March/April 2026

CLN Clinical Laboratory News

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**MEXICAN BIOBANK FINDINGS**

**>15%**

The percentage of people from the Yucatán Peninsula who carry a gene variant known to hinder statin metabolism.

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# The problem with lab plastics

**A chat with JALM's editor in chief**

**Ins and outs of remote blood collection**

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## FEATURES



## DEPARTMENTS



**Sample stability — particularly temperature regulation during transport and the time to centrifugation — poses one of the biggest hurdles for laboratory testing on remotely collected blood.**
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On the cover: Almost Green Studio / iStock

# Federal Insider

## ADLM congressional briefing urges lawmakers to ensure quality pediatric testing

The Association for Diagnostics & Laboratory Medicine (ADLM) held a congressional briefing on Wednesday, February 2 that highlighted several ways that Congress can improve the quality of care provided to the United States' 73 million children.

Danyel Tacker, PhD, DABCC, FADLM, clinical professor at West Virginia University Hospitals, highlighted the importance of newborn screening (NBS), which helps ensure that babies with rare but treatable conditions receive necessary testing. Congress can play a vital role in NBS by continuing to provide stable funding for this highly successful federal-state initiative.

Stanley F. Lo, PhD, DABCC, FADLM, pathology professor at the Medical College of Wisconsin, described the need for more accurate pediatric reference intervals (PRIs), which help physicians interpret test results and diagnose whether a child has a particular medical condition. Currently, most PRIs are based off of adult reference intervals, which can lead to misdiagnosis, inappropriate interventions, and increased healthcare costs. Congress has asked the Centers for Disease Control and Prevention (CDC) to develop a framework for addressing this issue.

Hubert Vesper, PhD, director of Clinical Standardization Programs at the CDC, discussed how the agency can use its existing infrastructure — without creating any new programs — to develop better PRIs. More than 50 healthcare groups, including ADLM, the American Academy of Pediatrics, and the Children's Hospital Association, have endorsed providing the CDC with the funding needed to improve these intervals.

Lastly, Dennis J. Dietzen, PhD, DABCC, FADLM, Megan Dishop Chair of Pathology and Laboratory Medicine at Phoenix Children's Hospital, discussed the critical role that laboratory developed tests (LDTs) play in meeting the testing needs of children. He stated that the congressionally mandated CLIA standards continue to provide the flexible, but rigorous oversight needed to serve pediatric patients.

### NEW LAW WILL DELAY MEDICARE CLFS CUTS

In January, the House of Representatives voted to pass the Consolidated Appropriations Act of 2026 (HR 7148). This bill, which the Senate also voted in favor of, was signed into law by President Trump on February 3 and will freeze Medicare Clinical Laboratory Fee Schedule (CLFS) cuts until January 1, 2027.

The yearlong delay comes after the scheduled implementation of the Protecting Access to Medicare Act (PAMA) rate cuts and laboratory reporting requirements had already begun on February 1. Approximately 800 laboratory services were slated to be cut by up to 15%. In addition to blocking these cuts, the Consolidated Appropriations Act of 2026 will delay the current PAMA reporting period from Feb.1–April 30 to May 1–July 31. Labs must now report their private payer payment data from the first 6 months of 2025, rather than from 2019. The Centers for Medicare and Medicaid Services will use this data to calculate CLFS rates for 2027.

The Congressional Budget Office forecasted that these changes will save the government $495 million over the next 10 years.

However, many medical societies, including the Association for Diagnostics & Laboratory Medicine, are still advocating for Congress to pass the Reforming and Enhancing Sustainable Updates to Laboratory Testing Services (RESULTS) Act. This bipartisan legislation would reform PAMA, addressing structural flaws in the CLFS that threaten access to essential diagnostic services.

### NIH FY 2026 BUDGET INCREASES UNDER NEW LAW

In February, President Trump signed into law the Consolidated Appropriations Act of 2026 (HR 7148), increasing the budget for the National Institutes of Health (NIH) in fiscal year 2026 by just

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under 1%, or $415 million, to $48.7 billion.

If the Consolidated Appropriations Act of 2026 had not been passed, biomedical research efforts would have been threatened by a proposed 40% cut to the 2026 NIH budget that the Trump administration originally put forth last spring.

Previously, the Trump administration had canceled, frozen, and delayed thousands of NIH grants, including those supporting students and researchers from underrepresented groups.

The Consolidated Appropriations Act of 2026 grants the NIH $48.7 billion for investments in biomedical research, including Alzheimer's disease and related dementia research, cancer research, diabetes research, and women's health research. In particular, the funding includes $7.35 billion for the National Cancer Institute, $6.59 billion for the National Institute of Allergy and Infectious Diseases, $663.2 million for the National Human Genome Research Institute, and $1.5 billion for the Advanced Research Projects Agency for Health.

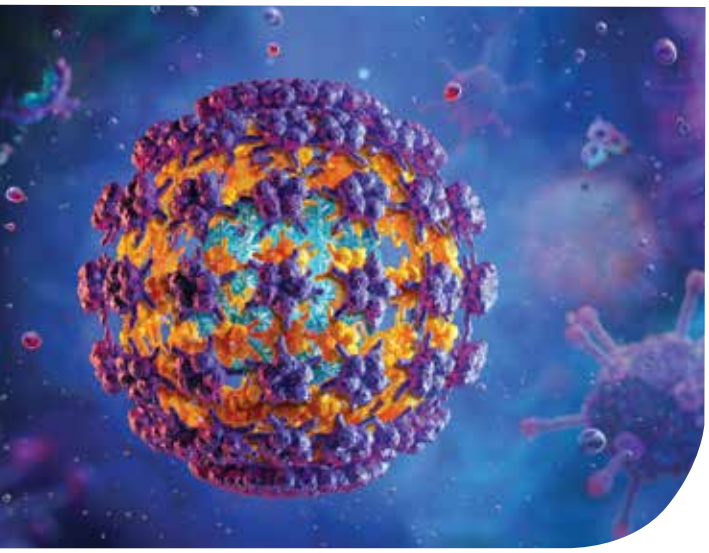
The new legislation also prevents cuts to indirect costs — payments the NIH makes to the institutions of grant holders to cover shared infrastructure. A year ago, the Trump administration tried to cap those costs at 15% of the total grant amount. However, that rate cap faced multiple lawsuits. In January, the U.S. Court of Appeals for the First Circuit affirmed an injunction barring the rate cap, which was set by the U.S. District Court for the District of Massachusetts in April 2025.

# Implementing self-collected patient specimens for infectious disease testing

BY ALLISON EBERLY, PHD, D(ABMM)

Allison Eberly, PhD, D(ABMM)

Self-collection, or specimens collected by the patient themselves, represents an innovative patient-centered strategy for expanding access to testing for infectious diseases. Over the past 2 decades, self-collection has demonstrated comparable or even superior performance relative to clinician-collected specimens for sexually transmitted infections (STIs) (*1*,*2*). While the uptake has been perhaps slower in the U.S. due to regulatory considerations, the SARS-CoV-2 pandemic in 2020 progressed the need for self-collected specimens, highlighting the practicality and potential to expand diagnostic reach. Self-collection of specimens for STI testing, including cervical cancer screening via human papillomavirus (HPV) molecular testing, shows promising results for expanding access to care (*3*).



For laboratorians, the task of implementing self-collected patient samples can seem formidable in terms of operationalization, regulatory compliance, and quality assurance. This article discusses key components of this process. While this discussion primarily focuses on self-collected specimens obtained in a clinic setting, many of the principles also apply to at-home collection. However, at-home collection introduces additional regulatory considerations, such as specimen stability, transport conditions, and temperature control, which are beyond the scope of this discussion.

## Engaging key parties

Most laboratories have likely already been approached by clinicians or administrative leaders regarding the availability of self-collection for infectious disease testing. Within the last 2 years, the Food and Drug Administration has approved multiple self-collection devices and tests for HPV testing, leading to highlights in the news. Before introducing any new specimen type or test, however, laboratories must clarify expectations regarding test performance, turnaround time, projected test volumes, and staffing needs. Understanding these operational requirements is critical to developing a feasible and sustainable implementation plan.

The best way to gain this understanding is to engage early and often with colleagues who will be impacted by self-collection. For infectious disease self-collected specimens, this will include infectious disease physicians and those in outpatient clinics, especially primary care providers and OB/GYNs for STI and HPV testing. Engaging subject matter experts early in the process also ensures that the laboratory understands the clinical need and potential impact on patient care.

## Regulatory and verification considerations

Your regulatory or accrediting agency may have specific guidance for self-collected specimens due to the potential for different preanalytical variables. Clinicians are trained to collect specimens consistently, whereas patients may have varying degrees of comfort and ability, potentially affecting specimen adequacy. For instance, a human target, serving as a control, may be necessary to confirm sufficient cellular material has been collected.

Verification or validation should be performed for each specimen type that will be acceptable for testing on an assay. Laboratories should refer to the regulatory minimum requirements, Clinical and Laboratory Standards Institute standards, or professional societies for guidance on the components to evaluate.

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Labs should also pay special attention to standards that accreditation and regulatory bodies are implementing regarding patient instructions for self-collected specimens. The College of American Pathologists (CAP), for example, recently added the requirement for laboratories to provide clear written instructions for patient self-collection that explain both sample collection and proper handling (*4*).

