

September/October 2026

CLN

Clinical
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News

DIAGNOSING
ALZHEIMER'S

34

circular RNAs could
distinguish this disease from
healthy aging

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An ADLM Publication | Volume 53, Number 5

Tackling the transition to a new LIS



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Clinical Laboratory News is published bimonthly (6 times per year — Jan./Feb., March/April, May/June, July/Aug., Sept./Oct., and Nov./Dec.) by the Association for Diagnostics & Laboratory Medicine (formerly AACC). 900 Seventh St., NW, Suite 400, Washington, DC 20001. Phone: +1 202.835.8756 or +1 800.892.1400 Fax: +1 202.877.5093. Contents copyright © 2026 by the Association for Diagnostics & Laboratory Medicine, except as noted. Printing in the U.S.A. POSTMASTER: Send address changes to ADLM, 900 Seventh St. NW, Suite 400, Washington, DC 20001.

Design and Production Management

Melissa H. Miller Designs

Correction: In the July/August 2026 issue of CLN, the article "The elusive search for a roadside cannabis DUI test" erroneously said that alcohol is a central nervous system stimulant. This was a typo. Alcohol is a central nervous system depressant.



The full text of *Clinical Laboratory News* can be found on EBSCO's CINAHL Complete database and is also searchable via the EBSCO Discovery Service



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Together with the patient's clinical presentation, clinicians can use [neurofilament light chain testing] to optimize the dose of [disease-modifying therapy], extend the interval between doses, and potentially switch or discontinue treatment altogether if needed.

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New ADLM policy report defines a central role for laboratories in healthcare AI

The Association for Diagnostics & Laboratory Medicine (ADLM) released a new policy report, “Artificial intelligence in laboratory medicine: Leveraging laboratory expertise to improve patient care,” outlining how laboratory quality systems can support the responsible implementation and governance of artificial intelligence (AI) across healthcare.

In the report, ADLM emphasizes that clinical AI raises many of the same quality and patient safety questions that laboratories routinely address when implementing diagnostic tests.

Laboratory medicine already operates within mature quality-management and regulatory frameworks that emphasize validation, quality assurance, continuous monitoring, proficiency testing, documentation, and accountability. Laboratory professionals routinely oversee complex diagnostic systems, manage large volumes of clinical data, evaluate analytical performance, and provide consultation regarding the appropriate interpretation and use of diagnostic information. ADLM argues that this expertise positions laboratories to serve as foundational governance and operational partners as AI becomes more integrated into patient care.

Despite this alignment, many healthcare AI tools are currently implemented through fragmented operational models that exist outside established laboratory governance structures. AI applications are frequently deployed as laboratory- or locally developed solutions managed through research, information technology, or vendor-controlled environments rather than through coordinated clinical quality systems.

ADLM recommends that policymakers and healthcare organizations establish risk-based governance frameworks, require independent validation and post-deployment monitoring, develop external quality-assessment and benchmarking programs, promote laboratory data harmonization and interoperability, and support workforce development. The report also calls for payment policies that recognize both the clinical value of AI and the resources required to govern it responsibly.

● ASCP STUDY ADVOCATES FOR IMPROVED FINANCIAL SUPPORT OF THE LABORATORY WORKFORCE

A recent study from the American Society for Clinical Pathology (ASCP) and the ASCP Board of Certification highlights the financial challenges facing students and professionals pursuing careers in laboratory medicine and underscores the need for continued advocacy around educational funding in this field.

The U.S. Bureau of Labor Statistics projects 22,600 position openings for clinical laboratory technicians each year between 2024 and 2034. For decades, there

have been ongoing concerns about the sufficiency of the supply of laboratory professionals to meet demand.

Despite persistent workforce shortages in laboratory medicine, little national data exists on how students and professionals finance their laboratory education or how educational costs may affect entry into and retention within the profession. This data gap complicates advocacy efforts, including efforts to secure eligibility for federal and state grants and student debt reduction programs for laboratory professionals.

To assess the cost of laboratory education and the funding sources

students use to finance their training, researchers conducted a national cross-sectional survey of 2,422 laboratory professionals, educators, and current or recent students across the United States and its territories. Researchers analyzed respondents' educational costs, financing methods, and student loan participation, including factors associated with reliance on student loans.

The study found that the cost of attending a laboratory education program generally falls at or below the lower end of national averages for educational expenses among students and working laboratory professionals. However,



the study also determined that respondents most often relied on personal funds, federal student loans, and private loans to complete their education.

The researchers recommended continued advocacy to ensure that laboratory professionals remain included in federal and state scholarships, grants, and loan forgiveness programs. Doing so will strengthen pathways into laboratory careers, ultimately securing recruitment and retention, the researchers said.

● CMS AND CDC SEEK FEEDBACK ON POTENTIAL CLIA UPDATES

The Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC) issued a request for information (RFI) seeking feedback on potential updates to CLIA regulations. The RFI does not propose specific regulatory changes but could inform future efforts to modernize the federal standards governing clinical laboratory testing.

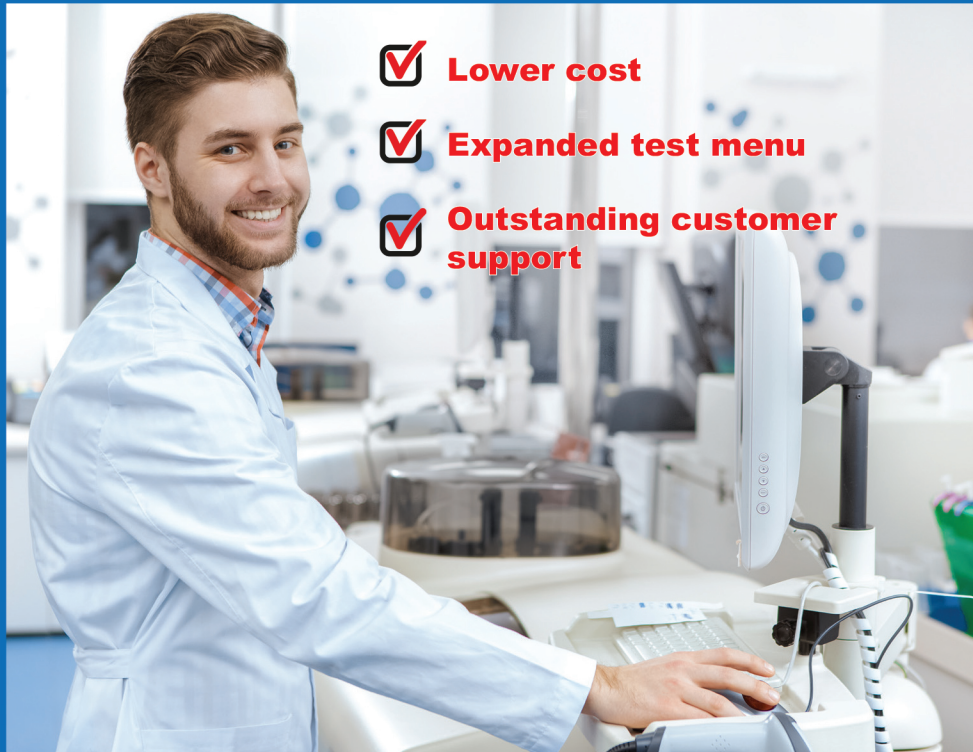
Laboratory technology has evolved considerably since CLIA regulations were implemented in 1992. The CMS and CDC are exploring whether regulatory changes may be needed to better reflect current laboratory practices, emerging technologies, and new testing methodologies. Feedback gathered through the RFI could help shape future rule-making efforts.

The RFI covers a wide range of issues relevant to laboratory professionals, including laboratory developed tests, next-generation sequencing, artificial intelligence, data-only facilities, laboratory personnel requirements, cybersecurity, and emergency preparedness.

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Where to find quality-assessed biological variation data: The EFLM Biological Variation Database

BY AASNE K. AARSAND, MD, PHD, CRAIG WEBSTER, FRCPATH, AND SVERRE SANDBERG, MD, PHD



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Craig Webster, FRCPath



Sverre Sandberg, MD, PhD

A new version of the EFLM Biological Variation Database — the primary resource for accessing quality-assessed biological variation (BV) data — was recently released. It can be found online at <https://biologicalvariation.eu> and is managed by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Technical Committee for the Biological Variation Database.

The database's 2026 iteration offers laboratory professionals and others an improved user interface and enhanced functionality. Today,

users can access more than 3,250 BV datasets extracted from over 600 published studies.

Structured appraisal and meta-analysis

BV data are reference data that serve many purposes, such as defining analytical performance specifications (APS) and reference change values (RCVs). Although numerous BV studies have been published over the past 50 years, their quality varies.

For that reason, all publications in the database are evaluated using

the Biological Variation Data Critical Appraisal Checklist (BIVAC) (1). This structured appraisal method, developed by the EFLM BV groups, assesses each study against 14 quality items. The BIVAC assessment appears alongside each dataset, supporting a transparent assessment of study quality.

Additionally, for each study, the BV database includes a minimum dataset that summarizes information essential for judging the applicability and transportability of BV estimates to local clinical practice.



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When several BV studies with acceptable quality are identified for a measurand, the database automatically provides global BV estimates derived from meta-analyses. Currently, more than 190 meta analysis-based global point estimates with confidence intervals have been published.

Data view and automatic calculation of APS and RCV

The database's website is intuitively structured, with three main access points: "Global BV estimates," "All BV datasets," and "BIVAC datasets by measurand." When accessing the global BV estimates, users will see all measurands for which BV data are included, including all identified BV datasets and global meta-analysis results if available. This enables users to choose either the global estimate or, if relevant, study-specific data appropriate for their patient population and the intended use of the BV data.

For measurands with meta-analysis estimates, APS and RCVs are automatically generated. The APS calculator provides specifications for imprecision, bias, total allowable error, and measurement uncertainty (2). The RCV calculator allows users to enter their own local analytical imprecision and select a probability level to help assess the significance of change between serial patient results in the context of local analytical performance.

Background and development

The database traces its origins to the EFLM's first Strategic Conference in Milan in 2014, during which attendees raised concerns about the reliability of available BV data. Building on the

foundational work of the EFLM Committee: Biological Variation (previously, Biological Variation Working Group), experts from Europe and beyond have contributed through successive EFLM task groups and committees to address the issues that were identified (3). Their efforts have clarified quality issues in BV studies and produced tools to improve both historical assessment and future study design.

The BIVAC appraisal mentioned earlier was a major output of this work, as was the more recent Standard for Reporting Biological Variation Studies (STARBIV) (4). These tools support rigorous evaluation of existing BV literature and promote higher standards for new studies.

STARBIV is now listed on the EQUATOR Network, an international initiative dedicated to improving the quality and transparency of health research. Its inclusion — alongside links to the STARBIV mind map hosted on the Biological Variation Database website — aligns BV reporting with established standards such as the Standards for Reporting Diagnostic Accuracy Studies.

The 2026 update of the EFLM Biological Variation Database provides a comprehensive, critically assessed repository of BV data supported by robust appraisal tools. It supports safe and effective use of BV information in laboratories and enhances users' confidence in applying BV-derived APS and RCVs to clinical decision making.

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References

1. Aarsand AK, Røraas T, Fernandez-Calle P, et al. The biological variation data critical appraisal checklist: A standard for evaluating studies on biological variation. *Clin Chem* 2018; doi.org/10.1373/clinchem.2017.281808.
2. Sandberg S, Coskun A, Carobene A, et al. Analytical performance specifications based on biological variation data — considerations, strengths, and limitations. *Clin Chem Lab Med* 2024; doi.org/10.1515/cclm-2024-0108.
3. Sandberg S, Carobene A, and Aarsand AK. Biological variation — Eight years after the 1st Strategic Conference of EFLM. *Clin Chem Lab Med* 2022; doi.org/10.1515/cclm-2022-0086.
4. Bartlett WA, Sandberg S, Carobene A, et al. A standard to report biological variation data studies — Based on an expert opinion. *Clin Chem Lab Med* 2024; doi.org/10.1515/cclm-2024-0489.



