July/August 2026

CLN Clinical Laboratory News

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**MEDIAN NfL AND GFAP CONCENTRATIONS IN WOMEN**

**1.72 pg/mL**

Higher than concentrations in men

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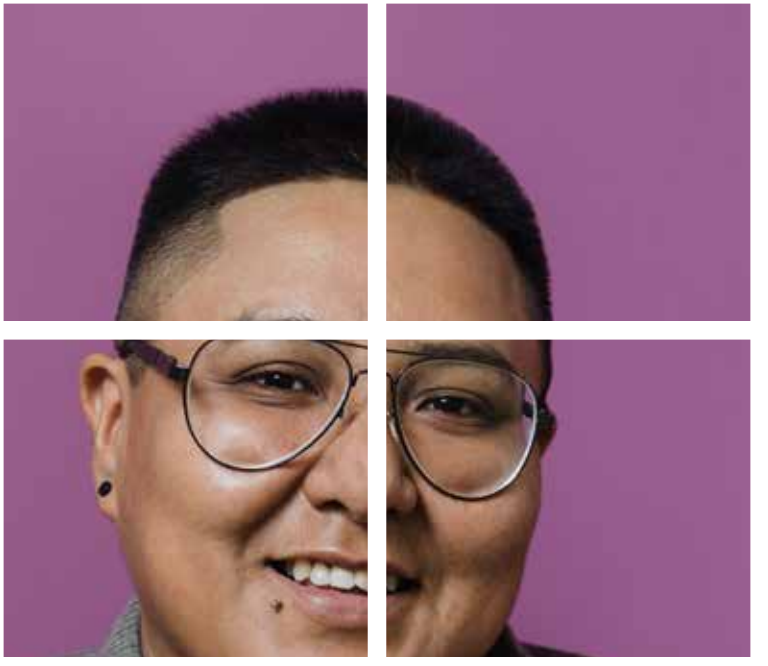
# First U.S. lab guidance for gender-diverse patients



## Testing for cannabis-impaired driving

## ADLM 2026 sneak peek

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**If laboratories do not engage, wearable data will be interpreted without analytical oversight, and clinical errors will follow.**
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# Federal Insider

## ADLM applauds House Committee on Appropriations approval of $5 million to improve pediatric testing

The House Committee on Appropriations has approved the Fiscal Year (FY) 2027 Labor, Health and Human Services (HHS), Education, and Related Agencies Bill, which includes $5 million for the Centers for Disease Control and Prevention (CDC) to improve pediatric reference intervals.

The development of better pediatric reference intervals is essential for children to get accurate diagnoses and effective care. The Association for Diagnostics & Laboratory Medicine (ADLM) commended the House Committee on Appropriations for supporting this initiative and urged legislators to pass this bill when it's taken up by the entire Congress.

The current lack of accurate pediatric reference intervals is a serious issue that can lead to incorrect diagnoses and treatments for children. To correctly interpret pediatric lab test results, providers must evaluate results within the context of reference intervals, which are the range of normal test values expected in a healthy child. If a test result falls outside of the reference interval, this alerts the pediatrician that a child might have a condition requiring medical intervention. However, limited access to samples from healthy children has significantly hindered the establishment of accurate pediatric reference intervals.

For many years, ADLM has led an ad hoc coalition of major healthcare groups that has worked to remedy this issue and that includes several pediatric organizations and medical device manufacturers. Fifty-four groups, including ADLM, have urged Congress to fund the improvement of pediatric reference intervals. Now that this funding has been included in the FY2027 House Labor, HHS, Education, and Related Agencies Bill, ADLM will advocate that Congress include it in any final budget package.

### NEW OFFICE OF MANAGEMENT AND BUDGET RULE COULD SIGNIFICANTLY CHANGE FEDERAL GRANT PROCESS

On May 29, 2026, the Office of Management and Budget (OMB) published a proposed rule in the Federal Register that would make significant changes to the current federal grant making process.

If finalized, the proposal would pose problems for scientific initiatives in several ways. For one, it would require senior political appointees to review grant proposals in advance to "ensure they demonstrably advance the president's policy priorities" — independent of peer review. The proposed rule states that peer review recommendations must "remain advisory" and not be "ministerially ratified or routinely deferred to" by senior appointees. If adopted, applicants may face greater uncertainty in award timing and outcomes and should be prepared for heightened scrutiny of the content in proposals.

Under the new OMB rule, federal agencies would have broad latitude to not only reject grant

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applicants according to the new proposal's process, but also terminate active grants found to be inconsistent with the administration's priorities or national interests.

The proposal seeks to establish a "domestic-first framework" for research and development awards, under which these awards must be given to entities that are U.S.-based. This would make agencies consider whether the international element of their scientific objectives is necessary, and limit expertise to domestic resources by blocking the use of research funds to collaborate with other countries. Additionally, the OMB proposal would bar awardees from using grant dollars to attend conferences, obtain professional memberships, or pay for publication costs.

Finally, the proposal would limit federal funding for certain diversity, equity, and inclusion-related activities; this and other changes above could affect some research on demographic health disparities, depending on how agencies implement the policy.

The Association for Diagnostics & Laboratory Medicine's Policy & External Affairs Core Committee is currently reviewing the proposed rule and will develop a response for the association.

The OMB is accepting comments through July 13.

### ● PROPOSED LAW TO UPDATE CLIA WITH NEW PROVISIONS FOR LDT OVERSIGHT

A bill introduced in the House of Representatives by U.S. congressman Neal Dunn (R-Fla.) in May would update CLIA to provide new provisions for oversight of laboratory developed tests (LDTs).

The bill, named the Enhancing CLIA Act of 2026, aims to provide new tools for tracking the performance and validation of LDTs and to clarify the status of these tests after the 2025 decision by the District Court for the Eastern District of Texas that they are medical services and not subject to Food and Drug Administration oversight.

"The Enhancing CLIA Act will strengthen innovation, increase transparency, and modernize regulation of laboratory developed testing services," Dunn said in a statement. "This legislation restores confidence in testing services while avoiding duplicative and burdensome requirements that limit patient access and slow scientific progress. We can ensure necessary oversight of the CLIA program without undermining the laboratories that deliver cutting-edge diagnostics to patients across the country."

The bill would direct the Centers for Medicare and Medicaid Services (CMS) to establish a database containing information on LDTs, including performance characteristics and validation information; enable labs to submit LDTs for voluntary third-party review to confirm that they are analytically and clinically valid; and create a system for centralized error reporting.

The bill would also establish a statute that LDTs are not medical devices, but professional services regulated by CMS under CLIA. Additionally, it would designate LDTs as including not only traditional wet lab assays but also analyses of lab information and data.

# Bench Matters

## Reducing blood culture contamination

**BY I'ESHA BOWENS, MHA, MLS (AMT)**

**I'Esha Bowens, MHA, MLS (AMT)**

Blood culture contamination (BCC) remains one of the most persistent preanalytical challenges in clinical microbiology. It directly affects patient outcomes, antimicrobial stewardship, and healthcare costs (*1*, *2*). Even small increases in contamination rates can result in misdiagnosis of bloodstream infections, unnecessary antibiotic exposure, and prolonged hospital stays (*2*, *3*). National benchmarks recommend contamination rates of ≤3%, with ≤1% considered optimal in high-performing laboratories (*1*).

This article describes a process improvement initiative implemented by our laboratory team at Baptist Memorial Health Care aimed at reducing BCC through staff education, workflow standardization, and reinforcement of evidence-based collection practices. The intervention highlights the role of laboratory leadership in strengthening diagnostic stewardship and improving preanalytical quality.

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### When collection errors cost patients

Blood cultures remain the gold standard for diagnosing bacteremia and sepsis. However, their clinical utility is highly dependent on proper specimen collection technique (*2*). BCC occurs when skin flora or environmental organisms are introduced into the culture bottle during collection, producing false-positive results that may be misinterpreted as true infection (*3*). Contaminated blood cultures lead to unnecessary antimicrobial therapy, additional diagnostic testing, and increased length of hospital stay (*2*, *4*). These outcomes negatively affect patient safety and increase healthcare costs (*4*). The Clinical and Laboratory Standards Institute (CLSI) and the Centers for Disease Control and Prevention emphasize that most contamination events happen because of preventable preanalytical errors (*1*, *5*).

Additionally, studies demonstrate that contamination rates above 3% are associated with significant clinical and financial burden, which reinforces the need for continuous quality improvement and standardized collection practices (*1*, *4*).

Internal quality monitoring at our institution identified BCC rates that exceeded institutional targets. A gap analysis revealed inconsistent collection techniques, variability in skin antisepsis practices, and differences in competency across personnel responsible for specimen collection. The improvement initiative that we subsequently undertook led to sustained BCC reduction, with the facility consistently maintaining BCC rates below 1% and reaching a low of 0.36%.

Key contributing factors to BCC included:

- Inconsistent chlorhexidine application and drying time;
- Variation in aseptic techniques across departments;
- Limited real-time feedback on contamination performance; and
- Lack of adherence to the standardized collection checklist.

These findings are consistent with national literature, which identifies decentralized blood culture collection systems as a major contributor to elevated contamination rates.

### Intervention strategy

The laboratory team implemented an intervention plan to address increased contamination rates. The plan included three key parts.

- **Education and competency reinforcement:** Targeted education sessions were delivered to nursing, phlebotomy, and laboratory staff. Training emphasized proper chlorhexidine skin antisepsis technique (*5*, *6*), full drying time prior to venipuncture (*5*), avoidance of site repalpation after disinfection (*6*), sterile technique throughout the collection process (*2*), and importance of separate venipuncture sites for culture sets (*2*, *3*). Evidence supports chlorhexidine-based antisepsis as a key intervention in reducing contamination

rates, with studies demonstrating significant reductions when consistently applied (*6*).

- **Standardization of collection process:** A standardized blood culture collection protocol was implemented across all collection areas to reduce variability. Core elements included step-by-step collection checklist (*5*), standardized venipuncture site preparation protocol (*5*, *6*), defined criteria for peripheral vs. line draws (*2*), and documentation of collection method and site (*4*).

  Standardization reduced variation in practice, a known contributor to preanalytical error in microbiology testing systems (*3*).
- **Real-time feedback and performance monitoring:** Monthly contamination rates were distributed to frontline staff and leadership. Units exceeding thresholds received targeted retraining and direct observation audits. This feedback loop supported laboratory collection accountability (*4*), rapid identification of training needs (*4*), reinforcement of correct technique (*5*), and engagement of frontline staff in quality ownership (*4*).

## Sustained gains

Following implementation of the intervention bundle, BCC rates demonstrated a sustained downward trend over subsequent reporting periods. Observed outcomes included:

- Reduction in contamination rate toward institutional benchmark (<3%) (*1*);
- Decrease in repeat blood culture orders (*2*);
- Decrease in patients' length of stay;
- Decrease in the overuse of antibiotics;
- Improved consistency in collection technique adherence (*5*); and
- Enhanced interdisciplinary collaboration between microbiology, nursing, and infection prevention teams (*4*).

Beyond quantitative improvements, staff demonstrated increased awareness of preanalytical quality and its impact on patient outcomes.

## Conclusion

BCC is a preventable, system-level patient safety issue rather than an isolated laboratory error (*2*, *4*). The majority of contamination originates during specimen collection, which makes preanalytical intervention the most effective control point (*3*). Evidence supports bundled interventions combining education, antiseptic optimization, and performance feedback as the most effective strategy for sustained improvement (*4*, *6*). Single interventions alone rarely produce long-term change. From a leadership perspective, laboratory managers play a central role in diagnostic stewardship by aligning clinical collection practices with laboratory quality standards.

Strengthening interdisciplinary communication ensures consistent expectations and accountability across departments (*4*). Reducing contamination also supports antimicrobial stewardship by preventing unnecessary antibiotic exposure, minimizing resistance risk, and improving diagnostic accuracy in suspected sepsis cases (*2*, *4*).

Sustained reduction in BCC requires a structured, multifaceted approach involving education, standardization, and continuous feedback. This project demonstrates that laboratory-led quality improvement initiatives can significantly improve preanalytical performance and patient safety outcomes. Ongoing monitoring and reinforcement are also essential to maintaining gains and ensuring long-term success in diagnostic stewardship.

*Interested in learning more? Attend the ADLM 2026 roundtable, "Blood culture contamination rates: Collaboration for sustainable improvements," on Monday, July 27 in Anaheim, California. Find out more at meeting.myadlm.org.*

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## References

1. Centers for Disease Control and Prevention. Prevent adult blood culture contamination: A quality tool for clinical laboratory professionals. https://www.cdc.gov/lab-quality/docs/BCC-Prevention_A-Quality-Tool_CDC.pdf (Accessed June 2026).
2. CLSI. Principles and procedures for blood cultures. CLSI guideline M47. 2023.
3. Hall KK, Lyman JA. Updated review of blood culture contamination. Clin Microbiol Rev 2006; doi: 10.1128/CMR.00062-05.
4. Wichmann C. Blood culture contamination in U.S. hospitals. Medical Laboratory Observer 2025; https://www.mlo-online.com/management/article/55314900/blood-culture-contamination-in-us-hospitals.
5. Self WH, Speroff T, Grijalva CG, et al. Reducing blood culture contamination in the emergency department: An interrupted time series quality improvement study. Acad Emerg Med 2013; doi: 10.1111/acem.12057.
6. Snyder SR, Favoretto AM, Baetz RA, et al. Effectiveness of practices to reduce blood culture contamination: A Laboratory Medicine Best Practices systematic review and meta-analysis. Clin Biochem 2012; doi: 10.1016/j.clinbiochem.2012.06.007.