The lab should take part in the creation of these specimen collection documents. While manufacturers may supply instructions in kit packaging, these materials may not always be user-friendly or accessible to all patients. Optimal patient instructions include stepwise procedures, visual aids, and language appropriate for the reading levels of the target population. Resources should also be available in multiple languages appropriate for the patient population. Labs should collaborate with patient-facing staff and institutional patient education content specialists to ensure the clarity and completeness of these instructions, as well as patient comprehension.

## Logistics and communication

Operational planning is essential for smooth integration of self-collected specimens into laboratory workflows. Laboratory leadership should coordinate with clinical teams to ensure collection devices are available, appropriately stocked, and accessible in clinic areas. The laboratory information system should distinguish between clinician-collected and self-collected specimens for result reporting and for monitoring quality metrics.

Clear communication channels are critical for notifying affected parties about new test availability, workflow changes, and go-live dates. Utilizing established institutional communications, such as internal newsletters, email updates, or laboratory liaison programs, facilitates broad awareness and adoption of new processes among both clinical and laboratory staff.

## Quality assurance and continuous improvement

Quality assurance is a cornerstone of laboratory operations, especially when new workflows and sample types are implemented. Standard operating procedures, job aids, and acceptance criteria must be updated to reflect new specimen types at implementation. Quality control plans should also be updated to include metrics relevant to self-collected specimens, such as rates of sample rejection or collection errors and invalid rates.

Tracking these metrics enables laboratories to identify trends, troubleshoot issues, and implement process improvements. A structured change-management approach, such as DMAIC (Define, Measure, Analyze, Improve, Control), can guide iterative improvements. For example, high invalid rates might prompt revisions to patient instructions or additional staff training. Regular review of quality metrics ensures the laboratory maintains high standards and supports patient-centered care.

## Conclusion

Self-collection for infectious disease testing will continue to evolve testing strategies over the next decade. By enabling easier access to testing, self-collection aligns with broader public health goals and may reduce barriers to patients accessing healthcare. For laboratorians, successful implementation requires balancing patient-centered practices with rigorous scientific standards, regulatory compliance, and operational feasibility.

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# The Sample

## Potential pregnancy reference intervals determined

Recent research highlights substantial changes in blood biochemistry during pregnancy and establishes a trimester-specific reference database for 24 biochemical parameters (Clin Chem 2026;72:192-205).

Establishing trimester-specific reference intervals in healthy individuals poses challenges. Few studies focus on the degree to which maternal adaptation influences clinical marker concentrations, and research varies widely in analytical methodologies, measured biomarkers, and study design. To address this gap, researchers aimed to establish trimester-specific reference intervals for key biomarkers in a well-defined prospective cohort. They used a framework established by the Canadian Laboratory Initiative on Pediatric Reference Intervals.

The researchers collected blood samples at 0 and 13 weeks, 14–27 weeks, 28–42 weeks, and 1–3 months postpartum, then analyzed 24 biochemical parameters from 135 healthy pregnant individuals of median age 33.

Seventeen biomarkers had statistically significant changes. They included alkaline phosphatase, alanine transaminase (ALT), aspartate transaminase (AST), gamma-glutamyl transferase (GGT), creatinine, urea, uric acid, albumin, total protein, C-reactive protein, sodium, phosphate, cholesterol, triglycerides, high-density lipoprotein cholesterol, ferritin, and free thyroxine. Alkaline phosphatase demonstrated marked increases throughout gestation with statistically significant differences between the second and third trimesters and the early postpartum period. The derived upper reference limit for alkaline phosphatase doubled from the second to third trimester, decreasing proportionally in the early postpartum period. ALT, AST, and GGT had consistent reference value patterns throughout gestation but increased at 1–3 months postpartum, the researchers found.

Despite elevated liver enzymes in the postpartum period relative to earlier gestation, most reference values were below the recommended upper limit for nonpregnant adults, with flagging rates from 0–13%. Lactate dehydrogenase did not demonstrate statistically significant changes throughout gestation or the early postpartum period.

Creatinine, urea, and uric acid showed dynamic reference value patterns across gestation. Creatinine and urea demonstrated statistically significant decreases in all trimesters relative to the postpartum period. Upper reference limits derived for creatinine increased by 0.43 mg/dL between the second trimester and 1–3 months postpartum. Further, flagging rates for creatinine using a nonpregnant adult reference interval during pregnancy ranged from 33% in the first trimester to 63% in the third trimester, stabilizing at 8% in the early postpartum period.

Reference intervals were developed using only the Abbott Alinity ci-series system, so the researchers called for additional studies to apply findings to other analytical platforms.

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## MEXICAN BIOBANK COULD HELP TO ADVANCE PERSONALIZED CARE

Data and findings from a Mexican biobank may aid treatment decisions in both Mexico and the United States, a recent study found (Nat Med 2026; doi.org/10.1038/s41591-025-04100-z).

Genetic testing for specific alleles often is recommended based on an individual's ancestry. However, the frequency of pathogenic and pharmacogenomic alleles across different Hispanic groups has not been well-characterized, and existing guidelines often fail to recognize the geographic and ancestral diversity within these populations.

In response, researchers analyzed data from the Mexican Biobank, which includes genetic information from 40,000 individuals across 898 of Mexico's urban and rural areas, including all 31 states and Mexico City. The researchers analyzed 6,011 of the samples with a commercially available genetic array to spot common variants known to affect drug response.

The researchers determined allele frequencies in each state in Mexico and found significant differences across populations and states. For example, nearly 40% of the Chiapas population carries two copies of the allele *rs2242480*, which is linked to slower fentanyl metabolism. In contrast, in the northern state of Sinaloa, only 10% of people do. People with origins in Chiapas, Oaxaca, and Yucatán might benefit from pharmacologic testing for different reasons depending on where they live, the researchers suggested.

The variant *SLCO1B1*, known to hinder statin metabolism, was found in less than 1% of Mexicans from northern states, but in more than 15% of people from the Yucatán Peninsula. Based on these findings, the researchers also suggested that national guidelines should consider adjusting statin dosing in these populations based on genetic testing to reduce the risk of myopathy and rhabdomyolysis associated with long-term exposure.

The researchers plan to make results available for 42,769 biomedically relevant genotyped variants through MexVar, a user-friendly platform designed to improve access to genomic data for the scientific community and to support genetic analyses for populations of Mexican descent worldwide.

**HPV sample self-collection increases cervical cancer screening uptake among underscreened women from marginalized low-income and racial and ethnic backgrounds.**

## SAMPLE SELF-COLLECTION EQUALLY GOOD FOR HPV AND STI SCREENING IN AN UNDERSERVED POPULATION

Equal proportions of women from marginalized backgrounds — nearly 1 in 6 — tested positive for human papillomavirus (HPV) and another of three sexually transmitted infections (STIs) in a recent study of sample self-collection in this population (JAMA Netw Open 2026; doi:10.1001/jamanetworkopen.2025.51345).

HPV sample self-collection increases cervical cancer screening uptake among underscreened women from marginalized low-income and racial and ethnic backgrounds, previous research shows.

To address this issue, the researchers conducted a secondary analysis of the My Body, My Test–3 study, a randomized clinical trial testing a mailed self-collection intervention to improve cervical cancer screening. In the secondary study, the researchers aimed to evaluate an intervention featuring streamlined testing for chlamydia, gonorrhea, and trichomoniasis, alongside HPV self-collected samples. Using mailed self-collection kits, they determined the prevalence of HPV and the other STIs with simultaneous testing of a population of low-income women in 22 counties in North Carolina, who were overdue for cervical cancer screening. The study randomized the 327 women to the trial intervention group with valid STI and HPV results. The researchers tested samples using the Aptima assay.

Among participants of median age 42, of which 8.6% were Hispanic, 44.7% were non-Hispanic Black, and 133 were non-Hispanic White. Nearly 1 in 6 participants, or 15.6%, tested positive for one of the other STIs, the same rate as those positive for HPV. Just over 2% tested positive for both. Risk factors for other STIs included non-Hispanic Black race and ethnicity, White race and ethnicity, having two or more sexual partners in the last year compared with having none, being single compared to being partnered, and smoking.

Among participants who tested positive for other STIs, 66.7% received follow-up care, the researchers reported.

# REDU PLASTIC

A ubiquitous component of the lab threatens both the environment and human health. Here's how lab professionals can reduce plastic pollution and enhance overall efficiency in healthcare delivery.

# CING WASTE

## IN LABORATORY MEDICINE

**BY SEEMA KHATTRI BHANDARI, PHD, AND JOE R. WIENCEK, PHD, DABCC, FADLM**

Single-use plastics are widely used in medicine because of their sterile nature, low-cost, and ease of handling. The United States healthcare sector alone generates 1.7 million tons of plastic waste each year (*1*), with clinical laboratories contributing substantially to the total. A recent analysis of waste generated from running basic metabolic panels on several major analyzer platforms revealed that the majority of waste components were plastic (*2*). Commonly used plastic items in the lab include syringes, blood collection kits and containers, culture dishes, pipette tips, urine collection cups, cuvettes, gloves, and specimen bags.