Tacrolimus immunoassay correlates well with mass spectrometry

An updated tacrolimus immunoassay on whole blood samples shows good agreement with an in-house liquid chromatography-tandem mass spectrometry assay (MS), a recent study found (J Appl Lab Med 2026; doi.10.1093/jalm/jfaf199).

Changing from the MS assay to the immunoassay substantially improved turnaround time (TAT) and workflow, the researchers noted.

MS quantifies tacrolimus accurately and with minimal metabolite interference. But it requires expensive analyzers, highly trained staff, and a manual process. In comparison, immunoassays have faster, simpler workflows but have been prone to cross-reaction with metabolites from tacrolimus and other drugs, leading to falsely elevated results.

The researchers compared their in-house MS tacrolimus assay to another tacrolimus immunoassay and performed a comparative analysis. The researchers also evaluated within-individual imprecision and total imprecision after implementing the immunoassay, plus changes and improvement to workflow and TATs.

The updated immunoassay correlated well with the in-house MS method, with a bias of 0.52 ng/mL. With the switch to the newer one, researchers saw a 42%–51% improvement in TATs across the median, 75th, and 90th percentiles, respectively.

After the switch to the immunoassay, the researchers determined

that similar TATs could be achieved with three daily batches instead of four. After reviewing a week's worth of time studies, a batch took an average of 2.3 hours to complete, with most variability based on batch size. Improvement was partly due to using automated analyzers and aligning number and timing of batches with volume and time of sample receipt.

The immunoassay's limitations include a need for some manual preparation and varied pipetting skills among automated lab staff. Study limitations include the lack of a formal interference study to determine cross-reactivity of metabolites or interferents, the researchers noted.

● CIRCULAR RNAS PREDICT ALZHEIMER'S DISEASE RISK

Recent research proposed 34 circular RNAs (circ-RNAs) in the blood as potential Alzheimer's disease (AD) biomarkers whose combined expression patterns accurately distinguished Alzheimer's disease from healthy aging

(Nat Med 2026; doi: 10.1038/s41591-026-04485-5).

Current AD blood tests offer reliable diagnoses by detecting markers of amyloid plaques that can yield positive results potentially decades before cognitive impairment, but provide little information about disease progression. CircRNAs, on the other

hand, resist degradation, are plentiful in the brain, and reflect changes occurring there.

To explore circRNAs as markers of patterns associated with future cognitive impairment before symptoms appear, researchers analyzed cross-sectional blood samples from 1,221 people, including healthy individuals and those with AD.

They looked for circRNAs associated with AD clinical status, A β and Tau stages, and progression to symptomatic AD. To develop and validate predictive models of AD diagnosis and disease progression, the researchers replicated their findings in independent samples from two cohorts.

After identifying a set of 34 circRNAs that were associated with AD, the researchers developed predictive models based on these associations that successfully identified individuals with AD pathology. These models performed similarly to those trained on data regarding the leading clinical blood-based biomarker for AD, the protein pTau217.

The researchers compared their predictive model, including these 34 circRNAs, amyloid- β , and Tau status, and replicated the model in 51 independent samples. Seventy-six were from AD patients and 475 were from patients without cognitive impairment. They also used the model in 1,767 samples from preclinical AD patients. Classification of biomarker-confirmed status by blood circRNAs had a higher predictive ability with area under the curve (AUC) of 0.945, versus plasma pTau217, with an AUC of 0.877.

The researchers also found evidence that circRNA changes begin approximately 2–4 years before the onset of clinical symptoms, which suggests that these molecules may capture biological processes closely linked to the transition from silent pathology to cognitive decline.

The researchers called for prospective validation in larger cohorts.

Unlike standard cholesterol tests, apoB measures the number of cholesterol carrying particles that can contribute to plaque buildup.

● APOB TESTING MAY BE A COST-EFFECTIVE PREVENTION STRATEGY

Apolipoprotein B (apoB) might be used as a cost-effective marker to guide primary prevention lipid-lowering therapy (LLT) and improve population health, a computer simulation study suggests (JAMA 2026; doi:10.1001/jama.2026.2986).

Unlike standard cholesterol tests, apoB measures the number of cholesterol carrying particles that can contribute to plaque buildup. Researchers say that makes it a more direct indicator of cardiovascular risk. Even with growing evidence supporting apoB, the test still is not commonly used in routine care, partially because measuring apoB generally requires an additional blood test beyond the standard cholesterol panel, increasing both cost and inconvenience.

The study examined whether it is worth spending extra money to use apoB instead of low-density lipoprotein cholesterol (LDL-C) or non-high-density lipoprotein cholesterol (non-HDL-C) to guide treatment intensifications as a means of primary prevention.

In a computer simulation and economic evaluation study, the researchers compared cost-effectiveness of using LDL-C, non-HDL-C, and apoB goals in a cohort of 250,000 atherosclerotic cardiovascular disease-free and statin-eligible U.S. adults, constructed from 4,149

National Health and Nutrition Examination Survey participants in the years 2005–2016.

Individuals started the simulation after lipid screening and received statin therapy based on 2018 American Heart Association and American College of Cardiology guidelines. The researchers intensified lipid-lowering therapy for patients who did not achieve these goals: LDL-C level less than 100 mg/dL, non-HDL-C level less than 118 mg/dL, or apoB level less than 78.7 mg/dL. The primary outcome was the incremental cost-effectiveness ratio. Strategies were considered cost-effective if they cost less than \$120,000 per quality-adjusted life year (QALY) gained in 2025 dollars, adjusted for inflation.

Compared with a non-HDL-C goal, 1,324 QALYs would be gained with an apoB goal, alongside a \$40.2 million increase in costs, yielding an incremental cost-effectiveness ratio of \$30,300 per QALY gained. Compared with an LDL-C goal, 965 QALYs would be gained with a non-HDL-C goal, alongside a \$2.1 million reduction in costs, the researchers found.

At a willingness-to-pay threshold of \$120,000 per QALY gained, an apoB goal was optimal in 65% of probabilistic analyses, and a non-HDL-C goal was optimal in 25%.

The cost of apoB testing was marginal. Higher costs reflected longer life expectancy and prolonged preventive treatment, the researchers noted.

**NAVIGATING THE RISKS AND
BENEFITS OF IMPLEMENTING**

A NEW LABORATORY INFORMATION SYSTEM

**Lessons learned
during a 5-year
transition to
a centralized
solution across
Alberta, Canada.**

There are many good reasons to transition to a new laboratory information system (LIS), especially when doing so is partnered and aligned with implementing a new clinical information system (CIS). In making this shift, clinical labs move away from fragmented patient information and healthcare workflows and toward centralized access to health information and best practices for all who connect with the new system.

But that does not mean the process comes without risks and obstacles. Indeed, such a transition raises numerous challenges related to standardization, testing, available resources, and other factors — all of which must be navigated with care.

To help others learn from our experience, this article highlights our implementation of a CIS and LIS after the formation of a health system in Alberta, a province within Canada that spans over 25,000 square miles. At the time of full implementation, Alberta Health Services (AHS) operated 106 acute care facilities and offered programs and services at more than 900 facilities throughout the province, including hospitals, continuing care facilities, cancer centers, and community health sites.

BY ALBERT TSUI, PhD, FCACB, AND ALLISON VENNER, PhD, FCACB



Before our CIS and LIS transition began, AHS had more than 1,300 independent health information systems, including five legacy lab information systems. During our journey of implementation, lab services moved from six clinical lab providers to two, and finally from two providers into a single lab provider for all of Alberta. Through a competitive process, Epic Systems Corporation was selected as the CIS for all health disciplines across the province, and Epic Beaker became the LIS.

To bring in one LIS across the province, all healthcare teams involved in the implementation agreed to multiple guiding principles (1), which helped to minimize conflict and maximize benefits. Some examples of principles that resonated from the clinical laboratory perspective included: putting patients and families first, moving fast, avoiding unhelpful variation, and using tools for transformation.

By prioritizing patients and families, the stakeholders maintained a strong focus on safety and augmenting the healthcare experience. Additionally, their commitment to making quick, clear decisions throughout the journey helped them keep up with steep timelines. Minimizing variation and including evidence-based guidance helped prevent unnecessarily complex builds and workflows. Finally, by focusing on transformation as the new technology came to fruition, the team stepped away from old inefficiencies and embraced a more streamlined approach.

IMPLEMENTATION

Implementing an integrated information system in laboratory services was a complex, multiphase process that required careful planning, coordination, and execution. This

project introduced a unified platform for laboratory ordering, specimen tracking, results reporting, and integration with the CIS. It required substantial technical, operational, and organizational changes to the lab environment.

As a first step, subject matter experts (SMEs), including medical and scientific staff as well as laboratory technologists from across Alberta, conducted a detailed planning and workflow analysis. During this multiyear operation, they mapped existing laboratory processes to identify current workflows, system dependencies, and variations across sites. This analysis informed the design of future workflows aligned with LIS functionality. Key implementation decisions included test menu configuration, result

component structure, incorporation of test utilization measures, and alignment with provincial standards and guiding principles. Stakeholder engagement ensured that laboratory requirements were accurately captured and incorporated.

System build and configuration — major components of implementation — involved configuring the LIS to include all laboratory tests, panels, reflex rules, reportable ranges, reference intervals, critical values, and specimen requirements, and then developing and validating interfaces between the LIS, middleware, and laboratory instruments to support bidirectional data flow. Accomplishing this required close collaboration between laboratory informatics teams, IT specialists, vendors, and operational leadership



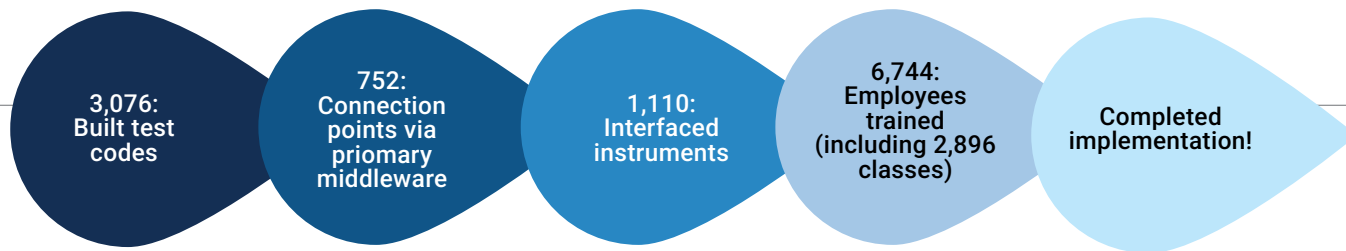


FIGURE 1. By the numbers: Implementation successes for the laboratory information system

to ensure both technical accuracy and operational feasibility. These professionals also worked together to check, update, and/or replace associated devices, such as computers, printers, and mobile devices.

System testing also played a critical role. This included the testing of individual test builds, interfaces, and laboratory workflows, and end-to-end validation from order entry through result reporting. Frontline laboratory staff and SMEs conducted user acceptance testing to simulate real-world scenarios and confirm system readiness. The issues they identified during testing were documented and resolved prior to the go-live phase, with repeated testing done as necessary.

Training and readiness activities were carried out concurrently with system build and testing. Laboratory staff received role-based training tailored to their responsibilities, including specimen collection and processing, analytical workflows, result verification, and reporting. Training methods included instructor-led classroom sessions, e-learning modules, and hands-on practice in training environments. “Super users” were identified and trained in advance to provide expertise and support local implementation. In parallel, SMEs and trainers collaboratively developed standard operating procedures and tipsheets to ensure consistency in daily operations and maintain the quality of laboratory services during and after the transition.

