January/February 2026

CLN Clinical Laboratory News

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IMPROVING ESTIMATION OF LDL-C

~10%–20%

The increase in correctly classified patients with low LDL-C enabled by a new equation.

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Puzzling over the latest thrombophilia testing guidelines

Spotlight on the DCLS degree

Drug testing for the ED

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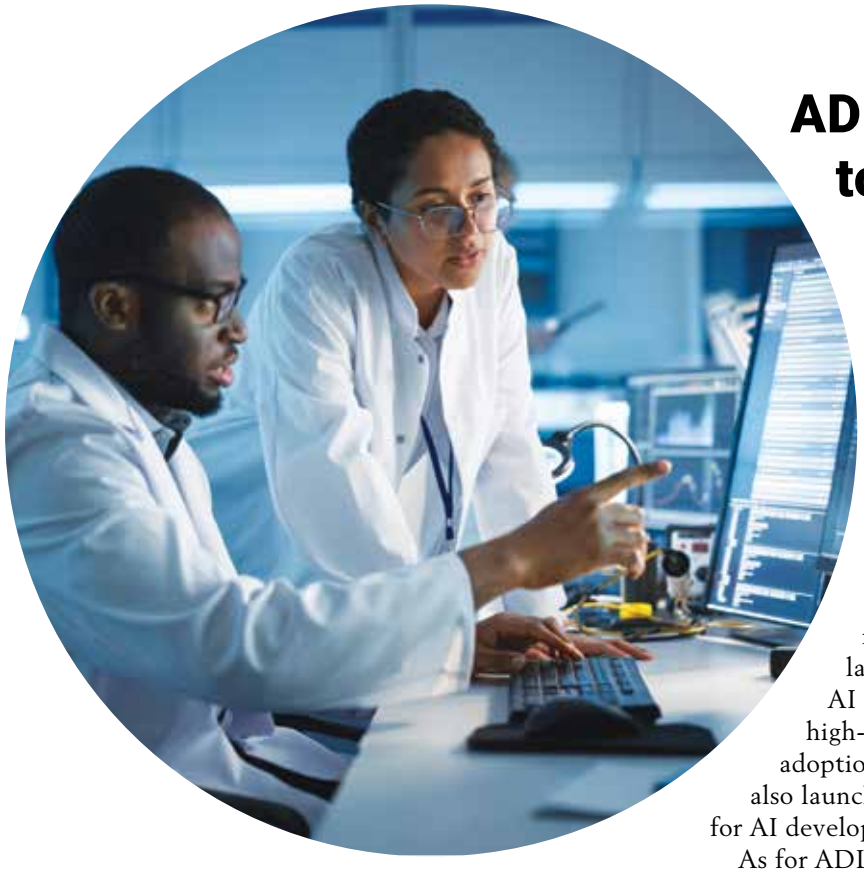

ADLM supports FDA effort to develop regulations for AI medical devices

The Association for Diagnostics & Laboratory Medicine (ADLM) has endorsed the Food and Drug Administration's (FDA) efforts to develop an appropriate regulatory framework for medical devices that utilize artificial intelligence (AI). In a letter addressed to the FDA's Digital Health Center of Excellence, the association offered several comments to assist the agency in this endeavor.

This contributes to a developing effort in the healthcare industry to govern healthcare AI amidst a lag in federal regulations. With legislators unlikely to pass a comprehensive law on the technology anytime soon, the Coalition for Health AI recently partnered with the Joint Commission to release high-level guidance to aid health systems in the responsible adoption of AI. The Utilization Review Accreditation Commission also launched a health AI accreditation program with two tracks, one for AI developers and another for AI users.

As for ADLM, its letter recommended that, when developing an AI oversight framework, the FDA should draw on lessons learned from the rigorous quality systems that clinical laboratories use to ensure test accuracy and reproducibility. Specific suggestions the association made include the following:

- All AI tools integrated with the performance of clinical laboratory tests should undergo a robust validation process similar to that which is used for laboratory tests themselves. This validation process should be used to characterize AI tools' performance and ensure safety for clinical use prior to use in patient care.
- Like laboratory quality systems, AI medical devices should undergo external evaluation via a third-party that assesses the accuracy of their performance. This mode of validation could be particularly helpful for AI tools that adapt over time.
- AI algorithms used in the performance of laboratory testing should also be subject to validation and verification protocols. Like any clinical laboratory test system, the use of these algorithms beyond the validated protocols should be restricted.

Finally, ADLM urged the FDA to include clinical laboratorians in the oversight of AI algorithms used in ordering and interpreting laboratory tests. Laboratorians understand the nuances of the performance and reporting of clinical laboratory testing, which is essential to mitigating the impact of variables that could cause AI tools to deviate from expected performance specifications.

BILL PROPOSED THAT COULD GAIN MEDICARE RECOGNITION FOR GENETIC COUNSELORS

The National Society of Genetic Counselors (NSGC) recently reintroduced a bill to Congress that would allow its members to bill Medicare.

The bill, H.R. 6280, which was introduced by U.S. Reps. Adrian Smith (R-Neb.) and Kathy Caster (D-Fla.), directs the Centers for Medicare and Medicaid Services to recognize genetic counselors as medical providers, allowing them to receive direct Medicare reimbursement. The bill requests that

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genetic counselors receive recognition specifically under Medicare Part B, which would allow direct beneficiary access to genetic counseling services.

Although genetic counselors do not currently receive Medicare recognition, other types of providers, including nurse practitioners and physician's assistants, can bill Medicare for genetic counseling services, even if they lack the master's degree-level genetics training that certified genetic counselors have. Medicare's lack of recognition has prompted some genetic counselors to question the value of the "genetic counselor" title.

Genetic counselors play a significant role in genetic testing. "[They] serve as connectors to the personalized care that could make all the difference for Medicare patients and their families facing diseases like hereditary cancer and Alzheimer's disease," Sara Pirzadeh-Miller, president of the NSGC and a cancer genetic counselor in Texas, said in a statement.

A counterpart bill, sponsored by Sens. John Barrasso (R-Wyo.) and Peter Welch (D-Vt.) will be introduced in the U.S. Senate in the coming months, NSGC said.

● REPORT REVEALS PRIVACY WEAKNESSES IN NIH CYBERSECURITY FOR ALL OF US PATIENT DATA

A recent report from the Office of Inspector General (OIG) identified shortcomings in cybersecurity measures intended to protect participants in the National Institutes of Health's (NIH) All of Us Research Program.

The NIH concurred with all five of the OIG's recommendations and described actions that it and VUMC have taken and plan to take to address them.

The Data and Research Center (DRC) houses the program's participant data and is maintained by Vanderbilt University Medical Center (VUMC), which received an NIH award to support managing it. In early November 2025, the OIG conducted an audit to examine whether the NIH ensured that VUMC had adequately limited access to research data, implemented required information security and privacy controls, and remediated information security and privacy weaknesses in accordance with federal requirements.

Based on the audit's findings, the OIG determined that, while VUMC had implemented some cybersecurity controls to protect participant data, NIH did not ensure that VUMC limited the access of authorized data users to the research data in accordance with the program's policies; communicate with VUMC about national security concerns associated with maintaining genomic data in order to enable the appropriate selection of privacy cybersecurity controls; or ensure that security and privacy weaknesses were remediated within federally required timeframes.

The OIG issued five recommendations to NIH to improve its oversight of the All of Us Research Program's DRC. These recommendations urged NIH to:

- Require that VUMC implement access controls to prevent internal users from accessing systems while abroad without verified approval.
- Require VUMC to implement a control to prevent the downloading of detailed participant data as required by the All of Us Data Use Policies.
- Formally communicate national security concerns related to maintaining genomic data to All of Us award recipients that use or maintain it.
- Require VUMC to reevaluate the security categorization for the DRC and DRC Researcher Workbench information systems considering these national security concerns.
- Require VUMC to update the remediation timeframe in its system security plans to comply with the timeframes in its award agreement with NIH.

In a written response to the audit, the NIH concurred with all five of the OIG's recommendations and described actions that it and VUMC have taken and plan to take to address them.

The essential partnership: Laboratory medicine professionals as drivers of in vitro diagnostics innovation

BY FREDERICK G. STRATHMANN, PHD, MBA, DABCC (CC, TC)

Frederick G. Strathmann, PhD, MBA, DABCC (CC, TC)

The rapid evolution of in vitro diagnostics (IVD) and clinical laboratory testing demands a sophisticated level of partnership between commercial manufacturers and the clinical laboratory community that leverages their combined strengths. Laboratory medicine professionals must be recognized not simply as end-users of diagnostic tools, but rather as co-producers of diagnostic quality and innovation. These professionals play a pivotal role in the healthcare system by providing services that are critical to patient well-being, diagnosis, treatment, and management. In particular, they can support vendor product development across four primary dimensions: clinical problem framing, design collaboration, evaluation partnership, and post-market data generation.

Labs as problem identifiers and innovators

Laboratory professionals are often the first to identify clinical needs that commercial solutions fail to address, thereby serving as problem framers for future vendor roadmaps (*1*). CLIA-designated high-complexity laboratories create laboratory developed tests (LDTs) either because a suitable Food and Drug Administration (FDA)-cleared IVD is unavailable, or because the lab needs to extend or modify existing kits to meet a specific clinical requirement. This process is common in rapidly evolving fields such as genetic testing, toxicology, and pediatric testing where the pace of scientific discovery often outruns the lengthy FDA review process.

In such cases, LDTs may serve as early prototypes for tests that could eventually be submitted to FDA for commercial authorization. This is one of the many ways in which laboratories actively fill gaps that vendors could address more effectively by routinely engaging with laboratorians in a wide variety of environments.

Labs as co-designers and evaluators of technology

The FDA's requirements for IVD clinical performance studies implicitly position clinical laboratories as essential partners in both study design and execution. As a result, IVD manufacturers rely heavily on clinical laboratories to demonstrate the reliability and robustness of new assays through reproducibility and performance studies. In particular, manufacturers are often dependent on clinical laboratories for essential needs such as access to clinical sites, patients, and specimens, as well as the timely and rigorous execution of clinical trials. Laboratory professionals are also critical in guiding vendors on real-world workflows, clinically relevant endpoints, and precise sample handling protocols (*2*).

Labs as stewards of interoperability and data quality

In the contemporary healthcare ecosystem, diagnostic data must flow seamlessly between laboratory analyzers, laboratory information systems (LIS), and electronic health records. However, nonstandardized encoding practices used by IVD manufacturers and other vendors lead to significant challenges in managing and analyzing laboratory data. Studies have shown that the integrity of data moving from the analyzer to the LIS can drop to as low as 59%, resulting in an actual data integrity rate of only 22%-68% throughout a single lab data lifecycle round-trip (*3*). This poor data integrity is often caused by manual transformation and translation errors.

To overcome these obstacles, the Association for Diagnostics & Laboratory Medicine (ADLM) supports efforts to improve the interoperability of laboratory test

results and calls for collaboration among healthcare providers, manufacturers, informatics vendors, and payers to establish a common framework for information standards (*4*). Laboratory experts need to be involved early in product design to define what standardized data elements are needed to ensure that information is consistently structured and interpreted across different settings.