# The Sample

## Neutrophil count reference range for Duffy-null patients proposed

A new Duffy-null-adjusted absolute neutrophil count (ANC) reference range may reduce the proportion of individuals classified as abnormal, according to recent research (J Appl Lab Med 2026; doi.org/10.1093/jalm/jfag056).

The Duffy-null variant, rs281477 on the *ACKR1/DARC* gene, causes a below-normal concentration of neutrophils for lab results. Approximately 60–65% of African Americans and 4% of Middle Eastern people have this genotype. If Duffy-null patients take methotrexate or azathioprine, they likely will be misdiagnosed with drug-induced neutropenia.

To evaluate the change in ANC among individuals with the Duffy-null genotype who take either drug, the researchers analyzed All of Us cohort data from 91 patients on methotrexate and 35 on azathioprine. The researchers also considered the designation of normal versus abnormal ANC under genotype-adjusted and unadjusted thresholds by using data from the UK Biobank. The primary outcome was the log-mean difference in ANC between 1 year before and 2 years after starting medication. The secondary outcome was odds of having normal ANC under genotype-adjusted versus unadjusted thresholds.

Among azathioprine users, those with the Duffy-null genotype showed statistically insignificant lower ANC. Among methotrexate users, those with the genotype demonstrated a statistically significant lower ANC, with a log-mean difference of -0.042. Evaluation of unadjusted ANC thresholds in azathioprine patients revealed that Duffy-null genotype patients' neutrophil counts were more likely to be abnormal (an odds ratio [OR] of 7.51; 95% CI, 1.64–34.43). Methotrexate users presented similar results (OR 4.35; 95% CI, 1.48–12.79). But under Duffy-adjusted thresholds, there were no significant differences between the genotypes in groups of people treated with either drug, according to the researchers.

The Duffy-adjusted absolute neutrophil count ANC reference range might help tens of millions of Americans by reducing unnecessary treatment interruptions, improving access to immunosuppressive therapy, and promoting more equitable clinical care, the researchers wrote.

### REFERENCE INTERVALS ESTABLISHED FOR NFL AND GFAP IN HEALTHY INDIVIDUALS

Concentrations of plasma neurofilament light (NfL) and glial fibrillary acidic protein (GFAP) should be interpreted in the context of an individual's demographic and physiological profile, recent research suggests (AMA Network Open 2026; doi: 10.1001/jamanetworkopen.2026.12793).

Previous research has shown changes in NfL and GFAP blood concentrations across a wide spectrum of neurological diseases, including preclinical and clinical Alzheimer's disease (AD), and after acute neurological trauma

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and cerebrovascular insults. Other studies have shown a strong association between NfL and age, as patients develop comorbidities.

To address the lack of NfL and GFAP reference ranges that account for age-related comorbidities, the researchers aimed to determine the association of age, sex, kidney function via estimated glomerular filtration rate (eGFR), and body mass index (BMI) with GFAP and NfL concentrations in a healthy population. They conducted a cross-sectional study including 7,989 individuals ages 30–90 with no cognitive impairment to generate and validate reference intervals. A comparison group included patients with subjective cognitive decline or mild cognitive impairment due to AD, AD dementia, frontotemporal dementia (FTD), dementia with Lewy bodies, vascular dementia (VaD), or multiple sclerosis. The researchers measured and quantified plasma NfL and GFAP reference intervals, defined over age and adjusted for sex, BMI, and eGFR.

The results showed that older age, lower BMI, and reduced kidney function were associated with increased plasma NfL and GFAP concentrations. Female sex was associated with increased GFAP concentrations. Median NfL and GFAP concentrations were 6.58 pg/mL and 23.4 pg/mL higher, respectively, in participants with severe kidney damage, compared with those with no kidney damage. Median NfL and GFAP concentrations were 1.72 pg/mL and 12.6 pg/mL lower, respectively, in participants with obesity compared with those with average weight. Median NfL and GFAP concentrations were 1.72 pg/mL higher in females, compared with males. NfL concentrations were most elevated in participants with FTD, with 92.5% having concentrations greater than the median. More than 91% of participants with VaD had NfL concentrations greater than the median. GFAP concentrations were most elevated in participants with AD dementia, among whom 82.7% had concentrations greater than the median.

To determine GFAP or NfL elevation in the context of patients' unique profiles, researchers developed a user-friendly web interface that allows clinicians to enter a patient's GFAP or NfL concentrations with age, sex, BMI, and eGFR to get a corresponding percentile estimate.

**The test may flag autism sooner than current assessments, thereby driving earlier diagnosis and better long-term outcomes.**

### URINE SCREENING TEST SPOTS MICROBIAL METABOLITES LINKED TO AUTISM

A urine screening test may help identify children ages 2–11 at risk for autism spectrum disorder (ASD) (Mol Psychiatry 2026; doi: 10.1038/s41380-026-03620-5), the researchers said.

The test may flag autism sooner than current assessments, thereby driving earlier diagnosis and better long-term outcomes, the researchers said.

Previous research found that a subset of children with ASD have unusually high urinary concentrations of microbially-derived metabolites (MDMs), such as p-cresol sulfate and indoxyl sulfate. The researchers hypothesized that these MDMs may affect neurodevelopment through the gut-brain axis and that most children with ASD have an imbalance in the microorganisms of the digestive tract. Using semiquantitative liquid chromatography and mass spectrometry (LC-MS), followed by targeted quantitative LC-MS, researchers measured concentrations of many MDMs in the urine of 52 children with ASD and 47 healthy, typically developing (TD) children ages 2–11 years.

Some of the microbial metabolites elevated in the ASD children — such as indole-3-acetonitrile and indole 3-acetoxidoximide — had not been measured previously in ASD. A total of 23 MDMs were statistically higher in ASD children compared with children without ASD. Almost all children with ASD had one or more MDMs at concentrations above any TD child, and sometimes 100–1,000 times higher. These metabolites included phenylalanine-derived, tryptophan-derived, and yeast-derived MDMs. On average, children with ASD had three MDMs at levels above any TD child.

Classification using one or more elevated MDMs yielded a sensitivity of 90% and a specificity of 100%, according to the researchers. These data also suggest that approximately 90% of children with ASD have a distinct phenotype of ASD defined by quantitative lab measurements in urine.

The researchers said they are validating their testing system in another cohort.

# Closing the care gap for gender-diverse patients

BY GRACE BROWNE

With recommendations on areas ranging from informatics to autopsy reports, new ADLM guidance aims to ensure that laboratorians and pathologists meet the needs of gender-diverse populations.

Gender-affirming hormone therapy changes the body in ways that matter in a clinical laboratory. Testosterone prescribed to transgender men and estradiol with or without anti-androgens given to transgender women shift some of the biological markers that labs routinely measure. Yet until now, laboratory medicine has had no dedicated guidance for interpreting those results.

To fill this gap, the Association for Diagnostics & Laboratory Medicine (ADLM) convened a group of pathologists, clinical chemists, endocrinologists, and clinicians who directly care for transgender patients. Together, the team devised the first comprehensive, U.S.-based laboratory medicine and pathology recommendations for the gender diverse population.

Before this point, guidance in this area primarily came from World Professional Association for Transgender Health guidelines and the Endocrine Society. These guidelines had some sections specific to laboratory medicine, said Gabrielle Winston-McPherson, PhD, DABCC, co-first author of the guidance document and director of clinical chemistry at the University of Wisconsin, Madison. But there hasn't been a place where she could go to get all of that information, she said.

The guidance document addresses key focus areas, including reference intervals and lab test interpretation; transfusion medicine; autopsy and medicolegal death investigation; surgical pathology and histology; and informatics.

"This is a way to expand people's understanding of gender, sex, and also the clinical laboratory's responsibility for providing inclusive results and reference intervals for the populations that they serve," said Dina Greene, PhD, co-chair of the guidance document and one of its co-corresponding authors, as well as clinical professor at the University of Washington in Seattle.

## REFINING REFERENCE RANGES

Defining the transgender population itself is difficult because of the sheer diversity it comprises. The document focuses primarily on adults who have been on gender-affirming hormone therapy for at least 6 months, since this is where the strongest data currently exists. The authors acknowledge that this excludes important groups, including adolescents, those early in transition, and nonbinary individuals who may not use hormones, but explain that this scoping reflects the current state of the literature rather than a judgement about those populations' needs.

Some of the most impactful recommendations can be found in the guidance on reference intervals. Reassuringly, the list of tests significantly affected by hormone therapy is relatively short. But room for improvement remains. "Laboratory values among transgender people on hormone therapy do not always correspond to their cisgender counterparts, and there is a great deal of variation between using the typical cisgender male and cisgender female ranges," said Zil Goldstein, FNP-BC, associate medical director at Callen-Lorde Community Health Center in New York City and a co-author of the guidance document.

Goldstein, who works in primary care, said she sees this confusion among clinicians trying to interpret laboratory results play out in her day-to-day work. "When we get reports back from the lab, we have highlights in red that show abnormal values, but these are often erroneous because the wrong normal range is being applied," she said. These inaccuracies can be confusing to providers who rely on the lab to report the most relevant reference ranges for the patient, she said. When reporting results, labs now can use the newly proposed reference intervals in the guidance document, which in turn will help time-pressed clinicians interpret results correctly and faster, said Goldstein.

For Greene, the most significant finding in the document was related to deciphering concentrations of estradiol, which is used for its feminizing effects and to suppress endogenous testosterone. The current guidance recommends that estradiol should be maintained in a range of 100–200 pg/mL. However, this new guidance document argues that there is insufficient evidence to support this range, and most evidence to date supports a broader range, said Greene. "Really, it needs to be looked at holistically as a combination of what the brain is saying, what testosterone is doing, and how your patient is feeling."

## DIGNITY IN DEATH

Beyond laboratory testing, the section on autopsy and medicolegal death investigations addresses a problem that is both clinical and ethical. Medicolegal death investigations currently do not abide by standardized guidance on documenting gender identity, which often results in inaccurate or absent reporting of gender identity in the official records. Over half of transgender decedents had the incorrect gender on their death certificates, according to one study that the guidance cites.

The guidance recommends that autopsy reports document both legal sex and affirmed gender identity, use the decedent's chosen name

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That single alteration changes which reference intervals the lab applies, which billing codes are used, and which clinical decision-support logic is used.

and correct pronouns, describe anatomical findings in gender-neutral terms, and note evidence of gender-affirming care without speculation.

"Part of the goal in medicine is dignity in life, as well as dignity in death, and language matters. So as much as we can use neutral language, I think that that's the way that we can make sure that we honor people while they're here, and afterwards as well," said Tiffany Thomas, PhD, co-first author of the guidance document and an assistant professor in the department of pathology and cell biology at Columbia University in New York.

## INFORMATICS IMPROVEMENTS

For Goldstein, some of the most notable recommendations are found in the section dedicated to informatics. The document describes the cascading effects that occur when a transgender patient changes their legal sex in an electronic health record. That single alteration changes which reference intervals the lab applies, which billing codes are used, and which clinical decision-support logic is used. For instance, a transgender man who has changed his legal sex to male may no longer receive prompts for cervical cancer screening or be prioritised for Rh-negative blood products in an emergency, both of which remain clinically relevant.

When it comes to informatics, the capabilities of different electronic health record systems vary widely. "What I really like in terms of our approach in the guidance document is how it looks at different ways that you can tackle some of these informatics issues and provides advantages, disadvantages, and risks for doing something one way versus another," Winston-McPherson said. For people reading this document, one of the first things that they might want to do is take a deep dive to understand the capabilities of their electronic health record systems. How do you pull in sex fields? Where does that come from? What options do you have? What are the tools that you have at your disposal to append a reference interval or ways in which you can trigger a particular comment? "I think that could help a lot of folks when they're trying to improve how they approach care for this population — just knowing what they can and can't do," she said.

The guidance document recommends the inclusion of an organ inventory within a patient's electronic health record, which would take the form of a table or checklist that documents the presence or absence of specific organs and dates of surgical procedures. "An organ inventory allows for more

precise interpretation of all laboratory results and guides preventive screening decisions like whether or not a patient needs a mammogram," Goldstein said.

## A STEP TOWARD SYSTEMIC CHANGE

Going forward, the document's authors are realistic that implementation will not be uniform. Some recommendations, particularly around informatics, will require institutional investment that not all laboratories are in the position to make immediately. Other recommendations touch on areas where the evidence base remains limited and clinicians may be uncertain. In the future, Winston-McPherson would like to see some kind of focused guide for implementation that laboratory professionals can have at hand, specific to whatever system they're working with.

There are also other challenges that plague the field in general that this guidance document only begins to tackle. There are two ways to read this document, Goldstein said: as a reference for working with transgender patients, or "as a recipe for systemic change in the laboratory to undo some of the transphobia baked into our medical system," she said. "These guidelines point out the ways in which our systems betray transgender people and prevent us from pursuing optimal health because our medical providers don't know how to interpret labs."

This guidance, Greene said, stands to help all patients, regardless of whether they are cisgender or transgender. "We all have sex hormone differences, and the guidance document is looking at how sex hormone differences play into human physiology," she said. The questions the guidance raises about how biological sex and hormone status interact with laboratory values have implications far beyond the gender diverse population.

