

Health 
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ADLM 2024 Takeaways

In July, Health Advances Diagnostics Team made our annual pilgrimage to ADLM (formerly AACC). Here are a few key takeaways:

- 1 Cautious Optimism for the Future of the Dx Industry**
- 2 Focus across a Few Select Industry Themes: AI, LDT Rule Impact, Precision Medicine**
- 3 Technology and Segment Focus on POC, Sepsis, and “Doing More with Less”**
- 4 Small Number of New Product Presentations**

Source: Health Advances analysis.

While the Dx industry remains in a challenging environment, the ADLM sentiment was one of cautious optimism.

ADLM 2024 Well Attended with Busy Expo Floor and a Sold-Out Annual Health Advances Cocktail Reception and Panel

US, EU, and Asia-based companies well represented at the Expo

DxPx, the only partnering conference dedicated to Diagnostics, Digital Health, Precision Medicine, and Life Sciences Tools, integrated into ADLM, drawing investors

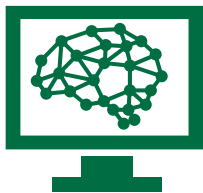
Dx Companies Hopefully: 2024 Better than 2023, and 2025 Continued Growth

Our discussions with OEMs and investors revealed a cautious optimism that solid base market growth, no longer clouded by COVID impact, will bring renewed enthusiasm and more opportunities

Investors Seeking Opportunities but Weary

Investors are looking to spend money on Dx companies but are cautious with where to deploy funds, focusing on making well-vetted and smart bets. Start-ups can improve chances of funding with a clear story and support from diagnostics focused consultancies and investors that know how to navigate the current environment.

Hot topics at ADLM 2024 included the role of AI in diagnostics, the LDT rule impact, and precision medicines growing importance.



Role of AI in Diagnostics

- Multiple session and panels (including Health Advances 15th Annual Reception and Panel) focused on this topic and numerous companies highlighted the role of AI in their portfolio
- Excitement centered around the potential impact of AI in diagnostic development, improvement of laboratory operations, and as part of algorithm-based tests
- Widespread recognition that hurdles to broad use of AI remain to be addressed, such as complexity of unbiased data collection and curation, limited infrastructure and expertise, regulatory uncertainty, and the need to educate the customer



Concern about the LDT Rule Implementation

- While concern about the rule and desire to stop its implementation are still topics of discussion, the focus has turned to preparing for implementation
- Labs are seeking insight into which RUO/ASR products will be made available as IVDs, if new sample types will be validated on existing IVD tests, and what other solutions will be provided to allow them to maintain test menu breadth and minimize send-outs
- No clear answers emerged from our discussions during ADLM—from the manufacturer perspective, vetting opportunities to expand IVD portfolios is complex
- Interestingly, in the two short weeks since ADLM, our team is seeing heightened focus among OEMs on answering this question



Bringing Precision Medicine Into the Dx Fold

- We noted a stronger presence of precision medicine companies and topics at ADLM this year, highlighting the growth opportunities in precision medicine and the need for traditional Dx companies to support access to such tests
- The presence of DxPx and the innovation award going to Mercy Bio are just two examples that highlight this theme

POC, sepsis management tools, and technologies that allow labs to do more with less where well represented on the Expo floor.



Multi-Analyte Platforms

- Multi-analyte platforms continue to develop with the potential to offer greater flexibility at POC and in the decentralized lab
- While not fully launched, ADLM presentations highlight development progress as does Genalytes first clearance (not at ADLM) and Truvian's July raise of \$74MM (also not at ADLM)



Uses electrical detection for cell counting, CC, and IA



Uses centrifugal microfluidics to perform hematology, CC, and IA



Capable of MDx, IA, CC, and Cytometry

Sepsis

- Numerous technologies working to improve sepsis patient identification and management were highlighted
- Technologies provide insight into risk of progression/severity, viral versus bacterial infection identification, and pre-culture pathogen identification



POC

- There were over 150 companies showcasing POC technology at the Expo
- A few examples updates from this group include:



PCR Pro submitted to FDA for OTC use



Starting clinical studies for 5min COVID/Flu A/B



510K cleared HemoScreen POC CBC



Gem Premier 7000 blood gas platform with hemolysis detection

Automation

- The role of automation was highlighted in many booths including Abbott, Siemens, Roche, and Beckman Coulter
- Siemens highlighted the AI driven Atellica portfolio with which consolidates 25 tasks to minimize hands-on time

Source: Health Advances analysis.

As always, ADLM is used to share exciting product announcements. A few notable examples include:



An example of POC/decentralized testing multidisciplinary multiplatform. Capabilities include cell counting, chemistry assays (electrolytes, small molecules, and proteins), and immunoassays (proteins). Promises rapid TAT and high performance at low cost.



The future cobas[®] Mass Spec analyzer*

Sold-out appointments to see this analyzer showcase the industry's anticipation of its official launch



Total lab automation system; open to analyzers from different vendors; standardized components configurable in many layouts



Point of care blood gas analyzer with first of its kind hemolysis detection



POC 5-minute PCR system



- AiPlex CTD assay: panel of eleven autoantibodies in one assay/test to support diagnosis of CTD , providing laboratories and clinicians with
- Abstract titled: *“Analytical Performance of a Novel, Fully Automated Multiplexed Microarray Immunoassay Prototype for the Simultaneous Detection of Fifteen Autoantibodies Associated with Connective Tissue Diseases”* was awarded first place in the ADLM 2024 Industry Division Best Abstract competition

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