The FDA's Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) collaboration exemplifies this approach, bringing together academic, federal, and industry partners to develop comprehensive solutions for clinical and semantic interoperability of IVDs across the entire data lifecycle (*5*). SHIELD aims to build a publicly accessible infrastructure to improve the quality, interoperability, and portability of IVD laboratory data.

Partnerships for implementing novel solutions

Laboratories have high expectations for collaborations with IVD manufacturers regarding the adoption and implementation of artificial intelligence (AI) and machine learning tools. Laboratory professionals widely predict that AI will have a dramatic impact on current diagnostic testing processes. The greatest immediate potential cited for AI applications is increased operational efficiency, achieved through automating repetitive tasks, mitigating manual labor, and improving diagnostic test utilization (*6*). This requires laboratories to guide vendors on validating AI-enabled products using outcomes data and real-world evidence to demonstrate clinical utility.

Tips for getting started with vendor partnerships

To initiate the process of collaborating with vendors and shaping product development, laboratory medicine professionals should focus on consistently providing meaningful feedback and engaging in structured dialogue with manufacturers. One direct pathway is participating in surveys commissioned by vendors and market research organizations, which seek input on laboratory needs, concerns, and expectations regarding new technologies.

Beyond formal research, professionals should seek other opportunities to convey diagnostic testing needs and offer input on workflow requirements. This engagement can occur during scheduled sales calls, where laboratories can provide meaningful feedback and discuss areas where commercial solutions may be lacking, thereby acting as clinical problem framers. Similarly, interactions at tradeshows can be leveraged to establish and refresh relationships with industry, helping to accelerate the pace of development and translation of advancements into routine clinical practice. The goal of this consistent engagement is to foster an interactive, bidirectional relationship that involves the exchange of ideas, resources, and expertise to accelerate diagnostic advancements.

In conclusion, the partnership between laboratory medicine professionals and IVD vendors must move beyond a transactional relationship to a fully integrated collaborative model. By embracing the critical roles of problem framers, co-designers, and data quality stewards, laboratory professionals ensure that regulatory requirements are met, innovation is fostered, and diagnostic tools achieve the highest levels of safety and clinical utility for patients.

References

1. The Pew Charitable Trusts. The role of lab-developed tests in the in vitro diagnostics market. https://www.pew.org/en/research-and-analysis/reports/2021/10/the-role-of-lab-developed-tests-in-the-in-vitro-diagnostics-market (Accessed December 4, 2025).
2. Durack DT, Dunn JJ. Fostering partnerships between industry and the clinical microbiology laboratory. J Clin Microbiol 2011; doi: 10.1128/JCM.01064-11.
3. Bernstam EV, Warner JL, Krauss JC, et al. Quantitating and assessing interoperability between electronic health records. J Am Med Inform Assoc 2022; doi:10.1093/jamia/ocab289.
4. ADLM. Interoperability of clinical laboratory results. https://myadlm.org/advocacy-and-outreach/position-statements/2023/interoperability-of-clinical-laboratory-results (Accessed December 15, 2025).
5. FDA. SHIELD. https://www.fda.gov/medical-devices/diagnostic-data-program/systemic-harmonization-and-interoperability-enhancement-laboratory-data-shield (Accessed December 4, 2025).
6. Rabbani N, Kim GYE, Suarez CJ, et al. Applications of machine learning in routine laboratory medicine: Current state and future directions. Clin Biochem 2022; doi: 10.1016/j.clinbiochem.2022.02.011.

Frederick G. Strathmann, PhD, MBA, DABCC (CC, TC), is senior vice president of global business and MOBILion Systems in Chadds Ford, Pennsylvania and additionally serves as a part-time CLIA lab director for multiple organizations.

+EMAIL: frederick.strathmann@mobilionsystems.com

The Sample

Update to equation for estimating LDL-C proposed

Researchers recently described a more accurate equation for estimating low-density lipoprotein cholesterol (LDL-C) and identifying high-risk patients who could benefit from more intensive lipid-lowering therapy (Clin Chem 2025; doi:org/10.1093/clinchem/hvaf099).

The original Sampson-NIH equation has been used widely to standardize routine LDL-C assays because of its accuracy, especially in individuals with high triglycerides or very low LDL-C levels. The equation uses standard lipid panel measurements, including total cholesterol, high-density lipoprotein cholesterol (HDL-C), and triglycerides, to calculate LDL-C without the need for a specialized ultracentrifuge.

The researchers aimed to improve the equation because recent guidelines emphasize the need to lower LDL-C levels. They developed and tested a modified Sampson equation by least-squares regression to match LDL-C by the β-quantification reference method. They combined terms into non-HDL-C, which is defined as non-HDL-C total cholesterol minus HDL-C, and forced the coefficient to be 1. Then they applied the equation to 24,590 lipid panel results from Mayo Clinic and 9,605 from the Further Cardiovascular Outcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk clinical trial of evolocumab.

The modified Sampson equation showed significant improvement in concordance with the reference methods when compared with other equations. By overall kappa analysis, it showed the best agreement at the 55 mg/dL cutoff point of 0.98, as compared with 0.96 for the original equation, 0.96 for Martin-Hopkins, and 0.94 for Friedewald. At the 70 mg/dL cutoff point, those figures were 0.97 for the modified equation, 0.94 for the original equation, 0.95 for Martin-Hopkins, and 0.92 for Friedewald.

Based on its net reclassification index, the new equation increases the percentage of correctly classified patients with low LDL-C by approximately 10%–20% compared with the other equations.

The equation could improve identification of high-risk and very high-risk patients who fall short of LDL-C goals and need more lipid-lowering therapy. The researchers called for further testing of it in more cohorts.

PLASMA PROFILE LINKED TO FAMILY HISTORY OF EARLY ONSET HEART DISEASE

A specific pattern of plasma proteins in the blood may indicate an increased risk of hereditary coronary atherosclerosis, a recent study finds (Circ Genom Precis Med 2025; doi: 10.1161/CIRCGEN.124.005220).

Much coronary heart disease (CHD) heritability can be explained by risk factors, but a significant proportion of CHD remains unexplained. The researchers wanted to identify circulating proteins associated with a family history of early-onset CHD and conduct further examination of the relationship between identified proteins and coronary atherosclerotic burden in subjects with and without a family history of CHD.

The researchers studied data on coronary atherosclerotic burden from computed tomography angiography and proteonomics for 4,521 Swedish subjects without known CHD. They retrieved records of myocardial infarction and coronary

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revascularization therapies in any parent or sibling of subjects from national registers in Sweden and adjusted the linear associations between family history for age, sex, and study site. The researchers also studied statistical interactions between proteins and family history to better understand the association between proteins and the coronary atherosclerotic burden. Then, they performed Mendelian randomization for causal associations between proteins and CHD by using genome-wide association study summary data from the UK Biobank Pharma Proteomics Project, an international effort that combines data from large scale genetic studies to identify risk loci for coronary artery disease and myocardial infarction, and FinnGen, a Finnish genomics and personalized medicine research project.

The researchers found family history of early-onset CHD in 9.5% of subjects and associations between family history and features of inflammation, lipid metabolism, and vascular function. The strongest associations were for follistatin and cathepsin D, neither of which were attenuated by adjusting for cardiovascular risk factors. Eighteen proteins were statistical interactors with family history in the association between each protein and the coronary atherosclerotic burden, especially the LDL receptor, transferrin receptor protein 1, and platelet endothelial cell adhesion molecule 1 (PECAM1).

Further analysis revealed a new association for follistatin and myocardial infarction, plus previously seen associations for proprotein convertase subtilisin/kexin type 9 (PCSK9) and PECAM1.

The experimental gene therapy restored and maintained immune system function in 59 of the 62 patients.

These findings establish a possible causal relationship between PCSK9, PECAM1, and follistatin and myocardial infarction, with implications for further understanding of the pathophysiology of CHD, the researchers wrote.

GENE THERAPY GIVES LONG-TERM IMMUNE PROTECTION FROM RARE DISEASE

Long-term findings in patients with severe combined immunodeficiency (SCID) due to adenosine deaminase (ADA) deficiency (ADA-SCID) point to the efficacy and safety of autologous CD34+ hematopoietic stem-cell lentiviral gene therapy for the disorder (N Engl J Med 2025; doi: 10.1056/NEJMoa2502754).

The current standard treatments for ADA-SCID — allogeneic hematopoietic stem-cell transplantation (HSCT) from a matched donor or weekly enzyme injections — have limitations and potential long-term risks. However, HSCT outcomes showed improvement in recent years, especially with the widespread adoption of newborn screening for SCID.

Clinical trials have examined lentiviral gene therapy for the life-threatening inborn error of metabolism. Third-generation self-inactivating lentiviral vectors have been engineered for improved safety by removing transforming elements that are part of the lentivirus genome to avoid transactivation of oncogenes. The researchers previously developed and reported on a self-inactivating lentiviral vector, EFS-ADA LV, in a study of fewer patients. They aimed to test its efficacy and safety in a comprehensive long-term follow-up.

Between 2012 and 2019, the researchers treated 62 patients who had ADA-SCID with busulfan nonmyeloablative conditioning, followed by transplantation with autologous CD34+ hematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human ADA. The primary efficacy end points were overall survival and event-free survival, defined as survival free from rescue allogeneic hematopoietic stem-cell transplantation, reinitiation of enzyme-replacement therapy, and additional gene therapy. Secondary end points included no receipt of immunoglobulin-replacement therapy, the presence of protective titers to tetanus or pneumococcal vaccines, and sustained discontinuation of fungal or viral prophylaxis.

The experimental gene therapy restored and maintained immune system function in 59 of the 62 patients. Overall survival was 100%, and event-free survival was 95%. All 59 patients who underwent successful gene-marked engraftment at 6 months lacked sustained need for enzyme-replacement therapy and had stable gene marking, ADA enzyme activity, metabolic detoxification, and immune reconstitution through the last follow-up. No patients had leukoproliferative events or clonal expansions, the researchers reported.

Demystifying the DCLS degree

By straddling lab medicine and clinical practice, Doctor of Clinical Laboratory Science (DCLS) graduates improve patient care.

It's been a little over a decade since the first student was accepted into a Doctor of Clinical Laboratory Science (DCLS) program in 2014. Although the DCLS is still relatively new, graduates with this unique degree already are making an impact in clinical laboratories, healthcare settings, and private industry.

"One of ADLM's organizational values is to enable diverse laboratory teams and empower them to improve population health," said Association for Diagnostics & Laboratory Medicine (ADLM) President Paul Jannetto, PhD, DABCC, FADLM, MT(ASCP). "Laboratory scientists play an important role, including graduates of DCLS programs. These professionals really exemplify the highest ideals of laboratory medicine."

BY JEN A. MILLER

WHAT IS A DCLS?

The DCLS is a doctoral-level degree that focuses on increasing the value of diagnostics. Healthcare professionals with a DCLS are qualified both to conduct research and serve on interprofessional healthcare teams. As of 2024, DCLS degree-holders also are board-eligible and qualified as CLIA high-complexity laboratory directors.