Still, the guidance document strives to begin to plug a major gap for a minority population. "This is an underserved, understudied population, and these recommendations are based on currently available studies. So we hope that there'll be more studies and that these recommendations can further evolve and become more refined," Thomas said.

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DATE/TIME
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**Proving whether a driver has been impaired by cannabis is notoriously tricky. Can new diagnostic approaches help?**

# The elusive search for a roadside cannabis DUI test

BY YAAKOV ZINBERG

On the evening of July 11, 2017, Douglas Fraser was pulled over near Everett Mall in Washington state for speeding and erratic driving. According to the state trooper on the scene, Fraser had full body tremors and performed poorly on several field sobriety tests (FSTs), including the finger-to-nose test and accurately estimating time. Fraser was arrested for driving under the influence (DUI). A subsequent test showed he had a blood concentration of 9.4 +/- 2.5 ng/mL of delta-9-tetrahydrocannabinol (THC), the main psychoactive compound in cannabis. Fraser admitted to smoking cannabis but said it was at least 20 hours before the traffic stop, at which point cannabis typically no longer has any effect.

Nevertheless, Fraser was charged under the state's *per se* DUI law, known as such because it deems a person intrinsically guilty of driving under the influence if they have a THC blood concentration of 5 ng/mL or higher, regardless of their behavior. Fraser sued up to the Washington Supreme Court, which upheld the *per se* law, citing research which says that 5 ng/mL of THC "appears to be related to recent cannabis consumption in most people," which in turn is "linked to" impaired driving.

The *State v. Fraser* case illustrates the scientific and legal complexities of trying to determine whether a driver has been impaired by cannabis. For alcohol, there's decades of research showing that a blood alcohol concentration of 0.08 strongly correlates with impaired cognitive and motor functions, as well as a simple tool — the breathalyzer — for measuring it at the roadside. Cannabis, on the other hand, has a more unpredictable effect on behavior and a more complicated metabolism in the body, which makes it difficult to detect the relevant molecules and to know how to interpret a positive test result. (The Washington Supreme Court justices acknowledged this discrepancy between alcohol and cannabis in their ruling.)

There's no dispute that cannabis can and often does slow reaction times and distort perceptions of time and distance; it's easy to understand why someone who's high shouldn't get behind the wheel. And drivers who show obvious signs of impairment can be convicted of a DUI without a blood test or breathalyzer.

But in the absence of clear evidence, the thorny question is this: At what point does someone who's consumed cannabis become impaired, and can this be tied to a number from a diagnostic test? Even the *State v. Fraser* verdict acknowledged that the logical progression of 5 ng/mL of THC in blood to recent use, and recent use to impairment, may not always hold true; research conducted since then further suggests that this chain of events is far from certain.

Situations like Fraser's will likely become more common. According to the National Center for Drug Abuse Statistics, 61.5 million Americans, or nearly 1 in 4, consumed cannabis in 2024. And a survey from the American Automobile Association Foundation for Traffic Safety found that 53% of cannabis users have driven within an hour after consuming the drug.

At the same time, Washington and five other U.S. states have *per se* laws ranging from a 1 to 5 ng/mL THC limit, while a dozen others have zero-tolerance laws, which say that driving with any amount of THC in one's system is illegal.

New diagnostic technologies currently in development, and a growing reliance among law enforcement on roadside testing, may help officers better identify drivers who've recently consumed cannabis. But can these efforts ultimately make roads safer while avoiding penalizing those who aren't actually impaired?

## SOLUBILITY AND MECHANISM OF ACTION

Alcohol can intoxicate in a matter of minutes thanks to its water solubility. It is absorbed into the bloodstream through the digestive tract and travels to the brain shortly thereafter. Alcohol's departure from the body also is predictable: the liver metabolizes ethanol at a rate of about one standard drink per hour and usually fully clears it 24 hours after consumption.

THC, in contrast, is highly lipid soluble, which presents a major challenge to efforts for detecting recent use based on body fluid concentrations. It's absorbed by fatty tissue, including the brain, and released slowly into the bloodstream. Chronic users, including those who take cannabis for medicinal reasons, can have baseline blood THC concentrations that exceed 2 or even 5 ng/mL long after any impairment has waned.

Additionally, THC has a more complicated mechanism of action. Whereas alcohol is solely a central nervous system stimulant, THC can act as a depressant, stimulant, and hallucinogen; there's far more variety in how people behave after cannabis use versus alcohol.

All these factors create uncertainty about how cannabis affects driving ability. To systematically address this question, Robert

Previous page and right: Ake Ngiamsanguan / iStock, Thales Antonio / iStock

Fitzgerald, PhD, and Thomas Marcotte, PhD, who both have leadership roles at the Center for Medicinal Cannabis Research at the University of California San Diego, conducted a randomized controlled clinical trial. With 191 participants, the trial was the largest of its kind. Participants smoked either a placebo, 5.9% THC, or 13.4% THC cigarette and underwent a driving simulation meant to replicate city and country driving and common traffic challenges, such as freeway merging.

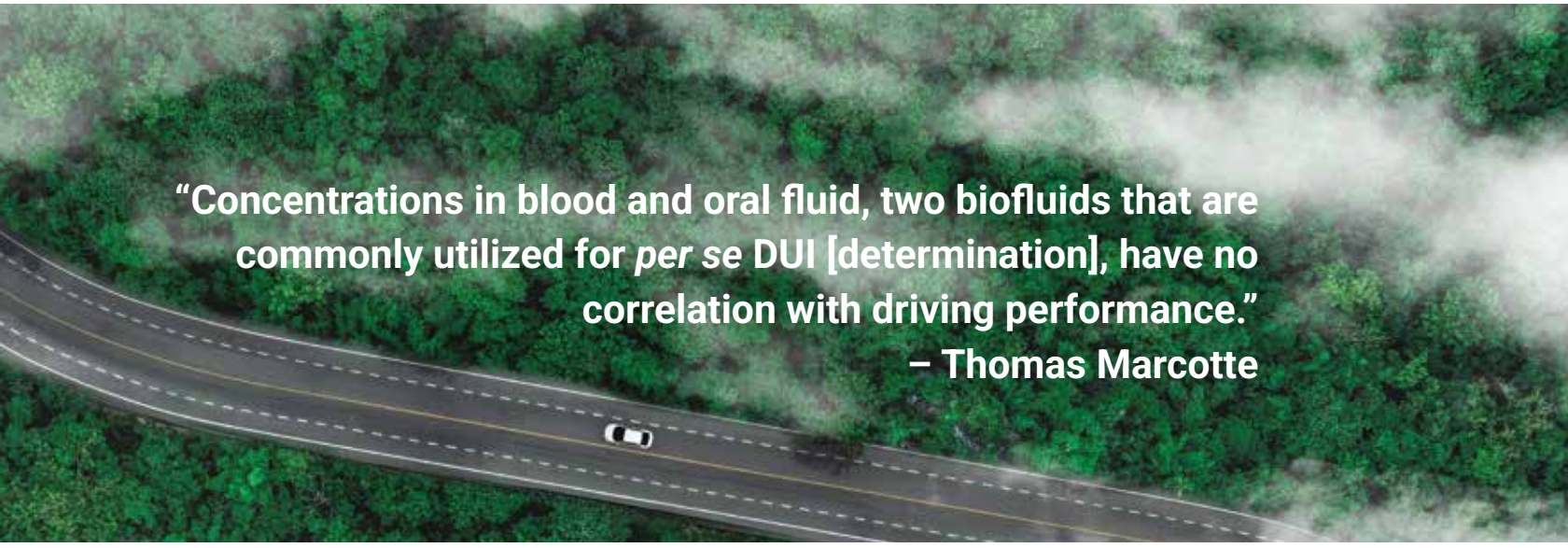
biofluids that are commonly utilized for *per se* DUI [determination], have no correlation with driving performance."

## FSTS IN COMBINATION WITH TOXICOLOGY RESULTS

During the trial, Fitzgerald and Marcotte also generated data on how effective FSTs might be in classifying cannabis-impaired drivers and the potential benefit of combining these tests with toxicology results.

When a police officer suspects that a driver has been impaired because of a substance, they'll typically conduct several FSTs that assess balance, attention, and coordination. Some officers are certified as drug recognition experts (DREs), trained to recognize impairment due to substances other than alcohol, and they conduct a standardized 12-step evaluation, the last step of which involves a review of available toxicology information.

In the trial, 11 DRE-certified officers were asked to perform FSTs on the participants and classify them as impaired or not impaired. (The officers did not perform the full DRE exam.) The FSTs correctly classified 81% of the participants who received THC as being impaired. But 49% of the participants who received the placebo cigarettes were also deemed impaired on the basis of the FSTs. However, when a cutoff of 2 ng/mL THC concentration in oral fluid was imposed on the FST determination, the number of placebo individuals classified as impaired dropped to zero.




Results from the study were first published in *JAMA Psychiatry* in 2022. Individuals in the THC arms had significantly worse driving scores compared with those who smoked the placebo cigarettes. But interestingly, there was no relationship between the amount of THC in blood and the scores, and not everyone showed significant impairment.

"If you look at all the evidence, THC is clearly impairing, and particularly so for some individuals," Marcotte said. "But concentrations in blood and oral fluid, two

"Adding toxicology results may be helpful in increasing the level of suspicion that cannabis was involved in driving impairment, and conversely, in identifying those who have not consumed cannabis recently," Fitzgerald, Marcotte, and co-authors wrote in a 2023 *Clinical Chemistry* publication. But these results don't demonstrate causality, they noted.

## ROADSIDE ORAL FLUID PILOT STUDIES

Blood samples, however, are hardly ever collected at the roadside.

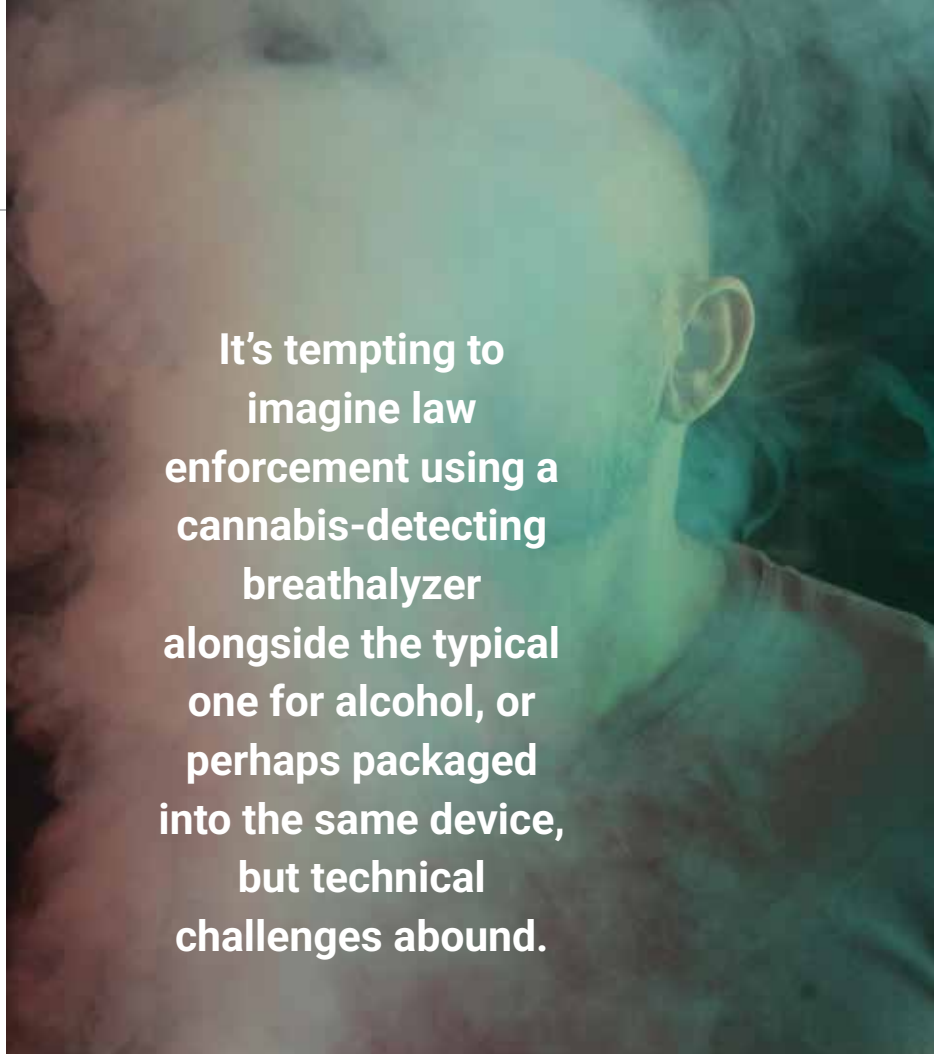
Blood draws for drivers suspected of being impaired typically take place at a police station, sometimes hours after a driving incident. In this span of time, blood THC concentrations can plummet, giving a potentially misleading picture of what was in a person's system when they were driving.

Collecting oral fluid, in contrast, is noninvasive and can read out THC concentrations within minutes. The Dräger DrugTest 5000 analyzer, for example, takes a cheek swab for saliva and relies on an enzyme immunoassay strategy to detect several drug classes, including cannabinoids.

A few U.S. states, including Alabama, Indiana, Michigan, and Minnesota, have deployed statewide pilot programs that equip law enforcement with oral fluid roadside devices. Initial results from these programs show that the devices can perform well in this setting. Based on this, Alabama has since implemented oral fluid testing as part of its standard roadside DUI screening.

