CLN DAILY
Clinical Laboratory News
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ADLM

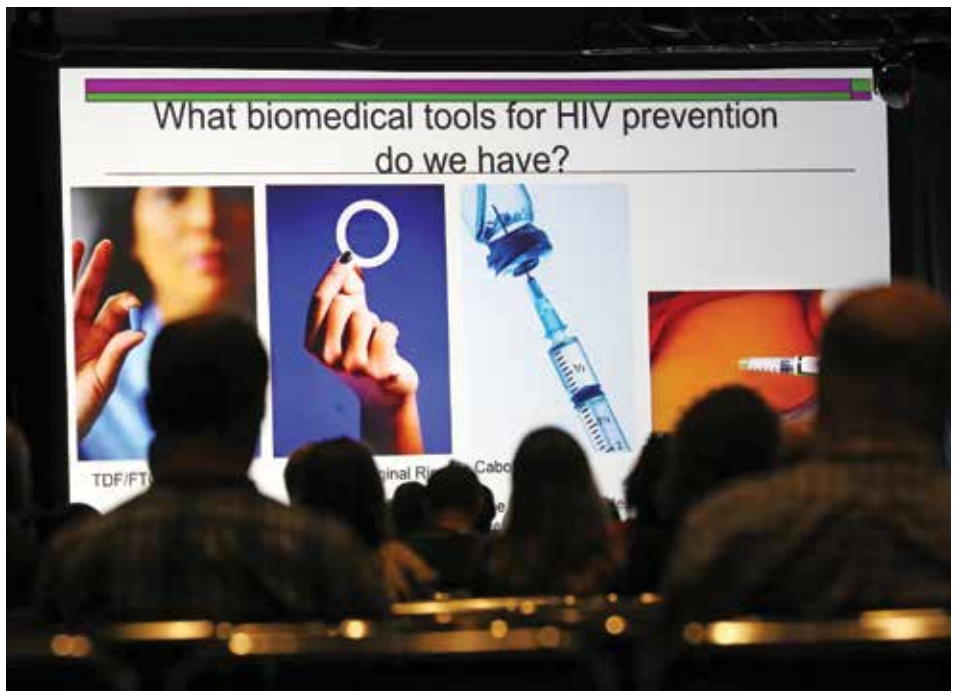
Preventing HIV through the power of choice

By Joel A. Lefferts, PhD

The value of reducing HIV transmission is almost incalculable when one considers the personal, societal, and healthcare burdens that come with each new HIV infection. In yesterday's plenary session, "Empowering Choice by Providing More Options in HIV Prevention," Sharon L. Hillier, PhD, shared some exciting new advances in this area.

Hillier is the Richard Sweet Professor of Reproductive Infectious Disease, vice chair for faculty affairs at the University of Pittsburgh School of Medicine, and the director of reproductive infectious-disease research at the Magee-Womens Research Institute. She started the session by challenging attendees to follow their passions and shared some of her own experiences as a woman starting out in academia at a time when gender inequality was arguably much more apparent than it is today.

Hillier then introduced a theme that she came back to throughout her presentation — the idea that people have both options (things) and choices (decisions) in life and in healthcare. While it's always good to have options, what matters most is the choices we make regarding those options.



Attendees listen to Sharon Hillier's Wednesday plenary Empowering Choice by Providing More Options in HIV Prevention.

She presented a comprehensive and eye-opening overview of various pre-exposure prophylaxis (PrEP) therapies available for HIV today, including a description of the clinical research used to prove their efficacy.

Hillier noted that PrEP can be highly effective, but only if it is used properly and consistently. She provided data showing a surprising lack of compliance with oral and other PrEP options. Moreover, in many clinical trials, participants' therapeutic adherence rates, which were grounded in measurements of plasma drug concentrations, hovered around 25% after three months on PrEP and declined further over time.

