## Clinical Chemistry Interest Group Workshop Report 73<sup>rd</sup> ASMS Conference, Baltimore Maryland

## Timothy Collier Matthew Crawford

The Clinical Chemistry workshop for the 72<sup>nd</sup> ASMS Conference on Mass Spectrometry and Allied Topics was held on June 4<sup>th</sup>, 2025, from 5:45 to 7:00 PM in Room 309-310 of the Baltimore Convention Center. This year's workshop was titled "The Interface of Biomarker Discovery, Clinical Algorithm Development and Regulatory Oversight", with Timothy Collier (Quest Diagnostics) serving as lead with co-lead Matthew Crawford (LabCorp) and was attended by approximately 50 participants. Attendee make-up consisted of a roughly 50/50 split of academia and industry, and a roughly even distribution of attendees who considered themselves early, mid, or late career.

The workshop was an interactive dialogue with a panel of community experts, including Will Fondrie (Talus Biosciences), Jihyeon Lee (Cedars-Sinai Medical Center), and Stephen Master (Children's Hospital of Philadelphia), discussing the regulatory challenges of translating biomarkers, particularly multi-analyte panels utilizing any mathematical algorithms. This discussion was performed using the NY State Clinical Laboratory Evaluation Program's Machine Learning Checklist as the guiding template.

## Discussions covered:

- The nature of "locked" vs. "unlocked algorithms"
- Understanding and being able to describe key variables and intended use for assays
- Identifying Software, Statistical Models and Al methods and processes used in assay development.
- Describing data, including demographic information, how features are selected, and determining whether sample cohorts are sufficiently powered to support identification of clinically significant effects.

From the post-conference survey, the session was mostly well received with the session scoring weighted averages of 4.2/5 for Quality, 4.3/5 for Topics, and 4.15/5 for Format.