In Minnesota's pilot program, 329 oral fluid tests (either using the Dräger DrugTest 5000 or Abbott's SoToxa instrument) were obtained after a traffic stop from 268 drivers suspected of using drugs. THC was found 177 times, or in about 54% of samples. Blood or urine samples also were collected from patients, and they found 220 hits for THC, an overlap of 80.5%. Similarly, a study from Norway showed that the proportion of false negatives for cannabis from the Dräger device compared with blood were 13.4%, with a false positive rate of 14.5%.

Although it doesn't linger in saliva for as long as it does in blood, oral fluid tests may not always yield a person's systemic THC concentration, because saliva is susceptible to contamination. For instance, if a person smokes a cigarette and gives an oral fluid sample a couple of minutes later, the diagnostic device might detect a high THC concentration, but this likely doesn't correspond to the concentration in other body tissues.



It's tempting to imagine law enforcement using a cannabis-detecting breathalyzer alongside the typical one for alcohol, or perhaps packaged into the same device, but technical challenges abound.

## BREATH AND BEYOND

Breath samples, on the other hand, have been shown to contain traces of consumed drugs and their metabolites while potentially minimizing the issue of contamination, which could lead to consistent results regardless of the mode of cannabis consumption. It's tempting to imagine law enforcement using a cannabis-detecting breathalyzer alongside the typical one for alcohol, or perhaps packaged into the same device, but technical challenges abound. THC concentrations in breath are several orders of magnitude lower than those of alcohol, and THC is far less volatile.

A team of researchers at the National Institute of Standards and Technology is undertaking the basic research that could one day form the basis for a cannabis breathalyzer used by law enforcement. Using an aerosol device that extracts cannabinoids from breath, the team was able to detect cannabinoids in breath after ingestion of cannabis-infused edibles — an important proof of concept.

## AN UNCERTAIN FUTURE

Yet alongside these developments is a body of research — including Fitzgerald and Marcotte's trial and work from the National Highway Traffic Safety Administration — showing a murky connection between THC concentration and

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driving impairment. Even those who believe in a strong correlation would concede that there's no scientific basis for choosing 2 or 5 ng/mL as the limit, which *per se* laws do.

All of which begs the question: If, at least for now, THC concentration can't be confidently tied to a level of impairment, what is the point of developing new diagnostic methods that might more accurately detect systemic THC levels?

Experts across all sides of the issue agree that toxicology testing should not be the only metric by which a driver is charged with a DUI. In combination with toxicology results, other factors such as driving behavior, officer observations (including FSTs), body camera footage, and witness observations should be considered.

And given that *per se* laws are on the books in several states, it's important to refine diagnostic technologies so that test results correspond with actual body levels of THC, said Kara Lynch, PhD, co-director of the core clinical laboratory at San Francisco General Hospital. Additionally, better tests "protect people who use cannabis from being wrongly accused," she said. "If someone used cannabis two or three days before their shift at work, and they test positive even though they're not impaired, then they can't work. There are consequences to society."

Ultimately, experts are united in calling for more research in several areas, such as how different forms of cannabis affect driving ability and whether biomarkers outside of THC might correspond to driving impairment.

**Yaakov Zinberg** is a writer based in the Boston area.

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# WHERE GREAT MINDS MEET

ADLM 2026 will unite innovators and experts in diagnostics and laboratory medicine in Anaheim, California, from July 26–30. Among the meeting's many highlights, five luminaries in the field will give plenary talks on timely topics in healthcare.

**SUNDAY, JULY 26**

### Diabetes prevention and treatment: A personal odyssey from bench to bedside

**David M. Nathan**

2026 Wallace H. Coulter Lectureship Awardee

Director, Clinical Research Center, Massachusetts General Hospital

Founder, Diabetes Center, Massachusetts General Hospital

Professor of medicine, Harvard Medical School

**MONDAY, JULY 27**

### Laboratory diagnostics for space medicine

**Kathleen McMonigal, MD**

Director, NASA Johnson Space Center Clinical Laboratory

**TUESDAY, JULY 28**

### Alzheimer disease biomarkers in Down syndrome

**Elizabeth Head, PhD, MA**

Dean's professor and vice chair for research

Department of pathology and laboratory medicine

University of California, Irvine

**WEDNESDAY, JULY 29**

### Advances in screening for cervical cancer both in the United States and globally

**Leeya Pinder, MD, MPH**

Director, Center for Global Cancer Control

Associate professor, division of gynecologic oncology

Department of obstetrics and gynecology

University of Cincinnati College of Medicine

**THURSDAY, JULY 30**

### Mass spectrometry-based discovery and translation of novel biomarkers into immune-based therapies for cancer

**Arun P. Wiita, MD, PhD**

Professor and interim chair, University of California, San Francisco (UCSF) department of laboratory medicine

Adjunct professor, UCSF department of bioengineering & therapeutic sciences

Assistant director, UCSF clinical cytogenetics laboratory

Director, UCSF Stephen and Nancy Grand Multiple Myeloma Translational Initiative Laboratory

Director, Physician-Scientist Pathway Program, UCSF departments of pathology and laboratory medicine

Investigator, Chan Zuckerberg Biohub San Francisco

Read on to hear more from the meeting's opening keynote speaker, David M. Nathan, MD, as he discusses the pivotal moments of his career — from major discoveries about HbA1c to the advent of glucagon-like peptide-1 receptor agonist medications — as well as new frontiers in diabetes care.

**And join us at the meeting** to hear his talk and the other plenaries and to explore the meeting's 250-plus educational sessions and 700-plus exhibitors.

# FIVE DECADES ON THE FRONTLINES OF DIABETES RESEARCH

**BY MORIAH SELLERS**

David M. Nathan, MD, is the founder of the Massachusetts General Hospital Diabetes Center, directed the Mass General Hospital Clinical Research Center from 1991 to 2025, and is a professor of medicine at Harvard Medical School. He is also the 2026 winner of the Association for Diagnostics & Laboratory Medicine's (ADLM's) Wallace H. Coulter Lectureship Award. He received this award in recognition of his pioneering studies on the treatment and prevention of diabetes — groundbreaking work that Nathan humbly attributes to his collaborations with numerous fellow clinical investigators, trainees, and bench scientists, as well as to the study participants who volunteered their time and effort to advance this research.

*Clinical Laboratory News* recently spoke with Nathan ahead of his upcoming plenary session at ADLM 2026 to reflect on the touchstones of his career and look to the future of diabetes testing and treatment.

## What led you to enter diabetes research?

It was somewhat happenstance. Medical science in the late 60s and 70s was advancing because of the development of the radioimmunoassay by Solomon Berson, MD, and Rosalyn Sussman Yalow, PhD. I had some contact with them when I was a medical student. The radioimmunoassay that they introduced allowed the very accurate measurement of small quantities of substances circulating in biological fluids, and the very first assay developed was for insulin. It drew me to endocrinology and diabetes specifically because we were starting to understand pathways and I very much like to solve puzzles. Understanding that these small substances had numerous downstream effects was of great interest to me.

## What specific areas of diabetes care and testing do you currently study?

Keeping in mind that I'm moving towards retirement, the studies that I continue to work on as I close down my career are expanding the information from what were huge investments by the National Institutes of Health (NIH) and the National Institute of Diabetes and Digestive and Kidney Diseases in particular.

One of these is the Diabetes Control and Complications Trial (DCCT), which ran from 1982 to 1993 and has continued through its long-term observational follow-up called the Epidemiology of Diabetes Interventions and Complications (EDIC)

study, which started in 1994 and is still ongoing today. The DCCT demonstrated the critical role of intensive therapy aimed at lowering the hemoglobin A1c (HbA1c) level for people with type 1 diabetes. Specifically, the trial showed that reducing A1c as much as clinically possible led to a myriad of benefits for this patient population. This finding underlies modern-day treatment of type 1 diabetes.

The vast majority of our living participants are still in the EDIC study — an invaluable population that we've collected data on for 95% of the time that they've had diabetes and over 65% of their lifespans. Because the DCCT results have extended the lifespan of people with type 1 diabetes, we now have a type 1 population that is living longer than at any time in history. However, with no prior experience with type 1 diabetes in older people, we don't know what happens to them. How do we help take care of them and, of course, help them take care of themselves? It's still a complicated disease and I'm pleased to continue contributing with my collaborators to the knowledge base that should improve the health of people with type 1 diabetes over their lifetime.

**"To me, the real importance of [glucose monitors] is that they provide the ability to 'close the loop' on insulin pumps. – David M. Nathan**

The second major trial, which began after the end of the DCCT and which I have chaired for the past 30 years, is the Diabetes Prevention Program (DPP). Type 2 diabetes was quickly increasing in the 1990s, having almost doubled in prevalence over the preceding 10–20 years. Prediabetes, which represents a group at particularly high risk for developing diabetes, currently affects more than 100 million people in the United States. In 1994, again with the support of the NIH, we began to plan a study to determine whether we could slow or stop this epidemic borne of the increasing prevalence of overweight and obesity in the population. The DPP ended in 2002, about a year ahead of schedule, after demonstrating that lifestyle interventions that reduce weight and increase activity levels and the medication metformin reduce diabetes development by an impressive 58% and 31%, respectively.

We continue to follow almost 1,700 of the original DPP population, exploring the long-term durability of the original interventions and other benefits associated with diabetes delay or prevention. Their average age is now 74. In this respect, both the DPP and DCCT/EDIC are looking at similar themes: How do aging and associated characteristics interact with diabetes? What is the best way to take care of these patients over the course of their whole lives?

### What's one interesting thing you've found from your research comparing HbA1c testing with continuous glucose monitoring?

I'm old enough that I was beginning my research around the time that self-monitoring of blood glucose was born. The first glucose monitors became available in the late '70s and early '80s. So now, fast forwarding 40 years, continuous glucose monitoring (CGM) has come about. And to me, the real importance of these devices is that they provide the ability to "close the loop" on insulin pumps.

The major downside of intensive therapy in type 1 diabetes was hypoglycemia. In the DCCT, the cost of lowering the risk of diabetes complications by 39% to 76% with intensive therapy was a three-fold increased risk of severe hypoglycemia. So, the ability to lower HbA1c to <7% (which had been adopted as the international standard of treatment based on DCCT/EDIC results) with less hypoglycemia was a major goal. CGM allows patients with type 1 diabetes to achieve goal A1c levels with less hypoglycemia. It accomplishes this by serving either as critical feedback in insulin pumps or as an early warning system in patients treated with injections. We shouldn't lose sight that that is the reason why CGM was developed.

But then, of course, there are commercial interests involved, and type 1 diabetes is a relatively rare disease compared with the 20-fold more people who have type 2 diabetes. Understandably, companies started looking at how CGM could be used in this larger population. I think the best justification for using CGM with type 2 diabetes is for people who are insulin-treated where, again, you want to make sure that their blood sugar isn't drifting low without them realizing it.

Despite my strong feelings against these devices being used in populations without demonstrated benefit, they are now being promoted for use in nondiabetic populations. Whether this increasing use of technology improves health in most people with type 2 diabetes — or in people without diabetes — remains to be demonstrated.

Regarding the question of CGM versus A1c, A1c is incredibly affordable, easy to measure, and rarely wrong. Some of the work that I've done has established the relationship between average glucose

levels and A1c. Improving on the generally excellent correlation between measured average glucose and HbA1c values is still important. A colleague of mine at Mass General named John Higgins, MD, and I have worked on such projects for the last decade.

## What are other exciting emerging trends in diabetes care today?

You know, glucagon-like peptide-1 receptor agonist medications (GLP-1s) have captured everyone's imagination. I was the first person to ever give a GLP-1 to a person with diabetes back in the late 1980s. And that's because of propinquity: My colleague Joel Habener, MD, who really was the father of GLP-1s, was down the hall from my laboratory. Joel and colleagues were identifying the differential processing of preproglucagon in different organs, isolating and synthesizing GLP-1, and figuring out what it did in animal models. I started working on measuring GLP-1 levels in fed and nonfed persons with both type 1 and type 2 diabetes and along the way was able to administer GLP-1, 7-37 to human volunteers. The major effect we noted was the stimulation of insulin secretion. We shouldn't lose sight that lowering glucose and HbA1c levels was the stimulus for the development of GLP-1s.

Now, GLP-1s' major commercial benefit is that they're highly effective for weight loss. The drugs decrease your appetite through a combination of central and gastrointestinal effects. GLP-1s also decrease heart disease and kidney disease — an entirely accidental finding. In 2008, the Food and Drug Administration began requiring the pharmaceutical industry to demonstrate that new diabetes drugs were safe for heart disease, because there was a drug for type 2 diabetes called Rezulin, or troglitazone, which appeared to increase the risk for heart disease. So, the manufacturers of the new diabetes medications, such as the GLP-1s, were required to do cardiovascular safety studies. Lo and behold, not only were they shown to be safe, they actually appeared to be protective.

If we can determine how to keep patients on these medications long-term, we may have made a major step in addressing the rampant prevalence of overweight and obesity and the consequent diabetes and heart disease that affect public health.

## One thing you'll be discussing at ADLM 2026 is the importance of funding from the NIH throughout your career. What's one thing you would not have been able to accomplish without NIH funding?