The go-live phase required extensive coordination and

operational planning among stakeholders to support the new LIS and CIS. Additional support structures were established, including command centers, on-site support personnel, and dedicated help desks. Laboratory workflows were closely monitored to identify and address issues in real time, ensuring continuity of services as best as possible during the transition.

Altogether, the implementation took 5 years and proceeded through nine phases (launches). The initial launch began in November 2019 and encompassed multiple sites, including one entire hospital, one separate hospital laboratory, one community hub laboratory, and multiple patient-collection sites. The project team collected feedback during early phases to identify areas that required adjustment during later launches. Subsequent phases were rolled out progressively across the province, with increasing efficiency and fewer reported issues at each stage.

By the time the whole implementation was complete, many notable feats had been achieved (Figure 1). Full provincial implementation was completed in November 2024. We identified many challenges and benefits along the way, as we describe here and summarize in Figure 2.

CHALLENGES

External factors

After the first implementation phase was finished in November 2019, the second phase was slated for completion within 6 months. However, the COVID-19 pandemic

shifted priorities and focus within the health system and delayed the second phase by approximately 6 months. Although this turn of events provided additional time for system build and preparation, it unexpectedly prolonged an interim state in which multiple LISs coexisted within the same geographical health region, which proved challenging to manage and confusing for frontline staff.

The laboratory network also experienced several major organizational changes and health system transformations over the 5-year implementation period. These shifts led to changes in leadership and evolving expectations and responsibilities, requiring staff to adapt to new organizational structures. The resulting uncertainty and competing demands diverted limited resources away from this major project and toward immediate priorities.

Standardization

Standardization becomes increasingly difficult as the scope of an initiative expands. Although a single hospital can align workflows and systems relatively easily, scaling processes across the province required the project leaders to address widespread variability in instrumentation, workflows and processes, and clinical and laboratory practices.

Achieving optimal standardization is a balancing act. Failing to address standardization can lead to inconsistencies that can affect the quality, clarity, and comparability of results, while focusing too heavily on it can result in reduced flexibility

to individual sites, the loss of valuable local practices, and increased resistance to change among health-care teams. Strong governance is the key to navigating these issues, so laboratory and clinical stakeholders can carefully weigh local needs against system-wide consistency.

System testing

System testing at each site was very valuable to identify errors and gaps that could have led to unexpected surprises after go-live. Although it consumed extensive resources and time, comprehensive testing was needed to provide a comfort level for medical and operational SMEs for signoff.

That said, in hindsight, we believe some of the testing plans were excessive for new sites and instruments. Once we developed a better understanding of the system's capability, we adopted a more streamlined approach in later launches. For example, provincially standardized reference intervals were initially tested at every laboratory regardless of whether other sites using the same instrument manufacturer had already been evaluated. Because the reference intervals are built into the LIS, we later realized we only had to test each instrument method one time.

Pre- and postanalytical processes

Because of the project's broad scope — including community and hospital-based ordering, sample collection, specimen routing, tracking, and other preanalytical activities — designing workflows for even a single site is complex. Scaling them across a province-wide laboratory network adds significant difficulty.

Moreover, although there were well-defined SMEs for laboratory areas like chemistry, hematology,

and microbiology, there was no early, dedicated oversight for pre- and postanalytical processes in this project. This gap contributed to multiple challenges during initial implementation, including specimens being sent to incorrect testing locations, inadequate tracking during inter-site transport that led to lost specimens, and errors in result routing that caused missing reports.

For that reason, formal governance structures were established within and across lab disciplines in later phases to strengthen these critical processes and manage issues and requests impacting clinical and laboratory workflows. The need to incorporate pre- and postanalytical oversight was a key lesson from this project.

Resourcing

The initial resource assessments severely underestimated what was required for this large-scale project. Medical and operational SMEs initially planned to spend a maximum of 20 hours per week on the initiative for a few months. They were not seconded or provided with protected time. Additionally, only one IT analyst was assigned to each lab discipline. With approximately 700 tests to build, the clinical chemistry discipline was severely understaffed. Insufficient resources led to delays, staff burnout, and reduced progress. The limited resources were

first realized as we were finishing preparations to launch the first sites and remained one of the main challenges throughout the 5-year implementation.

Practical recommendations

Reflecting on the challenges we encountered, we offer several recommendations to help others maximize staff retention and enable continuity of knowledge while maintaining a new LIS.

- Address standardization issues ahead of taking on this type of project whenever possible and practical. This includes areas such as instrumentation, reference intervals, critical values, reporting comments, sample types, and general lab processes.
- Develop system testing plans specific to the lab in a planning phase rather than during implementation. This will enable more appropriate resources and streamline testing.
- Establish governance structures within and across lab disciplines to address pre- and postanalytical processes. Include medical and operational leadership and SMEs who can make clear, appropriate, and rapid decisions, as well as oversee key lab workflows affected by the LIS.
- Advocate for sufficient resources to prepare, complete, and maintain the implementation. This

CHALLENGES

- External factors
- Standardization
- System testing
- Pre- and postanalytical processes
- Resourcing

BENEFITS

- Integration, connectivity, analytics
- Standardization
- Stronger connections
- Enhanced awareness of laboratories' value

FIGURE 2. Benefits and challenges of an LIS implementation

includes dedicating medical, technical, and operational time that does not compete with typical daily workloads, as well as ensuring that the appropriate lab representatives are available for both high level and “on the ground” decisions.

BENEFITS

Integration, connectivity, and data analytics

Adopting a unified LIS across sites enables data sharing and improved access to results across the province, allowing for remote support and consultation to facilitate troubleshooting and decision-making. This connectivity opens new opportunities to use aggregate data for quick data visualization and dashboards. For example, integrated systems allow for real-time monitoring of test volumes, turnaround times, and quality metrics to support continuous quality improvement and strategic decision-making. They also create a foundation for innovation and research that connect detailed laboratory data with clinical information (2).

Standardization

Variability across legacy-system processes requires standardization and alignment with LIS capabilities wherever possible. Adopting common processes, methodologies, and reporting formats reduces variability and enhances consistency in results. Standardization also improves efficiency by minimizing duplication, simplifying training, and streamlining workflows. For example, it ensures that elements such as procedures, reference intervals, and critical values are consistent across sites for the same instrumentation. Doing so supports the development of provincial clinical care pathways.

During the implementation of this project, it became evident to healthcare leaders that laboratory services are fundamental to all areas of clinical care.

Stronger connections

Initiatives like this one can strengthen connections both within and beyond the laboratory. Namely, integrated systems foster collaboration across laboratory sites, enabling shared expertise, coordinated strategies, and improved resource utilization. They also promote robust partnerships between lab professionals and clinical care teams, laying the groundwork to develop evidence-based lab practices and drive appropriate test utilization. These relationships reinforce that the laboratory is an essential partner in clinical decision-making and not simply a background service.

Enhanced awareness of laboratories' value

Laboratory testing informs a substantial proportion of clinical decision-making, yet its contribution frequently goes underrecognized. During the implementation of this project, it became evident to healthcare leaders that laboratory services are fundamental to all areas of clinical care. In fact, laboratory readiness became a key factor in determining “go/no-go” decisions prior to each implementation phase. Additionally, the laboratory plays a critical role in reviewing and providing feedback on order sets and serves as an essential contributor to clinical care pathways and initiatives.

Implementing an effective LIS and CIS is a big task. Although the process requires significant risk,

including many elements that may not be known at the project outset, the rewards are considerable. In our experience, the benefits outweighed the challenges. With thorough resourcing and extensive preparation, many of the difficulties can be overcome, resulting in a holistic, valuable, and highly advantageous system. 🍀

References

1. Alberta Health Services. Connect Care vlog: Why does Connect Care matter? https://publicshare.albertahealthservices.ca/Main/assets/cmio/AHS_CC_Vlog_Goals.pdf (Accessed June 2026).
2. Chishtie J, Sapiro N, Wiebe N, et al. Use of Epic electronic health record system for health care research: Scoping review. *J Med Internet Res* 2023; doi: 10.2196/51003.

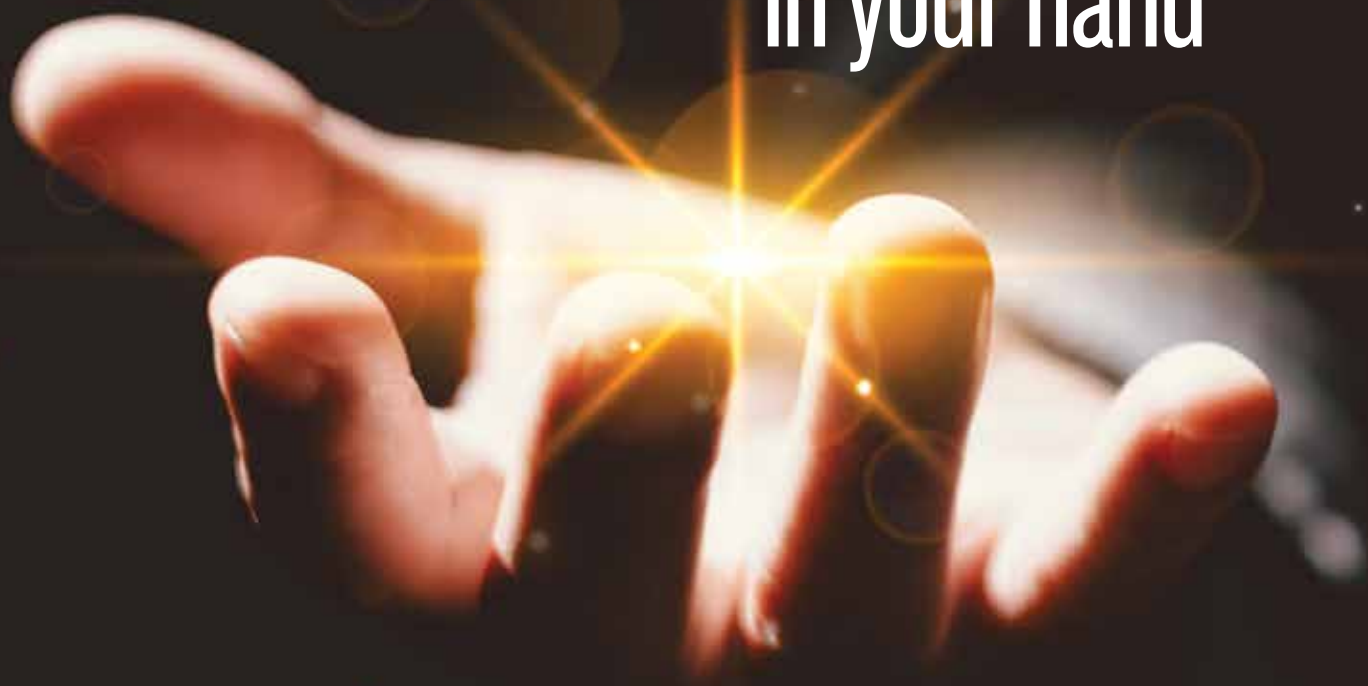
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Putting the
power
of the lab
in your hand



BY KAREN BLUM

If you attended the ADLM 2026 meeting this summer, you may have noticed some excited screaming and jumping up and down. That was the reaction of the nine employees of Kompass Diagnostics upon learning they had received this year's Disruptive Technology Award from the Association for Diagnostics & Laboratory Medicine (ADLM). Kompass was recognized for its electrical transduction architecture (ETA), a compact testing platform developed to bring laboratory-grade analytical capabilities to resource-limited settings.