Previous page and left: Almost Green Studio / iStock

Although undoubtedly convenient, plastics pose pressing challenges. From production and distribution to disposal, the entire life cycle of plastic contributes significantly to rising carbon emissions. Additionally, as the worldwide population grows, so does the demand for medical services. This surge, combined with advances in diagnostic technologies and an expanding menu of available tests, has led to a dramatic increase in laboratory testing — and a corresponding rise in plastic waste.

The potentially hazardous nature of medical waste adds to these complexities. In most cases, such waste is incinerated to eliminate harmful pathogens. Although this process reduces the volume of waste by up to 90%, incineration can release toxic chemicals, including carcinogenic dioxins and furans, into the environment. Discarding healthcare waste in landfills is a cheaper alternative, but that approach also comes with problems (*3*). Nonbiodegradable plastic waste eventually breaks down into smaller particles called microplastics, which have been linked directly to infertility, multiple endocrine disorders, and increased risk of cancer (*4*).

Given that experts predict plastic production will triple by 2060, plastic pollution is an escalating global crisis. This article describes how clinical lab professionals can critically examine laboratory waste streams, identify opportunities to prevent and reduce plastic use, and adopt safe, sustainable alternatives appropriate for healthcare settings.

## A SHIFT TOWARD SUSTAINABILITY

To address the plastic crisis, experts urge a societal shift away from the traditional linear economy, characterized as a "take, make, waste" model, toward a circular approach that involves extending the lifecycle of materials through reuse and recycling.

Echoing this philosophy, the World Health Organization promotes a waste-management hierarchy that ranks methods ranging from least to most desirable as: disposal, recycling, reuse, reduction, and prevention (*5*). By prioritizing prevention and reduction, this framework supports sustainable practices that align with the principles of a circular economy.

So, where do clinical laboratories fit in? They can contribute meaningfully by promoting responsible and appropriate test utilization. Estimates show that each year, labs conduct about 4 to 5 billion medical tests, and studies suggest that 40%–60% of them may be unnecessary (*6*). Although the financial costs of excessive testing are discussed often, the environmental consequences — particularly the waste footprint — are mostly overlooked.

## PREVENTION AND REDUCTION

Erroneous lab results can lead to repeat testing or unnecessary follow-up testing, which in turn contributes to increased waste generation — not to mention compromising patient care and driving up healthcare costs. For laboratory staff and other healthcare professionals, education and ongoing retraining have been shown to reduce the occurrence of these errors.

Research indicates that 60%–70% of laboratory errors occur at the preanalytical phase, or before samples even reach the lab. Primarily stemming from manual processes, preanalytical errors can encompass a range of issues, including incorrect test requests, problems with test naming, mistakes related to patient preparation and sample collection, mislabeling, and mishandling or improper transportation of specimens.

Laboratorians can partner with clinicians and optimize clinical decision support systems to reduce the likelihood of these problems. For example, electronic medical record systems can be modified to remove the option to order daily labs by default or to alert clinicians when recent results for a test remain stable.

Collaborating with providers also can improve sustainability. With rapidly expanding test menus, it is understandable that clinicians experience uncertainty and challenges when ordering tests and interpreting results. Lab

**Although reusability should be encouraged, it must be balanced with practical considerations of overall cost, resources, accuracy, and safety.**

professionals must make themselves accessible for consultations to reinforce appropriate test utilization and provide expert input as needed (*7*).

They can also help promote sustainable quality control (QC) procedures. Although QC plays a vital role in ensuring accurate and reliable results, traditional methods often produce significant waste. For instance, conventional QC involves aliquoting liquid samples into separate cups for analysis, adding steps and materials to the workflow.

However, newer QC systems use tubes that can be scanned directly and loaded onto analyzers, eliminating the need for aliquoting (*8*). This not only streamlines the process, but also reduces plastic and improves overall lab efficiency. As these innovations become more accessible, lab leaders should reassess their QC requirements for each analyte and adopt approaches that balance accuracy with sustainability.

Recent studies have shown that small-volume blood collection tubes can reduce transfusions in intensive care. Similarly, the choice of blood collection tube sizes also can make a huge impact on plastic waste. A recent letter to the editor of a clinical chemistry journal, which centered on diagnostic stewardship around vitamin D test ordering, showed that switching from 5 mL to 3.5 mL tubes could result in substantial plastic avoidance. Over a 1-year period, this minor 1-g difference in plastic between the two tube sizes resulted in a cumulative estimate of 98,820 g of plastic saved (*9*).

## REUSE AND RECYCLING

When prevention is not feasible, reusing materials offers another sustainable solution for clinical laboratories. However, this practice must be carefully managed to minimize the risk of contamination and ensure patient safety. Glass items, for example, can be cleaned and sterilized for repeated use, reducing reliance on single-use plastics. And when appropriate safeguards are in place, refillable pipette tips can be viable alternatives to preloaded tip boxes.

That said, the shift to reusable materials comes with tradeoffs. Cleaning and sterilization processes consume water and electricity, which contribute to carbon emissions and operational costs. They can also increase the workload for laboratory staff, potentially requiring additional personnel. Although reusability should be encouraged, it must be balanced with practical considerations of overall cost, resources, accuracy, and safety.

Recycling waste also should be considered wherever possible. One study found that, over the course of a year, approximately 21% of the waste produced from conducting complete metabolic panels was recyclable, consisting of paper, plastic, cardboard, and other materials labeled with appropriate recycling codes (*10*).

In healthcare settings, plastic waste is rarely recycled due to concerns about contamination with hazardous biochemical substances or biological fluids. For example, blood collection tubes — a major source of plastic waste in clinical laboratories — are not commonly recycled. Institutions and manufacturers have recognized this issue and are researching the use of blood collection tubes made of plastics that can be safely recycled following decontamination (*11*). Laboratorians should champion innovative approaches like this, promote them within our community, and encourage manufacturers to adopt similar sustainable practices.

## LEVERAGING DEMAND

With demand comes supply, and clinical laboratories must take the lead in demanding sustainable products. Vendors and manufacturers increasingly recognize the need and the growing demand for sustainability in laboratory medicine. For instance, clinical chemistry analyzers often rely on plastic reagent packs designed for a fixed number of tests. Our studies have identified these packs as a significant source of plastic waste, especially since they cannot be recycled because of contamination with biohazardous materials (*2*,*10*).

We know of at least one vendor that has approached this by increasing the number of tests per pack, thereby reducing the overall volume of plastic waste generated. Lab leaders can use request-for-proposal processes as a strategic opportunity to prioritize vendors

**Labs can incorporate sustainability criteria into their procurement guidelines and prioritize suppliers and vendors who use eco-friendly materials.**

committed to environmentally responsible practices.

Labs can also take advantage of emerging resources that provide third-party verification of products' environmental impact. For example, some manufacturers have adopted the ACT Ecolabel 2.0, developed by the nonprofit organization My Green Lab, to transparently communicate key information through an easy-to-read label.

Additionally, clinical labs can incorporate sustainability criteria into their procurement guidelines and prioritize suppliers and vendors who use eco-friendly materials, streamline water and energy usage, minimize plastic in products and packaging, and provide recycling or take-back programs. By doing so, they not only align purchasing decisions with sustainability goals, but also help catalyze broader industry shifts toward greener standards.

As healthcare demands continue to rise, the need for environmentally responsible practices will only intensify. Reducing our dependence on plastic limits the environmental impact of plastic production. Moving forward, meaningful progress will require innovation, policy reform, and a unified commitment to sustainability across the healthcare sector. Lab professionals can play a lead role in driving this transformation.

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# OPEN TALK ABOUT OPEN ACCESS

**A conversation with *The Journal of Applied Laboratory Medicine's* new editor in chief, Ian Young, MD, about the future of the journal, academic publishing, and laboratory medicine.**

BY JEN A. MILLER

On January 1, 2026, Ian Young, MD, became the new editor in chief of the Association for Diagnostics & Laboratory Medicine's (ADLM's) *The Journal of Applied Laboratory Medicine* (*JALM*). As a previous deputy editor and associate editor of ADLM's journal *Clinical Chemistry*, he is already familiar with the association's publications.

Young serves as the chief scientific advisor for the Department of Health in Belfast, Northern Ireland, U.K., and as the department's director of research and development for health and social care. He is also a professor of medicine at Queen's University Belfast and consultant chemical pathologist at Belfast Health and Social Care Trust.

We spoke to Young about the path he took into clinical chemistry, the trends he sees in laboratory medicine, and how he's working to ensure the success of the journal's new gold open access model. Under this model, journal content is free to read and reuse at the time of publication. The content also still undergoes the same rigorous peer-review and quality-assurance processes as traditional subscription-based academic journals.

### What brought you to laboratory medicine?

I got an undergraduate degree in biochemistry and did my medical training in the U.K., where a medical degree generally requires 5 years of study with the option of an additional residency.

Through all of that, I maintained a strong interest in biochemistry, which drew me towards metabolism and diagnostics in clinical biochemistry. Then I trained as a chemical pathologist, as we call it in U.K. terms.

Clinical practice in the U.K. works a bit differently than in the U.S. As a medically qualified chemical pathologist, I have seen patients throughout my career. I've run outpatient clinics while also being involved with the laboratory. In other words, I've been able to combine being a physician with being a laboratory specialist and academic — and a few other things along the way.