My entire career wouldn't have been possible without NIH funding. I've chaired three highly impactful, NIH-sponsored multicenter studies and participated in several others. I think it's fair to say that none of them would have been supported by industry. Nothing against industry, but its primary focus is developing drugs for diseases rather than for prevention. Similarly, studying interventions that don't involve medications and comparing available therapies in comparative effectiveness studies is not in industry's wheelhouse. Companies have no financial incentive to erase a disease or compare their medication against competitors.

NIH funding is critical on several levels beyond the support of large studies that are important to public health, and I fear that it's under threat. NIH is really the lifeblood of training young investigators and supporting biomedical research. Without NIH funding, the pipeline of investigators will slow to a trickle. The large-scale, long-term projects that have shown how to reduce the chronic morbidity and mortality associated with diabetes and how to prevent — or at least delay — the onset of diabetes would never have been conducted without the NIH.

## Will you be presenting any new research or findings during your talk at ADLM 2026?

I was asked to provide a retrospective of my career, weaving my laboratory work into my clinical research because, frankly, the laboratory elements were foundational. If we didn't have A1c, we couldn't have done many of these studies. If we didn't have basic scientists developing GLP-1s, we wouldn't have those drugs and the studies that rely on them. So the major themes I will focus on will be the interdependence of clinical and basic laboratory work being at the heart of major advances in diabetic research, and my concern about the future.

**Moriah Sellers** is a writer based in the Lexington, Kentucky, area.



A Q&A WITH ASHLEY ZARLING

# Managing reimbursement of molecular testing for infectious disease

By Karen Blum

FOCUS ON MOLECULAR DIAGNOSTICS

Getting proper reimbursement to conduct genetic and molecular testing for infectious disease has become an increasing concern for laboratories. *CLN* spoke with Ashley Zarling, director of business development and marketing with Doc Lab, for tips and insight. Zarling provides consulting to laboratory professionals in physicians' offices and reference laboratories to help them communicate effectively with payers and navigate the reimbursement process.

*The content of this interview was edited for length and clarity.*

**What are the main reasons labs don't get paid equally for genetic and molecular testing?**

The root cause is we don't have enough data to create a Category 1 CPT code, which works as a protection and a commercialization strategy for laboratories. When you're billing under nondescript codes, there's always a risk that a payer may redefine the code in a way that's unfavorable to you. So having a good CPT coding strategy to get reimbursed fairly is paramount.

Second, it's important to consider whether your tests are being utilized in medically necessary ways that are recognized by the industry. It's always a good idea to internally audit your tests to ensure their use-case is defensible.

**Is it more difficult to get paid equally for genetic/molecular testing compared with other assays?**

Yes. Manufacturers are required to get approval from the Food and Drug Administration (FDA) to sell in vitro diagnostics. Thus, historically, many manufacturers skipped trials and sold components of their tests to labs that then used these components to create laboratory developed tests. This moved the requirement to run trials off the manufacturer and onto the lab. Because this type of testing is cutting-edge, the science often advances faster than coding can be established, necessitating the use of nondescript CPT codes.

Labs were able to get reimbursed really well for this testing for a long time. But while patients are still getting serviced and providers have the benefit of quicker, more accurate testing, laboratories are now struggling to get paid in full for these tests.

**How does the lack of equitable reimbursement impact labs and patient care?**

Labs are closing that don't typically have the volume to make money off of blood tests, but that do have enough volume to make money off of PCR testing. As a more cutting-edge science, this infectious disease testing had somewhat decent profit margins.

At the end of the day, these labs are for-profit. They're not getting grants from the government. So laboratorians are losing their jobs. Sales reps are losing their jobs. And it's not a small number.

Moreover, the impact can be far more dire than losing labs. If patients lose access to molecular and genetic testing for infectious disease, there are long-term implications that involve hospitalization and death. In addition, when you strip PCR testing away from the laboratory, you might lose your blood testing too.

**How can labs increase reimbursement for genetic/molecular testing?**

Engage early with the payer. Before you collapse your test, ask the payer if they're willing to negotiate. For example, can you ask for a carve-out so you can still supply the test to a subset of your population? That process can be intense — which is why labs sometimes bring in industry consultants to help. You don't have to be in-network to navigate a carve-out.

Longer term, you'll need to come up with two things: clinical utility data and a CPT coding plan. Underneath a single CPT code, there are pathways forward to do that. Individual labs, if they want to continue with certain testing, either have to join a group that has clinical utility data or start producing such data themselves.

**What best practices should labs follow to ensure they're selecting the proper CPT codes?**

It can be really challenging. Labs

historically follow the American Medical Association (AMA), but the recently reinterpreted National Correct Coding Initiative policy goes exactly against the AMA. That means that AMA advocacy will need to occur at an industry-wide level.

**What processes can labs implement to ensure their documentation meets payer policies?**
Again, reach out to the payer. A lot of the policies are not publicly posted, but there may be internal auditing processes in place. Rather than asking about individual patients or claims, connect to the provider education teams to ask what they want at a big-picture level.

At the end of the day, it comes down to internal compliance and auditing at the lab. Pull 10 random samples off your accessioning line and request chart notes on them. Does the order match the requisition? Do the ICD codes? Does the patient presentation?

Then come back a week later: Were the results utilized? Did they change the patient's treatment plan? You can track the data to find the outliers. You're going to come across problems, and you're going to need to educate your providers.

**How can labs make effective use of appeals in cases of underpayment or when legitimate claims are denied?**
This is where that provider education piece comes in. Even though lab professionals don't provide direct patient care, they need to make sure — to the best of their ability — that patients who should be sent for a culture are sent for a culture, and that patients who are justified for PCR can get sent for PCR.

That way, when you appeal, you should have analytical validity data to draw on. For example, it might show that a patient had a failed treatment plan after culture, or they were at high risk of urosepsis or septic shock.

Finally, be concise. The best appeals compress information. If you want to provide additional details or add citations, you can always put them in links or QR codes. But a payer should be able to grasp what they might have gotten wrong within 2 minutes. Make your argument succinct and persuasive.

**How do clinical validity and clinical utility differ? How can labs prove each, and why is it important to do so?**
Clinical validity refers to being able to prove that a test can detect what you say it can detect when a patient presents at a clinic. Clinical utility is about being able to ensure that what you detect can actually change patient outcomes.

There are a lot of screening tests that are not reimbursable and not commercialization-ready even though they absolutely can do what they say they can do. The reason is that they do not impact patient outcomes, whether in the form of giving people a better chance of survival or reducing their hospitalization time.

So, after you've established clinical validity, clinical utility is the next bar to clear. And it's important to do so because payers only want to pay for things that change their patient outcomes.

**As payers continue to adjust coverage policies and requirements, how can labs future-proof their success?**
Make investments in clinical utility data, CPT coding strategies, and banding together with others in the industry to approach the AMA, Centers for Medicare and Medicaid Services, or other relevant entities.

Also, ask providers to write letters stating how your test has impacted their patients. Anecdotal or not, written testimonials provide powerful evidence that your providers want specific tests. These provider champion letters — and patient champion letters if you can get them — will provide helpful leverage for your negotiations with payers. Also ask your providers to track data you can use. For instance, did patients' urinary tract infections resolve following their PCR testing?

It's a lot to take on, but you need to start somewhere. It's really about planning: Which pieces can we take on this quarter, next quarter, and the quarter after that? Before you know it, you will have future-proofed your way to a long-term strategy.

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A Q&A WITH MICHAEL ASTION, MD, PHD, AND DARCI STERNEN, MS, CGC

# Practical strategies for getting reimbursed for genetic and molecular testing

By Karen Blum

FOCUS ON MOLECULAR DIAGNOSTICS

Increasing reimbursement for genetic and molecular testing is a little bit of an art. We spoke with Michael Astion, MD, PhD, medical director of regional laboratories at Seattle Children's Hospital, and Darci Sternen, MS, CGC, a laboratory genetic counselor at Seattle Children's, for their recommendations. Astion and Sternen are active members of Patient-centered Laboratory Utilization Guidance Services (PLUGS), a laboratory stewardship collaborative co-founded by Astion to improve laboratory test ordering, interpretation, and reimbursement.

**What steps has your lab taken to support strong reimbursement for genetic and molecular testing?**

**Sternen:** Around 2012, we developed a pre-authorization process to make sure we were setting our institution and our patients up for reimbursement success. When a provider wants to order a genetic test, they first submit a pre-authorization request rather than the test order. We have a laboratory genetic counselor team that reviews the request, assigns appropriate CPT codes, and then routes this through our insurance processing department to ask the insurance payer for pre-authorization before the test is performed. Then, when the test is actually ordered, we have the information documented in the system so our billing department can make sure the pre-authorization is attached.

In addition, another purpose of the pre-authorization is that if an insurer decides not to cover the test, the clinical team can inform the family, and they can make an educated decision about whether they want to proceed with testing.

**Astion:** Most PLUGS members have set up systems for maximizing the chance that pre-authorization will be approved for medically necessary tests. In fact, we have a whole set of tools for both patients (www.schplugs.org/plugs-patient-toolkit) and laboratories (www.schplugs.org/insurance-alignment) to overcome a pre-authorization denial. With some insurance companies, the patient has to drive the appeal, and in some cases, the lab can drive it, so you have to have tools for both. The big emphasis when we talk about getting paid, is that we're talking about tests that are medically necessary.

**What best practices does your lab follow to help ensure that you're selecting the proper CPT codes?**

**Sternen:** When we assess a test during the pre-authorization process, we look to see what that test entails and what methodology and genes are involved, then we go directly to the CPT code book to find a code that is appropriate for that test. For some, there are codes that are very specific to the test or the indication, like the *CFTR* gene associated with cystic fibrosis. For others, such as larger gene panels where there's not a specific code, we can assess if an "unlisted procedure" code is appropriate. If it's a send-out test, we also refer to the reference lab's website and compare the code they're using against what we think is appropriate.

**Astion:** Most labs that have a staff member involved in billing and coding follow a standard set of rules to find the closest CPT code, which occasionally is a proprietary laboratory analyses (PLA) code, a subset of the CPT coding system that is associated with individual proprietary tests from specific manufacturers.

Where labs tend to face problems is with their own laboratory developed tests (LDTs). Let's say an LDT is expensive or it has some proprietary elements, and the lab invested a lot of money into developing it. They have to decide if they want to crosswalk into the regular CPT coding system or get a proprietary lab code. There are advantages and disadvantages to each. Insurance systems are tuned currently to deny PLA codes because the majority do not have sufficient evidence to be put into clinical practice. The door for new, PLA-coded tests tends to be closed, and labs have to open it by showing a significant amount of evidence. Once they do that, the PLA code is advantageous, but sometimes that only happens after years of using the test without getting paid. With the regular CPT code, you might get paid a little less, but you're getting paid.

**What processes has your lab implemented to help ensure that your documentation meets payer policies?**

**Sternen:** For genetic testing, in addition to the test name, CPT, and ICD-10 codes, we attach clinical documentation to the pre-authorization request. This documentation specifically includes the provider clinic note that supports the medical necessity of the test — not just the rationale for why they want to order the testing, but also how the test results might change care. The goal is to send one communication to the payer that has all the documentation they need to understand the utility of the test for that patient. When we receive a denial, we can appeal with additional information if needed, but we've worked very hard with our providers and partners to provide medical necessity templates so they can state that upfront rather than needing to submit a separate communication later.

**How do you use appeals to get reimbursed if legitimate claims are denied?**

**Astion:** There are two kinds of denials: the easy ones and the hard ones. For the easy ones, sometimes something is administratively missing, so it just has to be filled in. The two major forms submitted, the CMS-1500 and the UV40, both have electronic versions with a lot of fields, so you can have an inadvertent error in fields representing the lab, the healthcare facility, patient demographics, or the insurance plan. Those are relatively straightforward to correct.

The harder ones are when the insurance company says a test is not medically necessary, or that it's experimental, investigational, and unproven. If they say it's medically not necessary, it usually means they have a policy where if you met inclusion criteria, you would get coverage and the lab would be paid. In that case, what you try to do is look at the case and provide additional information to show that it meets criteria. In the case of experimental, investigational, and unproven, that's difficult because it's usually denied in all cases. It's harder to appeal. You have to convince the payer to change their policy permanently or allow an exception for that case.

**Sternen:** Across the PLUGS network, we've also found that it's very important to have the right people assisting with reviewing the pre-authorization and denials. The laboratory genetic counselors in our system can help support providers, especially the increasing number of non-genetics providers from neurology, pulmonology, and other specialties who order genetic testing these days. Our lab genetic counselor team can review the denial with them and see if there's a way to strategize overcoming that. We have examples where our team caught that it was just a misunderstanding from the insurance payer; they were denying a different test, and we were able to provide clarification and additional strength for the medical necessity language.

**As payers continue to adjust coverage policies, coding requirements, and prior authorization rules, what strategies is your lab using to adapt and maintain reimbursement levels?**

**Astion:** Lab testing can be lucrative. Unfortunately, the profit motive can lead to overtesting and offering tests prematurely, before there is strong evidence for clinical use. Insurance companies face a significant amount of inadvertent waste and purposeful abuse and fraud. As PLUGS members, we try to make a trade with them. We help them identify waste, abuse, and fraud, which saves them money, and then we say, "Hey, does the help we provide fertilize the ground for having a guardrails policy instead of a strict policy?" The guardrails allow for a broader range of evidence-based practice, especially for individuals with severe diseases, such as metastatic cancer, multi-system autoimmune or infectious diseases, or rare inherited diseases. So sometimes we provide insurance companies with a policy that we think is a guardrails policy, or we send them edits to their policies, often comparing them to our own, which they often welcome.