Mingoo Kim, CEO of the company, described being named as an award finalist alone as a "huge win" for Kompass. Receiving the award — both from the audience and the judges — was the icing on the cake. "I think the audience really appreciated us because we weren't discrediting conventional technology," Kim explained. "My view is that, throughout history, every innovation has served its purposes all for the better. What we're doing is just adding on to what's existing to fill in a new need."

As medical care shifts more toward the home, some self-collection devices have emerged, but those are still shipped back to the lab, Kim said. "If we could test in the home, that would be much more efficient and cost-effective. That's what we're trying to do."

THE VISION THAT LAUNCHED THE COMPANY

The company's chief technology officer, Hyoarm Joung, PhD, spent 25 years in diagnostic research and development in academia and industry settings. He has a track record of commercializing point-of-care tests, Kim said. "He is a visionary. For the past 25 years, he

has always dreamed of building diagnostics that exhibit the same high performance as a laboratory instrument, but [are] accessible for home use — so very cost-effective but also small and easy to use." Conventional technologies haven't yet been able to meet that vision.

Joung partnered with June Jang, PhD (now the company's chief scientific officer), an expert in semiconductors he had worked with at a national laboratory about 10 years prior. Jang was focused on commercializing field effect transistors (FETs), a type of semiconductor device, as scalable biosensors. Once Joung and Jang started collaborating, Jang asked Kim to come on board as CEO. Kim was a friend of Jang's from engineering classes at Johns Hopkins University who went on to work in corporate research and venture capital. Together, the three of them birthed Kompass.

Based in Chicago, the company is building on two intellectual properties exclusively licensed from Joung and Jang's most recent employers, the University of California, Los Angeles, and the University of Chicago.

The company was launched with the vision of accelerating healthcare's shift toward the home setting, Kim said. "Today [the market] is small, but if we look out a decade from now, two decades from now, that field is going to be massive," he said. "I think the whole industry agrees that testing will continue to get closer to the patients, but no one really has had an idea of what that actually looks like. ETA is our approach to realizing that vision."

AN ELECTRICAL APPROACH TO DETECTION

At the heart of the technology is the ETA, an electrical method of



**Kompass Diagnostics
won the**

**2026 ADLM
Disruptive
Technology Award**

**for a palm-sized
multimodal electrical
sensing platform that
enables chemistry,
immunoassay, and
molecular testing at
the point of care.**

sensing biomarkers. Unlike conventional methods that rely on optical detection, such as fluorescence or chemiluminescence, for example, ETA converts biological and chemical reactions into electrical signals that can be detected using semiconductor electronics.

“This assay method works across chemistry, immunoassay, and molecular diagnostics,” Kim said. “Regardless of what your analyte or biomarker is, it’s able to turn that target recognition event into charge signals.”

In a chemistry assay such as glucose testing, for example, a target-specific reaction generates charged species that ETA can detect. With molecular tests, amplification of the target nucleic acid produces changes in charge that can be electrically detected. In immunoassays, target recognition is coupled to a conjugate-based reaction that generates a detectable charge signal.

“Once charge signals are generated, they are directed, by an electric field, toward an electrode surface where they can be detected,” said Kim. “Detection is confined to that electrode surface, which allows the system to exhibit high signal specificity and minimize matrix interference. The resulting electrical signal is then relayed to an FET remotely connected to the electrode.”

FROM FERTILITY TO VIRAL TESTING

To start, Kompass is building Eltra, a point-of-care device that measures fertility hormones for in vitro fertilization or other treatments. “Fertility is a specialty that requires rapid results for same-day treatment decisions, which is why most fertility clinics operate their own in-house laboratories,” Kim said.

However, building and operating an in-house lab is expensive, particularly given the relatively low

daily testing volumes of fertility clinics compared with large hospitals. Alternatives are scarce: Blood measurements of estradiol, progesterone, and luteinizing hormone — which clinicians use to time egg retrieval or intrauterine insemination — may be outsourced to a local laboratory, but doing so often sacrifices the rapid turnaround needed for same-day treatment decisions. And even with an in-house laboratory, current workflows take several hours to return results to clinicians, a limitation that constrains monitoring visits to the early morning.

With Eltra, Kompass hopes to significantly reduce the cost of in-house fertility testing, Kim said. “Over the past decade, we’ve seen more than a double increase in the demand for fertility treatments, but we’re still only meeting 25% of total demand. We need to expand access to fertility care, and reducing the infrastructure required for hormone monitoring could make it easier for providers to expand capacity and open new points of care. How can we reduce these barriers to serial hormone monitoring, which directly impact clinical outcomes? By developing a much leaner device that can get the same, high-quality results to providers.”

Eltra is designed to provide results within 10 minutes during a patient appointment, using just 10 μ L of blood, and it could be used by multiple clinic staff members, from nurses to phlebotomists to ultrasound technicians. Obstetrician-gynecologists and their staffs could also use it in partnership with fertility clinics.

Kompass is still developing Eltra and is eyeing the first half of 2028 to conduct clinical studies and the first half of 2029 to submit a dual submission to the Food and Drug Administration (FDA) for clearance and a CLIA waiver, Kim said.

Another product the company is developing using ETA is an ultrafast molecular test for respiratory viruses including COVID-19, influenza, and respiratory syncytial virus (RSV) based on isothermal amplification. Many existing rapid molecular tests take around 20 minutes or longer, Kim said, while early testing of Kompass’ platform has demonstrated results from a nasal swab in approximately 3 minutes.

“If we can give faster results, that means you can screen, triage, and discharge patients faster,” he said. “Imagine a pediatric setting during flu season, and there’s a lot of patients, and you have to screen them. A parent with a sick child doesn’t want to wait another 30 minutes [for results] after seeing the physician, and the clinic wants to clear out the waiting area.”

Kompass aims to finalize the design of its respiratory virus test by the first half of 2028.

Home care is on the horizon for later, with these two applications for clinical use serving as deliberate steps on the path. “[By bringing testing to CLIA-waived point of care, for example,] we can first demonstrate that the technology performs reliably in the hands of minimally trained users, and build trust within the clinical community,” Kim said. Demonstrating strong performance on an application like this creates a foundation for eventually putting testing directly into patients’ hands at home.

“We see this as a continuum, much like the evolution of glucose monitors from centralized lab testing, to point-of-care testing, and ultimately, to testing in the home,” Kim said.

WINNING OVER THE SKEPTICS

People are initially doubtful when they hear that this one platform can do chemistry, immunoassay, and



**"We see this as a continuum,
much like the evolution of glucose
monitors from centralized lab test-
ing, to point-of-care testing, and
ultimately, to testing in the home."**



molecular testing in a palm-sized device using 10 μ L of blood and still be as sensitive as a laboratory instrument, Kim said, so Kompass brought their whole team to their booth at ADLM 2026 to share information and answer questions.

"They come with skepticism, and we're transparent about, 'This is what we've figured out. This is what we haven't, but we know how to approach it.' People leave convinced. That's what we were aiming for at the conference, and I think we did achieve that," Kim said.

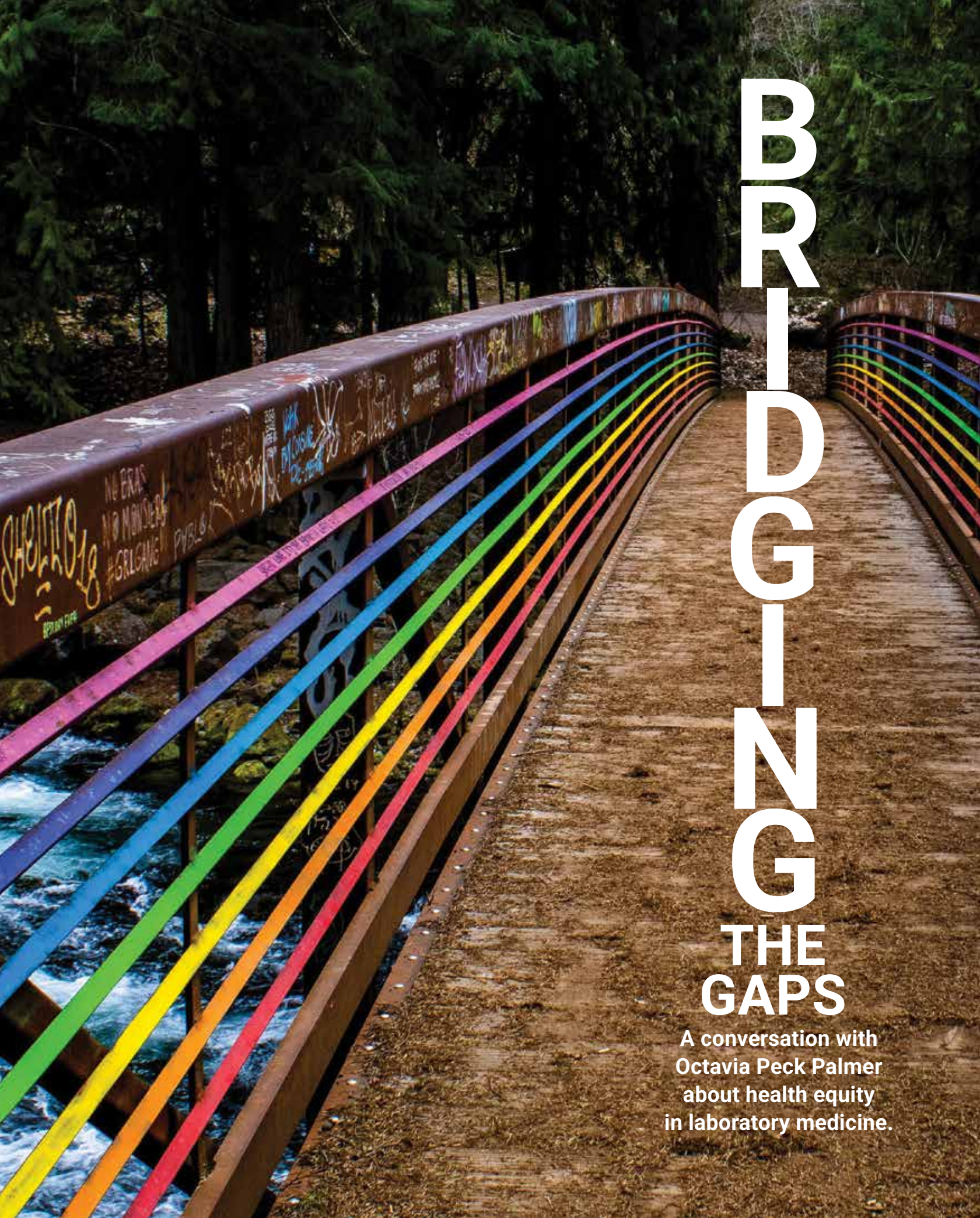
The Kompass team edged out two other finalists: Anvil Diagnostics, which became a finalist for its MycoScan assay, and Augurex Life Sciences, which earned finalist status for its SPINEstat immunoassay.

MycoScan is believed to be the world's first panfungal digital PCR blood test, capable of identifying nearly any fungal pathogen in a single, 3.5-hour workflow using 2 mL of plasma. The technology uses semi-specific primers that generate unique multilocus "fingerprints" for each target pathogen. Three active pilots are demonstrating real-world detection of *Aspergillus*, *Mucorales*, and *Fusarium* in patient samples.

SPINEstat is a blood-based diagnostic for axial spondyloarthritis. The technology measures multiple autoantibodies to 14-3-3eta, a joint-derived protein integral to inflammatory disease pathways. This immunoassay has achieved FDA Breakthrough Device Designation and regulatory approvals in Canada and Great Britain. 🍷

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BRIDGING THE GAPS

A conversation with
Octavia Peck Palmer
about health equity
in laboratory medicine.