To help attendees better understand the causes behind this noncompliance, Hillier invoked the metaphor of a bridge. Just as a bridge

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Clinical implications of abortion law changes: What lab professionals need to know

By Mark A. Zaydman, MD, PhD

The Dobbs decision issued by the U.S. Supreme Court in June 2022 overturned Roe v. Wade and with it, nearly 50 years of federal abortion-access protections. Two years later, the political, legal, and real-life ramifications of this decision are still not fully understood. In this morning's plenary session, "Projected Health and Social Consequences of Ending the Federal Protection for Abortion in the United States," Diana Greene Foster, PhD, will present data on the causes and consequences of unintended pregnancy. She will describe how the Dobbs decision is impacting patients and discuss the role of the clinical laboratory in this environment.

This plenary promises to be a compelling examination of the current state of abortion access and its implications on the field of laboratory medicine.

Foster is a professor of obstetrics, gynecology, and reproductive sciences at the University of California, San Francisco. She was awarded a 2023 MacArthur Fellowship in recognition of her important work to fill "a void in our understanding of how reproductive health policies impact an individual's physical, mental, and socioeconomic well-being." She is also the lead investigator of the Turnaway Study, a landmark prospective longitudinal study that compared the effects of unwanted pregnancy for women who received or were denied an abortion. Foster's work provides crucial scientific evidence to inform an ongoing politically and emotionally charged discourse with profound implications for the lives of pregnant people.

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INSIDE SECTION A

The SYCL and ADLM Board of Directors teams gather prior to the start of Laboratory Feud: Yachana Kataria, left, David Macias, Caroline Nottingham, David Shiembob, moderator Paul J. Jannetto, Joe El-Khoury, Laura Parnas, Dan Holmes and Bonny Lewis Van. Congratulations to SYCL on their victory!

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1. Lippi G, von Meyer A, Cadamuro J, Simundic A-M. Blood sample quality. *Diagnosis*. 2018;6(1):25-31. doi:10.1515/dx-2018-0018

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Airing your dirty laundry: Resolving lab errors and noncompliance

By Mike Kelliher, PhD, DABCC

From an early age, we are taught not to air our dirty laundry in public. In Tuesday afternoon's session, "You Did What Now? Addressing Questionable Laboratory Practices," Jacqueline Hubbard, PhD, C(ASCP), DABCC, NRCC, and Grace Williams, PhD, DABCC, turned that philosophy on its head, highlighting some egregious examples of laboratory errors and regulatory noncompliance so attendees could learn from the mistakes of others.

Most clinical laboratorians are not exposed to large-scale errors or noncompliance during their training, so it can be daunting to face these issues when they come up as part of a new job. A primary goal of the session was to reduce the stigma and embarrassment that may accompany sharing instances of errors and noncompliance.

Attendees participated in a choose-your-own-adventure style session, where they selected the four examples they wanted to see featured from a compilation of challenging and shocking scenarios that Hubbard and Williams solicited from clinical laboratories across the country. The first example described a laboratory that had never performed a single-reagent new lot qualification study or "lot-to-lot" check. "These are real scenarios," Williams told the crowd after they reacted with gasps and laughter.

Cherri Phillips discusses her group's answer to a question during the session You Did What Now? Addressing Questionable Laboratory Practices.

Attendees participated in a choose-your-own-adventure style session, where they selected the four examples they wanted to see featured.

Using the Situation, Background, Assessment, Recommendation (SBAR) communication framework, Hubbard and Williams identified the situation, provided relevant background information, gave a high-level assessment, and guided the audience through the recommendation and resolution. Attendees discussed potential solutions in small groups and were encouraged to share their approaches with everyone. This exercise highlighted how incorporating several perspectives can lead to improved decision-making.

Common themes emerged after each scenario was discussed. Among the most prevalent were the need for education, training, and detailed standard operating procedures (SOPs). Hubbard argued that we should not assume someone else will make the same decision we would. By maintaining an accurate record of how to operate instruments and troubleshoot problems, laboratory staff will always have a reliable resource to draw on.