The best example of this is the widespread adoption of the PLUGS exome/genome policy that covers 60-70 million lives in the United States. This policy has gotten broader coverage for exomes and genomes while blocking medically unnecessary exomes and genomes. What we try to do is align with the insurance company, not thoughtlessly advocate for testing.

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BY NICHOLAS SPIES, MD

# Optimizing AI: The RISE approach to chatbot prompting

Modern large language models (LLMs) are transformer-based neural networks trained to predict the next "token" (defined loosely as the next word) in a sequence given its preceding context (*1*). They can do this effectively because they have been trained on enormous amounts of text from books, articles, websites, and more.

Today's chatbots also receive training called "reinforcement learning with human feedback," in which people rate the answers the model gives. This helps it learn to follow instructions and avoid harmful responses (*2*).

Three practical implications follow. First, the model has no privileged access to the truth; rather, it produces statistically plausible, aesthetically pleasing text conditioned on whatever the user supplies. Second, output is generated one token at a time, so the model cannot revise an earlier commitment without being prompted to do so. Third, all instructions, examples, and supporting documents share a finite context window. That means that any material placed in that window will compete for the model's attention.

A chatbot prompt is therefore an active specification of the role, input context, reasoning process, and output format that the user expects. In the clinical laboratory, where errors may directly impact patient care, the gap between a useful and a misleading response often lies in how rigorously the prompt was constructed.

The RISE (role, input, steps, expectations) framework provides a structured discipline for that construction (see Table 1, online). Each of the four components of RISE is supported by published evidence demonstrating that prompt design materially affects accuracy, hallucination rate, and adherence to user constraints.

### Role: Contextual conditioning of the model

Assigning the model a role at the outset of a prompt (e.g., "You are a board-certified clinical chemist reviewing a method-validation study") biases its output distribution toward the vocabulary, conventions, and reasoning patterns of that domain.

Kong et al. demonstrated that role-play prompting improves zero-shot reasoning across mathematical and symbolic benchmarks, with gains that scale with model size (*3*). In laboratory practice, role specifications should be precise rather than generic. For example, "expert in liquid chromatography-tandem mass spectrometry method development" may yield better-calibrated output than "scientist." Similarly, "laboratory director responding to a College of American Pathologists inspector" produces materially different framing than "laboratorian." Role framing also acts as a soft constraint on register and intended audience.

It's worth noting that role assignment alone does not eliminate hallucinations. Moreover, prompts that request elaborate personas can introduce stylistic affectation without substantive gain. Treat "role" as scaffolding for the remaining RISE elements, not a guarantee of accuracy.

### Input: Explicit instructions with positive and negative examples

The largest single gain in output quality typically comes from the clarity of the instruction itself. Ouyang et al. showed that human-aligned models follow explicit constraints far more reliably than implicit ones, with corresponding reductions in hallucination prevalence and improvements in instruction adherence (*2*).

For laboratorians, this means specifying both what the response should contain and what it should exclude: required elements (e.g., "cite primary literature with PubMed identifiers"), prohibited content (e.g., "do not cite lay press, blog posts, or nonpeer-reviewed sources"), and domain constraints (e.g., "limit recommendations to those consistent with current Clinical & Laboratory Standards Institute [CLSI] Evaluation Protocol guidelines").

"Few-shot" examples provide one or more solved instances of the target task in the prompt. Using them further sharpens the chatbot's behavior, particularly for structured tasks like classifying free-text comments, extracting numerical results from narrative pathology reports, or generating standardized validation summaries.

When practical, include a worked example of the desired output rather than describing it abstractly. If authoritative reference material is available, pasting the relevant passages into the prompt grounds the model on source text that the user controls and reduces the risk that it will substitute plausible sounding but unverified content of its own. Examples of such

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reference material might include a CLSI document, an internal standard operating procedure, or a manufacturer's package insert.

### Steps: Decomposition and sequential reasoning

Complex laboratory tasks — such as performing a root-cause analysis of an out-of-control quality control event or designing a verification study for a new analyzer — rarely yield strong single-shot answers. Wei et al. demonstrated that chain-of-thought prompting, in which the model is explicitly instructed to reason step by step, substantially improves performance on multistep problems, and that this benefit grows with model scale (*4*).

The practical corollary is to ask the chatbot to provide a plan before asking it to execute. The prompt "First, outline how you would approach this problem; then I will review your plan before you carry it out," allows the user to inspect and correct the reasoning trajectory before committing the model to giving a long but possibly flawed output.

Decomposition has a second benefit specific to safety-critical environments: It surfaces the assumptions the model makes. A laboratorian reviewing an interim plan can intercept an erroneous statistical assumption, an outdated guideline reference, or an unsupported leap in inference before it propagates into a final deliverable.

As a concrete example, rather than asking the model to "design a verification study for our new sodium method," provide a stepwise prompt: Ask the chatbot to deliver, in order, an itemized list of the performance characteristics to be evaluated, the recommended sample size and acceptance criteria for each characteristic, and finally a draft protocol. You can also include explicit instructions for the chatbot to allow the user to review the output between each step. Newer reasoning-tuned models perform some of these steps internally, but it's still valuable to include explicit user-driven decomposition whenever a task requires domain expertise that the model may not reliably possess.

### Expectations: Specifying output structure and content

The final RISE component is a precise specification of the deliverable itself. Output expectations should address audience (e.g., "write for an audience of clinical pathologists and laboratory scientists"), register (e.g., "use formal academic prose and avoid colloquialisms"), format (e.g., free prose, structured table, JavaScript Object Notation [JSON], Markdown), length, and any required elements (e.g., executive summary, methods, and references). When output will be consumed downstream by software — for example, when a model-generated structured report will enter into a laboratory information system — it's essential to use explicit schema specification, such as a JSON template.

Negative specification in prompts matters as much as positive. Including constraints can meaningfully alter model behavior. Examples include: "Do not invent citations," "Do not summarize beyond what is supported by the provided documents," and "Flag uncertainty explicitly rather than smoothing it over." Singhal et al. showed in their evaluation of Med-PaLM that even capable medical LLMs require careful prompting and grounding to approach clinically acceptable accuracy on consumer health questions (*5*); explicit expectations are a primary mechanism by which the user enforces that discipline at the point of use.

### Prompting improves with practice

The RISE framework is not a magic incantation; rather, it is a structured habit that aligns user input with the mechanisms by which transformer-based models can produce useable text. Although each element is supported by peer-reviewed evidence, applying them well to real-world laboratory problems — such as assay troubleshooting, validation planning, regulatory documentation, literature synthesis, or structured extraction from pathology reports — requires iterative refinement.

Thus, clinical laboratorians should treat prompt engineering as they would any other technical competency. Start with well-bounded tasks for which expert review is feasible to verify accuracy. Then systematically compare model output to that review, documenting any necessary prompt revisions and the effect that each revision has on performance. Periodically aggregate and evaluate the results to guide future efforts.

Like other skills, your prompting ability will strengthen with time: A laboratory team that systematically practices prompting will produce more accurate, reproducible, and defensible LLM-assisted output than the same team using ad hoc prompting. The most important next step is also the simplest: Try it for yourself!

*View the references and table online at myadlm.org/cln.*

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BY ALYSSA JOHNSON AND EMILY A. MALOUF

# Transforming molecular testing through unified leadership and data transparency

In the evolving landscape of precision oncology, the gap between clinical guidelines and real-world practice presents a persistent challenge. For patients with non-small cell lung cancer (NSCLC), comprehensive molecular profiling is widely recognized as the standard of care, which enables clinicians to identify actionable mutations and guide targeted therapies (*1*,*2*). Yet in day-to-day practice, many oncologists still rely on single-gene assessments or fluorescence in situ hybridization (FISH) testing — often in an effort to reduce costs or accelerate results.

At the University of Washington (UW) Medical Center in Seattle, this well-intentioned approach created a cascade of unintended consequences.

In this article, we describe how the genetics division leadership and program operations team within the UW department of lab medicine and pathology addressed these issues in 2024 and 2025, enabling our institute to consistently provide comprehensive molecular profiling to patients with lung cancer.

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## When "faster" testing slows everything down

At first, oncologists' preference for single-gene and FISH testing appeared practical. However, these tests often failed to provide the comprehensive insights needed to make treatment decisions and led to additional rounds of testing and longer overall timelines.

The impact was felt most acutely in the cytogenetics laboratory, where a surge in *ALK* and *ROS1* FISH orders strained capacity. Turnaround times for critical STAT testing increased, and what should have been a streamlined process became an increasingly reactive one.

Because these limited tests reported on only a handful of genes, molecular directors and ordering providers were frequently drawn into case-by-case discussions to determine which results should be prioritized. Preliminary report emails, once an exception, became routine. Meanwhile, thoracic oncology cases required repeated workflow exceptions and disrupted standardization across the system.

## A structural advantage

Although the challenges were multifactorial, the UW genetics division was uniquely positioned to respond to interconnected inefficiencies in a coordinated way with centralized leadership across molecular diagnostics, cytogenetics, and supporting teams. This unified oversight became the foundation for meaningful change, ensuring that improvements in one area would translate across the entire testing ecosystem.

## Aligning with clinicians

A critical early step was engaging clinical leadership. Change in laboratory processes cannot succeed without clinician buy-in, particularly when it affects ordering practices.

The thoracic oncology service line director, Keith Eaton, MD, played a pivotal role in this effort. As a trusted clinical leader, he bridged the gap between laboratory operations and provider concerns. By clearly articulating the benefits of comprehensive molecular profiling — not only for workflow efficiency but also for patient outcomes — he helped bring physicians into alignment. His leadership ensured that the transition was both decisive and cohesive.

## The somatic metric dashboard

Despite these efforts, one fundamental question remained: where, exactly, were delays occurring?

Traditional turnaround-time metrics provided only a partial view, often failing to capture the full journey from test order to final report. Without this visibility, it was difficult to prioritize interventions or measure progress.

The solution was the development of a somatic metric dashboard — a tool that would become central to the division's transformation (see Figure 1, online). Launched in the second quarter of 2024, the dashboard established baseline performance metrics and tracked turnaround times across the entire testing process. It also enabled comparison against clinical benchmarks, including recommended timelines for genomic testing and treatment initiation.

For the first time, teams across multiple laboratories were working from the same data. This fostered accountability, aligned priorities, and created a common language for discussing performance.

### The outlier review process

The dashboard's real impact came from how the data was used. In the third quarter of 2024, the division introduced a Turnaround Time Outlier Report, which was built directly from the dashboard. Each month, cases that exceeded expected timelines were reviewed.

What followed was a disciplined, collaborative process. Pre-analytical and analytical teams examined each outlier to identify root causes — whether delays stemmed from specimen acquisition, processing workflows, sequencing schedules, or reporting practices.

These findings were then synthesized and presented to senior leadership to create a direct link between frontline observations and strategic decision-making. Importantly, the focus remained on the most impactful tests and the most frequent sources of delay to ensure that efforts were targeted and effective.

### Small changes, big results

One of the most striking outcomes of the outlier review process was the realization that meaningful improvements did not always require major investments.

Several operational adjustments delivered immediate results. Increasing sequencing runs from once to twice per week expanded capacity and reduced backlog. Adjusting sign-out schedules to ensure two directors were available to review results minimized reporting delays. Together, these changes reduced turnaround time by 12 calendar days — a substantial improvement achieved with relatively modest effort.

Additional refinements, including targeted staffing increases and improvements in tissue acquisition processes, further strengthened performance.

### Finding and fixing hidden delays

The outlier reports also brought attention to less obvious bottlenecks. Holiday weeks, for example, consistently showed increased turnaround times. The issue was not the holiday itself, but the reduction in sequencing runs during those weeks.

By maintaining two runs per week, regardless of holidays, the laboratory eliminated an average of six delays per month — demonstrating how data can drive effective solutions for problems that may have otherwise been overlooked.

Specimen transport presented another opportunity. Reliance on standard shipping introduced variability and delays, particularly for samples arriving from external partners. Implementing a dedicated courier system streamlined this process and improved overall reliability.

### Catalyzing culture change

Beyond the operational gains, this initiative reshaped how the division approached problem-solving. The combination of unified leadership, transparent data, and structured review created a culture of continuous improvement.

Teams were no longer reacting to issues in isolation. Instead, they were working collaboratively, guided by shared metrics and a clear understanding of system-wide performance.

The presence of a single division head overseeing multiple laboratories was instrumental in sustaining this culture. It ensured that improvements were coordinated, priorities remained aligned, and progress in one area reinforced the progress in others.

### Advocacy beyond the lab

At the same time, efforts were under way to address barriers outside the institution. Insurance coverage and prior authorization requirements often influence testing decisions, sometimes steering providers toward less comprehensive options.

Engagement with patient advocacy groups and participation in legislative discussions helped shape a more supportive environment for molecular testing.

### A model for the future

The transformation of molecular testing workflows at our institution offers a compelling example of what can be achieved when leadership, data, and collaboration come together (see Figure 2, online).

The somatic dashboard provided the visibility needed to understand performance. The outlier review process created focus and accountability. And unified oversight enabled the rapid, system-wide implementation of solutions.

Most importantly, these efforts translated into better outcomes for patients. They delivered faster, more comprehensive results and supported timely, informed treatment decisions.