The key difference between a DCLS and other advanced laboratory degrees is that DCLS graduates don't solely work in laboratories. They're also part of patient care teams that collaborate closely with clinicians to order and interpret tests, thereby accelerating and enhancing clinical practice.

As part of their training, DCLS students complete a residency in which they participate in clinical rounds in healthcare settings. "As a result, they gain a holistic view of multidisciplinary care teams within the healthcare system," said Jannetto. The experience enables them to help bridge the gap between laboratory science and clinical practice.

Four institutions now offer DCLS programs: Rutgers University (the first to offer the degree), the University of Texas Medical Branch, the University of Kansas, and the University of Cincinnati. More universities are working toward adding them in the future.

WHY WAS THE DCLS CREATED?

The degree was created with two goals in mind: to reduce medical errors and to address critical laboratory personnel shortages.

According to the National Academy of Medicine, between 210,000 and 400,000 preventable patient deaths occur in United States hospitals each year, many of which are caused by laboratory errors. A 2023 study in the *Journal of Patient Safety* found that 77.1% of diagnostic-testing errors happen in the preanalytical phase, 13.5% in the analytics phase, and 8% in the post-analytical phase. Human error is the most frequent cause, playing a role in 58.7% of cases.

The DCLS degree gives non-physician laboratory scientists a valuable opportunity to directly impact patient care, particularly by giving them more influence over the preanalytical phase. "They can update clinicians in real time as to why a test got rejected, or guide them in collecting samples properly, so they're not hemolyzed," said Jannetto. They also can counsel clinicians on the right test to use in the first place to prevent inappropriate assays from being ordered, rejected, and then reordered because clinicians didn't understand the reason behind the initial rejection. "Now a DCLS can be right there to prevent the delay of patient care," Jannetto added. "These graduates are having immediate impact and value."

Michael Laposata, MD, PhD, professor of pathology at the University of Texas Medical Branch, helped launch his institution's DCLS program after observing a need for high-level professionals who were cross-trained in laboratory medicine and patient care. DCLS students get that hands-on experience through their residencies. "We needed people who were clinically trained," he said. "You wouldn't graduate a surgeon without experience doing surgeries. How are you going to help in the clinical setting if you don't have any training?"

Staffing shortages remain a critical problem for clinical laboratories. Moreover, because older workers — and lab leaders — are retiring without enough staff to replace them, the impact of these deficits reaches even the highest levels. DCLS degrees offer a new pathway to cultivate lab professionals with the experience to take over those jobs.

Amitava Dasgupta, PhD, professor of pathology and laboratory medicine at the University of Kansas Medical Center, sees this as a natural progression in the understanding of who can run a clinical laboratory. He sees a parallel from when he was coming up in his own career. Back then, he was

"As a result, they gain a holistic view of multidisciplinary care teams within the healthcare system." — Paul Jannetto

told that medical directors needed to have an MD. However, eventually that changed, and PhDs were considered satisfactory credentials. "Now the Centers for Medicare & Medicaid Services is doing the same thing for DCLS degrees," Dasgupta said.

WHAT ARE RECENT DCLS GRADUATES DOING NOW?

As more DCLS graduates enter the field, they bring their distinctive skills to healthcare settings and industry.

Melody Nelson, DCLS, CC(NRCC), MS, MLS(ASCP), is a clinical assistant professor of pathology and laboratory medicine at the University of Kansas Medical Center and assistant director of the core laboratory at the University of Kansas Health System. Before starting the DCLS program at the University of Kansas, she was a laboratory scientist for about 10 years, and her experience included working as a manager in a core lab that supported a primary healthcare system. She went on to receive her DCLS degree in 2023.

"I saw the value of a consultation-type model where the lab is always within reach," she said. She had an open-door policy, which led to clinicians coming to her with their ordering questions. That made her realize there "really was an appetite" for someone with a DCLS-level degree.

Nelson's positive residency experience reinforced to her that she'd made the right decision in pursuing a DCLS, especially when clinicians would consult her during rounds. "I was able to do problem-solving work and liaise between the laboratory and interdisciplinary teams," she said. She cultivated a deeper understanding of where the lab intersects with patient-care models. "We care about patients, but the way that we care is different than [clinicians] do, and we have to intersect at the right point to not make it a challenge," she said.

LaShanta Brice, DCLS, MLS (ASCP)SH, graduated with her DCLS from the University of Texas Medical Branch in 2021. She entered the DCLS program after realizing that a traditional doctorate was not the right fit for her. It was a risk, but one that paid off. After working in the clinical laboratory setting for 15 years, she moved to industry. Brice now serves as the scientific engagement and clinical education scientist for Diagnostica Stago.

Much like those in clinical practice, DCLS graduates who go into industry jobs bridge two worlds. "When you look at scientific affairs or clinical affairs roles, oftentimes they don't have the voice of the laboratorian," Brice said. "What works in theory may not work in practice." She too credits doing clinical rounds as part of her education for giving her a unique perspective on laboratory medicine and patient care as a whole.

Brice believes that she was the only candidate with a DCLS when she first began talking to industry employers about job opportunities.In the time since, however, she has noticed other in vitro diagnostic companies listing the DCLS as a qualifying degree for open positions.

HOW DO DCLS GRADUATES CONTRIBUTE TO HEALTHCARE?

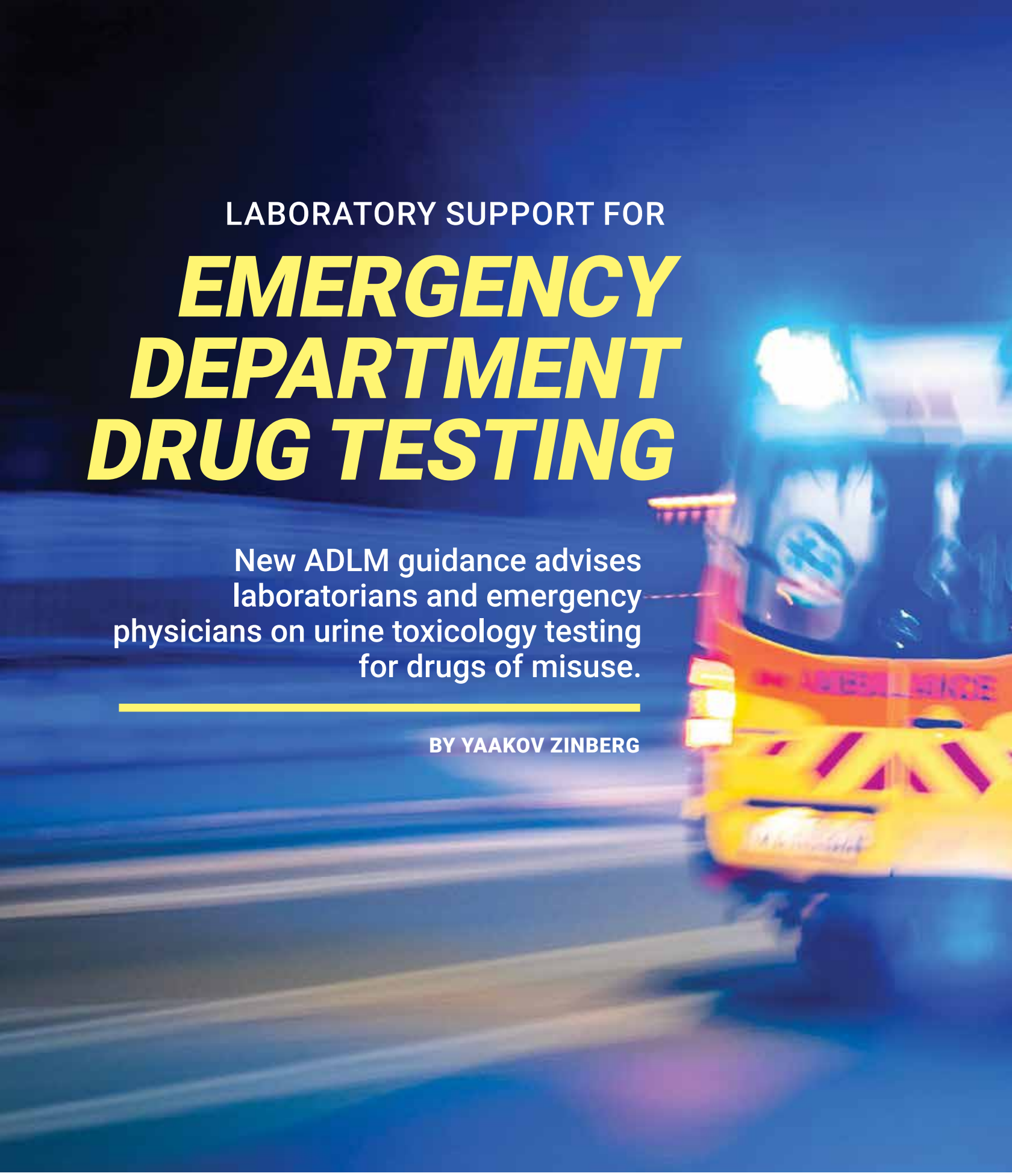
Although there are hurdles for any new degree to overcome before gaining wide acceptance, DCLS graduates have been proving their value with immediate impact in healthcare. "ADLM will continue to support all of our MLS professionals, including DCLS graduates, as we adapt to today's complex healthcare challenges," Jannetto said.

In 2024, ADLM formed a DCLS task force to develop strategies to support the integration, advancement, and success of DCLS professionals in laboratory medicine. Kacy Peterson, DCLS, MBA, MLS(ASCP), DLM (ASCP), is currently serving as chair of the task force. "We are one laboratory community, and the task force is working to bring additional visibility to the unique value DCLS add to the laboratory medicine team," Peterson said.

Brice doesn't see the DCLS and PhD as competing degrees. Rather, she views them as working together like a seesaw. For example, her colleague, a PhD biochemist, does a lot of laboratory theory, which complements Brice's practical focus. "My job on the seesaw is to balance some of that theory and say 'that works in theory, but not in practice' or 'this does not work in theory and we need to tweak it before we commercialize it,'" she said.

As more DCLS graduates enter the field, they forge connections that are greatly needed right now, said Laposata. For example, when analyzing results, they can look beyond simple measures such as blood count, electrolytes, and common proteins to assess how those values fit together and inform the bigger picture. "We need people who can look at those lab test values and say, 'Whoa, this cancer patient has congestive heart failure,'" Laposata said. "That link has been missing for 40 years."

Jen A. Miller is a freelance writer who works in Audubon, New Jersey.
+BLUESKY: @byjenamiller.bsky.social



LABORATORY SUPPORT FOR

EMERGENCY DEPARTMENT DRUG TESTING

New ADLM guidance advises laboratorians and emergency physicians on urine toxicology testing for drugs of misuse.

BY YAAKOV ZINBERG

Christopher Holstege, MD, chief of the University of Virginia's Division of Medical Toxicology, recalls a time when he and his colleagues didn't routinely test for fentanyl use in patients who arrived at the emergency department (ED) with symptoms of drug use. "For the majority of my career at the University of Virginia, we didn't have fentanyl on the drug screen," he said. "We just didn't see it that much."