### What is your 5-year goal for JALM?

To start, I want to say how fortunate I am to inherit a journal that is already in a good place, thanks to the excellence of former editor Robert H. Christenson, PhD, and his team.

As I look ahead to the next 5 years, I'm committed to ensuring the success of *JALM*'s transition to a gold open access journal. This model offers many advantages. For one thing, the work published in the journal can be immediately accessed by anyone anywhere, regardless of the resources available to them. Additionally, authors can be confident that their work will be accessible to a bigger audience, and the widespread availability of new *JALM* content will showcase ADLM and its community on a global level.

At the same time, the journal will remain focused on publishing high-quality work that is relevant to the field. That hasn't changed. Every issue will help move laboratory medicine forward.

I also want to increase the international reach of the journal while maintaining significant representation of ADLM members among its authors.

### How will open access affect those who want to publish in JALM?

It's important to emphasize that nobody should feel inhibited from publishing in the journal by lack of resources. Authors concerned about open access fees can contact the journal office to discuss their specific situation and options.

We have a few ways to help people with the cost of publishing. Many prospective authors work in countries where the publisher or university press can reduce or waive publication fees entirely because of where the author is based. Additionally, many institutions have agreements with publishers that allow people affiliated with their institution to publish without charge. We encourage anyone interested in publishing in

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the journal to check if that is the case for their institution. Authors who are ADLM professional members members will also receive a substantial reduction in publication fees.

ADLM strives to keep publication fees as low as possible, and *JALM* is very competitive with other open access journals in the field.

**What's driving adoption of the open access model?**

It's a topic of active discussion in the U.S. and internationally. Increasingly, major funders require the research they finance to be published in gold open access journals or similar publications. Another driver is open access supporters who are very active in the research world. Obviously, there are others who are less enthusiastic about this publishing model, but I'm keen to embrace the advantages it offers.

**What trends do you see emerging in laboratory medicine?**

I think anybody working in our field recognizes the transformative potential of artificial intelligence and data analytics in relation to both test selection and interpretation.

We also continue to see substantial advances in our understanding of basic biology, particularly in the molecular space. These developments will translate to new diagnostic tests and approaches, even if their entry into routine practice is often slower than we anticipate.

Additionally, I'm interested in the global trend of focusing on the clinical utility of diagnostic testing rather than analytic accuracy alone. We need tests to be high-quality and standardized, but we must also address important questions around their impact in particular clinical situations.

Finally, I think there's increasing interest in the sustainability of laboratory medicine. How does our field impact resource utilization, and how can we ensure that we do our work as efficiently as possible?

**What hurdles does laboratory medicine face in the next 5 to 10 years?**

To an extent, the hurdles our field faces are influenced by local factors in country-specific environments. Funding models are very important and differ across countries, although they generally share a drive towards increased efficiency.

I'm also concerned that more advanced technologies are not equally available to all patients, both across and within countries. Important breakthroughs should be implemented as equitably as possible.

**What's one exciting thing your lab is working on right now?**

In my laboratory and my area of research, we're looking at how using nutritional biomarkers can give us better insight into someone's diet than relying on their answers on dietary questionnaires. Surveys aren't always accurate because our memories aren't perfect. We also have a tendency to tell people what we think they want to hear. Ideally, biomarkers would not lie.

**If you could magically make something happen in laboratory medicine, what would it be?**

I would like to ensure that all the tests we use in the laboratory are perfectly standardized, so that every lab would always provide the same result given a particular sample.

**What advice would you give to early career laboratory medicine professionals?**

I've always been struck by something I read when I was young from Samuel Johnson, who was the compiler of the first meaningful English dictionary. He said that everyone he knew who was very successful started work early in the morning and continued all day. In other words, be prepared to put in the effort.

The second thing I would say is that, if you don't love what you're doing, you need to be doing something else.

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Product Spotlight

# One sample, eleven pathogens — designed for today's lab

By Jessica Palomino, PhD

**Introduction**
Gastrointestinal (GI) infections remain a common cause of illness (*1*), yet overlapping symptoms and diverse etiologies can complicate timely diagnosis and treatment (*2*). Laboratories are being asked to deliver faster, more definitive answers, without adding complexity to already stretched workflows. The Xpert® GI Panel is designed to meet that need with a single, multiplex PCR test built for clarity and efficiency.

**What the Xpert® GI Panel does**
Xpert® GI Panel is a multiplex, sample to answer PCR test that identifies 11 clinically relevant GI pathogens — bacterial, viral, and parasitic — from a single stool sample. Its design reflects a targeted approach: covering high value pathogens implicated in acute gastroenteritis while avoiding organisms with negligible impact on clinical management or high rates of colonization, which increase rates of co-detection that complicates interpretation (*3*).

**The case for rapid, reliable GI detection**
Traditional diagnostic workups often involve culture, antigen tests, microscopy, and multiple specimen collections. These methods are time consuming and labor-intensive. Sensitivity also varies across techniques. Delayed results can contribute to unnecessary imaging, empiric antibiotic use, and extended isolation days (*4*).

**How the panel works**
The panel runs on GeneXpert® systems with 10-color technology that enables multiplex detection of 10 or more PCR targets. GeneXpert systems automate sample extraction, nucleic acid amplification, and detection, with a load-and-go workflow that requires less than 1 minute of hands on time.

**Key features**
- 11 GI pathogens (bacteria, parasites, viruses)
- <1 minute hands on time
- ~74 minute time to result
- Closed cartridge system to reduce contamination risk
- Designed to consolidate multi step traditional workflows
- Stool samples in Cary Blair transport media

**Benefits for clinical laboratories**
The panel consolidates multiday, multimethod investigations into a single standardized workflow. With timely and appropriate diagnostic testing, labs can potentially reduce culture burden and multiple reflex assays, and lessen reliance on microscopy specific expertise. The simple workflow is designed to help streamline operations with convenient on demand testing. And for clinicians relying on lab outputs, clinically relevant information can guide isolation decisions and promote antimicrobial stewardship, allowing teams to respond promptly to suspected outbreaks and high-risk cases.

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

AN INTERVIEW WITH SHANNON HAYMOND, PHD

# The power of data in laboratory medicine

The Association for Diagnostics & Laboratory Medicine's (ADLM's) new Data Science in Laboratory Medicine Certificate Program is designed to give clinical laboratorians and pathologists an edge in a field increasingly driven by data and analytics. Participants will learn how to set up effective data governance structures; request and process lab data appropriately; address issues of data integrity, accuracy, and structure; and evaluate when and how to use machine learning approaches.

*Clinical Laboratory News* recently spoke with Shannon Haymond, PhD, DABCC, FADLM, former ADLM president and faculty member of the data science certificate program, about this exciting new educational offering and the important role of data science in today's labs.

**Why and how did you end up making data science one of your areas of expertise?**

As a clinical lab director, I frequently encountered situations where I felt like we had data that could guide me, but I didn't have the right access or tools to use it.

Data science wasn't really a part of my training. As a clinical chemistry fellow, I learned basic statistics, but beyond that I didn't have the skills I needed. In 2015, when I saw that my dear friends Stephen Master, MD, PhD, FADLM, and Daniel Holmes, MD, FRCPC, were teaching a course on the R statistical programming language, I enrolled. The course, called "Breaking up with Excel," focused on the power of using R for data preparation, analysis, and visualization, particularly in cases where Excel is unsuitable or limited. It helped me to see that this type of tool and skillset was what I was missing and needed.

After recognizing that my own laboratory could benefit from using data science, I convinced my boss to make it an area of emphasis across the department. I decided that, if I was going to lead this effort, I needed to expand my education. I enrolled in a master's program in predictive analytics, where I learned a bunch of stuff I didn't know I needed to know about databases, data visualization best practices, and more.

What really compelled me from that point forward was that knowledge that more people in our field could benefit from learning about data science. This isn't widely covered or required in current undergraduate clinical laboratory science, PhD clinical fellowship, and pathology residency programs. There's a pathway for MDs to formally build these skills through informatics fellowships. Increasingly I hear of PhDs completing data science-focused master's programs, like I did. Given the interest from the community and a lack of available options focused on application in lab medicine, I felt it was important for ADLM to offer a certificate program on this topic.

**What is one way your lab uses data science to improve testing?**

In 2017, we began a journey to use data science and analytics more broadly throughout the department. We built a culture where people now expect to have data and visualizations to guide their decision-making and problem solving.

We also have projects underway in genomics interpretation, where we're looking to augment and automate workflows with artificial intelligence (AI) and large language models (LLMs). Additionally, we help our bioinformatics staff and laboratory directors to extract data from clinical notes, which we can use to better understand which variants we should prioritize.

**What do you hope labs will be able to accomplish with data science in the future?**

I hope we find ways to develop AI tools such as LLMs that provide accurate, reliable, safe, and predictable results.

**Are there any hopes for data science that you think are unrealistic?**

I don't think so. I tend to be pretty optimistic. However, I do think that we underappreciate the limitations of some of these technologies. We have a lot of work to do to make them safe and reliable.

**What hurdles face the development of data science in laboratory medicine over the next 5 to 10 years?**

Cybersecurity challenges. There's a big gap between the solutions we need and what vendors can currently achieve, which can make

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implementation difficult in a healthcare system.