BY MORIAH SELLERS

Health equity is often discussed as an aspiration in healthcare, but for Octavia Peck Palmer, PhD, FADLM, it has been a guiding principle throughout her career. A past president of the Association for Diagnostics & Laboratory Medicine (ADLM), founder of the association's Health Equity and Access Division, and recipient of the Humans of ADLM – Diversity, Equity, and Inclusion (DEI) Leadership Award, Peck Palmer has shaped conversations within laboratory medicine about how to ensure everyone has access to high-quality care.

Her work spans advocacy, education, and systems-level change. From leading efforts to embed DEI and health equity into ADLM's strategic priorities to helping remove race-based adjustments from estimated glomerular filtration rate (eGFR) reporting, she has consistently identified and addressed barriers that prevent patients from receiving the care they need.

We recently spoke with Peck Palmer, who is division director of clinical chemistry at the University of Pittsburgh School of Medicine, about her commitment to health equity, the impact of her Ask a Laboratorian initiative, and the reasons why she believes that health literacy is essential to advancing better outcomes.

Q: What led you to become an advocate for health equity and DEI?

The fact that so many people are medically underserved. I have been fortunate to access and experience quality healthcare. However, knowing that I

participate in a healthcare ecosystem that not everyone can access equally is disappointing. I believe that making sure all people can connect with care is part of my job.

Q: Among the many things you've achieved in this area, what are you most proud of?

Going into the community and talking to individuals about clinical tests and how to articulate their healthcare needs to their provider, whether that's a physician, nurse, or nurse practitioner. Sometimes these discussions also help patients communicate more effectively with family members who are trying to help them navigate their health.

The University of Pittsburgh operates philanthropically supported community engagement centers across the region, including one in Homewood, which is historically one of Pittsburgh's largest predominantly Black neighborhoods. After talking with the center's director, Vernard Alexander, about our Ask a Laboratorian initiative, he invited the University of Pittsburgh School of Medicine's department of pathology to visit the center and engage with the community. My colleague Nathan Clemons, PhD, D(ABMM), MLS(ASCP)CM, a clinical microbiologist, and I spent time with the community introducing ourselves and our profession. We used this opportunity to help individuals learn about clinical tests and their significance and how to navigate their patient portals.

Q: Tell us about Ask a Laboratorian.

Lab medicine and pathology professionals constantly have conversations about how to demonstrate our value as a field. How do we become more transformational, responsive, and proactive? Ask a Laboratorian

was designed to help accomplish those goals. It's a community-centered initiative designed to improve health literacy and empower individuals to take active roles in their care. I am very proud of it!

A similar initiative called Ask a Pharmacist sends pharmacists into communities to teach people how to dispose of expired drugs correctly, understand drug contraindications, and make sense of their symptoms.

Because laboratorians aren't in front of patients all the time, I was inspired by that model as a means of communicating who we are and what we do. I decided to reach out to see if community engagement centers would be receptive, since their mission is to ensure individuals are equipped to live healthy lives.

Ultimately, building understanding of clinical testing across communities helps people recognize laboratory medicine as integral to their care.

And we regularly look for ways to improve our approach, too. For example, Ask a Laboratorian's next visit to a community engagement center will be in October, and we plan to survey participants ahead of time to make sure we have the resources they need prior to us getting there.

Q: Can you share examples of the work you've done to advance DEI at ADLM?

Prior to becoming president, I founded ADLM's Health Equity and Access Division and chaired the DEI

Knowing that I participate in a healthcare ecosystem that not everyone can access equally is disappointing. I believe that making sure all people can connect with care is part of my job.



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steering committee, which aimed to understand how the association values DEI and health equity as outcomes of the work we do.

Around that time, while serving on the Board of Directors, I was appointed to the ethics task force. It was a natural progression, since there's no way to untangle ethics from health equity and DEI: Delivering ethical care demands working to reduce bias.

All of that led to me having the honor to serve as ADLM's 2023-2024 president. I knew, based on the equity work I had already done, that we needed to go a little bit deeper as an organization. Specifically, we needed to infuse DEI in everything we do, and that could only be done by updating our strategic plan.

I've always believed that, when it comes to equity, it's more important to speak through your actions than your words. I believe ADLM operates in a manner that communicates it values health equity. It's right there in our mission: better health for all.

Q: How have people benefited from your work in health equity and/or DEI?

Championing DEI and health equity benefited patients across the University of Pittsburgh Medical Center health system when our clinical laboratories adopted a new estimated glomerular filtration rate (eGFR) equation that does not include race as a variable. Before this change, laboratories routinely reported two different eGFR values from the same specimen — one calculated with a race coefficient and one without — leaving clinicians to decide which value applied based on how the patient's race had been documented or self-identified.

If a patient self-identified as Black or the healthcare professional selected Black as the patient's race,



the patient's eGFR was calculated and adjusted using Black race as a variable. However, studies have shown that using this approach has likely harmed patients by leading to delays in care, referral services, donor candidacy, and transplants. As a result, in 2021, a task force comprised of the National Kidney Foundation and the American Society of Nephrology recommended clinical laboratories adopt the CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) 2021 creatinine equation, which estimates kidney function without a race variable. I led the adoption of the new eGFR algorithm for use across the healthcare system, an initiative that my department fully supported.

Q: You were nominated for the Humans of ADLM – DEI Leadership Award, but ADLM also wants people to apply for this award on their own behalf. What would you say to encourage self-nominations?

The key reason is it normalizes DEI and health equity, which should be integral components of our profession and how we practice. We can all partner with our medical colleagues and communities to improve healthcare access and delivery. You can be the impetus for change. And nominating yourself demonstrates how well you prioritize not only your career,

but also the outcomes of your work — that is, what your career can do for others.

Many of us lose sight of the fact that one day we may be a patient in the healthcare system, if we haven't been one already. Think about building a system where you'd want to receive care for yourself and your loved ones. If we do that consistently, that's where the DEI and health equity show up. We all want to have the best possible opportunity to get diagnosed and treated in a timely manner, leading to optimal outcomes.

After all, what is healthcare about if it's not about equity? Of course, patients won't all have the same health status, but we intuitively know that intentionally delivering highly variable and biased care would be atrocious. If we're going to provide healthcare, it must be with the intention of delivering the highest quality care to each person.

Q: What advice would you give to lab professionals who want to advance DEI and health equity but don't know where to start?

Understand the principles of DEI and what health equity means. Think about your day-to-day life and practice. Is there a gap in access that aligns with one of those principles? Does your work allow for health equity to be realized? How do you relate to these issues?

Once you do that, you've got your blueprint. Then you can find your champions, which could include your chair, CEO, supervisor, or lab manager, and start working with them.

I'd love it if people reached out to me. I'm happy to help them map out blueprints for their own areas. 🍷

Moriah Sellers is a writer based in the Missoula, Montana, area.



BY MICHAEL ASTION, MD, PHD, AND JANE DICKERSON, PHD

Four tips for managing conflict in laboratory stewardship

Laboratory stewardship programs ensure proper test ordering and interpretation while reducing financial toxicity for patients. Implementing stewardship policies usually goes well, since most clinicians are competent and committed to doing a terrific job.

However, this article is not about them. Rather, it's about the smaller, but still significant, percentage of clinicians who push back on established laboratory stewardship policies, creating friction with lab professionals who are also committed to doing a terrific job. In these situations, lab leaders can benefit from cultivating their skills in conflict management.

Managing conflict in stewardship is not about being nice; nor does it require you to act like a bully. Rather, it is about deploying a toolkit and having the courage of your convictions. Based on our experiences, as well as those of other members of PLUGS (the Patient-Centered Laboratory Utilization Guidance Service), we have assembled four practical tips to help laboratory leaders manage stewardship conflicts effectively.

1. Reduce or eliminate emotional emails and texts

A foundational rule of conflict management in laboratory stewardship is to dramatically reduce or eliminate the use of email and text messages to express emotional content. If a clinician gets upset about a restricted test order, firing off a clever, lengthy defense only communicates that you are not a seasoned conflict

management professional.

When disagreement arises, email and text can be easily misinterpreted and often escalate the situation. If you feel compelled to write a heated response detailing why an ordering provider's demands are unreasonable, our advice is to go ahead and write it — but save it to a personal journal and practice the ancient art of the "letter never sent." Once your anger has dissipated, delete the draft and schedule an in-person meeting.

Stewardship application: Imagine that a clinician sends an angry, three-page, bulleted screamer of an email to a lab professional because a new test panel was sequestered for review by the stewardship process. Rather than responding in kind, consider communicating the following succinct and professional message by email or text: "Hello, I received your note about the panel. Can you please send me some times when we can schedule a personal meeting or Zoom call to discuss? I have good availability tomorrow and Wednesday as well. Thanks."

2. Stick to the facts

When a stewardship boundary is enforced, clinicians may become defensive, introducing tangential arguments or even attacking your character or the performance of the lab.

The best way to counter this is by remaining factual. Your job is to address the lab stewardship problem without condescending to the person criticizing you. Adopt the philosophy that you are dealing with a competent clinician who comes to work to do a terrific job — which is

usually correct. Specifically, do not allow the conversation to drift into a debate about who is more ethical, or how well clinical practices were managed at a previous institution.

Hate will grow like a weed if you nourish it with the fertilizer of "I'm smarter than you" or "I couldn't care less about your previous hospital." Good stewardship practice is to depersonalize the situation and frame your responses in terms of established policies and the rationale behind them.

3. Prepare face-saving measures and plan the space to meet

Conflict management is not about wielding your authority, as temporarily satisfying as that might feel. Instead, before entering an important stewardship meeting where there has been some previous conflict, identify realistic face-saving measures to help the clinical team accept stewardship policies and boundaries without feeling minimized.

Furthermore, at in-person meetings, it is worthwhile to arrange the space in a way that helps lower the emotional temperature. Thus, if a meeting requires multiple laboratory representatives and clinical stakeholders, avoid a confrontational layout where opposing teams line up on opposite sides of a conference table.

Arrive early, mix up the seating arrangement, and bring a lab team that matches, but does not exceed, the professional status and hierarchy of the attendees. In one-on-one interactions where there is a history of conflict, it can sometimes be helpful to invite a neutral third party to

promote calm behavior. For virtual meetings, ask everyone to turn their cameras on. This can help de-escalate situations, since seeing faces builds empathy.

Stewardship application: A medical department strongly resists transitioning from an expensive, unapproved external laboratory for cancer genomic profiling to an equally valid, highly efficient in-house assay. Instead of issuing a blanket denial, the stewardship team prepares a face-saving compromise. The laboratory agrees to allow the use of the external vendor to test for one highly complex tumor sub-type where the data are still evolving, while establishing the in-house assays as the standard for the remaining cancer profiles.

Additionally, the stewardship team arranges for collaborative educational and research opportunities regarding the in-house test, so that care providers and lab personnel can learn, teach, and perhaps even publish together. Face-saving measures protect the dignity of all parties while supporting the overarching clinical and academic goals of your institution.

4. Be a “broken record” with key phrases

When clinicians realize that a laboratory policy is firm, they may attempt to widen the argument to overwhelm a younger supervisor or administrator. In these moments, a reasonable approach is to employ a “broken record” technique. This involves choosing a concise, calm, and accurate core phrase and repeating it as needed to keep the discussion on topic.

Pairing the broken-record technique with specific, non-escalating phrases allows the supervisor to acknowledge the clinician’s

perspective while firmly maintaining stewardship guardrails. Useful phrases include:

- *“This meeting is specifically about ...”* This keeps the stewardship goals narrow and prevents historical grievances from derailing the discussion.
- *“I appreciate that you said that ...”* This affirms that the clinician has been heard without agreeing to deviate from standard policy.
- *“That would be a separate conversation. With regard to this meeting ...”* Use this when a provider tries to bring up unrelated personal or operational complaints.