That changed around 2013, when synthetic opioids, including fentanyl, began flooding the illegal drug supply. As the toxicology team at the University of Virginia started seeing greater fentanyl usage in the area, they worked with their laboratorian colleagues to incorporate a fentanyl test as part of their standard urine drug screening panels.

Updating drug testing panels to reflect local usage is an essential point of collaboration between EDs and the labs that run these tests. EDs often test for drugs of misuse — a less stigmatizing term for what were historically called "drugs of abuse" — in trauma patients, those who present with altered mental status, and special populations such as pediatrics. Emergency physicians observe the trends in and symptoms of drug use and know which tests their patients likely need, whereas laboratorians best understand which tests are available and how they work. Both play an instrumental role in ensuring patients get accurate and timely drug screen results.

The expertise of both sides, and their joint efforts, become all the more crucial as new drugs emerge. "We're seeing such a plethora of drugs hit society," Holstege said, adding that a lot of new opiates are hitting the market. At the same time, the emergence of new tests and testing methodologies for detecting these drugs makes EDs and labs better suited to respond but also gives them more options to weigh in any given drug use situation.

In response to this changing landscape, the Association for Diagnostics & Laboratory Medicine (ADLM) released an up-to-date guidance document (for which Holstege served as an advisor) that is designed to help both laboratorians and emergency physicians navigate testing for drugs of misuse.

NEW GUIDANCE FOR A NEW ERA

In 2003, the National Academy of Clinical Biochemistry — which is now called the Academy of Diagnostics & Laboratory Medicine — released a guidance document on ED drug testing. Twenty-three years later, an update was long overdue.

"It's probably easier to say what hasn't changed than what has [since 2003]," said Christine Snozek, PhD, co-director of clinical chemistry at Mayo Clinic in Phoenix, Arizona and co-author of the updated document. For starters, the new document recommends that EDs test for certain drugs and drug classes, such as fentanyl, oxycodone, and benzodiazepines, which were absent from the 2003 guidelines; conversely, use of propoxyphene and tricyclic antidepressants has declined, so testing for these drugs is no longer recommended.

Additionally, there have been improvements to the immunoassays emergency physicians often rely on for drug testing. For example, some laboratories now offer screens that can detect a broader range of benzodiazepines, Snozek noted. And mass spectrometry, which the guidance document recommends in cases where an immunoassay is insufficient and the result will inform the patient's care, was not an option for many EDs in earlier decades.

"The ability to run a high-resolution mass spectrometry test on an ED sample in 2003 basically didn't exist," Snozek said.

The purpose of this testing, though, has remained constant: Instead of informing the emergency care a patient receives, identifying the drug or drugs they've been exposed to helps inform subsequent interventions.

"It's not going to guide immediate management, because even if we get the results back in an hour, you're not going to wait an hour to treat the patient," said Stacy Melanson, MD, PhD, associate medical director of clinical chemistry at Brigham and Women's Hospital in Boston, and guidance document co-author. The results can, however, "confirm your suspicion and help with more of a downstream management of the patient."

For instance, a patient who arrives at the ER with signs of a drug overdose will immediately receive treatment, such as breathing assistance or naloxone, to manage their symptoms. Subsequently, a positive test on a urine drug screen could lead to a referral for behavioral medicine. Alternatively, a child with altered mental status testing positive for a drug of misuse could necessitate the involvement of Child Protective Services.

Urine drug screening also can obviate the need for more invasive

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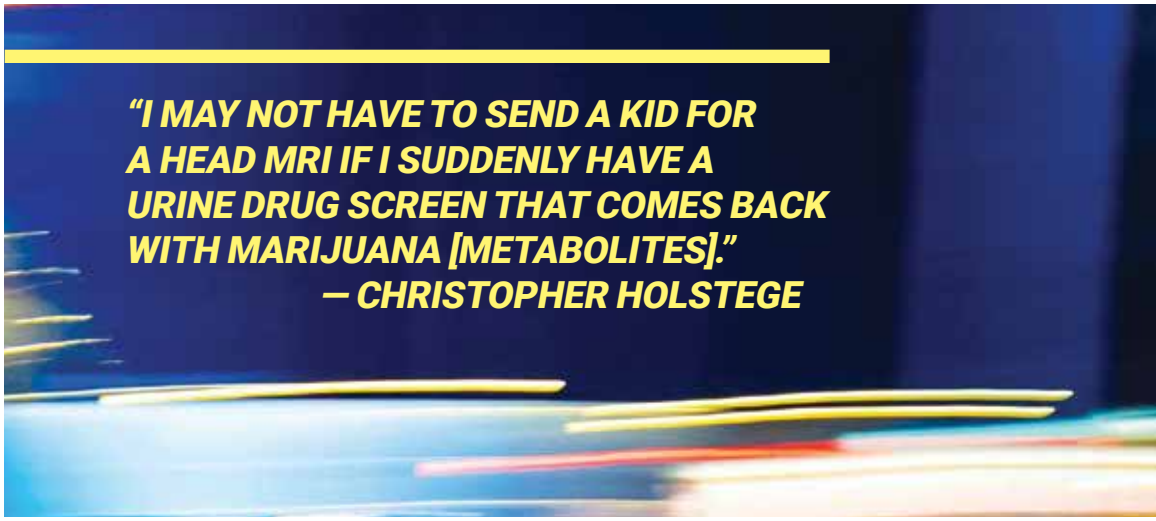
and resource-heavy testing.

"I may not have to send a kid for a head MRI if I suddenly have a urine drug screen that comes back with marijuana [metabolites]," Holstege said.



TESTING LIMITATIONS AND POSSIBLE SOLUTIONS

Compared with testing blood and saliva, urine offers the best combination of ease of collection, comparatively higher drug concentrations, and better availability of assays. However, urine can test positive for drugs after their effects have subsided, Snozek noted.

"A urine positive doesn't necessarily correlate to the person's behavior or symptomology at the moment," she said. Thus, the document advises laboratories to educate EDs on the possibility that a positive result might indicate only past exposure, not a drug-related effect on current behavior.

Immunoassays are the most common method used for urine drug testing because of their rapid turnaround time and high-throughput compatibility, but the tests have several limitations. Cross-reactivity in broad-specificity drug class tests can cause false positives, while a test not sensitive enough or not designed to detect a particular substance can lead to false negatives.

In these situations, mass spectrometry-based tests can be instrumental in arriving at an accurate result but are themselves limited by the higher cost and complexity of running the assays, which can lead to a longer turnaround time. The document advises providers to consider if these factors will interfere with patient care, especially for those who might be discharged before results arrive.

Some EDs can order mass spectrometry tests from labs housed within their institution, which can mitigate those considerations. With that said, the guidance document is most relevant to hospital clinical laboratories that primarily use immunoassay tests and that might need to send samples to other labs for mass spectrometry testing.

"We tried to make the document as practical as possible, so it wasn't really aimed at top tier reference laboratories with the best mass spectrometry technology," Snozek said.

Mass spectrometry tests are used in cases where emergency physicians suspect drug use but immunoassays come up empty. It's often through these more advanced tests that new trends in drug usage are identified.

"These tests may not change care, but we want to know exactly what the patient got into so that we have some idea of what's going on in the community," Holstege said. This in turn informs those doing public health prevention work.

EDUCATION AND COLLABORATION

A large body of evidence suggests that providers may not be fully prepared to interpret drug test results. One study showed that most emergency providers report having received little to no training in the interpretation of drug tests, and another showed that most emergency physicians could not name the drugs tested for at their hospital.

"There's a lot of confusion [among] the clinicians on the drug screens: What do they mean? What's the utility of them?" Holstege said.

To address this, the guidance document advises clinical laboratories to provide EDs with relevant information on drug testing and interpretation. Labs can append comments to test results that note the possibility of false positives and negatives for a given immunoassay and direct emergency physicians to other educational materials that delve into why tests may be inaccurate.

As drug use patterns change and new tests become available, EDs

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and labs must engage in regular conversation about which tests they offer; the document recommends at least one such review per year.

"Clinicians really need to get to know their laboratory personnel," Holstege said. The two often need to collaborate. In one recent example, Holstege had a patient presenting with all the typical signs of opioid exposure, including respiratory depression and response to naloxone, but the opioid panel came back negative. He communicated his strong suspicion of an opioid exposure to his laboratorian colleagues, who did further testing and obtained a positive result for nitazene, a synthetic opioid that's been misused at growing rates in recent years.

EDs and labs should create protocols together for when to opt for mass spectrometry testing, including when to do so without a prior immunoassay. This requires the availability of affordable and accessible instruments and facilities, which in turn requires more federal funding.

"I would love to see the United States government put money into better detection methods at the hospitals," Holstege said, especially in support of mass spectrometry testing in areas with great need.

"Emergency physicians rely heavily on laboratory results for a lot of their patients," Snozek said. The ADLM guidance document aims to help EDs and laboratorians work together in support of their patients.

Yaakov Zinberg is a writer based in the Boston area.

+LINKEDIN: www.linkedin.com/in/yaakov-zinberg-276056198

Does provoked VTE warrant thrombophilia testing?

With only indirect evidence to draw on, experts offer a cautious answer: sometimes.

When the American Society of Hematology (ASH) released its 2023 guidelines for thrombophilia testing in the management of venous thromboembolism (VTE), one recommendation stood out as a significant departure from previous suggestions: For patients with VTE provoked by transient, nonsurgical triggers (such as hospitalization, injury, pregnancy, or combined oral contraceptives) who completed primary short-term anticoagulant treatment, the ASH panel suggested testing for thrombophilia to guide treatment duration (Blood Adv 2023; doi: 10.1182/ bloodadvances.2023010177). The panel suggested indefinite anticoagulant treatment for those patients found to have thrombophilia and treatment cessation for those who didn't.

Because about 15% of the estimated 1 million cases of VTE in the United States are associated with these nonsurgical factors, this guidance could significantly increase test volumes for clinical laboratories by driving testing requests for inherited and acquired thrombophilia, according to Anna Merrill, PhD, DABCC, codirector of clinical chemistry and a clinical associate professor of pathology at the University of Iowa (Clin Chem 2025; doi: 10.1093/clinchem/hvae167).

Whether such a rise in testing has occurred yet remains unclear. Nevertheless, lab leaders should work to optimize appropriate testing and foster relationships with ordering physicians that promote informed, individualized decision-making.

BY KAREN BLUM

ABOUT THE GUIDELINES

The thrombophilia-testing guidelines are part of a series of VTE guidelines from ASH, said Saskia Middeldorp, MD, PhD, professor and head of the department of internal medicine at Radboud University Medical Center in Nijmegen, the Netherlands. Although clinical guidelines are ideally based on evidence from randomized, controlled clinical trials, no such studies exist in this case. That's because standard practice has been not to test for thrombophilia in patients with VTE. "We had to develop an entirely new methodology based on indirect evidence or modeling the effects of testing," Middeldorp explained. "Much to our surprise, there were some recommendations that actually challenged this dogma of 'do not test.'"

Although most patients fall into high- or low-risk categories for recurrence of VTE, some of those with major transient provoking factors are at intermediate risk, Middeldorp said. This includes women who take oral contraceptives and those who have had pregnancy-related clots — a group previously lumped in with provoked VTEs from major surgery or trauma, with a recommended anticoagulant treatment duration of 3 months.