*View the references and figures online at myadlm.org/cln.*

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# ADLM 2026 CLINICAL LAB EXPO PRODUCT SHOWCASE


## Barcoded Magnetic Beads (BMBs)

Applied BioCode has developed Barcoded Magnetic Bead technology that combines microparticles with digital barcodes for multiplex immunoassays or molecular detection. This patented technology allows immobilization of oligonucleotides and proteins (antibodies or antigens) on the surface of BMBs for multiplex analyte detection. It enables 4,096 unique barcodes to be easily scanned and eliminates ambiguity in identification.


## 5-Plex Multiplexing with MGB Probes

Maintain multiplex assay performance with TaqMan™ ABY™, JUN™, and Cy5™ MGB probes. Detect up to 5 targets with high sensitivity and specificity using proven MGB chemistry. Achieve greater throughput, fast turnaround, and simplified ordering.

## Applied Biosystems™ NGS Hybrid Capture Solutions

Applied Biosystems™ NGS hybrid capture solutions support a sample-to-hybrid capture target enrichment workflow that helps generate high-quality, sequencing-ready libraries for efficient short-read sequencing. Uniform coverage and high on-target performance help labs use sequencing capacity more effectively. ---For Research Use Only. Not for use in diagnostic procedures.

## B•R•A•H•M•S MR-proADM KRYPTOR test

Thermo Scientific™ B·R·A·H·M·S MR-proADM™ is a test for early risk assessment in critically ill patients, complementing B·R·A·H·M·S PCT™ in sepsis management to help improve patient care. Stay ahead in critical care diagnostics with the combined power of PCT and MR-proADM on the B·R·A·H·M·S™ KRYPTOR™ analyzer family. 510(k) pending

## Diagnostic Services

Diagnostic Services integrates development, manufacturing, and regulatory systems to support compliance and scalable diagnostic performance across the lifecycle, which may help reduce operational and regulatory risk while supporting execution in complex global markets.

## EXENT® System

The EXENT System is the latest innovative solution from the Binding Site, part of Thermo Fisher Scientific. The system combines the EXENT Analyzer with the EXENT GAM Assay* to provide a fully automated solution to isotype and measure monoclonal proteins. The EXENT® System combines EXENT® Analyser with Immunoglobulin Isotypes (GAM) for the EXENT® Analyser. *EXENT GAM Assay refers to Immunoglobulin Isotypes (GAM) for the EXENT® Analyzer.

## LabLink™ 360 quality assurance software

LabLink™ 360 is a quality assurance platform that speeds up QC review by bringing data, instruments, and insights into one central dashboard. It allows teams to monitor results in real time, spot issues sooner, and simplify troubleshooting, helping labs run more efficiently. *Barcodes available for selected platforms. Not all products are CE marked or have FDA clearance for sale in the U.S.

## MAS™ Omni™ Max Quality Controls: Load-&-Go

Thermo Scientific™ MAS™ Omni™ Max quality controls streamline daily QC with load-and-go barcoded* tubes that reduce manual steps, eliminate data entry, and improve turnaround time, helping laboratories simplify workflows, reduce errors, and focus more on patient testing.

## Thermo Scientific TSQ Certis Triple Quad Mass Spec

Thermo Scientific™ TSQ Certis™ Triple Quadrupole Mass Spectrometer delivers reliable, high-performance targeted analysis with advanced hardware and software. Designed for maximum uptime and productivity, it supports biopharma, clinical, environmental, and food testing labs with fast scanning, robust operation, and streamlined workflows.

# ADLM 2026 CLINICAL LAB EXPO PRODUCT SHOWCASE


## The Blood Gas Control Reinvented

Blood gas quality control, reimagined. CueSee® BGEM combines blood gases, electrolytes and metabolites in a revolutionary glass-ampoule delivery system that minimizes air exposure and pre-analytical errors. Five levels, 15-minute open-vial stability and broad instrument compatibility make BGEM testing safer, simpler and more reliable.


## One Drop. Four Answers. Complete Confidence.

Why run multiple controls when one can do it all? CueSee® Coag combines PT, INR, ACT and aPTT in a single control containing real plasma and blood cells. Five levels deliver broad reportable ranges while the innovative dual-chamber design provides fast activation, easy sampling and compatibility with virtually all POCT coagulation systems.


## All Real. All Fractions. All Yours.

The first CO-oximetry control built with real hemoglobin derivatives across clinically relevant ranges. CueSee® CO-OX delivers measurable $O_2$Hb, COHb and MetHb levels in one innovative device, enabling comprehensive verification of all major Hb fractions on virtually any CO-oximeter. Real hemoglobin. Real performance. Real confidence.


## Built for i-STAT. Ready for More.

Purpose-built for Abbott i-STAT BGEM cartridges, CueSee® VeriSTAT CSR combines blood gases, electrolytes, metabolites and hematocrit in a single ready-to-use control. The innovative CueSee® Ringe eliminates glass handling, reduces pre-analytical errors and provides 15 minutes of open-vial stability, allowing multiple tests from a single device.


## Precision Under Pressure

When standard controls stop, Hyperbaric CSR starts. Designed for extreme $pO_2$ and $pCO_2$ verification, this innovative blood gas control helps laboratories validate high-end analytical measurement ranges with confidence. Delivered in the CueSee® Ringe (CSR), it combines exceptional stability, safe handling and simplified testing for critical applications where accuracy matters most.

## GR01 HPLC A1c Analyzer

Tosoh's GR01 HPLC A1c Analyzer is a fully automated analyzer that harnesses Tosoh's proprietary non-porous ion exchange HPLC column technology to deliver accurate, reproducible A1c results in just 50 seconds — while also detecting the most common hemoglobin variants. The GR01 delivers excellent precision with CVs ≤ 1.1% (NGSP Units).

## LeadCare® II

LeadCare® II brings CLIA-waived blood lead testing to the point of care — so you can test, educate, and act in a single visit. For physician offices, every well-child visit is an opportunity to protect a child's development and long-term health. With rapid results, LeadCare® II eliminates delays and enables immediate counseling and confident next steps when it matters most.


## StatID PRO™ COVID-19/Flu A&B

StatID PRO™ assays are lateral flow immunochromatographic tests designed for rapid, multiplex detection of respiratory pathogens. With simple workflows and clear visual results, these assays support efficient testing and timely clinical decisions at the point of care or in the lab.

## DxU 1800 System

The DxU 1800 Fully Automated Urinalysis System helps deliver accurate, results and seamless workflow. It integrates the DxU 1800c Urine Chemistry and DxU Microscopy Series analyzers with Digital Flow Morphology and Auto Particle Recognition(APR) software. With a broad test menu and strip image capture linked to patient results, it reduces manual steps and enhances efficiency—enabling a simple, automated walkaway experience focused on patient care.

# ADLM 2026 CLINICAL LAB EXPO PRODUCT SHOWCASE

## Diaphragm Liquid Pump -FD 1.200

KNF diaphragm liquid pumps for dosing applications combine maximum performance with minimum size. The use of chemically resistant materials enables the pumps to convey virtually any type of liquid, whether neutral or corrosive. They are dry-running, self-priming, and maintenance free.

## BreathID – Urea Breath Testing for H. pylori

The BreathID Smart and Lab devices deliver rapid, non-invasive urea breath testing of H. pylori with lab-grade precision. Automated, intuitive, and compact, BreathID provides accurate results in minutes for both initial diagnosis and post-treatment eradication confirmation.

## BD BACTEC™ FXI.

Designed for the realities of today's clinical microbiology labs, BD BACTEC™ FXI Culture System unites proven clinical performance, advanced automation, streamlined workflows, gravimetric individual blood volume measurement, and scalable capacity. By illuminating sample quality, vial status and workflow priorities, it brings new clarity to the blood culture process, empowering clinical teams to move faster and with greater confidence in the fight against bloodstream infections and sepsis.

## Xevo™ TQ Absolute XR IVD Mass Spectrometer

"The Waters Xevo™ TQ Absolute XR IVD Mass Spectrometer is designed for regulated clinical laboratories requiring robust, sensitive, and reliable LC-MS/MS performance. Featuring innovative StepWave™ XR Ion Guide technology, it delivers exceptional resistance to contamination, enhanced sensitivity for low-level analytes, and consistent quantitative results while supporting high-throughput clinical testing workflows.

## Xevo™ TQD IVD Mass Spectrometer

The Waters Xevo™ TQD IVD Mass Spectrometer delivers reliable, routine LC-MS/MS performance for clinical diagnostic laboratories. Designed for regulated testing environments, it provides robust quantitative analysis, simplified operation, and proven analytical performance for a broad range of clinical applications, helping laboratories achieve accurate results with confidence and efficiency.

## BD COR™ System

High-Throughput Automation Without Compromise. The BD COR™ System is a fully automated, high-throughput molecular solution designed to scale routine testing while protecting staff time and lab resilience. The BD COR™ System offers innovative HPV testing that keeps up with evolving guidelines and patient needs with BD Onclarity™ HPV assay with at-home self-collection. (Self-collected vaginal specimens can be tested as an alternative specimen type when cervical sampling is either contraindicated or cervical samples otherwise cannot be obtained.)

## Labcorp Fentanyl Urine Visual Test

The Labcorp Fentanyl Urine Visual Test is an FDA-cleared, moderate complexity rapid urine test delivering results in 10 minutes. Designed for use by laboratory professionals, it detects norfentanyl to identify exposure and support fast clinical decisions, overdose prevention education, and timely patient care.

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A new entry point for automation. Deploy microbiology automation where you need it the most with the BD Kiestra™ ReadA+BarcodA intelligent labeling, incubation, and imaging system. Begin your automation journey with incubation to streamline workflows, enhance operational efficiency, and optimize the value of your resources.


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- Benzodiazepine Plus
- Buprenorphine
- Carisoprodol/ Meprobamate
- High Sensitivity Opiates
- Zolpidem

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ARK Diagnostics, Inc.

# Regulatory Roundup

## Roche gets CE mark for multiple sclerosis neuroinflammation test

Roche's Elecsys Neurofilament Light Chain (NfL) test received CE mark approval for the detection and assessment of neuroinflammation in patients diagnosed with relapsing-remitting multiple sclerosis, the company recently announced.

The blood test measures the NfL protein to detect neuroinflammation associated with multiple sclerosis. It gives clinicians a minimally invasive way to monitor the biological damage caused by the disease. The assay could help make more regular monitoring a reality for more people living with the disease and result in earlier and better-informed clinical management, Roche said.

Performed on Roche's widely available cobas instruments, the Elecsys NfL test provides standardized and consistent results and ensures reliable insights regardless of where the test is carried out, the company said.

Although early and regular monitoring of disease activity plays a critical role in treatment optimization, some patients can find it difficult to access routine assessments such as MRI scanning that would allow timely detection of changes in their condition. With traditional testing for multiple sclerosis often limited by geographic, financial, or logistical barriers, Elecsys NfL will make frequent monitoring more practical and accessible, according to Roche.

### FDA APPROVES NATERA BLADDER CANCER TEST

Natera recently announced Food and Drug Administration (FDA) approval of Signatera CDx as a companion diagnostic for use with adjuvant Tecentriq (atezolizumab) immunotherapy in muscle-invasive bladder cancer (MIBC). Specifically, this approval authorizes the use of Signatera CDx to identify patients with MIBC who are circulating tumor DNA minimal residual disease (MRD)-positive and may benefit from Tecentriq treatment.

This follows the October 2025 *New England Journal of Medicine* publication of results from the global Phase III IMvigor011 trial, which was sponsored by Genentech, the company that developed Tecentriq. The trial results demonstrated that Signatera MRD-positive patients treated with immunotherapy achieved significant improvements in disease-free survival and overall survival (OS), while Signatera MRD-negative patients achieved 97% 2-year OS with no adjuvant therapy at all.

According to Natera, this is the first companion diagnostic approval in the field of blood-based MRD.

### FDA APPROVES ESOPHAGEAL AND GASTROESOPHAGEAL CARCINOMA COMPANION DIAGNOSTIC

Agilent Technologies recently received Food and Drug Administration (FDA) approval for PD-L1 IHC 22C3 pharmDx, Code SK006, as the only companion diagnostic to help identify patients with esophageal or gastroesophageal junction (GEJ) carcinoma who may be eligible for treatment with Keytruda (pembrolizumab), Merck's anti-programmed cell death protein 1 therapy.

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**The designation is based on study results showing a 96.7% sensitivity for schizophrenia, 100% specificity for bipolar I disorder, and 98.3% overall accuracy.**

Keytruda is indicated for the treatment of patients with locally advanced or metastatic esophageal or GEJ (tumors with epicenter 1–5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation in combination with platinum- and fluoropyrimidine-based chemotherapy for patients with tumors that express programmed death-ligand 1 (PD-L1) with a combined positive score of 1 or greater.

The FDA previously approved other companion diagnostic indications for the test with Keytruda, including nonsmall cell lung cancer and esophageal squamous cell carcinoma; cervical cancer and head and neck squamous cell carcinoma; triple-negative breast cancer; gastric or GEJ adenocarcinoma; and epithelial ovarian, fallopian tube, and primary peritoneal carcinoma.

### ● FDA APPROVES NEW GUARDANT360 LIQUID CDX

Guardant Health recently earned Food and Drug Administration (FDA) approval for its new Guardant360 Liquid CDx.

The test is the largest FDA-approved liquid biopsy panel, assessing a 100-times wider genomic footprint than the previously approved Guardant360 CDx.

