Clinical Chemistry Workshop Summary

The Clinical Chemistry Interest Group Workshop, held Tuesday evening of ASMS, discussed the implementation of the Laboratory Developed Test (LDT) Guidance document from the Food and Drug Administration (FDA). Approximately 70 scientists attended; 2 panelists opened the discussion with perspectives from the laboratory side (Brent Dixon, Physicians Choice Laboratory) and the manufacturer's perspective (Scott Kuizdale, Shimadzu).

Opening remarks introduced the framework of the LDT guidance and provided a launching point for a conversation on the future of mass spectrometry in clinical diagnostics. Individuals with salient experience in FDA oversight of diagnostic testing joined the workshop, providing insight on the breadth of LDT's in the clinic (Alan Rockwood, Lab Director of ARUP), the required workload for submission of tests to the FDA (Mike Morris, project lead for the first FDA approved mass spec assays) and the future of discovery work translating to patient care (Steve Hunsucker, Integrated Diagnostics).

Additional discussions focused on the impact to future patient testing. Scott Kuizdale indicated the loss of newly developed technologies to European and Asian colleagues as new assays would not be available in the United States long after acceptance elsewhere. The timeline for guidance implementation was discussed, with Russell Grant (LabCorp) briefly addressing legislative efforts in Congress to redevelop the process of laboratory developed tests. Colleagues from the Mayo Clinic and Aegis Toxicology elucidated the inverse relationship of cost to submit to reimbursement rates for novel tests, changing the conversation to laboratory economics.

Tim Garret, Univ of Florida brought up the impact to academic discovery laboratories and challenges to technology transfers for newly discovered biomarkers in the new LDT paradigm. More than 15 attendees directly engaged in conversation related to the night's topic, as the forum format only required the session chair to dash about the room with the microphone. The session ended with general announcements of upcoming clinical diagnostic events and closed at approximately 655 pm.