Through their modeling exercises, the guideline authors estimated that testing that group of patients and continuing treatment in those found positive for thrombophilia would save enough recurrent thromboses — 21 in 1,000 patients — to conditionally recommend offering testing.

"That was somewhat shocking to us, because we as a panel were also raised with the idea that, with a provoked clot, you stop treatment and don't test," Middeldorp said. "This raised quite some discussion, if I say it politely."

38% of patients with VTE provoked by nonsurgical factors will be found to have thrombophilia.

All recommendations in the guidance are conditional because of the methodology, Middeldorp noted. Although critics stated that guidelines frequently are used as "cookbooks or bibles," she said, "this is a fantastic resource to do personalized medicine. The way I use it in my clinical practice is that now, at least, I can justify the fact that I do thrombophilia testing in some patients — but first we discuss the potential implications."

WHAT'S CHANGED

Previously, ASH guidelines recommended that most patients with an unprovoked VTE with no determined cause should be treated with anticoagulants in perpetuity because they're at high risk for recurrence, Merrill said. Those with a provoked VTE for any reason typically underwent a few months of anticoagulant treatment, after which testing for thrombophilia was not advised.

"Those were the two options, and both argued against thrombophilia testing," she said.

The new recommendation is based on estimates from observational studies that indicate that 38% of patients with VTE provoked by nonsurgical factors will be found to have thrombophilia by laboratory testing, and that continuing anticoagulation therapy indefinitely in these individuals will decrease their VTE recurrence risk from approximately 8% to approximately 1% in the first year, with only a small increase in bleeding risk, Merrill said.

However, the guidance does not look at benefits beyond 1 year, she explained. "We know that the longer you take an anticoagulant, the more likely you are to have a bleeding event, and as you get farther away from the time at which you had a VTE, your chance of recurrence goes down," she said. Most patients with longer courses will likely be put on direct oral anticoagulants (DOACs), a safer option than warfarin, she added.

IMPACT YET TO BE DETERMINED

It's hard to predict whether the guidelines will be implemented widely. "[They] did make a fairly big splash, because they were different than the standard practice before that," said Stephen Jenkins, MD, associate professor of medicine and medical director of the thrombosis service at the University of Utah Health. However, testing for thrombophilia patterns still may vary widely depending on where physicians practice and train, he said. At his institution, the culture favors the "minimalist" side for such testing. "The question we always ask before testing is, 'Is this going to change our management?'"

Because most patients fall into high- or low-risk scenarios, there generally isn't a strong role for thrombophilia testing, Jenkins said.

"Anytime somebody has a clotting event, the main question we ask is 'What provoked this clot? Was it out of the blue, or did they just have a total hip replacement?'" he said. If it's provoked by a surgery — a strong risk factor for a blood clot — that patient has a very low risk of getting a future clot if anticoagulation is stopped.

"If the clot happened out of the blue, we know those patients have a

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very high risk of a recurrent clot if we stop anticoagulation. So testing them for thrombophilia doesn't help a lot either, because even if they test negative, we'll still recommend that they stay on anticoagulation because they have such a high clotting risk," Jenkins said.

Jenkins' institution does test patients for an acquired thrombophilia called antiphospholipid syndrome, because a positive result changes clinical management. In that situation, guidelines recommend using warfarin, he said.

Academic centers likely already performed frequent testing for thrombophilia based on preference and culture, Jenkins said. "I predict that these guidelines probably have increased the amount of thrombophilia testing mostly based on the fact that guidelines give you permission to go forward with it where maybe there wasn't a super strong rationale for testing before."

Since the guidelines' publication, Jenkins said that he has found himself testing more. "I'm more willing to entertain different scenarios and talk more with patients about the conditions where it might be helpful," he said.

Although she hasn't yet systematically studied the impact, Merrill, too, said that some of the hematologists at her institution "are not super fond of the recommendations, because there's very low certainty." But if the guidelines were followed perfectly across the nation, an estimated 150,000 patients would fall into the category of provoked VTE for whom testing is now recommended. "That could have pretty significant consequences," Merrill said.

Middeldorp, who is based in Europe, isn't aware of the impact in the U.S. "I do think that it raised controversy amongst experts, and that had to do with the fact … that it's a modeling exercise," she said. Thrombophilia testing also was questioned in the national "Choosing Wisely" campaign on judicious use of testing, in which experts recommended not to test in clots provoked by surgery, suggesting "expert advice" instead when VTE occurs in the setting of pregnancy or hormonal therapy.

TESTING CONCERNS

Testing for thrombophilia when a patient has an acute clotting event brings potential for false positive results because functional assays detect levels of proteins affected by an acute clot, Jenkins said. For example, if a laboratory tested a patient in the acute setting, results might indicate that they have a protein C or protein S deficiency when they don't. A patient then could be prescribed an anticoagulant longer than needed. For that reason, he said, it's recommended to wait at least 3 months after the clot to test.

Additionally, anticoagulants themselves can affect test results, so lab professionals should take this into consideration when running tests. Better yet, request that patients stop the medications before testing, Merrill said.

A GAME PLAN FOR LABORATORIES

Regardless of whether clinical laboratories conduct thrombophilia testing in-house or outsource it, laboratorians should develop good relationships with their hematology providers, explain the laboratory's capabilities, and decide on their recommended first-line test, Merrill advised. For example, there are several ways to test for protein S deficiency that measure total protein S antigen, free S antigen, and protein S activity. Moreover, certain tests are recommended over others if a patient still takes anticoagulants, she said.

"It's a good time for labs to understand what they offer for thrombophilia testing and to ensure that the testing they offer is the recommended first-line test," she said. "That will help prevent diagnostic error."

Because the strength of evidence is pretty low in these guidelines, Merrill advises against labs promoting that testing must be done in these circumstances. "Deciding whether to follow these guidelines really should be up to the provider and should come from their discussions with their patients."

Laboratory directors also could ensure that order sets in electronic records direct clinicians to select the appropriate tests at the appropriate time, Jenkins advised.

Laboratory professionals performing thrombophilia testing should review patient charts or conduct screening tests to look for anticoagulant medications that might interfere with results, or conduct screening tests to see what medications are in the samples that get sent out for thrombophilia testing, Merrill added. A higher proportion of samples may be from patients on anticoagulants, she noted.

Don't assume that all providers who order thrombophilia testing know how anticoagulants might interfere. "As laboratories, we should look for opportunities to take a more active role in providing interpretive guidance," Merrill said. "That could be comments that are sent along with your results. Make sure they're valid and digestible, and that they will be meaningful for those reading the results."

Karen Blum is a freelance medical and science writer in Owings Mills, Maryland.

+EMAIL: karen_blum@verizon.net

AN INTERVIEW WITH PATRICK MATHIAS, MD, PHD

Embracing data science in lab medicine

Mathias highlights the scope and relevance of ADLM's new data science certificate program.

In January 2026, the Association for Diagnostics & Laboratory Medicine (ADLM) is launching a Data Science in Laboratory Medicine Certificate Program designed by and for clinical laboratorians. Through real-world examples, the program will highlight how to use data to address daily lab challenges. Participants will learn about core data science concepts and get practical tools to optimize processes, improve testing algorithms, reduce errors, and enhance efficiency.

We spoke to Patrick Mathias, MD, PhD, lead faculty member of the new program, about what he hopes participants will gain from it, and how he first became interested in data science. Mathias is associate professor and associate medical director of the informatics division in the department of laboratory medicine and pathology at the University of Washington School of Medicine, and also serves as the department's vice chair of clinical operations.

How did data science become one of your areas of expertise?

My undergraduate degree is in electrical engineering. As part of that education, I learned a bit of computer science. At the time, data science was still an emerging discipline, so it was not on my radar at all. After receiving a master's degree in electrical and computer engineering, I attended medical school for an MD/PhD. During that period, I conducted research that introduced me to the computer programming language R, which is used to analyze data. Although data science was not part of my long-term plan, I was intrigued.

Then I did a residency in laboratory medicine and clinical pathology because I wanted to apply my engineering background to the diagnostic space. That's when I learned about clinical informatics and realized I wanted to pursue it as a subspecialty. I started to see the value of working with diverse data sets that include data generated in the lab, as well as data from electronic medical records (EMRs) that lives outside of the lab. I began thinking about how to use larger data systems to improve patient care.

How does your lab use data science to improve testing and patient care?

At the most basic level, we monitor our quality metrics across the organization. In addition to tracking routine measures like turnaround times for our tests, we're getting deeper into laboratory information and EMR data to assess patient wait times and other measures of care. And we're leveraging automation to do it without having to put in a lot of manual work. For example, we gather patient satisfaction data from interactive kiosks that patients use after phlebotomy visits.

So we do a lot of the same things that other laboratories do, but we've used data science to take that to the next level. We aim to measure the full impact of how patients interact with the laboratory and compare our lab's performance with national benchmarks for patient satisfaction and other service delivery metrics.

As data science becomes more sophisticated, what do you hope labs will be able to accomplish with it in the future?

I want labs to contribute positively to patient outcomes, not just by using data from routine testing, but also by looking into the EMR. For example, how can we use this information to identify gaps in care? How can we as a laboratory think more holistically about patients? And how can we support the processes within our healthcare systems that are dependent on the laboratory? I want as many people as possible to learn about data science. Capturing just a small amount of the data that lives outside of the laboratory could make a big difference in patient health outcomes.

On the flipside of that question, what's something people want data science to accomplish that may not be realistic?

There's a lot of hype around artificial intelligence (AI), with the hot thing right now being large language models (LLM) such as ChatGPT and Claude. While I think there's a lot of value in these new tools and models, there

FOCUS ON **DATA SCIENCE**

are also inflated expectations that LLMs will solve all of our problems.

As with any nascent technology, we have a new set of tools, and we're thinking critically about how to apply those tools to benefit our patient population. Researchers already use AI in both small pilot studies and larger, more ambitious prospective trials. But we also need to understand that these efforts may not lead to the rosy outcomes people expect, at least in the short term. That being said, I'm an optimist by nature, and I think AI technology will ultimately lead to great things.

One concrete example: At my institution, we have used AI to predict how many patients will come to one of our phlebotomy areas three to four days from now. The model works pretty well, but the challenge is figuring out how to implement it to deliver improved patient outcomes. In reality, it's really hard to make an employee come in early for a predicted patient surge. Even though AI forecasts something operational, we have a lot of hurdles to clear before that information can become useful for patients.

What other hurdles face data science in lab medicine over the next 5 to 10 years?

Building awareness among laboratorians poses the biggest hurdle. We need education and training to help lab professionals understand the strengths and weaknesses of these technologies. Like any new tool, data science has a gradual on-ramp. It will take time before people fully understand how to deploy new tools.

In general, data science as a field is much more mature than it was when I started out. At the same time, it still lacks reliable resources that relay its principles and how to incorporate them into healthcare training programs. That was one of the motivations behind introducing ADLM's data science certificate program. We wanted to ensure that our community has solid foundational materials that they can use to develop this knowledge.

Why is it important for laboratory medicine professionals to learn about data science?