Stewardship application: A disgruntled care provider demands that the lab rapidly process and send out a sample for a new test that has not been approved by the stewardship committee.

Despite feeling intimidated, the junior laboratory supervisor smartly chooses to deploy the following broken record technique: “I appreciate that you are concerned about your patient’s timeline for this test. Our policy is that a new test being ordered rapidly like this must be reviewed by the laboratory physician on call. She will call you to discuss it in the next 30 minutes.”

If the provider continues to vent, the supervisor remains calm, repeating: “I hear your frustration. Our policy is that a new test request like this is reviewed by the laboratory physician on call. She will contact you in the next 30 minutes.”

Preparing for a long-term collaboration

The most successful laboratory stewardship programs reduce the chance of a high-conflict scenario by actively participating with clinical teams and regularly giving them positive reinforcement for their

excellent test ordering practices. This helps the lab team avoid becoming the “bummer” department that only shows up to deliver bad news, deny tests, or issue corrections to clinicians.

When lab leaders develop a reservoir of goodwill, clinicians are more likely to perceive stewardship policies as rational and protective rather than as bureaucratic obstacles.

Summary checklist for laboratory stewardship leaders

- Strongly reduce the use of email or text messages for any emotional or conflict-driven communication.
- Stick to clinical data and facts; do not respond to personal attacks in kind and do not initiate any.
- Bring appropriate peers to stewardship meetings and mix up the seating arrangements.
- Use the “broken-record technique” to maintain guardrails, depersonalize conflicts, and move toward resolution.

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BY SANJAI NAGENDRA, MD, MMM



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Guidance Services

The Goldilocks principle in hematology: Practical, case-based lessons in laboratory stewardship

Clinical history is one of the most effective yet underused stewardship tools. It can help clinicians to assess pretest probability and gauge disease risk. For instance, a recent viral infection can explain lymphocytosis. An inflammatory state, such as rheumatoid arthritis, may account for thrombocytosis. Severe anemia accompanied by petechiae is suspicious for marrow abnormality. A focused clinical history can alter the interpretation of lab results and eliminate the need for costly additional tests.

Appropriate levels of investigation can also vary by clinical setting. For example, a tertiary-care center may pursue a lymphocytosis case more aggressively with flow cytometry, while a rural hospital may use a stepwise approach that calls for a smear review before jumping to ancillary testing.

As it stands, research suggests that healthcare professionals often get it wrong. Up to two-thirds of all hematology and coagulation testing may be overutilized, while underutilization of necessary tests approaches 45%. Overutilization can lead to false-positive results and unnecessary follow-up, while underutilization may result in chronic conditions remaining undiagnosed.

And any abnormal result could prompt a cascade of additional evaluations, sometimes leading to invasive tests such as bone marrow or tissue biopsies. Research indicates that nearly 20% of complete blood counts (CBCs) show at least one “abnormal” value.

Inappropriate testing causes both financial and psychological toxicity. In a survey of patients referred to a hematologist for benign conditions, 46% reported increased anxiety and 30% feared a cancer diagnosis. Distress worsens with hematology, often located in oncology centers, which can make patients mistake a benign referral for a cancer evaluation (1). These harms create a measurable burden that stewardship programs must consider alongside the risk of missed diagnoses.

To help promote appropriate utilization, multiple professional societies have launched “Choosing Wisely” campaigns, which have closely evaluated 17 hematology and coagulation testing practices (2). In this article, I present several cases that underscore the wisdom of using a practical “Goldilocks” approach that takes into account clinical history and practice setting. The goal is not too much testing, not too little testing, but just the right amount.

Case 1: Mild lymphocytosis

A 58-year-old male veteran with a 25-pack per year smoking history presents with fatigue. The patient denies fever or night sweats. His white blood cell (WBC) count is $11 \times 10^9/L$ (normal, $4-10 \times 10^9/L$), absolute lymphocyte count is $5.8 \times 10^9/L$ (normal, $1.2-3.0 \times 10^9/L$), and hemoglobin and platelets are normal. Physical exam reveals no lymphadenopathy or hepatosplenomegaly.

Question: Should flow cytometry be ordered immediately?

Discussion: Tobacco use is a recognized cause of reactive lymphocytosis; WBC counts are higher in current smokers and normalize following cessation (3). The absence of lymphadenopathy, cytopenias, or constitutional symptoms decreases the likelihood of a lymphoproliferative disease.

The review of a peripheral blood smear triggered by analyzer flags remains a key method for differentiating reactive from clonal lymphocytes. If the morphology is benign, consider a repeat CBC before proceeding to advanced studies such as flow cytometry.

In tertiary-care centers with onsite flow cytometry, testing may occur quickly; however, in resource-limited laboratories, a stepwise triage approach avoids unnecessary send-out costs and mitigates patient anxiety without sacrificing diagnostic accuracy.

Outcome: Serial CBCs demonstrated stable lymphocytosis. Smear review showed a polymorphous population of small, mature-appearing lymphocytes without morphologic atypia. The lymphocytosis was attributed to smoking-related reactive changes.

Stewardship pearl: Not every case of mild lymphocytosis requires immediate flow cytometry. Diagnostic intensity should be guided by clinical probability, persistence, and associated findings.

Case 2: Persistent thrombocytosis
A 48-year-old woman with

perimenopausal menorrhagia presents with a hemoglobin level of 10.1 g/dL (normal, 12-16 g/dL), mean corpuscular volume (MCV) of 75 fL (normal, 80-100 fL), and a platelet count of $510 \times 10^9/L$ (normal, $150-450 \times 10^9/L$). There is no splenomegaly or family history of thrombosis.

Question: Should *JAK2*, *CALR*, and *MPL* mutation testing be ordered immediately?

Discussion: Most thrombocytosis (85%–90%), including extreme levels ($\geq 1,000 \times 10^9/L$), is secondary to reactive causes. Both the Intensive Care Consortium and World Health Organization have diagnostic criteria for important thrombocythemia that mandate exclusion of secondary causes before molecular testing for a genetic mutation.

In a study of 1,202 patients with thrombocytosis, 83.1% had secondary causes, of which iron deficiency accounted for 11.1% (4). The combination of menorrhagia, microcytic anemia, and thrombocytosis points to iron-deficiency–related reactive thrombocytosis.

The stewardship question is not whether molecular testing has value; it is whether it is the most effective next step in the workup. Most clinical laboratories can assess ferritin levels, and a full iron panel can be reflexed if the result is equivocal. This simple step can resolve the diagnostic question before committing you to costly molecular testing.

Outcome: Iron studies confirmed deficiency (ferritin, 8 ng/mL; normal, 15-150 ng/mL). Following iron replacement, hemoglobin normalized to 13.2 g/dL, and platelets decreased to $310 \times 10^9/L$. Molecular testing was not required.

Stewardship pearl: Evaluate common and reversible causes of thrombocytosis before escalating to advanced molecular testing.

Case 3: Pancytopenia with rare circulating blasts

A 67-year-old man presents with 2 weeks of fatigue and easy bruising. His WBC is $0.4 \times 10^9/L$ (normal, $4-10 \times 10^9/L$), hemoglobin is 8.4 g/dL (normal, 13-17 g/dL), and platelets are $42 \times 10^9/L$ (normal, $150-450 \times 10^9/L$). The analyzer generates a blast flag, and rare, atypical cells are identified on smear review.

Question: Can additional testing wait?

Discussion: Here, underutilization is the stewardship issue. Severe pancytopenia with abnormal cells suggests acute leukemia. Current guidelines advise a CBC and smear review by a pathologist if atypical cells are present and a bone marrow aspirate in suspected cases (5). Morphologic assessment, flow cytometry, cytogenetic analysis, and molecular testing are all key for initial evaluation.

In this setting, rapid diagnostic escalation is not overuse, but good stewardship. Community hospitals without onsite hematopathologists should have established protocols for rapid specimen referral to ensure that critical diagnoses like acute leukemia are not delayed.

Outcome: Bone marrow examination confirmed acute myeloid leukemia. The patient was rapidly referred to a tertiary care facility for definitive therapy.

Stewardship pearl: Stewardship does not always mean reducing testing. High-risk findings require urgent escalation.

Key lessons

Clinical history and pretest probability are important to hematology stewardship, helping clinicians select and sequence diagnostic tests with clear clinical reasoning. Clinical decision-support integrated into order entry improves appropriate test ordering without increasing diagnostic

error. Multimodal interventions combining education, audit, and digital tools have achieved significant reductions in test ordering with substantial cost savings (2).

Figure 1 (view online) illustrates a stewardship-guided framework for stratifying hematologic abnormalities into sequential evaluation or immediate escalation pathways based on clinical risk. The diagnostic pathway selected is contingent on the resources available in the healthcare setting. Although the availability of specialty testing directly influences both the sequence and speed of evaluation, clinicians should embrace a stepwise approach based on the pretest probability of disease.

Unnecessary testing can cause substantial psychological distress among patients and also increase their risk of iatrogenic complications (1). These issues are particularly concerning for individuals with benign conditions who will not derive any clinical benefit.

Laboratorians have an opportunity to lead test stewardship by defining smear-review criteria, implementing reflex testing, adding interpretive comments, and developing clinical decision-support tools.

Conclusion

The goal of stewardship is not fewer tests but appropriate diagnostic intensity. The Goldilocks principle applies here: Use the right test for the right patient at the right time in the right setting.

View the references online at myadlm.org/cln.

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LABORATORY
STEWARDSHIP
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Highlights of the innovations that exhibitors displayed at this year's ADLM Annual Meeting



Aperio GT Elite Digital Pathology Solution

The Aperio GT Elite™ solution*, from Leica Biosystems, delivers an end-to-end digital pathology workflow engineered to scale, from first adoption through enterprise deployment. The integrated ecosystem seamlessly connects the Aperio GT Elite scanner, Aperio iQC software, the Aperio HALO AP platform, and the Aperio AI Store to deliver speed, intelligence, and certainty at scale.

*Aperio GT Elite, Aperio iQC, and Aperio AI Store are for Research Use Only. Not for use in diagnostic procedures. Aperio HALO AP is for in vitro diagnostic use.



ExionLC MD system

The ExionLC MD system delivers high-performance UHPLC separation with the robustness and reproducibility required for clinical workflows, empowering labs to generate consistent, high-quality LC-MS/MS data with confidence.



SCIEX OS software

SCIEX OS software is an intuitive software platform for LC-MS/MS data acquisition, processing, and reporting, built for maximum impact in the clinical diagnostic laboratory.



The Future of Diagnostics. Meet GeneXpert® G3

The Third-Generation GeneXpert® (G3) reimagines the trusted GeneXpert system with advanced technology designed for the future of molecular diagnostics. Featuring a modern architecture, enhanced connectivity, and an intuitive user experience, G3 helps customers confidently navigate evolving testing needs while maintaining the simplicity they trust.



Xpert® GI Panel

Simultaneous detection and identification of DNA and RNA from multiple bacteria, parasites and/or virus from stool samples in Cary Blair transport media in around 74 minutes.



Sonication STAR: Automated FFPE DNA/RNA Extraction

The Sonication STAR is a fully automated workstation for FFPE tissue extraction and purification. Integrating Covaris focused ultrasonication with Hamilton liquid handling, it delivers consistent, high-quality DNA and RNA for NGS and genomic profiling workflows. The validated, walkaway solution reduces hands-on time, minimizes variability, and supports flexible throughput from 8 to 96 samples.



