials at NIST, and explained NIST's role in the development of reference measurement procedures for various clinical assays. Many audience members asked questions about the process for developing SRMs as well as NIST's interest in developing other materials/matrix-dependent SRMs in the future. The post-conference survey indicated that the audience enjoyed and appreciated the speakers. However, some respondents found the information to be slightly redundant to what was available on the internet.

In an effort to make the workshop interactive for the audience, polls were implemented through the session to gauge the audience's level/understanding of standardization/harmonization. Below is an example of the information obtained from the poll. All audience members were able to access the poll via text, downloading the Poll Everywhere app, or accessing the poll website. We found this method of engaging the audience effective as the discussion was slow in the beginning of the session. The post-conference survey results suggested that the audience experienced no difficulty in accessing and interacting with the poll. However, the audience felt that the results from the polls should have been discussed in more detail throughout the session.



Two break-out discussions immediately followed the presentations by the speakers. We had two scenarios for discussion, but the first created the biggest response, which may lead to a follow-up topic for next year.



Ultimately, the discussion regarding the scenario was centered on the metabolic profiling of multiple components, the use of multiple internal standards, and issues with classical QA/QC procedures that are optimized for one metabolite. An even larger discussion broke out from this initial topic at the end, which was focused on screening versus diagnostics using mass spectrometry. Participants mentioned issues with flow injection analysis, which is often used in newborn screening, and the limited *m/z* real estate available for internal standards in a complex profile screen versus chromatography (GC or LC). In the later approach, participants argued that one can utilize as many standards as there are peaks to measure. The difference between the two approaches is time, accuracy, and precision. While this discussion was engaging and provoked comments from multiple people in the audience, the post-conference survey indicated that some participants felt uncomfortable with the heated discussions and wanted more structure in the discussion prompt.

We, the clinical chemistry workshop chairs, agreed that perhaps a more structured workshop on screening versus diagnostics using mass spectrometry-based technology would be a great discussion topic next year. This workshop discussion may also be sculpted around the different clinical chemistry sectors – e.g., public health and specialized center of excellence laboratories, large commercial laboratories, and/or hospital-based laboratories.

Submitted 7/17/2019 by Dr. Candice Z. Ulmer, Co-Chair of the ASMS Clinical Chemistry Interest Group