Laboratory medicine has always had a responsibility to produce large volumes of objective patient data. Downstream users of that information include clinicians and healthcare systems, many of whom don't understand the limitations of that data. Laboratory professionals should be in the driver's seat when it comes to ensuring appropriate data usage. We should inform our colleagues about what can and cannot be learned from the information available.

What does ADLM's data science certificate program cover?

We spent a good amount of time deliberately designing the most useful curriculum for laboratorians. We started by asking the broader informatics community which topics they found most valuable in the realm of data science. From there, we created a foundational program meant to promote data literacy and reinforce basic concepts such as how healthcare data is generated and used; principles of analysis, statistics, and visualization; and AI applications in the laboratory.

We also tried to frame all of these topics around where the data comes from, how laboratorians should conceptualize data, and the best practices for data collection and analysis.

What sets this program apart from other data science educational programs?

I don't know that there's any other program that focuses quite this intensely on laboratory medicine, with a faculty that includes pathologists and specialists in laboratory medicine who can share real-life experience and examples.

Once people complete this program, what should they be able to do in practice?

We hope to provide people with the framework to think about what their local resources are within their laboratories and who to work with to get the data they need. We want them to learn good principles for using that data and drawing insights from it.

Within ADLM, we envision delivering additional data science content through the ADLM Annual Meeting and other educational materials like webinars and publications. These resources will build on the certificate program's foundation, with deeper dives into specific areas like AI, data visualization, data management, and the newest applications of those techniques in laboratory medicine. This program is just the first step in a longer learning journey.

Jen A. Miller is a freelance journalist who lives in Audubon, New Jersey.
+BLUESKY: @byjenamiller.bsky.social

FOCUS ON **DATA SCIENCE**

BY KATRIN M. CARLSON LEUER, PHD; ELIZABETH LEETH, CGC;
JAIME DUNCAN, CGC; KRYSTAL FERNANDEZ, CGC

Leveraging EMR functionality and centralized support to optimize genetic testing

Navigating genetic testing preauthorization and order triage can be challenging for healthcare institutions. In addition to understanding insurance requirements, lab leaders and other healthcare professionals must manage an increasing number of genetic tests, track rapidly changing molecular methodologies and ordering providers, and ensure clinical teams have access to specialist support as needed.

For more than 15 years, multidisciplinary experts at the Ann and Robert H. Lurie Children's Hospital of Chicago (Lurie Children's) have worked together to create an integrated approach to genetic testing stewardship. By sharing key insights and recommendations from our experience, we aim to help those at other institutions looking to optimize their own genetic testing processes.

LABORATORY STEWARDSHIP FOCUS

Establishing an advocacy team

Our hospital's early efforts to centralize support for genetic testing included the development of The Genetic Testing and Counseling (GTAC) Support Center within Lurie Children's Center for Genomics. This group includes a diverse team of laboratory directors, genetic counselors, clinicians from both genetics and nongenetics divisions, pharmacists, and finance and compliance professionals. The GTAC Support Center's strategic pillars include laboratory stewardship, laboratory test interpretation and reporting, and clinical genetic counseling and education.

The laboratory stewardship team within the GTAC Support Center acts as a liaison between ordering providers, clinical laboratories, and various departments — including pathology, finance, and financial clearance. Because the team is well versed in clinical genetics, laboratory genetics, and insurance and billing practices, they provide guidance to healthcare providers through a dedicated hotline, emails, and a digital-communication hub within the Epic electronic medical record (EMR) system. Using a variety of methods and platforms, the stewardship team ensures that all questions about ordering and documentation are addressed promptly, facilitating a proactive approach to effective genetic test utilization.

In addition, the stewardship team educates providers on the latest test options, methodologies, and insurance authorization processes. The team uses an internal, institution-wide website to share practice guidelines, policy documents, and template letters of medical necessity. Capitalizing on EMR functionality that routes pending orders to the stewardship team, team members also review all outpatient genetic test orders for appropriateness, optimal test and reference lab choice, and accurate billing codes.

These efforts have optimized and standardized genetic testing practices within our institution. The centralized nature of the GTAC Support Center ensures that genetic test stewardship is managed consistently, regardless of the clinical department requesting the test.

Recommendation: Consider establishing a centralized stewardship team to manage genetic testing workflows within your healthcare institution. Streamline their work via EMR technology.

Enhancing efficiency with integrated teams

To further bolster stewardship, healthcare leaders within Lurie Children's strategically positioned genetic counselors in various clinical departments that have high volumes of genetic test orders. These include neurology, cardiology, ophthalmology, oncology, and endocrinology. Importantly, these embedded genetic counselors are current or former members of the stewardship team or prior participants in training programs with the team.

By distributing Lurie Children's genetic counseling resources across specialties, more clinicians have access to expert guidance regarding test selection and interpretation. This decentralized, yet coordinated, approach fosters a collaborative environment that supports both optimal test utilization and preauthorization compliance. The use of crossfunctional organizational structure minimizes variability and supports consistent application of stewardship protocols.

Recommendation: Integrate genetic counselors with foundational knowledge of laboratory stewardship within specialty patient care teams

while maintaining centralized management.

Centralizing preauthorization efforts

Navigating insurance requirements for genetic testing can be complicated. To address this, our hospital's finance department designated a team within the financial clearance group to manage the preauthorization workflow for all genetic tests ordered across the institution. By integrating specialized knowledge within the financial clearance function, Lurie Children's enhanced communication and collaboration between the stewardship team and clinicians. More broadly, centralizing the preauthorization process alleviated the need for all providers to navigate insurance authorization portals and processes related to genetic testing.

Recommendation: Establish a centralized preauthorization team with specialized knowledge in genetic testing.

Maximizing automation within the EMR and beyond

Automation through the EMR has been fundamental to Lurie Children's success in genetic test stewardship and insurance authorization. We use electronic workflows for laboratory stewardship, preauthorization communication, preauthorization request routing, preauthorization status visual signaling, and order status communication. The automation tracks and documents the entire journey from order to utilization review to preauthorization submission to final determination and ensures that all stakeholders are promptly informed every step of the way.

In recognition of the complexity of the circumstances under which genetic tests are ordered, Lurie Children's developed a flexible system that allows for multiple workflows depending on the test ordered.

Workflow 1: To minimize insurance denials, high-cost genetic tests that are billed institutionally require laboratory stewardship review and preauthorization approval prior to sample collection. Once approved, the EMR updates the order status with a visual indicator, signaling that sample collection and testing can proceed.

Workflow 2: To maximize efficiency, tests that are not institutionally billed and thus do not require preauthorization (for example, third-party or sponsored tests) undergo laboratory stewardship review, but bypass the financial clearance team.

Workflow 3: To prevent critical diagnostic delays, orders for urgent somatic testing, such as somatic oncology tests and panels, bypass laboratory stewardship but route to the preauthorization team. In these cases, preauthorization is conducted concurrently with sample collection and testing.

Workflow 4: Pharmacogenomic testing follows the required laboratory stewardship and preauthorization process as outlined in Workflow 1, with review by a pharmacist specializing in pharmacogenomics as opposed to the laboratory stewardship team.

Lastly, Lurie Children's has developed user-friendly business analytics tools to assess the effectiveness of our laboratory stewardship and preauthorization efforts. The hospital utilizes these tools to monitor the workflows, highlight any issues needing attention, and support ongoing improvement.

Recommendation: Use systems to their fullest capacity, incorporating automation for efficiency and improved coordination between clinical and administrative teams. Design digital processes that allow for flexibility and variation among various testing scenarios. Develop analytics tools to monitor efforts and identify areas for improvement.

Looking ahead

Lurie Children's continues to innovate by exploring machine-learning applications that predict the likelihood of insurance coverage and automate the documentation of medical necessity. Future developments might include incorporating predictive analytics to reduce claim denials and refining Epic's automation features to perform real-time insurance verification.

Recommendation: Invest in emerging technologies to predict coverage outcomes and integrate advanced data analytics into preauthorization workflows.

Conclusion

By adopting a structured, technology-driven approach to genetic test stewardship, Lurie Children's has reduced administrative burdens, improved patient care, and promoted financial sustainability.

Katrin M. Carlson Leuer, PhD, is the scientific director of the Cytogenetics Laboratory at Ann and Robert H. Lurie Children's Hospital of Chicago.

Elizabeth Leeth, Jaime Duncan, and **Krystal Fernandez** are certified genetic counselors who serve on the GTAC lab stewardship team.

+EMAIL: ELeeth@luriechildrens.org

BY LISA M. JOHNSON, PHD

A collaborative approach to improving cytokine testing

Cytokine panels are important tools for investigating excessive inflammation and immune dysfunction. For more than 15 years, Seattle Children's Hospital maintained a cytokine panel to support its participation in clinical trials. Although the hospital's panel was originally designed to help distinguish between sepsis and cytokine release syndrome, its use evolved as providers from a variety of specialties — including immunology, rheumatology, hematology-oncology, and gastroenterology — began ordering it to assess a broader range of conditions (*1*,*2*).

Over time, it became clear that the panel wasn't meeting the varied clinical needs it had grown to support. Moreover, the time-consuming manual testing process placed a significant burden on laboratory staff (*2*,*3*).

To manage the increasing demand and the labor-intensive nature of cytokine testing, the laboratory director at Seattle Children's used laboratory stewardship practices to implement a triage process. The director began reviewing all cytokine orders with providers to determine which cases required rapid in-house testing (1–2 day turnaround) versus those that could be sent to a reference laboratory (approximately 1-week turnaround) (*4*).

Although this approach reduced in-house testing volume by about 30% over 1 year, there was still room for improvement. Most of the test requests at the hospital were for critically ill patients who required results more urgently than a send-out could provide.

For that reason, the laboratory team initiated a structured, collaborative review process with all clinical specialties ordering cytokine testing to plan for the next revision of our cytokine platform. Given our prior experience, our main goals were to make the platform more analytically efficient and clinically relevant. We describe this process here.

Step 1: Determining clinical need

To align testing with clinical priorities, the lab team began discussions with providers 2 years before switching cytokine platforms. As part of this dialogue, we developed an online survey listing the most common cytokines available across reference laboratories. The survey asked the departmental leaders to select the three cytokines most relevant to their patient populations. This was important because cytokine panels vary widely in scope, containing anywhere from five to more than 20 analytes (*1*–*3*).

This approach allowed the lab team to identify the highest-value markers across specialties. The survey revealed six cytokines of importance to the providers: IL-1beta, soluble IL-2R, IL-6, IL-8, IL-10, TNFα, and IFNγ.

In comparison, our old cytokine kit had IL-2, IL-4, IL-6, IL-8, IL-10, TNFα, IFNγ, and GM-CSF. Several of these cytokines were rarely elevated in clinical samples (IL-2, IL-4, GM-CSF), and therefore we learned from this process that a shorter panel would be more clinically relevant for our patients.

Step 2: Conducting feasibility study and evaluating methods

Based on these results, the laboratory started considering the Luminex, MesoScale Discovery, Protein Simple Ella, and Siemens Immulite platforms. All of these platforms had most of the clinically relevant cytokines. However, we'd learned from our previous panel that we also had to factor analytical complexity, cost, and faster turnaround times into our decision.