Companion diagnostic indications for the previously approved version of Guardant360 CDx transfer to the newly approved version of Guardant360 Liquid CDx, according to the company. The newer version uses Guardant's Smart Platform, which integrates genomic and epigenomic profiling from a single blood draw, providing a several-fold increase in sensitivity for circulating tumor DNA detection compared to the previous version.

The newer test is also the first liquid biopsy to simultaneously define genotype and key phenotype information. It delivers results in as few as 7 days, providing information for clinical decisions regardless of tissue availability, line of therapy, or practice setting, according to Guardant.

### ● FDA BREAKTHROUGH DEVICE DESIGNATION FOR SCHIZOPHRENIA AND BIPOLAR DISORDER BLOOD TEST

Laguna Diagnostics has received Food and Drug Administration (FDA) breakthrough device designation for its mRNA Gene Biomarker Test, designed to help differentiate schizophrenia and bipolar disorder in symptomatic patients.

Research suggests misdiagnosis rates for these conditions may exceed 50%, with current methods often requiring up to 3 years to reach a conclusion, Laguna said.

The test uses mRNA biomarker signatures from a blood sample to generate an objective probability score. The test is intended for use in conjunction with clinical assessment and other patient information.

Laguna said the designation is based on study results showing a 96.7% sensitivity for schizophrenia, 100% specificity for bipolar I disorder, and 98.3% overall accuracy.

The FDA designation does not guarantee marketing approval. Laguna said it is pursuing further validation studies.

### ● FOUNDATIONONE FDA-APPROVED AS COMPANION DIAGNOSTIC FOR NSCLC MUTATION

Foundation Medicine recently announced that it received Food and Drug Administration (FDA) approval for its FoundationOne CDx as a companion diagnostic for Tepmetko (tepotinib) to identify patients with metastatic nonsmall cell lung cancer harboring MET exon 14 skipping alterations.

The announcement follows an initial approval in November 2024, when the FDA first approved FoundationOne Liquid CDx as a companion diagnostic to identify patients who may be eligible for Tepmetko from a blood plasma sample. With the more recent approval, the FDA now allows both tissue and liquid biopsy approaches from Foundation Medicine's tissue and liquid biopsy tests to be used to identify patients who may be eligible for tepotinib treatment.

The recent approval for FoundationOne CDx is the first to include the company's real-world data-based service. It supports drug and diagnostic label expansion by supplementing clinical trials with curated real-world evidence and integrated regulatory support. Drawing on data from more than 150,000 patients in the Flatiron Health-Foundation Medicine Clinico-genomic Database, Foundation Medicine can generate relevant and harmonized real-world data cohorts. These reduce the need for incremental patient enrollment and maintain the rigor required for regulatory use in companion diagnostic projects, the company said.

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# Industry Playbook

## LabCorp and CHOP to work together on advanced pediatric diagnostics

LabCorp and Children's Hospital of Philadelphia (CHOP) recently announced a strategic collaboration to speed up the discovery, development, and nationwide availability of specialized pediatric diagnostics.

CHOP and LabCorp said they intend to create a joint pediatric diagnostics innovation pipeline. It will identify, develop, and expand new pediatric-specific tests and technologies in key clinical areas, such as oncology, metabolic disease, and autoimmune conditions. These diagnostics will deliver more accurate, age-appropriate insights for children by accounting for their unique biology, developmental stages, and physiological ranges. Traditional adult-oriented diagnostics often overlook these factors, CHOP and LabCorp said.

Officials from both organizations said their collaboration will deliver these new specialized tests to children and their families more efficiently and at greater scale.

### PTS DIAGNOSTICS DISCONTINUES A1C PRODUCT

The PTS Diagnostics A1CNow+ Controls (REF 737) has been discontinued in the United States and the Maldives due to supply chain limitations, the manufacturer recently announced.

PTS will continue to support any remaining product through its labeled expiration date. This change is not related to product quality or performance, the manufacturer said.

PTS Diagnostics recommends HbA1c controls manufactured by Nova-One Diagnostics to support continued quality control testing. Nova-One A1C Control Solutions (NOD13111-100 and NOD13122-100) are compatible with the A1CNow+ system and may be used for routine quality control testing in place of A1CNow+ Controls.

The Nova-One product includes liquid control material that requires no reconstitution, normal and abnormal control levels for routine quality control verification, and formulation via stabilized human whole blood to simulate patient samples, PTS Diagnostics said. Additionally, Nova-One has a kit that includes disposable pipettes, requires no charge sample mounting slides, and offers refrigerated stability for up to 180 days when properly stored.

### ROCHE TO ACQUIRE PATHAI

Roche recently announced it has entered into a definitive merger agreement to acquire PathAI, a United States-based digital pathology and artificial intelligence (AI)-powered technology company that serves pathology laboratories and the biopharma industry.

Roche said that PathAI's Image Management System with advanced AI analysis and workflow capabilities will complement its own digital pathology portfolio to drive laboratory efficiency. By joining Roche's companion diagnostics and PathAI's advanced AI platform, Roche officials said they hope the acquisition will accelerate clinical therapy, foster the discovery of new biomarkers, create novel diagnostic tools, and speed personalized healthcare.

The acquisition strengthens Roche's position in digital pathology, which involves creating high-resolution digital images from physical tissue on slides, allowing use of AI tools to facilitate diagnostic workflows and provide patients with faster results, the company said.

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### ORIGIN SCIENCES PARTNERS WITH PRIMERDESIGN ON NOVEL RECTAL MUCOSAL EXTRACTION WORKFLOW

Primerdesign, which is part of the Novacyt Group, and Origin Sciences have announced a strategic partnership on a new protocol that optimizes DNA extraction from novel rectal mucosal samples.

The partnership involves Origin's OriCol, which enables reliable, rapid, minimally invasive sample collection of rectal mucus for colorectal cancer and advanced adenoma testing. Primerdesign offers capabilities in custom assay development and nucleic acid extraction solutions as part of its exsig Mag range.

The companies said that they intend to develop robust and reproducible sample collection and nucleic acid extraction workflows with consistent performance and high DNA yields from rectal mucus samples. The samples contain cells and molecular signals shed from the lining of the entire colon, providing a diverse and consistent biospecimen for representative gut examination. The workflows will be suited for detecting the earliest signs of gastrointestinal disease, as well as residual disease monitoring, treatment selection, and recurrence surveillance.

### TELCOR ACQUIRES SAMPLE HEALTHCARE

The laboratory technology company Telcor recently announced its acquisition of Sample Healthcare.

By combining its revenue cycle system with Sample's artificial intelligence (AI)-driven workflow platform, which is designed to execute revenue cycle and clinical operations workflows, Telcor will offer tools that help organizations execute high-impact workflows such as prior authorizations, appeals, payer follow-up, and document processing, the company said.

The new, combined platform enables organizations to execute high-impact revenue cycle workflows, reduce dependency on labor-intensive processes, and improve collections, speed, and accuracy, Telcor said.

Sample Healthcare will continue to offer its standalone platform, enabling organizations to execute workflows within their existing systems. Sample's platform uses AI to interpret unstructured data and execute multistep workflows. Deployments can be in use within weeks, with most customers starting with a targeted workflow and expanding with proven return on investment. Customers can deploy the Sample platform independently or as part of the Telcor platform.

### PATTERN BIOSCIENCE INFECTIOUS DISEASE TRIAL HITS ENROLLMENT HALFWAY POINT

Pattern Bioscience recently announced that it now has more than 1,000 samples in its ongoing multicenter United States clinical trial evaluating the Pattern Pneumonia ID/AST Panel and Panel System.

Researchers aim to collect 2,000 samples in the study, which is intended to support a 510(k) regulatory submission for Pattern's first commercial test. According to the company, the test is the first culture-free, rapid phenotypic identification and antimicrobial susceptibility testing (ID/AST) panel for critically ill patients with suspected pneumonia, a leading cause of sepsis.

Currently, clinicians must often wait 2–4 days for conventional culture-based methods to return pathogen identification and antimicrobial susceptibility results. This delay contributes to higher mortality, prolonged intensive care unit stays, and the spread of antimicrobial resistance. Pattern's single-cell microbiology technology would speed up care by analyzing bacterial cells directly from respiratory specimens, enabling pathogen identification and phenotypic antimicrobial susceptibility results in hours, the company said.

Pattern officials said that the test would be a way to quickly get patients appropriate antibiotic therapy based on phenotypic susceptibility data and that this capability does not exist today.

## Index to Advertisers

# Ask The Expert

## Incorporating wearable data into clinical workflows to improve health outcomes

By Earnest J. P. Daniel, PhD

**Why should laboratory professionals care about wearable devices?**

**a:** Wearable devices are now generating clinically relevant data at an unprecedented tsunami scale. Patients with diabetes, hypertension, obesity, and cardiovascular disease produce endless data from continuous glucose monitors (CGM), wearable electrocardiography patches, blood pressure devices, pulse oximeters, and sleep trackers. Yet most of this data remains within proprietary apps and is not integrated into the electronic health record (EHR), resulting in a disconnect from clinical decision-making.

Labs should take deliberate steps to integrate wearable data into existing laboratory data systems. First, Food and Drug Administration (FDA)-approved devices should be treated as analytical tools that must be validated with the same rigor that we use to validate laboratory assays. Second, labs should use selective, threshold-based integration into existing laboratory information systems (LIS) rather than attempting to import raw continuous data streams.

If laboratories do not engage, wearable data will be interpreted without analytical oversight, and clinical errors will follow. Clinical laboratories are uniquely positioned to serve as the integration hub with device manufacturers because we already specialize in validating methodologies, managing longitudinal patient data, and defining clinical thresholds. This is not a disruption but a natural extension of what we already do well.

**What does CGM tell us that traditional cardiometabolic markers don't?**

CGM extends clinical insight beyond HbA1c by capturing time in range and glycemic variability (Diabetes Care 2024; doi.org/10.2337/dci24-0073). The current consensus endorses coefficient of variation (CV) as a standardized measure of glycemic variability, with CV >36% indicating clinically significant instability (Diabetes Care 2017; doi: 10.2337/dc17-1600). For example, two patients may have identical HbA1c values yet completely different glycemic variability profiles. It is the patient with high variability who carries greater cardiometabolic burden, but this is not evident from a 3-month HbA1c.

CGM is well established for hypoglycemia prevention through real-time alerts. However, recent evidence suggests that time below range alone does not fully predict severe hypoglycemia and must be interpreted within clinical context (Diabetes Care 2026; doi.org/10.2337/dc25-2353). For hyperglycemia, CGM-integrated insulin systems improve glycemic stability and allow earlier detection of deterioration toward metabolic decompensation.

Beyond glucose, heart rate variability reflects autonomic dysfunction and cardiometabolic risk, while blood pressure wearables are moving toward broader clinical adoption. The laboratory's role is to integrate these dynamic signals with traditional biomarkers such as lipid profiles, high-sensitivity C-reactive protein, and natriuretic peptides to create a more complete risk assessment.

**How should laboratories operationalize integration?**

Data integration must happen at three levels. At the data ingestion level, application programming interfaces that are compatible with fast healthcare interoperability resources allow device platforms to communicate seamlessly with LIS and EHR systems, ensuring interoperable data transfer. At the data processing level, continuous signals must be converted into clinically interpretable summary metrics using standardized validated algorithms. Finally, wearable metrics should be integrated alongside traditional laboratory results in unified, clinical dashboards.

*Interested in learning more? Attend the ADLM 2026 roundtable, "AI-driven precision medicine: Integrating wearable data streams to stratify cardio-metabolic risk and management," on Monday, July 27, in Anaheim, California. Find out more at meeting.myadlm.org.*

**Earnest J. P. Daniel, PhD,** is a clinical chemistry fellow from Baylor College of Medicine and Texas Children's Hospital in Houston.

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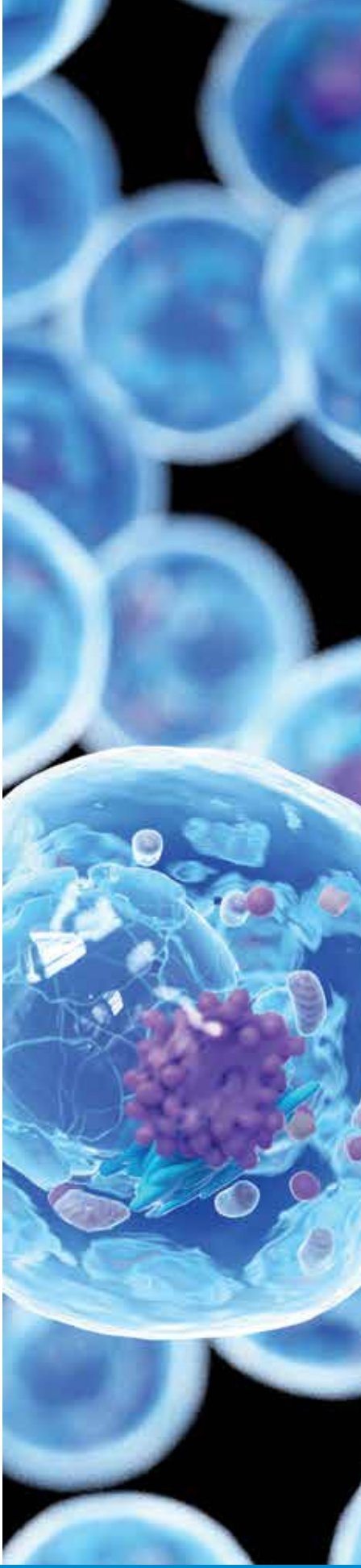



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