Software costs and integration capabilities also have been barriers, but some of these new tools are improving at an impressive rate.

Another limitation has to do with building and upskilling the workforce. It's not just lab directors who need to be able to interact with these technologies — the folks working in labs must also improve their data literacy and computational thinking skills. Just because people have more access to data doesn't mean they know what to do with it. We need to stay on top of those skills.

**What will ADLM's data science certificate program cover?**
When we conceived the program, we based it on expert consensus. In other words, we asked data science experts in our field, "What do you think the key learning objectives are for lab medicine professionals and trainees?" We then developed our curriculum around the areas where we saw very high agreement.

Topics covered in the program include data management, data security, data visualization, and machine learning. The program not only explains important concepts, but also teaches people how to apply them. For example, participants learn how to evaluate machine learning and how to formulate data requests. We really try to enable people to work with data themselves and communicate effectively with IT and data science experts.

**Just because people have more access to data doesn't mean they know what to do with it. We need to stay on top of those skills.**

**What makes the program unique compared with other data science educational programs?**
We feel great about the content of the program, which was vetted by numerous experts and covers must-know skills for everyone. It was developed by people who are passionate about data and have extensive experience teaching it to laboratory medicine professionals.

Although you can find data science education everywhere, and some of it is even free, this certificate program was designed specifically for the laboratory medicine community. The examples provided will be very relatable to this audience. This specificity will help learners feel more engaged with the material and improve the translatability of the skills they learn to their work.

**Once people complete this program, what should they be able to do in practice?**
We don't expect people to walk away as experts in data science, but they will have a solid foundation of critical skills. After they finish the program, they will be more effective with accessing data, managing data, doing data visualization, and communicating about data. They will also understand the basics of how to assess and evaluate machine learning applications.

**What should their next steps be if they want to learn more?**
ADLM has several practical resources they can use to further their skills or practice what they learned.

After taking the course, they can get started on their own projects. I also recommend attending the ADLM Annual Meeting and other events where people can learn more in a focused area of data science.

**What advice would you give to lab professionals who want to get started in data science?**
Learning this stuff is step one. What's really going to propel you is using it to address your own problems. You need to have strong internal motivation to do this, since applying data science to your everyday work can be hard at the start when you are first gaining access to data and tools and building your skills. Starting with the areas you find most interesting is a great way to accelerate your learning and deepen your enthusiasm. It can even be fun! Data science skills are very sought-after these days, so mastering them can also boost your career. In short, being able to leverage data to solve problems is very powerful.

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AN INTERVIEW WITH ANTHONY KILLEEN, MD, BCH, PHD

# Harnessing data science in laboratory medicine

In January, the Association for Diagnostics & Laboratory Medicine (ADLM) launched a Data Science in Laboratory Medicine Certificate Program designed specifically for clinical laboratorians and pathologists. The new program teaches participants how to set up effective data governance systems; request and process lab data appropriately; ensure data integrity, accuracy, and structure; and evaluate when and how to use machine learning. In short, it puts laboratory professionals at the forefront of some of the most transformative technologies in healthcare.

To gain more insight, *Clinical Laboratory News* spoke with Anthony Killeen, MD, BCh, PhD, DABCC, FADLM, a faculty member for the program and ADLM past president. Killeen talked about the state of data science in the clinical laboratory and the need for this exciting educational offering.

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

I got into data science later in my career. The University of Minnesota, where I'm a professor of laboratory medicine and pathology with an interest in clinical chemistry, serves as a central laboratory for a large number of clinical trials, many of which the National Institutes of Health funds.

These trials generated many data points, which we then passed off to coordinating centers that had statisticians to analyze them. I thought, "gosh, I'd like us to analyze some of that data ourselves." Then I earned a master's degree in evidence-based healthcare and medical statistics at Oxford University.

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

We use a lot of data science, mostly statistical analysis, to assess quality control in our clinical trials lab. Among other metrics, we investigate the long-term stability of analytes in stored specimens, such as frozen blood samples containing glucose. We want to know how long such samples are stable. Is it 3 months? Three years? Ten?

We're also looking at implementing real-time monitoring of patient results as a statistical quality control. For instance, if a patient's glucose assay begins to drift away, we can gauge that something's wrong before the actual quality controls flag it.

Additionally, we use data science in computational pathology. Although I'm not personally involved in this work, other lab leaders analyze the information gleaned from high throughput genetic sequencing, for example.

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

One of the most exciting developments is the integration of laboratory medicine with higher-end artificial intelligence (AI) and machine learning capabilities.

Clinical laboratories have always generated huge amounts of data on a daily basis. But hardware and software were not readily available for doing higher-end analytics. AI is changing that.

To share an illustrative example from everyday life: For a long time, labs were operating similarly to ATM machines. We'd receive a sample — like a card in the machine — and spit a number back out, similar to an ATM's cash output. While the ATM might give you a receipt with your balance on it, it doesn't usually provide any additional information, such as whether there's a sale at Nordstrom or that the gas you just paid for is 50 cents cheaper across the street.

Now imagine if we could take a lab result and generate a report filled with similarly useful, interpretive medical information. For instance, we might learn whether a lab value has risen by 10% within the last 24 hours, prompting a possible flag, or if lab results don't align with imaging findings from the same patient. If you could put those pieces together, you could get a powerful, predictive prognostic tool. That's the goal: to extract a wealth of valuable information out of the data we already generate.

**Are there any hopes for data science that you think are unrealistic?**

I'm optimistic that a lot of good things will happen. That said, as with any other tool, we need to be very careful about ensuring the accuracy of the information we

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glean through data science. There needs to be appropriate caution before you implement all new technologies. You must validate that they work as intended by doing reality checks along the way.

**What hurdles face data science in lab medicine over the next 5 to 10 years?**
One of the limitations is laboratorians' lack of familiarity with the technology. We will need to train people in how to use these tools, become comfortable with them, and gain proficiency with them. Clinical laboratory professionals at multiple levels must understand the basic principles of data science and acquire the skills to apply them effectively. Not everybody will learn coding languages like R or Python, but lab professionals should grasp the goals of data science projects in their labs and know how to evaluate data outputs.

It's also important to understand the costs. Although a software package may be free to run, the information generated in a project may have financial implications, which should be considered on the front end as much as possible.

**Why is it important for laboratory medicine professionals to learn about data science?**
We're at the beginning of a big wave of data science applications in lab medicine. If you have the right tools, you can take millions of numbers and extract a story out of them. It's really exciting.

**If you have the right tools, you can take millions of numbers and extract a story out of them. It's really exciting.**

More broadly, laboratorians need to be cognizant of the larger technical and scientific landscape in which they operate. To stay up to date on how key trends shape your own field, you must not only stay abreast of the literature, but also be able to critically evaluate it.

**What will ADLM's data science certificate program cover?**
It's an introductory course for people who either work in laboratory medicine or who are at least familiar with it and want to expand their skillset. Participants will engage with 12 hours of educational content from prerecorded lectures and take a test to assess what they learned.

**What distinguishes this program from other data science educational programs?**
The program was developed to meet the specific needs of professionals working in the context of lab medicine. While other professional development offerings might target engineers or social scientists, this one has educational materials and examples taken from the clinical lab. It's very focused.

**Once people complete this program, what should their next steps be?**
They should get engaged in a couple of projects in their own institution so they can apply the skills they learned. Although this is not a full-year course or degree program, it does provide a solid framework that should empower people already familiar with laboratory medicine to use data science in their work.

I hope participants attend the ADLM Annual Meeting and present abstracts based on their projects, write papers on what they're doing, and otherwise share their efforts.

I also want to add that, although the certificate program is open to both ADLM members and non-members alike, ADLM members in particular can go on to join the association's Data Science and Informatics Division. The community has an online forum where people can discuss what they're doing and any problems they encounter.

**What advice would you give to lab professionals looking to get started in data science?**
Jump in and do it! If you work in lab medicine, now is the time to start your journey in data science.

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BY MICHAEL ASTION, MD, PHD

# Financial reimbursement from payers: Essentials for the fair treatment of clinical laboratories

LABORATORY STEWARDSHIP FOCUS

The primary financial goal of laboratory stewardship is to achieve financial alignment between patients, labs, and payers. Reaching this goal involves cultivating a shared understanding of medical necessity. When all parties are aligned financially, patients are protected from financial toxicity, labs are paid fairly for medically necessary testing, and insurance companies do not pay for fraud, waste, quackery, or abuse.

Our previous work published by the Association for Diagnostics & Laboratory Medicine, which is based on findings from PLUGS (Patient-Centered Laboratory Utilization Guidance Services) and PLUGS collaborators, focused on the perspectives of payers and patients (*1*,*2*) and explored medical necessity policies (*3*), the revenue cycle (*4*), and other topics.

In this article, we highlight clinical laboratory perspectives on financial fairness.

Table 1 shows a consensus list of what clinical laboratory leaders desire regarding financial fairness from payers.

**Transparent and accessible coverage criteria.** Laboratories need access to clear, comprehensive coverage policies that address medical necessity and administrative policies that cover payable ICD-10 codes, prior authorization requirements, and bundling rules. These policies should be readily available to ensure timely filing, fair claim adjudication, and informed test ordering. When applicable, laboratories should be informed about which third-party vendors their payers are using for payment integrity or lab benefits management.