INSTAND-CMS Approved PT schemes

In 2026, three proficiency testing schemes for virology and one for general immunology provided by INSTAND were approved by CMS for compliance with the CLIA amendments <https://www.cms.gov/files/document/2026-approved-proficiency-testing-programs-clia.pdf> Ask our team for additional information on the four approved schemes and the new schemes that were added to our application for 2027.

ADLM 2026 CLINICAL LAB EXPO PRODUCT SHOWCASE



HemoCue® Plasma/Low Hb System

Deliver STAT plasma-free hemoglobin results within 60 seconds after centrifugation with the HemoCue® Plasma/Low Hb System. This compact analyzer enables rapid in-house hemolysis assessment without manual spectrophotometry, send-outs, or complex laboratory-developed tests.



HemoCue® Hb 801 & Hb 201 DM Systems

HemoCue® Hb Systems bring ease of use and convenience together with rigorous standards to provide you with lab-quality results at the point of care. Backed by 40 years of proven clinical performance, HemoCue offers information you can rely on to provide patients with the best care possible.



HemoCue® Glucose 201 and Glucose 201 DM Systems

The professional solution for lab-quality glucose testing at the point of care. HemoCue® Glucose 201 Systems are analyzers, not meters. Providing results closely correlated with a reference lab method, they are cleared for supplementing clinical evidence in the diagnosis of diabetes. The HemoCue Glucose® 201 Systems also provide the ability to perform CLIA-waived gestational diabetes screening in-office.



30th ADLM International CPOCT Symposium

October 14–16, 2026 • Pittsburgh, PA

Join us at the Association for Diagnostics & Laboratory Medicine's International CPOCT Symposium in Pittsburgh, PA.

For two full conference days, you'll explore the latest in POCT from interdisciplinary experts, engage with companies in the exhibit hall, and network with peers during poster hall receptions. The symposium promises to deliver:

- Stimulating discussions on the latest science
- Cutting-edge technological advances through a keynote lecture
- Dynamic format including scientific sessions, panel discussions, and interactive poster receptions.

The world of critical and point-of-care testing is driven by the need for accurate, rapid diagnosis that is integrated into healthcare systems. To meet this need, new and emerging CPOCT technologies are continually advancing the field with an increasing global adoption in many healthcare settings.

Register now: myadlm.org/ICPOCT

ADLM Association for
Diagnostics &
Laboratory Medicine

Regulatory Roundup



FDA approves colorectal cancer blood screening test

Freenome and Abbott recently announced Food and Drug Administration (FDA) approval of SimpleScreen CRC, a new blood-based screening option for colorectal cancer (CRC) in adults ages 45 and older who have average risk for the disease.

Abbott will exclusively commercialize the test in the United States this fall, the companies said.

The test detects signals associated with colorectal cancer from cell-free DNA in blood. The FDA approval was based on results from a prospective clinical validation study that enrolled more than 48,000 asymptomatic, average-risk adults between the ages of 45–85 scheduled for screening colonoscopies. In a prespecified analysis adjusted to match the U.S. census, SimpleScreen CRC detected colorectal cancer with 81.1% sensitivity and advanced precancerous lesions with 13.7% sensitivity, including 30.7% for advanced precancerous lesions with high-grade dysplasia. The test showed 90.4% specificity for advanced colorectal neoplasia.

SimpleScreen CRC is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals, Freenome and Abbott said.

SimpleScreen CRC expands choices for healthcare providers and helps remove many barriers that keep people from screening, Abbott officials added.

● FIRST DIAGNOSTIC EBOLA BUNDIBUGYO TEST ON WHO EMERGENCY USE LISTING

The World Health Organization (WHO) has added the first molecular diagnostic test for Bundibugyo virus (BDBV), a type of Ebola virus, to its Emergency Use Listing (EUL).

WHO assessed the genetic blood test for quality, safety, and performance and ensured it meets minimum international standards and addresses low- and middle-income countries' needs.

Testing capacity for BDBV had increased from up to 400 tests

per day to a broader network of labs with a combined capacity of more than 2,000 tests per day, WHO said in July.

Additional applications for BDBV in vitro diagnostics submitted through the EUL procedure are currently under review.

WHO said it is working with other international health organizations on a joint validation platform to rapidly evaluate the performance of a selection of diagnostic products. These include laboratory-based molecular tests, near-point-of-care molecular tests, and antigen rapid diagnostic tests.

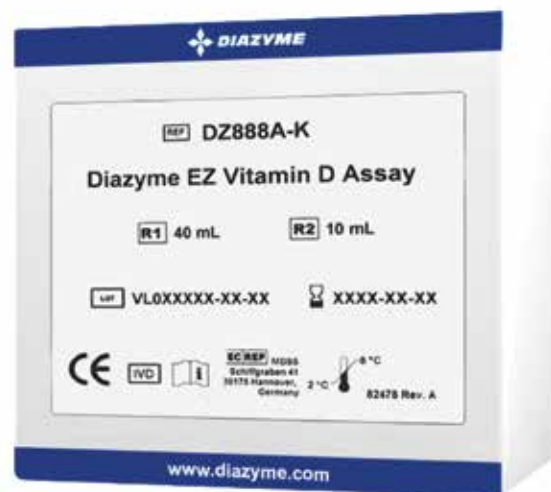
The platform will generate critically needed clinical evidence on the performance of these products in outbreak settings.

● VAGINITIS PCR TEST GETS FDA CLEARANCE

The Food and Drug Administration (FDA) has granted Roche 510(k) clearance for its cobas BV/CV assay. This diagnostic PCR test provides results for both bacterial vaginosis (BV) and candida vaginitis (CV) from a single vaginal swab sample.

The test detects DNA targets for multiple organisms associated

Product Spotlight



Streamline vitamin D testing with Diazyme's EZ Vitamin D Assay

FDA-cleared 25-OH vitamin D assay for general clinical chemistry analyzers

Diazyme Laboratories' EZ Vitamin D Assay is the first and only two-reagent, latex-enhanced immunoturbidimetric assay designed for use on general clinical chemistry analyzers. This fully automated assay enables laboratories to perform high-quality 25-hydroxyvitamin D (25-OH vitamin D) testing in-house without specialized instrumentation, delivering accurate, efficient, and cost-effective results.

Why choose the Diazyme EZ Vitamin D Assay?

The Diazyme EZ Vitamin D Assay combines automation, accuracy, and operational efficiency to help laboratories confidently assess vitamin D status.

- Fully automated workflow: Eliminates sample pre-treatment and pre-dilution, simplifying laboratory workflows while reducing
- hands-on time.
- Measures total 25-OH vitamin D: Quantifies both 25-OH vitamin D₂ and 25-OH vitamin D₃ with equal recognition, providing a reliable assessment of overall vitamin D status.
- Designed for general chemistry analyzers: Compatible with automated clinical chemistry analyzers, allowing laboratories to perform vitamin D testing in-house without investing in dedicated immunoassay systems.
- High performance: Delivers precision with a coefficient of variation <10%, a linear measuring range of 7.6–147.8 ng/mL, and excellent correlation to the liquid chromatography-tandem mass spectrometry reference method.
- Trusted quality: Food and Drug Administration (FDA)-cleared,

CE Marked, certified through the Centers for Disease Control and Prevention Vitamin D Standardization Certification Program (VDSCP), and meets the performance targets established by the Vitamin D External Quality Assessment Scheme Advisory Panel.

Vitamin D testing plays an important role in assessing vitamin D sufficiency. The Diazyme EZ Vitamin D Assay provides laboratories with a rapid, accurate, and standardized solution that improves workflow efficiency while delivering dependable results for clinicians. Its simple two-reagent format, high throughput, and broad analyzer compatibility make it an excellent choice for laboratories seeking to expand in-house vitamin D testing capabilities.

When clinicians test for only one pathogen at a time, they can miss cases caused by the untested viruses.

with BV. They include *Gardnerella vaginalis*, *Atopobium vaginae*, and *Lactobacillus spp.* The test also detects *Candida* species associated with CV, including *C. albicans*, *C. glabrata*, *C. krusei*, *C. parapsilosis*, *C. tropicalis*, and *C. dubliniensis*.

The sample is collected using a clinician-collected or clinician-instructed, self-collected vaginal swab in cobas PCR Media in a healthcare setting. This enables diagnosis from a single sample that also can be used for broader sexual-health testing.

Accurate vaginitis diagnosis is a cornerstone of effective treatment, yet misdiagnosis is close to 50%, raising the risk of recurrence, Roche said. Diagnosis remains challenging because of non-specific symptoms. Meanwhile, most tests, including microscopy and pH testing, lack precision.

● FDA EMERGENCY USE AUTHORIZATION GRANTED FOR ULCERATIVE SKIN LESION TEST

Seegene recently announced Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for its Allplex HSV-1&2/VZV/MPXV Assay, a multiplex real-time PCR test designed to detect multiple viral pathogens associated with clinically overlapping lesion presentations simultaneously.

The assay identifies herpes simplex virus type 1 and type 2, varicella-zoster virus, and monkeypox virus. Allplex is the first multiplex PCR test in the United States market designed to simultaneously and differentially detect

viral pathogens of ulcerative skin lesions, Seegene said.

The pathogens that the test detects frequently present with similar clinical symptoms, such as vesicular or pustular lesions. They are difficult to distinguish by appearance alone. When clinicians test for only one pathogen at a time, they can miss cases caused by the untested viruses. This product addresses an unmet market, Seegene said.

● FDA CLEARS HOME TEST FOR MULTIPLE RESPIRATORY VIRUSES

Visby Medical has announced Food and Drug Administration (FDA) clearance for its Visby Medical Flu and COVID-19 Test.

The test detects COVID-19, influenza A, and influenza B. It is the first multiviral PCR home test, the company said.

Visby added that the PCR test, which provides results in 30 minutes, detects disease early in the course of infection when viral levels are lower. Early detection is very important because antiviral medication such as Paxlovid and Tamiflu are most effective when begun early.

The test will be eligible for flexible savings account and health savings account reimbursement, Visby said.

● MELANOMA GENE EXPRESSION PROFILE TEST GETS FDA BREAKTHROUGH DEVICE DESIGNATION

SkylineDx recently announced it has been granted Food and

Drug Administration (FDA) Breakthrough Device designation for Merlin CP-GEP, a clinicopathologic gene expression profile (CP-GEP) test designed to support risk assessment and clinical decision-making in patients with stage IB (T1b/T2a) cutaneous melanoma.

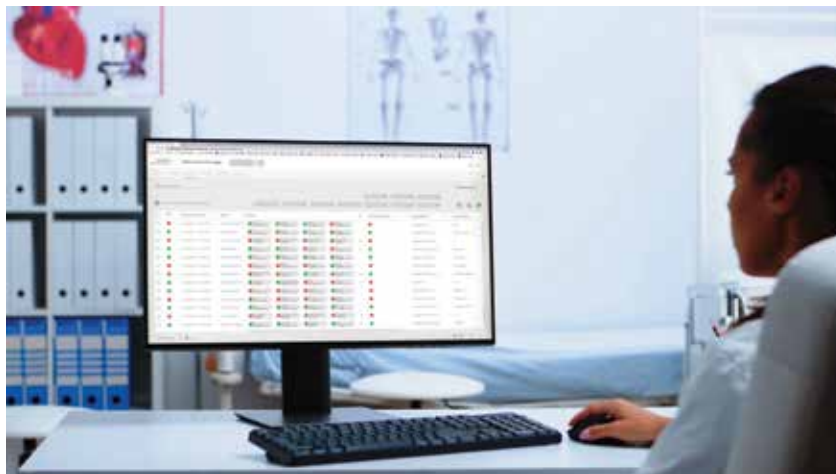
These patients have thin tumors up to 2 mm thick with ulceration or slightly deeper growth that has not spread to nearby lymph nodes or distant parts of the body. The patients are a clinically important population in whom accurate assessment of metastatic potential is critical for guiding management, the company said.