This interactive session was filled with real-world examples and useful tools for attendees to take back to their organizations. Attendees learned that there is no such thing as a perfect laboratory and that multiple solutions exist for most problems. All laboratories have their fair share of dirty laundry, and airing it for others gives everyone an opportunity for collective quality improvement.

Can laboratory testing alter the course of preeclampsia?

By Hannah Brown, PhD

Preeclampsia is a complex, rapidly progressing multisystem disorder that affects up to 8% of pregnancies. It occurs after 20 weeks of gestation and is characterized by elevated maternal blood pressure and fetal growth restriction. With up to 60% of preeclampsia-related deaths believed to be preventable, the importance of early diagnosis cannot be overstated. In this afternoon's session, "Preeclampsia in the United States: Clinical Details, Best Practices in Laboratory Medicine, and Impact of Foundational Support," three experts, including a physician, a laboratorian, and a patient advocate, will provide a comprehensive overview of the disease, its impact in the U.S. and globally, and advances in large-scale and point-of-care laboratory testing, particularly in resource-limited areas.

Emily Rosenfeld, DO, will open the session by describing the clinical features and presentation of preeclampsia. "There is a difference between preeclampsia presentation and population impact in the U.S. vs. worldwide," said Rosenfeld. While some of the signs and symptoms of severe preeclampsia are objective, they can overlap with other conditions, such as autoimmune disease and underlying chronic hypertension. These nonspecific symptoms present a diagnostic challenge, and there has been a growing interest in identifying biomarkers that can predict the development of preeclampsia with severe features.

Early testing is critical, since small interventions can profoundly impact the management of high-risk pregnancies.

Next, Sydney Strickland, PhD, DABCC, will discuss recent advances in laboratory testing to screen for the development of preeclampsia and progression to severe features. The laboratory testing advancements have been driven by studies from 2017 and 2018 that were originally conducted in Europe, according to Strickland. This research "demonstrated the ability of biochemical and biophysical markers to predict which women would go on to develop preeclampsia later in pregnancy over traditional demographics-based risk assessments used by NICE and ACOG," Strickland noted.

Recently, serum tests for two placenta-related proteins — placental growth factor (PlGF) and soluble fms-like tyrosine kinase-1 (sFlt-1) — have been approved by the Food and Drug Administration. The ratio of these two markers can be used to assess how likely it is that individuals who have been hospitalized for hypertensive disorders of pregnancy in the second or third trimester will progress to severe preeclampsia within the next two weeks. Early testing is critical, since small interventions like home blood-pressure monitoring can profoundly impact the management of high-risk pregnancies. Strickland will illustrate this point by sharing real-world cases of patients who benefited from novel preeclampsia biomarker tests.

Finally, Laney Poye, MIA, of the Preeclampsia Foundation, will round out the session by giving attendees insight into the current state of preeclampsia in the United States. The U.S. maternal mortality rate is nearly 3-10 times higher compared to other industrialized nations. In addition, Black women experience preeclampsia 2.6 times more often than White women. "With such striking metrics, early identification and risk assignment through laboratory testing of those women who will develop preeclampsia and especially early onset with or without severe features is essential," Poye said. The clinical laboratory can play an increasing role in improving outcomes for pregnant women.

Preeclampsia significantly affects both maternal and fetal health, but it is difficult to diagnose in the absence of specific biomarkers. Attendees at this session will come away with a greater appreciation for the importance of collaborating with other healthcare professionals to improve patient care and advance research and initiatives focused on reducing the negative impact of preeclampsia in the U.S. and globally.