**Timely and prior notification of policy and fee schedule changes, with reimbursement that allows for a profit.** Laboratories should be notified in advance of any changes to medical policies, claims rules, or fee schedules impacting reimbursement. This includes adjustments to the list of payable or unpayable diagnosis codes for a laboratory service. Sudden or retroactive changes undermine labs' trust in the fairness of healthcare finance. Moreover, new restrictions on testing have adverse financial consequences for labs. A fair price list is an obvious desire.

**Reimbursement for covered elements of a test panel.** When a laboratory test includes both covered and noncovered components (e.g., expanded gene panels, autoantibody panels, allergy panels, infectious disease panels), laboratories should receive reimbursement for the medically necessary portion rather than a blanket denial of the entire service.

**Reasonable administrative burden.** Laboratories should not face disproportionate prior authorization or documentation requirements, especially for low-cost or time-sensitive tests. They should be allowed to submit appeals in bulk when the rationale for the appeals is based on the same or similar issues. Additionally, they should be permitted to submit prior authorization requests on their own behalf; prior authorization requests for laboratory services

**Table 1.** The six desires of laboratory leaders regarding financial fairness from payers

| |
|---|
| Transparent and accessible coverage criteria |
| Timely and prior notification of policy and fee schedule changes, with reimbursement that allows for a profit |
| Reimbursement for covered elements of a test panel |
| Reasonable administrative burden |
| Balanced treatment when coding is complex |
| Reimbursement for the standard of care |

should not be restricted to the ordering provider.

Given the timeline of laboratory services, and the reality that patients and providers need timely results, prior authorization often is not practical to obtain before performing a medically necessary test (e.g., cancer genomic profiling that determines timely and specific treatment). Therefore, when a service is denied by a payer simply because prior authorization was not obtained, laboratories must have the right to substantiate medical necessity post-service.

**Fair treatment in the context of coding complexity.** Laboratories should not be penalized for ICD-10 coding conflicts or exclusions, such as "Excludes 1" rules, especially when a test is medically necessary and would be covered by one of the codes. In the context of insurance claims and laboratory testing, an "Excludes 1" note indicates that two specific ICD-10 codes cannot be reported together. In other words, the two conditions are not both reimbursable when they appear on the same claim for the same encounter.

The challenge arises when both an excluded and a payable ICD-10 code appear on the claim. In some cases, this can trigger automated denials for the entire claim, rather than just the relevant procedure in the "Excludes 1" notes. Additionally, the procedure sometimes is denied, even though either of the two codes causing the Excludes 1 edit is clinically appropriate.

## Laboratories deserve payment for tests that align with the standard of care.

For a diagnosis that has not been established yet, and for which lab testing is being used to help determine the diagnosis, payable ICD-10 codes should include the major signs, symptoms, and risk factors related to the diagnosis. The payable ICD-10 codes should not be restricted to codes for specific diseases and syndromes before they have been diagnosed.

**Reimbursement for the standard of care.** Laboratories deserve payment for tests that align with the standard of care. The standard of care and evidence-based medicine often are in alignment, such that the standard of care is based on strong evidence. This is the case for common conditions such as atherosclerotic cardiovascular disease.

However, in rare diseases and in patients with multiple comorbidities, the standard often is based on weaker evidence (e.g., prospective, observational studies or retrospective studies). In these cases, nuances in clinical practice that align with the standard of care should be reimbursed, and the insurance policies should provide guardrails on practice rather than narrow rules.

By addressing the six desires outlined in this article, payers, providers, and other healthcare professionals can strengthen their relationships with lab leaders and ensure that laboratories are paid fairly.

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BY MICHELLE STOFFEL, MD, PHD; KLINT KJELDAHL, CT(ASCP); BRENDA TOMANEK, MLS(ASCP); AND JAMES GRACE, MD

# Rewriting one system's lab stewardship story

LABORATORY STEWARDSHIP FOCUS

Effective laboratory stewardship is essential in healthcare, but that doesn't mean it's easy. Building a sustainable, clinician-driven program requires structure, collaboration, and involving the right parties.

In 2016, healthcare leaders at M Health Fairview — a partnership between the University of Minnesota, University of Minnesota Physicians, and Fairview Health Services — launched a laboratory stewardship initiative centered around a single academic hospital. Although there was strong intent and laboratory-led momentum behind the effort, limited multidisciplinary engagement and informatics support made adoption challenging. Without system-wide alignment, progress slowed, and the enterprise faltered.

Luckily, that's not the end of the story. In 2021, M Health Fairview revisited the effort, with a fresh, system-level perspective and commitment to change. With support from ARUP Laboratories' healthcare advisory services, leaders formed a planning committee to redefine the vision, draft a charter, and identify key parties. They focused on community and collaboration.

## Laying the groundwork

This time around, the initiative faced new logistical and staffing challenges because of COVID-19, and leaders were required to emphasize reducing wastage and optimizing specialized testing. In the midst of the pandemic, laboratory functions gained leadership's awareness, which prompted timely action.

For example, the laboratory transitioned to a new laboratory information system (LIS): Epic's anatomic and clinical pathology Beaker modules. This shift presented new electronic health record (EHR) ordering and clinical decision support tools, in addition to richer data for creating reports that highlighted areas of needed intervention.

The LIS changes further increased the lab's visibility with executive leadership, giving the stewardship committee sustained momentum. The clinician-led, multidisciplinary collaboration included physicians, pharmacists, nurses, operational leaders, IT personnel, and informatics specialists. Laboratory informatics and administration leaders aligned stewardship goals with EHR functionality, data access, and clinical workflows, ensuring that provider input shaped decisions.

With ARUP's support, the committee leveraged expertise from the broader laboratory community through online forums, referrals, and national organizations such as the American Society of Clinical Pathology (ASCP) and Patient-centered Laboratory Utilization Guidance Services (PLUGS). Committee members asked for collegial consultations and engaged in knowledge-sharing about specific strategies and lessons learned.

The team built a strong foundation by defining roles and responsibilities, establishing a charter and mission, creating a data-driven process for prioritizing and approving initiatives, developing templates for meetings and reporting, and identifying IT and data needs to support intervention.

In January 2022, the Lab Stewardship Steering Committee was formally launched with broad representation across the care continuum, including professionals from ambulatory care, infectious disease, pediatrics, hospital medicine, pharmacy, nursing, quality, IT/informatics, and pathology.

## Data as the foundation for progress

The committee spent most of its efforts during their first year developing and validating the data tools to inform priorities and guide change. These tools included native EHR analytics such as SlicerDicer and the ARUP Analytics Comprehensive Dashboard to review test volumes, orders per encounter, and cost impact. The data gleaned from these tools enabled a spectrum of insights, ranging from understanding healthcare utilization at the population level to learning how one individual used a given test. It provided a 10,000-foot view of the overall testing landscape.

## Early wins and building momentum

With the structure in place, the committee quickly identified and prioritized initiatives, including daily lab utilization optimization, a metagenomic NGS access and ordering intervention, inpatient thrombophilia testing optimization, peripheral blood morphology review reduction,

and the formation of a system laboratory and pathology diagnostics committee (Table 1, online).

Early wins in these areas established credibility and highlighted the value of a coordinated, clinician-led approach.

### Case highlight: Daily laboratory utilization, system strategy

One of the most collaborative initiatives focused on providing clinical decision support to prevent automated daily recurring lab orders, particularly for high-frequency tests such as complete blood counts (CBCs) and basic metabolic panels (BMPs). Historically, these tests could be ordered without expiration for the duration of a patient's stay, which led to unnecessary utilization and increased costs.

After extensive collaboration with frontline providers, IT, and system clinical and laboratory leadership, the committee implemented a new EHR ordering design: Daily laboratory orders would expire after a maximum of 3 days, requiring renewal if still clinically appropriate. To support this change, 10 new laboratory test order codes were created with built-in expiration logic.

Recognizing the need for flexibility, the team carefully reviewed and exempted specific order sets, such as those used in the ICU, neurology, pharmacy, oncology, and long-term acute care settings, where continuous monitoring is essential. These exemptions were tightly controlled and tied to provider specialty profiles in the EHR.

The rollout affected about 700 order sets and was executed with minimal disruption despite its broad scope. Providers received virtual support, along with proactive education and communication to help address concerns. Issues were reported through the system's incident reporting tool, ensuring tracking and accountability for resolution. Evaluation of the early intervention data and continued monitoring for needed improvements is in progress.

### Impact-driven strategy

What began as a stalled initiative has evolved into a dynamic, clinician-led systemwide program that continues to grow. The Laboratory Stewardship Steering Committee now meets regularly, tracks interventions and outcomes, and reports directly to executive leadership, ensuring visibility and alignment with broader system goals.

A centralized SharePoint portal was developed and continuously updated to serve as the program's documentation hub and collaboration space. It houses all stewardship work, including charters, meeting minutes, project tracking tools, and educational materials. The portal also includes a submission form for new project ideas. This form makes it easier for clinical staff and leaders to contribute to ongoing improvement efforts.

### Intentional sustainability

This journey didn't happen overnight. Every step has been purposeful. From its early beginnings in 2016 to its strategic relaunch in 2021 and formal committee launch in 2022, the program has steadily matured into a model of sustainable, systemwide transformation. The timeline reflects a willingness to pause, reassess, and rebuild with intention.