SkylineDx added that Merlin is the only commercially available GEP test that combines clinic CP variables with GEP into a single algorithm. Merlin is also the only GEP test that provides a binary stratification of all patients based on being high or low risk for metastasis, and thereby assigns them to the appropriate surgical action categories as listed in evidence-based cancer treatment, prevention, and screening guidelines, SkylineDx said.

In conjunction with other established clinical criteria, Merlin CP-GEP supports patient selection for sentinel lymph node biopsy, may inform discussions regarding follow-up strategies, and facilitates shared decision-making between healthcare providers and patients.

Prior to the designation, CP-GEP had already been recognized by the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology as a predictive GEP test that may be used to support metastatic risk assessment and clinical decision-making in T1b and T2a melanoma patients.

Product Spotlight



Time matters: Why point-of-care informatics must give time back to healthcare teams

By Anand Kapai

Every day, point-of-care teams manage growing volumes of data, while overseeing complex testing networks, and balancing quality, compliance, and operational demands. As healthcare networks generate more information than ever, the challenge is no longer collecting data. The challenge is turning that data into meaningful insight to help teams make faster decisions and work more efficiently.

The next generation of point-of-care data management cannot be about adding another software layer. Healthcare needs solutions that remove friction from daily work. That means bringing device, operator, quality control, patient-result, and workload data together in workflows that help teams focus on what needs attention most.

That is why Siemens Healthineers developed Atellica Connect POC Insights with extensive input from point-of-care

coordinators and laboratory professionals. Rather than adding complexity, the platform helps to simplify oversight and streamline workflows. The result is more than data management. It is a smarter way to support quality, efficiencies, and confidence across the point-of-care testing program.

One of the most important shifts in healthcare technology is the move from passive reporting to actionable insight. Atellica Connect POC Insights helps teams move faster from data to decision. Built-in analytics and interactive data help visualize trends across workload, device events, QC, patient results, and operator certifications.

That may sound operational, but the clinical impact is real. Informatics is more than data management. It is a way to improve governance, quality, and consistency across the point-of-care testing program.

Innovation in healthcare should not be measured only by features, interfaces, or technical specifications, but by whether a solution gives time back.

When time is returned, it goes somewhere better: back to patients, quality, staff development, problem-solving, process improvement, and the human side of care.

Because time is our greatest asset. And in healthcare, every minute matters.

Visit our website to learn how Atellica Connect POC Insights can help your point-of-care testing program save more time.

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Seegene eyes syndromic PCR for respiratory infections

Seegene launched a large-scale initiative aimed at gathering clinical evidence to support a transition from virus-centered testing toward syndromic PCR for respiratory infections.

The Global Million Clinical Study will generate large-scale clinical evidence on comprehensive PCR testing across diverse healthcare settings worldwide, Seegene said. The company wants to use its findings to verify clinical usefulness of comprehensive, symptom-based syndromic testing, with a goal of establishing new global standards for respiratory infection diagnostics.

The initiative follows a study of Seegene's STAgora platform, which found that respiratory infections often involve multiple pathogens. After analyzing approximately 260,000 respiratory PCR test results from children from birth to age 5 over a 42-month period, company researchers found that the respiratory viral panel testing yielded a positivity rate of 87%. Of the positive cases, 78% carried pneumonia-causing bacterial pathogens. Similarly, pneumonia-causing bacterial panel testing showed a positivity rate of 76%, with 88% of positive cases also testing positive for viral pathogens.

Pediatric respiratory infections sometimes progress to serious conditions such as pneumonia or sepsis. Having comprehensive pathogen information early in the clinical evaluation process supports appropriate diagnostic and treatment decisions, Seegene said.

● NEURODEGENERATIVE DISEASE-FOCUSED COLLABORATION INVOLVES EXTRACELLULAR VESICLE-ENABLED IMMUNOASSAYS

NanoSomiX recently announced plans to collaborate with Beckman Coulter Diagnostics on development of next generation immunoassays for neurodegenerative diseases.

The companies share an interest in addressing long-standing challenges in detecting low abundance, brain specific biomarkers in blood, NanoSomiX said. Its proprietary platform focuses on extracellular vesicles (EVs) derived from defined brain cell populations, including neurons and glial cells.

EVs — particularly brain derived EVs — offer a noninvasive way to access meaningful signals from the brain using a small volume of blood, NanoSomiX officials said. The companies' EV-based immunoassays measure biomarkers from neuron and other brain cell-derived EVs, supporting research into disease mechanisms, progression, and therapeutic response. Working with Beckman Coulter Diagnostics will help translations of this scientific foundation toward scalable, automated immunoassay solutions for both research and clinical settings, the officials added.

NanoSomiX has developed and published unique EV based immunoassay platforms applicable to a

wide spectrum of neurodegenerative diseases and neuro injury. The platform is compatible with high-throughput testing systems, positioning it as a strong foundation for translational research and scalable immunoassay development.

● PARTNERSHIP FOCUSES ON ASTHMA AND COPD DIAGNOSTICS

bioAffinity Technologies recently announced a collaboration with Pictor to develop and commercialize bioAffinity Technologies next-generation diagnostic tests that provide a more complete picture of lung inflammation in patients with asthma and chronic obstructive

pulmonary disease (COPD).

The collaboration will integrate bioAffinity's expertise in flow cytometry with Pictor's targeted proteomic analysis platform to analyze immune cell populations and cytokine profiles associated with airway inflammation, the companies said.

The partners anticipate that this will result in a high-throughput laboratory test that bioAffinity Technologies will offer to help physicians identify the inflammatory pathways driving an individual patient's disease. Such a test will support more informed decisions when considering advanced therapies, including Food and Drug Administration-approved biologics and emerging targeted treatments, bioAffinity Technologies said.

● **ACQUISITION OF CLINICAL METAGENOMICS PLATFORM AIMED AT BETTER INFECTION DIAGNOSIS**

The German corporation Bruker recently announced the acquisition of the DISQVER clinical metagenomics platform from Noscendo.

The DISQVER platform provides advanced bioinformatics and reporting to support rapid and comprehensive whole genome sequencing directly from cell-free DNA in human blood samples. It also enables metagenomic next-generation sequencing (mNGS) analysis of microbes directly from blood samples, further expanding Bruker's NGS-based infection detection capabilities.

The mNGS analysis can be done directly from cell-free DNA samples from blood in fewer than 24 hours after sample receipt. This advanced mNGS clinical research approach can be valuable for

bloodstream infections, sepsis, endocarditis, and other severe infectious diseases, Bruker said.

Following the acquisition, DISQVER remains available for research use only while Bruker progresses its registration for diagnostic purposes.

The acquisition adds more NGS applications to Bruker's metagenomics portfolio and enhances the support that the company provides for earlier decision-making in sepsis, bloodstream infections, and severe infections, company officials said.

● **PARTNERSHIP TO EXPAND NGS-BASED HOMOLOGOUS RECOMBINATION DEFICIENCY**

Burning Rock Biotech Limited and Myriad Genetics recently entered a global technology licensing agreement and partnership to speed development and commercialization of new homologous recombination deficiency (HRD) testing solutions.

Through the collaboration, Burning Rock will expand the clinical capabilities of its myChoice HRD plus test by adding the prostate Genomic Instability Score (prGIS) algorithm. Currently, the company has commercialized this test in China.

Presently, the prGIS algorithm evaluates multiple genomic scar features, including telomeric allelic imbalance, large-scale state transition, and genome-wide imbalance, to evaluate HRD status in prostate cancer patients.

Burning Rock also will leverage Myriad's algorithms for GIS, licensed globally except in Japan, and prGIS, licensed globally except in Japan and the United States. Burning Rock will combine these algorithms with its expertise in assay development and commercialization to develop a new

generation of HRD testing kits on its proprietary OncoScreen Plus platform, the company said.

TEMPUS TO ACQUIRE PERSONALIS TO ADVANCE CANCER MONITORING

Tempus AI has entered into a definitive agreement to acquire Personalis, Tempus announced recently.

The acquisition will expand Tempus' capabilities in minimal residual disease (MRD) and support of patients from diagnosis and treatment selection to recurrence and monitoring.

The acquisition builds on the companies' previously existing partnership, which involved Tempus' investment in Personalis and commercialization of the company's NeXT Personal MRD test. The new deal combines Tempus' multimodal data platform, artificial intelligence capabilities, and precision oncology portfolio with Personalis' tumor-informed MRD technology to expand access to longitudinal monitoring and create new opportunities to advance biomarker discovery.

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Implementing neurofilament light chain testing

What is NfL and why is it important?

a: Neurofilament light chain (NfL) is a cytoskeletal protein that maintains neuronal structural integrity. In patients with axonal damage, NfL can serve as a nonspecific indicator of severity and can be measured in cerebrospinal fluid and plasma. In particular, the ability to measure NfL in plasma provides a less invasive option for assessing conditions involving neuroaxonal damage such as multiple sclerosis (MS). This biomarker also may facilitate a reduction in the use of more expensive monitoring tools such as MRI. NfL may detect relapse earlier than MRI and allow providers to rapidly step up treatment in certain patients while minimizing exposure to potent medications in others.

Because NfL reflects axonal damage but does not indicate a specific cause, it is not recommended for use in diagnosis. Its primary value lies in prognosis, monitoring disease progression, and assessing the efficacy of disease-modifying therapy (DMT). Accordingly, in 2023, the MS consortium recommended NfL testing for these purposes in confirmed MS cases. Together with the patient's clinical presentation, clinicians can use NfL to optimize the dose of DMT, extend the interval between doses, and potentially switch or discontinue treatment altogether if needed.

Apart from MS cases, NfL may be useful in other neurodegenerative conditions including amyotrophic lateral sclerosis (ALS). Studies show a correlation between

plasma NfL levels and ALS progression. Although no official guidance exists for NfL use in ALS, the Food and Drug Administration (FDA) recently granted accelerated approval for Tofersen, an ALS treatment that showed a 55% reduction in plasma NfL levels in patients with SOD1-ALS. Therefore, NfL may be useful for monitoring Tofersen therapy in ALS.

How can labs implement NfL testing?

When deciding whether to offer NfL testing, labs should first figure out the expected test volume. In low-volume scenarios, offering NfL as a send-out test makes the most sense. With higher volumes, labs should consider in-house NfL testing. Consultations with neurologists and other clinicians will provide a sense of how much volume is expected.

Labs considering in-house NfL testing will have to validate their assay as a laboratory developed test (LDT) since there are no FDA-approved options. To do this, labs must determine reference intervals, analytical sensitivity and specificity, test accuracy and precision, reportable range, and clinical validity.

Determining reference intervals is an especially significant challenge when validating an NfL assay. Since NfL levels change with age, multiple age-specific reference intervals are needed, which greatly increases the scale and complexity of this validation. Selection of reference individuals is further complicated by the fact that other conditions that may influence NfL concentrations,



By Onyeka Obidi, PhD

including diabetes, heart, and kidney disease, are more common in older patient populations. Labs should carefully define inclusion and exclusion criteria to ensure accurate final reference intervals. They also should collaborate with neurologists on this process.

After validation, clinical implementation can commence. For labs that already offer NfL as a send-out test and are implementing a different test method in-house, an extensive rebaselining period may be needed since NfL methods are not standardized. The lab should communicate with clinicians about the change in testing platform and anticipated changes in results to prevent erroneous interpretation of test results. Labs also may create mechanisms to monitor NfL testing to ensure that providers are ordering the test for the right patients and to answer the right clinical questions.

In conclusion, labs considering in-house NfL testing should understand the challenges involved in NfL test validation, collaborate with clinicians to create test utilization criteria, and evaluate the impact on patient care post-implementation.

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