At Seattle Children's, the laboratory has already had experience using the Immulite platform for over 10 years, and the laboratory technologists felt this was the best solution to address their goal of analytical efficiency. Therefore, all parties involved agreed that the cytokine panel available on the Siemens Immulite platform best met the goals of analytical efficiency and clinical relevance.

Although this method did not include interferon gamma (IFN-γ), the lab already offered a validated assay for CXCL9, a stable downstream marker of IFN-γ signaling.

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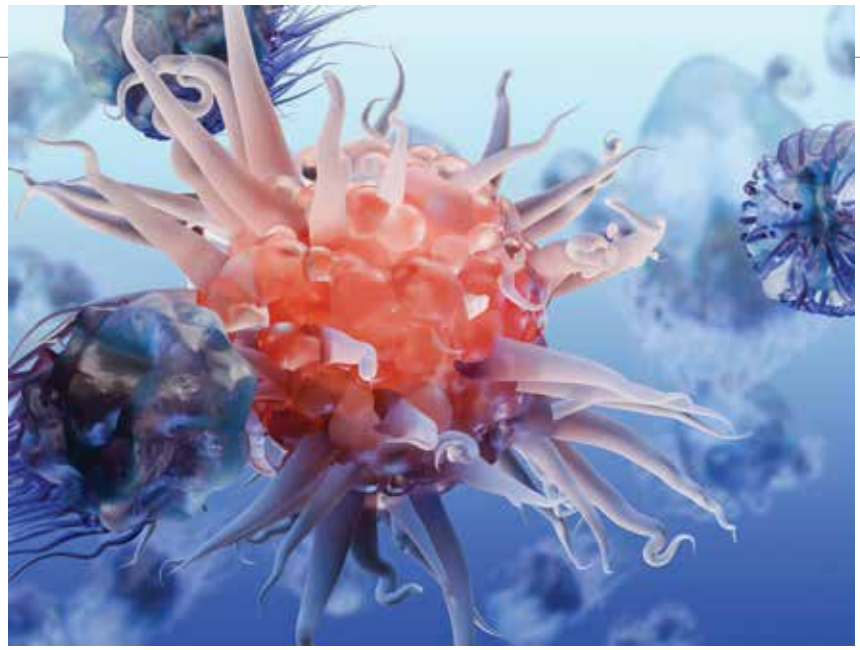


The lab team obtained reagents to perform a feasibility study, confirming the platform's suitability.

Transitioning cytokine testing to Immulite offered multiple advantages: Compared with the previous assay, it reduced workload and hands-on time for technologists, improved accessibility through random-access testing, and offered significantly faster turnaround times that allowed providers to make better assessments of hyperinflammation cases.

Step 3: Engaging stakeholders

With provider leadership support established from the initial survey and discussions, the lab's next step was to present the data and rationale for the new panel to the clinical teams. During departmental meetings for each specialty, lab leaders reviewed their survey findings, compared the existing and proposed cytokine panels and platforms, and outlined the expected operational and clinical benefits. These discussions allowed for transparent communication and consensus-building across specialties.

Because the cytokine assay is best suited for evaluating severe inflammation or immune dysfunction, it was critical to ensure that providers fully understood its appropriate use, strengths, and limitations (*1*,*4*). The laboratory team outlined processes for ordering the cytokine panel with a 1–2 day turnaround time for clinically urgent treatment scenarios; they explained that, because these cases needed to be reviewed by a lab fellow or director, providers must contact the laboratory immediately to expedite their request. Otherwise, the lab will offer the panel 1 day a week. The new cytokine panel was rolled out hospital-wide in December 2025.

Adoption of the new platform has also reduced the complexity associated with sending out nonurgent requests. The team decided to discontinue the send-out option and instead simply classify testing on the Immulite platform as either "urgent" or "routine."

Outcome

The transition to the new cytokine panel has been well received. Providers are enthusiastic about improved clinical relevance and faster turnaround times, while laboratory staff appreciate the simplified workflow. Although the change was gradual — reflecting the hospital's long history with the previous panel — it exemplified a thoughtful, collaborative approach to laboratory process improvement (*4*,*5*). Ultimately, this effort strengthened communication and improved the laboratory team's relationships with providers from a variety of specialties who care for critically ill patients.

Lisa M. Johnson, PhD, is a clinical chemist at Seattle Children's Hospital and an associate professor in the department of laboratory medicine and pathology at the University of Washington.

+EMAIL: Lisa.Johnson2@seattlechildrens.org

1. Gallo PM, Kim J, McNerney KO, et al. Serum cytokine panels in pediatric clinical practice. J Allergy Clin Immunol 2025; doi: 10.1016/j.jaci.2024.08.030.
2. Liu C, Chu D, Kalantar-Zadeh K, et al. Cytokines: From clinical significance to quantification. Adv Sci (Weinh) 2021; doi: 10.1002/advs.202004433.
3. Knight V, Sepiashvili L. Cytokine testing and challenges for diagnostic and clinical monitoring use. J Allergy Clin Immunol 2025; doi: 10.1016/j.jaci.2024.11.025.
4. Dickerson JA, Fletcher AH, Procop G, et al. Transforming laboratory utilization review into laboratory stewardship: Guidelines by the PLUGS National Committee for Laboratory Stewardship. J Appl Lab Med 2017; doi: 10.1373/jalm.2017.023606.
5. White TE, Wong WB, Janowiak D, et al. Strategies for laboratory professionals to drive laboratory stewardship. Pract Lab Med 2021; doi:

Regulatory Roundup

FDA issues final guidance on emergency IVD approval

The Food and Drug Administration (FDA) has finalized guidance that outlines criteria for using in vitro diagnostic tests (IVDs) during public health emergencies.

Replacing draft guidance issued on May 6, 2024, the final guidance issued on Sept. 3, 2025, describes the factors the FDA intends to assess in deciding whether to issue an enforcement policy. These include the need for accelerated availability of IVDs, their risks, availability of appropriate, authorized, or approved alternative tests, and availability of sufficient mitigations to address risks of false results.

When considering use of unapproved tests, the FDA will consider public health need and potential benefits and risks associated with those tests. The benefits may include timely clinical management of patients and effective infection control. In addition to false results' effect on patient care, risks could involve severe consequences from life-threatening diseases and complexity of IVD technology. The FDA will consider factors that could reduce the risk of false results from unapproved or unauthorized IVDs.

The FDA must consider access to alternative approved or authorized IVDs available and whether there is adequate time for an IVD to receive emergency use approval, the guidance said.

FDA 510(K) CLEARANCE EXPANDS USE OF HEMOSONICS SYSTEM FOR OBSTETRIC PROCEDURES

HemoSonics, a medical device company focused on acute bleeding management, recently announced that it has received 510(k) clearance from the Food and Drug Administration for expanded use of its Quantra Hemostasis System with QStat Cartridge in peripartum obstetric procedures.

The Quantra Hemostasis System delivers rapid, real-time coagulation insights at the point of need, empowering clinicians with actionable data to protect pregnant individuals at risk of experiencing postpartum hemorrhage during childbirth.

According to the World Health Organization, severe bleeding after childbirth is the leading cause of maternal mortality globally and causes 21.1 deaths per 100,000 live births in the United States.

The Quantra System uses a proprietary medical-grade ultrasound technology that measures the coagulation properties of a whole blood sample. The system requires minimal resources to maintain, is easy to operate and interpret, and typically provides comprehensive whole-blood coagulation analysis in less than 15 minutes, HemoSonics said.

TOSOH BIOSCIENCE GRANTED FDA 510(K) FOR HBA1C TESTING ANALYZER

Tosoh Bioscience has received Food and Drug Administration 510(k) clearance for its next-generation Tosoh Automated Glycohemoglobin Analyzer

HLC-723 GR01 (GR01) for HbA1c testing, the company said.

The GR01 is designed for diagnosing diabetes, identifying patients at risk of developing it, and long-term glucose monitoring. GR01 offers results in just 50 seconds, according to Tosoh.

Compact yet powerful, the GR01 meets the needs of mid- to high-volume laboratories. It offers the throughput of a high-capacity system with streamlined operation, automatic buffer changes, and walkaway functionality to maximize efficiency and reduce hands-on time, Tosoh said.

The analyzer's intuitive touchscreen interface and lab information system connectivity simplify workflow integration, Tosoh said. According to the company, the GR01 delivers coefficients of variation less than or equal to 1.1% and thus provides reproducibility and reliability to help clinicians make confident diagnostic and therapeutic decisions in diabetes management.

The GR01 is Tosoh's next leap forward in HbA1c testing because it provides speed, precision, and simplicity in one compact system, company officials said.

COMPANION DIAGNOSTIC FOR ACUTE LEUKEMIA GRANTED FDA DE NOVO CLASSIFICATION

The FDA has granted de novo classification to the OGT CytoCell KMT2A Breakapart FISH Probe Kit PDx as a companion diagnostic for Syndax's first-in-class menin inhibitor, Revuforj (revumenib), OGT announced recently.

Revuforj is approved for the treatment of relapsed or refractory acute leukemia with a *KMT2A* translocation (*KMT2Ar* acute leukemia) in adult and pediatric patients 1 year or older. OGT's CytoCell KMT2A Breakapart FISH Probe Kit PDx detects clinically relevant rearrangements that occur in patients with acute leukemia, allowing clinicians to quickly identify patients who may be eligible for treatment with Revuforj.

An estimated 95% of patients with *KMT2Ar* acute leukemia have a *KMT2A* translocation. The *KMT2A* gene at 11q23.3 is commonly rearranged in acute leukemias, especially in infants, OGT said.

PACBIO GETS FIRST REGULATORY APPROVAL FOR LONG-READ SEQUENCING IN CHINA

PacBio recently announced that through its long-standing partnership with Berry Genomics, the Sequel II CNDx system has received Class III medical device registration approval from the National Medical Products Administration (NMPA) in China.

The Chinese approval marks the world's first regulatory clearance of a clinical-grade long-read sequencer, PacBio said.

With the Sequel II CNDx system, clinicians can access a complete picture of the genome in a single test that captures single nucleotide variants, insertions and deletions, copy number variants, structural variants, and repeat expansions with exceptional accuracy, PacBio said. The system leverages PacBio's proprietary Single Molecule, Real-Time (SMRT) technology, which is the only sequencing technology capable of delivering both high accuracy and long read lengths of 20 kb and greater, the company said.

High-incidence genetic disorders such as thalassemia often involve complex variants that are difficult or impossible to detect using short-read sequencing. When paired with Berry's clinical thalassemia assay and software system, this approval delivers the first end-to-end long-read sequencing workflow for China's hospitals and diagnostic laboratories, optimized for carrier, prenatal, newborn, and rare disease testing, PacBio said.