A key factor in the program's long-term success has been its commitment to sustainability and embedding long-term value in healthcare delivery. The Laboratory Stewardship Steering Committee now operates with defined annual goals, a dedicated financial analyst, and a structured process for tracking both clinical and financial outcomes. This ensures that stewardship efforts remain aligned with broader system priorities and will continue to deliver measurable value year over year.

The team actively monitors metrics (Table 2, online). Insights inform timely adjustments, such as refining order sets, the ability to focus on targeted use cases for deeper analysis with custom reporting to better conserve limited analytics resources, and engaging providers and specialty groups for feedback and suggestions. By prioritizing clinician leadership, investing in infrastructure, and staying committed to collaboration and transparency, the health system has built a laboratory stewardship program that not only supports better patient care, but also serves as a blueprint for sustainable, systemwide transformation.

*View the tables at myadlm.org/cln.*

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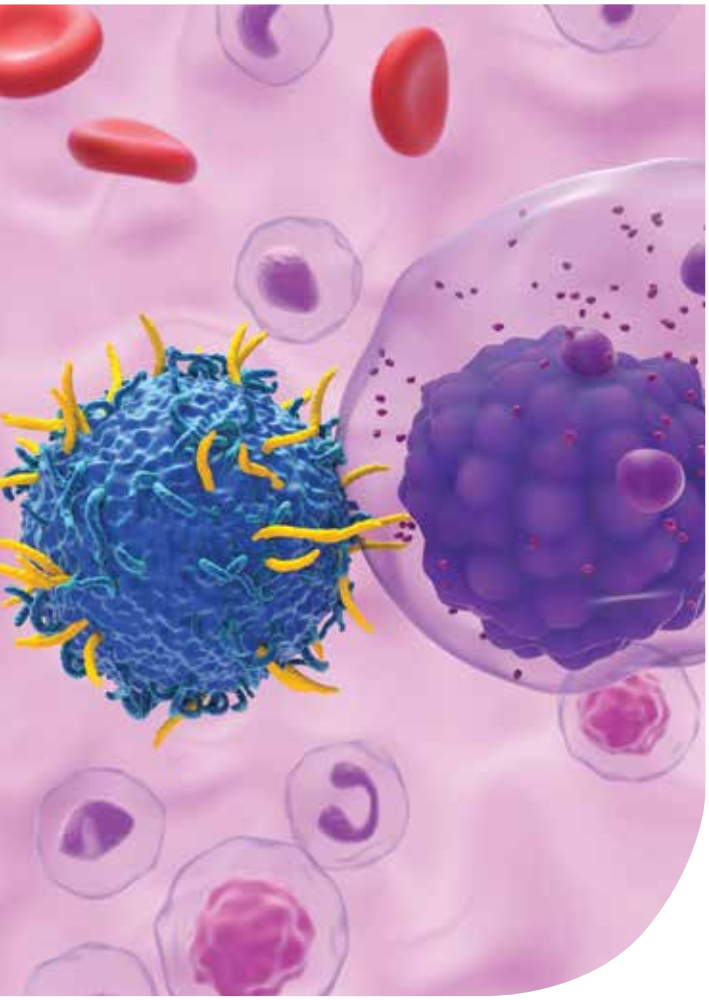
# Regulatory Roundup



## FDA issues draft guidance on MRD in multiple myeloma drug trials

The Food and Drug Administration (FDA) in January issued draft guidance on using minimal residual disease (MRD) and complete response as primary endpoints in clinical trials of drugs and biologics for multiple myeloma (MM), with the goal of their accelerated approval. Diagnostic companies that produce MRD tests expect this guidance to positively affect their businesses as more clinical trials make use of their tests.

Intended to provide new, more sensitive options for efficacy assessments, FDA's draft guidance gives specific recommendations for designing such trials. In issuing the guidance, FDA acknowledged that prior accelerated approvals that used overall response rate as an endpoint already have surpassed high bars for response. Meanwhile, future trials require increasingly more patients to demonstrate statistically significant improvements in overall response rates, the draft guidance said.

The guidance defines MRD and the MRD negativity rate in bone marrow, determined with flow cytometry or next-generation sequencing for patients who have already achieved a complete response.

After an FDA-pooled analysis of data that analyzed the relationship between MRD and long-term outcomes, the FDA's Oncologic Drugs Advisory Committee in 2024 accepted MRD as an endpoint for accelerated approval of drugs or biologics for MM patients. The FDA had previously released general recommendations for industry on using MRD in developing drug and biological products for treating patients with blood cancers.

Companies with products that are granted accelerated approval using MRD or complete response as endpoints still must verify clinical benefit via progression-free or overall survival, the draft guidance said.

### SURVEY SHOWS EU REGULATIONS AFFECTED MEDICAL DEVICE INVESTMENT

More than half of medical device companies in the European Union (EU) have reduced their product portfolios to cope with the complexities of EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), a study conducted for the European Commission by the consultancy EY found.

The research, which was conducted between 2023 and 2024, showed that 17% of medical device companies have stopped producing devices entirely because of high certification costs and administrative burden. The study's goal was to identify the key benefits and challenges associated with the MDR and IVDR regulatory governance structure and to examine how these regulations affect innovation and patient safety. The findings were based on an online survey with 470 respondents, 41 targeted interviews, four workshops, three stakeholder consultation workshops, and a benchmarking exercise.

In December 2025, the European Commission proposed a new regulation to streamline the regulatory pathway for medical devices.

### FDA APPROVES CEPHEID'S FAST GI PANEL

Cepheid recently announced that it has received Food and Drug Administration clearance for Xpert GI Panel, a multiplex PCR test designed to provide fast and accurate detection of 11 clinically relevant gastrointestinal (GI) pathogens from a single patient sample.

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The test simultaneously detects and identifies important bacterial, viral, and parasitic pathogens directly from stool specimens in Cary-Blair transport medium. The streamlined workflow requires less than 1 minute of hands-on time and delivers results in approximately 74 minutes, Cepheid said.

The test runs on Cepheid's GeneXpert systems equipped or upgraded with 10-color modules, which enable simultaneous detection of 10 or more pathogens or biomarkers.

### SEQUENCING PLATFORM GETS EUROPEAN APPROVALS

Oxford Nanopore Technologies' GridION Dx is now both U.K. Conformity Assessed and CE-marked, the company recently announced.

The GridION Dx is a compact, scalable sequencing platform designed specifically for diagnostic applications. It leverages proprietary Oxford Nanopore technology to enable real-time, long-read sequencing of DNA and RNA.

GridION Dx's first application will be infectious disease characterization. The first product, available in partnership with bioMérieux, will integrate with AmPORE-TB, a multidrug-resistant, research only tuberculosis assay. This test is on a defined pathway towards becoming a fully regulated in vitro diagnostics (IVD) assay on GridION Dx, Oxford Nanopore said.

These developments make GridION the company's first IVD device registered in the United Kingdom and Europe, set up Oxford Nanopore for future adoption in regulated clinical markets, and reflect the company's long-term commitment to sequencing-based diagnostics, Oxford Nanopore said.

### HOLOGIC INTRODUCES DIGITAL PATHOLOGY CAPABILITIES WITH EXPANDED CE MARKING

Hologic recently announced that its Genius Digital Diagnostics System has achieved expanded CE marking in the European Union.

Now approved for whole slide imaging for review of both cell and tissue specimens, the system enables imaging of a broader range of patient sample types.

Genius Digital Diagnostics System allows labs to capture high-quality digital images of cell and tissue specimens and digitize, store, distribute, and review them on a single platform. In contrast, most laboratories rely on multiple systems for review of different patient sample types. This separation can create inefficiencies for the lab, increase operational costs, extend turnaround times, and create additional work for lab staff.

### AUTOMATED INSULIN DELIVERY ALGORITHM IN APP GETS FDA 510(K) CLEARANCE

Diabeloop has received Food and Drug Administration (FDA) 510(k) clearance for its DBLG2 application as a Class II interoperable automated glycemic controller.

**The app analyzes glucose data in real time and adjusts insulin delivery to maintain blood sugar levels within an optimal target range.**

The app is available for Android and iOS and pairs with a continuous glucose monitor (CGM). Designed to automate and personalize insulin delivery for patients with type 1 diabetes, the app analyzes glucose data in real time and adjusts insulin delivery to maintain blood sugar levels within an optimal target range.

DBLG2 has a self-learning module that applies improvements to the patient's algorithm parameters based on estimated glycemia history and insulin delivery quantities from the patient's history.

The clearance and interoperability status positions Diabeloop as a central player in the global diabetes ecosystem and opens the door to multiple launches in the United States in 2026 and 2027, the company said. It added that the FDA has also approved the Diabeloop Predetermined Change Control Plan, a mechanism that allows the company to evolve its device according to a preestablished protocol for integrating new pumps or CGMs that conform to FDA requirements, without having to resubmit a 510(k) filing.

# Industry Playbook

## ARPA-H awardees to develop lymphatic system diagnostics

The U.S. Department of Health and Human Services' Advanced Research Projects Agency for Health (ARPA-H) has selected 11 research and development teams to develop a comprehensive diagnostic toolkit for earlier detection of lymphatic system problems, the agency recently announced.

The teams will be part of the Lymphatic Imaging, Genomics, and pHenotyping Technologies (LIGHT) program, which will invest $135.7 million in lymphatics research over 5 years.

The lymphatic system plays roles in the spread of cancer, heart failure, chronic inflammation, and neurodegenerative disorders. It also is a major contributor to diabetes, obesity, chronic kidney, liver, and lung diseases, long COVID, and Lyme disease. Although imaging and genetic diagnostics for other organ systems have surged ahead, lymphatic diagnostics lag decades behind, ARPA-H said. Millions of Americans with lymphatic dysfunction, including lymphedema, receive misdiagnoses or are never diagnosed.

Many awardees' goals are laboratory-related. They include developing a device to measure lymphatic flow and obstruction in real time, devising a method for precisely diagnosing and classifying pediatric lymphatic anomalies, and developing a score for detecting lymphatic dysfunction and predicting lymphedema risk. Other lab-related objectives include discovery of biomarkers and targeted imaging agents for liver and gut lymphatics, building an artificial intelligence (AI)-powered predictive tool, and a comprehensive diagnostic platform that integrates AI-enabled biomarker technologies, high-resolution photoacoustic imaging, and multimodal genetic-epigenetic predictors.

### COLLABORATION AIMS TO ACCELERATE PRECISION ONCOLOGY

The University of Texas MD Anderson Cancer Center and SOPHiA Genetics recently announced a collaboration to develop data-driven tools to accurately analyze, interpret, and translate diagnostic results into clinical practice.

As part of the collaboration, MD Anderson and SOPHiA GENETICS will develop an advanced next-generation sequencing oncology test that translates complex multimodal data into actionable insights with greater speed and scale.

MD Anderson researchers will use SOPHiA GENETICS' artificial intelligence to create bioinformatics pipelines that enable clinicians to interpret complex RNA-sequencing data. The collaboration will explore new ways to characterize tumor evolution in real time, strengthen the reliability and reproducibility of complex genomic testing, and enhance identification of optimal clinical trials or research avenues for individual patients.

### RESEARCH FOCUSES ON EARLY ALZHEIMER'S DISEASE BLOOD TEST

A major international research project is underway to test whether a fingerprick blood test that detects phosphorylated tau 217, glial fibrillary acidic protein, and neurofilament light polypeptide could be used to help diagnose Alzheimer's disease.

The fingerprick test uses a simple plasma separation card that does not need refrigeration. It can be stored and shipped to a laboratory for analysis at ambient temperature. The study will compare the test with a

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variety of other experimental Alzheimer's disease tests, including speech tests, retinal scans, cognitive tests, and gold standard PET scans and MRI scans.

The project is part of the Global Alzheimer's Platform Foundation's Bio-Hermes-002 study, a cross-sectional study that will result in a blood, cerebrospinal fluid, retinal, digital, MRI, and PET brain imaging biomarker database.

### PARTNERSHIP TO ADVANCE CANCER DIAGNOSTICS THAT EXAMINE INTRACELLULAR DNA FOLDING

Fox Chase Cancer Center and Arima Genomics recently announced a partnership to develop advanced diagnostics based on analysis of the three-dimensional structure of DNA.

The collaboration, which includes Fox Chase's Cancer Epigenetics Cancer Institute (CPI), aims to help physicians better identify genomic changes that traditional testing methods may miss.

CPI will leverage Arima's Hi-C-based technology — which captures how DNA folds and interacts inside cells — in its diagnostic workflows for lymphoma and sarcoma through Arima's Aventa Lymphoma and Aventa FusionPlus tests.

Unlike conventional DNA sequencing, which breaks the genome up into millions of tiny reads that lose their spatial relationships, Arima's platform allows for analysis of the 3D architecture of the entire genome, revealing important structural changes. This expanded view offers more accurate insights into how a tumor forms and evolves, Fox Chase Cancer Center and Arima Genomics said.

### COLLABORATION WILL ADVANCE LIQUID BIOPSIES IN THE U.S.

A strategic collaboration between Pangea Laboratory and Gene Solutions will validate artificial intelligence-driven liquid biopsy assays for use in cancer detection, characterization, and monitoring within CLIA-certified and College of American Pathologists (CAP)-accredited laboratory settings in the United States market.

The collaboration will initially focus on validating two flagship assays from Gene Solutions. One is SPOT-MAS, a type of liquid biopsy that integrates circulating tumor DNA epigenomics, the physical, nonrandom fragmentation patterns of circulating cell-free DNA, and genomics to detect early cancer signals from a single 10 mL blood draw.

The other test, K-4CARE, combines comprehensive genomic and transcriptomic profiling with molecular residual disease detection to guide targeted therapy selection and deliver longitudinal circulating DNA-MRD monitoring insights.

Pangea Laboratory will leverage its integrated validation platform and regulatory expertise to oversee all analytical and clinical validation activities for Gene Solutions' innovative multiomics technologies.

### COLLABORATION FOCUSES ON NEXT-GENERATION METASTATIC BREAST CANCER SEQUENCING

A partnership between KDA Group and AstraZeneca Canada aims to improve next-generation sequencing for patients with metastatic breast cancer, KDA Group recently announced.

This partnership will use KDA's digital platform Medherize, integrated with the Quebec health record, known as Dossier Santé Québec (DSQ). Medherize consolidates laboratory results, clinical alerts, and patient-reported information into a single workflow for clinicians.

The companies plan to integrate targeted digital alerts within Medherize to prompt timely testing, interpretation, and clinical action, thereby supporting consistent adoption of precision oncology practices across the care continuum.

This approach also aligns with a new Quebec Ministry of Health and Social Services framework for community pharmacists regarding oral anticancer medication practices, including analysis of treatments based on laboratory results. Medherize will connect pharmacists to relevant DSQ information and enable automatic receipt of lab results, clinical alerts, and patient-reported adverse events to facilitate more consistent follow-up.

## Index to Advertisers

# Ask The Expert

## The ins and outs of remote blood collection

By Ria C. Fyffe-Freil, PhD, MS, NRCC

**What is remote blood collection?**

**a:** Remote blood collection refers to scenarios where patients collect their own blood either at home or outside of a traditional phlebotomy setting. Often, remote blood collection is synonymous with "self-collection." However, it also can refer to healthcare providers using emerging technologies such as autonomous robotic phlebotomy devices and small, handheld capillary blood collection devices when venipuncture is not available (Technology [Singap World Sci] 2018; doi: 10.1142/S2339547818500048).

Currently, an assortment of remote collection devices have obtained varying degrees of regulatory approval. These devices typically collect capillary blood, and several of them use small needles or blades combined with vacuum technology to collect a relatively painless sample from the patient's upper arm.

As of early 2026, the most prevalent applications of remote blood collection include chronic illness monitoring, wellness laboratory testing, and decentralized clinical trials. Importantly, remote blood collection holds numerous benefits for patients. It makes testing more accessible, particularly for the many patients around the globe who have to travel several hours to get their blood drawn by phlebotomy professionals. Other benefits include reduced cost and stigma, particularly with sexual health testing.

**How do you transport remote blood samples?**

Laboratories have several options for collecting, storing, and transporting blood in a remote setting. These include filter papers, volumetric absorptive microsampling (VAMS) devices, and microtainer tubes (with or without anticoagulant for plasma and serum, respectively) that connect directly to a device. Dried blood spots on filter papers or VAMS devices are typically more stable over longer periods of time, while microtainer tubes are used for more immediate testing needs or larger volume collection.

Typically, filter papers and VAMS devices are best suited for research or biobanking, as the volume collected is too small for routine clinical laboratory testing. Additionally, many high-throughput clinical laboratories do not have a workflow established for extracting samples from filter paper or VAMS devices. Microtainers work best for the automated clinical laboratory, as there are preestablished workflows for handling these tubes because of the prevalence of their use in neonatal and pediatric patients.

**What are the challenges of processing and analyzing these samples?**

To ensure optimal and accurate results, laboratory staff must consider several factors when receiving remotely collected samples. These factors include time since collection, separation of the plasma and serum from cells, storage and transport conditions, sample source, sample quality and volume, and the regulatory status of the device and tube type used to collect and transport the blood sample.

Because the safety and efficacy of many remote collection devices is still being investigated, the laboratory must be included in any discussions about using remote blood collection for patient care. Currently, sample stability — particularly temperature regulation during transport and the time to centrifugation — poses one of the biggest hurdles for laboratory testing on remotely collected blood, because it can cause inaccurate results. Innovations in this area would greatly improve access to remote blood collection in communities across the globe.

Additionally, not all analytes exhibit biologic equivalence in capillary versus venous blood samples; thus, laboratory directors must carefully evaluate the sample source for suitability. Validating new collection methods and tube types is part of standard laboratory workflow, so forming a collaborative interdisciplinary team to investigate these requests is vital for quality patient care.

Overall, as laboratorians, it is our responsibility to consider the comprehensive situation when clinical or research teams request remote blood collection.

**Ria C. Fyffe-Freil, PhD, MS, NRCC,** is the director of clinical chemistry and an assistant professor in the department of pathology, microbiology, and immunology at the University of Nebraska Medical Center in Omaha, Nebraska.

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