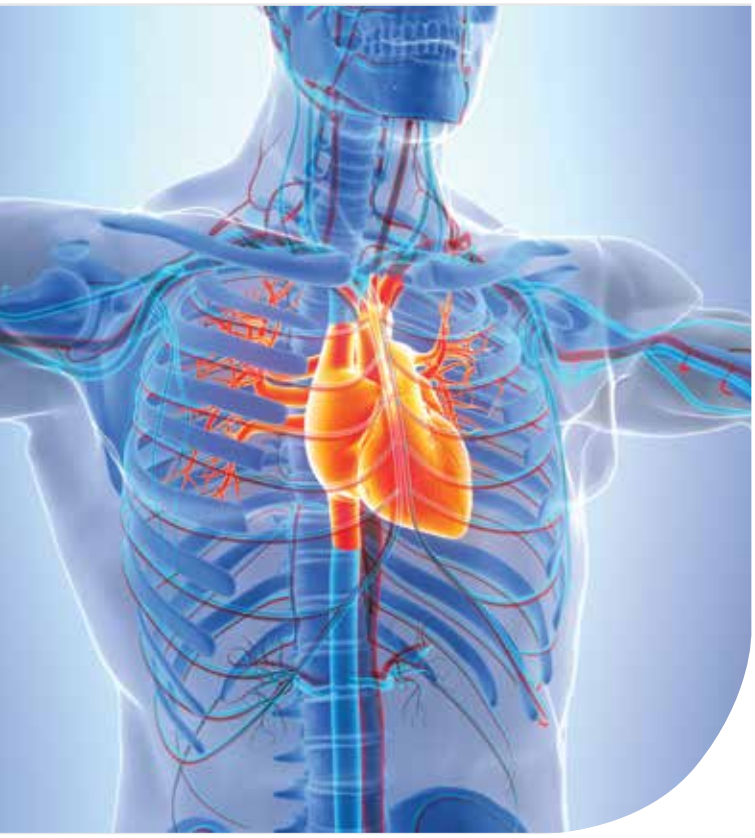
DIASORIN GETS FDA 510(K) CLEARANCE FOR MULTIPLEX RESPIRATORY TEST

The Food and Drug Administration recently granted Diasorin 510(k) clearance for its Simplexa COVID-19 & Flu A/B & RSV Direct kit, a sample-to-answer test for the detection of SARS-CoV-2, influenza A virus, influenza B virus, and respiratory syncytial virus directly from nasopharyngeal and nasal swab specimens.

Designed for use on the Liaison MDX system, the assay is suitable for both hospital and commercial laboratories. It delivers rapid differential detection of four targets in approximately 45 minutes.

By providing a clearer and more complete understanding of a patient's condition, the test enables healthcare providers to tailor treatment plans more effectively, which leads to improved patient outcomes and reduction of unnecessary treatments during the respiratory virus season, Diasorin said.

Industry Playbook



Partnership in India to develop cardiac AI dataset

Bayoshiti AI, an Indian subsidiary of Biostate AI, has partnered with Narayana Health to develop the first artificial intelligence (AI) models designed to predict cardiovascular disease in Indian populations.

The estimated 65 million Indians with coronary artery disease develop it 5–10 years earlier than most other ethnic groups in Europe and the U.S. In spite of this, Indians are still diagnosed with tools that are calibrated based on patient data from these regions that is primarily collected from non-Indian populations. To address this discrepancy, Biostate AI and Narayana Health planned a study that will train AI on the molecular data from 12,000 Indian patients at the Narayana Institute of Cardiac Sciences and analyze complete RNA profiles to detect heart disease before structural damage appears on conventional tests.

The collaboration aims to improve the economic viability of population-scale molecular diagnostics through the use of Biostate AI's patented BIRT technology, which sequences complete RNA profiles by the parallel processing of multiple patient samples. Narayana Health will provide the patient population for training AI models and the clinical infrastructure to validate them.

Once the AI models are validated, the study will provide proof-of-concept for deploying similar approaches to other high-burden diseases and underserved populations, the companies said.

PARTNERSHIP TO ADDRESS WORKFLOW REPORTING FOR SEQUENCING PANEL

A new comarketing and distribution partnership between OGT and Qiagen Digital Insights will enable OGT's SureSeq next-generation sequencing (NGS) panel customers to purchase QCI Interpret, Qiagen's tertiary analysis software, as part of a complete SureSeq NGS workflow solution, unlocking comprehensive analysis from sample to report.

The partnership expands OGT's bioinformatics capabilities by integrating Qiagen's advanced tertiary analysis solution, QCI Interpret, with its SureSeq NGS panels. Built for variant interpretation and clinical reporting, QCI Interpret delivers artificial intelligence-powered, expert-curated classifications along with oncologist-reviewed summaries and transparent evidence links. Through this collaboration, SureSeq NGS panel users will gain access to streamlined, high-confidence genomic insights and efficient, scalable reporting from sample to result.

The partnership will give its customers an end-to-end NGS workflow and access to the world's largest knowledge base, increasing customers' confidence in variant classification, OGT officials said.

Qiagen officials said that the partnership addresses mounting challenges from the complexity and volume of NGS testing because it helps customers to scale confidently, reduce turnaround times, and improve outcomes for patients.

COLLABORATION FOCUSES ON ATOPIC DERMATITIS

SciBase Holding recently announced expansion of its collaboration with Castle Biosciences, including a license agreement, a loan agreement, and the companies' first joint clinical study to develop a test that predicts flares in patients diagnosed with atopic dermatitis (AD).

The two companies first entered into a collaboration and license

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agreement in June 2025. The expanded agreement gives Castle increased autonomy over the manufacturing process. Under the separate loan agreement, Castle will provide 20 million in Swedish krona to SciBase.

SciBase said the loan gives it necessary resources to ramp up production and maintain uninterrupted growth. The collaboration will also help the company accelerate the adoption of Nevisense, a point-of-care technology that uses electrical signals and artificial intelligence to help dermatologists more accurately detect melanoma, the company said.

Castle's current portfolio consists of tests for skin cancers, Barrett's esophagus, and uveal melanoma. The company also has active research and development programs for tests for these diseases.

PARTNERSHIP TO TEST 100,000 PATIENTS FOR HEREDITARY RISK OF CANCER AND HIGH CHOLESTEROL

University Health Network's (UHN) Princess Margaret Cancer Centre and Helix, a precision health organization, recently announced a partnership to launch one of the largest population genomics studies in Canada.

The OurGenes Study aims to enroll up to 100,000 participants over 5 years to advance precision medicine and early detection of hereditary health risks.

Study participants will receive testing for well-established genetic conditions, including hereditary breast and ovarian cancer associated with the *BRCA1* and *BRCA2* genes, Lynch syndrome, and familial hypercholesterolemia.

The study's screening results will allow participants and their healthcare teams to make proactive decisions about their health. By conducting screening at scale, the study will also allow Princess Margaret Cancer Centre to identify and address health risks that may disproportionately affect certain communities. Participants' genetic information, which includes the entire protein-coding regions of the genome, will also be available to support future research at UHN.

Participant samples will go to Helix for whole exome sequencing. Participants will receive results, access to genetic counselling, and ongoing genomic insights about their health throughout their lifetimes.

COLLABORATION AIMS TO AUTOMATE SINGLE-CELL TRANSCRIPTOMIC WORKFLOWS

SPT Labtech and Alithea Genomics have announced a collaboration to develop an automated solution for single-cell transcriptomics.

The collaboration integrates Alithea Genomics' ultrasensitive single-cell RNA-sequencing technology, Mercuriu Flash-seq, with SPT Labtech's firefly liquid handling platform, creating a scalable and reproducible workflow for transcriptomics research. The automated workflow is immediately available to customers worldwide through SPT Labtech and Alithea Genomics' application support teams.

The collaboration addresses a bottleneck in the rapidly expanding single-cell transcriptomics field, which is driving advances in cell biology, immunology, and drug discovery. Many workflows remain limited by manual library preparation steps, which can introduce variability and constrain throughput. This collaboration aims to rectify this issue by combining firefly's low-volume precision dispensing with Alithea Genomics' scalable RNA-sequencing chemistry, thereby improving reproducibility, throughput, and accessibility for single-cell studies. As demand for higher-throughput, cost-efficient single-cell sequencing grows, the ability to automate sensitive RNA-sequencing protocols becomes essential for academic and research environments.

SPT Labtech officials said that the collaboration is a step toward broader automation of complex RNA workflows, supporting the growing integration of transcriptomics into translational and clinical research.

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Ask The Expert

Strategies labs can use to minimize blood draw volumes

By Emily Ryan, PhD, DABCC

Why minimize blood draw volumes?

a: Minimizing blood draw volumes for patients is critical because repeated phlebotomy can quickly accumulate, leading to significant blood loss over the course of a hospital stay. This loss contributes to hospital-acquired anemia or iatrogenic anemia. Anemia, both at admission and at discharge, is linked with increased complications associated with mortality and readmission rates. It is for these reasons that projects minimizing phlebotomy blood loss can fall into larger hospital quality projects. By optimizing blood draw volumes laboratorians can play a pivotal role in supporting patient safety and quality care initiatives.

What can a laboratory do to reduce blood loss due to phlebotomy?

There are four foundational strategies that laboratories can implement to minimize phlebotomy-related blood loss:

- Use closed blood sampling devices: These systems, such as venous arterial blood management protection systems (VAMPS), return the blood used to clear IV lines back into circulation, significantly reducing wastage.
- Reduce the size of collection tubes: Transitioning from traditional 6-10 mL tubes to smaller vacutainers (2-3.5 mL) or microtainers can substantially decrease the total blood volume drawn.
- Bundle orders for a single collection instance: Coordinating multiple laboratory collections into one blood draw minimizes the number of venipunctures and the cumulative volume of blood collected.
- Point-of-care testing (POCT): While this can reduce laboratory blood draws, it should be reserved for situations that make operational sense and do not overburden clinical staff. As an example, consider respiratory therapists performing blood gas analyses on analyzers available in the intensive care unit (ICU). Adding electrolyte testing on those blood gas analyzers may decrease the need to collect another tube for the main lab.

In our practice, we rely heavily on closed blood sampling devices in the ICU and microtainers for patients who refuse blood products or are stable but severely anemic. While POCT has its place, it should be considered carefully to avoid interfering with patient care and staff efficiency.

Are microtainers the only option?

When we began our blood conservation efforts over 15 years ago, microtainers were the most consistently available option from vendors. Today, the landscape has changed, and vacutainers are now available in smaller sizes (2-3.5 mL). Modern laboratory automation and analytical instruments are also equipped with sensitive liquid level sensors, allowing seamless use of varied tube sizes.

We use microtainers for whole blood hematology and perform offline specimen processing in chemistry followed by a false-bottom tube that is automation ready. Microtainers are 1%-2% of our overall adult inpatient volume and only have a slight impact on turnaround time (for example, the median turnaround time for a complete blood count is now 16 minutes versus 10 minutes).

Where do I start to tackle blood loss due to phlebotomy?

I would start in the acute care setting and assess each patient's daily blood loss due to laboratory testing. To do this, calculate a daily total blood volume for each patient, which your laboratory information system should be able to help with. Find out how many specimens are collected from lines as well. Hopefully there is a collaborator in nursing or quality, or maybe a transfusion coordinator, that can help with this. If patients consistently lose more than 50 mL daily due to phlebotomy, there is room for improvement. Closed sampling devices should be explored, especially for difficult sticks.

Emily L. Ryan, PhD, DABCC, is a clinical lab director at Advocate Clinical Laboratories and oversees the hospital-based laboratories in Georgia.

+EMAIL: emilyluryan@gmail.com

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