The ripple effect: Understanding the implications of FDA's LDT oversight on patient care

By Hannah Brown, PhD

Laboratory developed tests (LDTs) are indispensable and often hold the key to identifying rare medical conditions. They also provide critical data to clinicians when existing FDA cleared tests fall short. However, on May 6, 2024, the FDA announced a final rule extending its oversight to LDTs, sending shockwaves throughout the healthcare community. This regulatory action is poised to have a significant impact on patient care, as it may limit the ability of physicians to order specialized diagnostic tests. On Tuesday evening, ADLM President Octavia Peck Palmer, PhD, DABCC, moderated a special session on LDTs, "How FDA oversight of LDTs will affect patient care: A conversation with ADLM, the American Medical Association, the Children's Hospital Association, and a patient advocate."

Meghan Delaney (middle) discusses the implications of the new FDA rule during the LDT Special Session featuring (l to r) Octavia Peck Palmer, Geoff Hollett, Sarah Braswell and Dennis Dietzen.

The session began with a video highlighting the power of LDTs, with an emphasis on newborn screening. The immediacy of newborn screening results provided life-altering information that greatly impacted children's lives at the time of testing, but also their care for years to come. The film set the focus for the session on the most vulnerable of patients: children.

Geoff Hollett, PhD, a senior policy analyst representing the American Medical Association, emphasized the way the rule will undermine clinician's ability to provide care. "FDA's rule was developed at lightning speed with minimal input from the public," Hollet added.

Another key point Hollett made was the uncertainty that shrouds the final rule. With uncertainty comes abstention, Hollet posited: "Practices will close, effective tests will not be offered, and patient care will get worse because of fear of noncompliance."

Representing the Children's Hospital Association, Meghan Delaney, DO, MPH, next commented on the vital role of LDTs in pediatric care, emphasizing the devastating impact of the new FDA rule in this patient population. "There is no difference in how [FDA approved and laboratory developed] tests perform," Delaney said. "They are accurate and provide clinical information for patients and physicians." Delaney also noted that the "additional administrative burden and associated costs have serious implications for our ability to provide timely diagnostics for the nation's children."

Sarah Braswell, a caregiver and patient advocate, rounded out the presentations by illustrating the value of LDTs from a parent's

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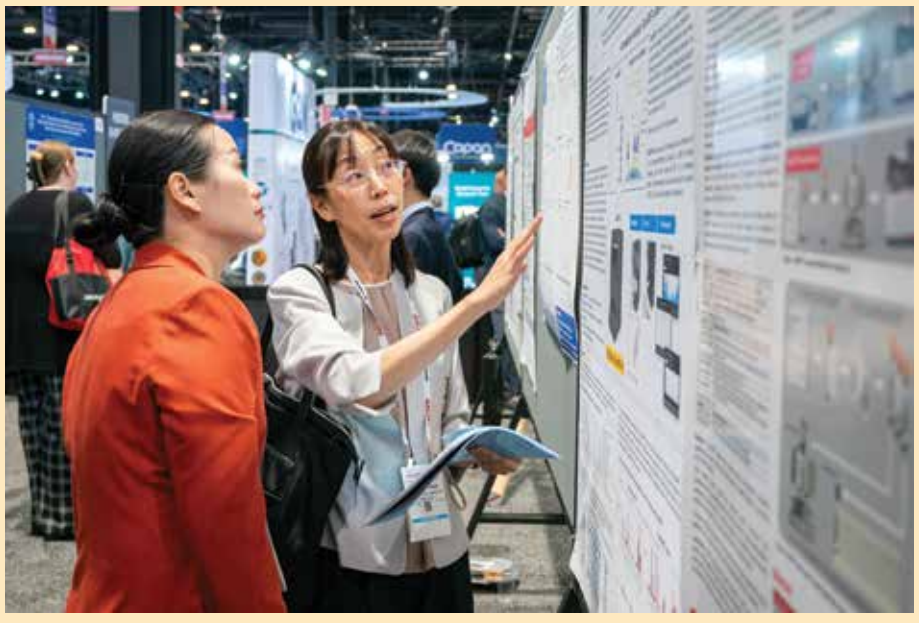
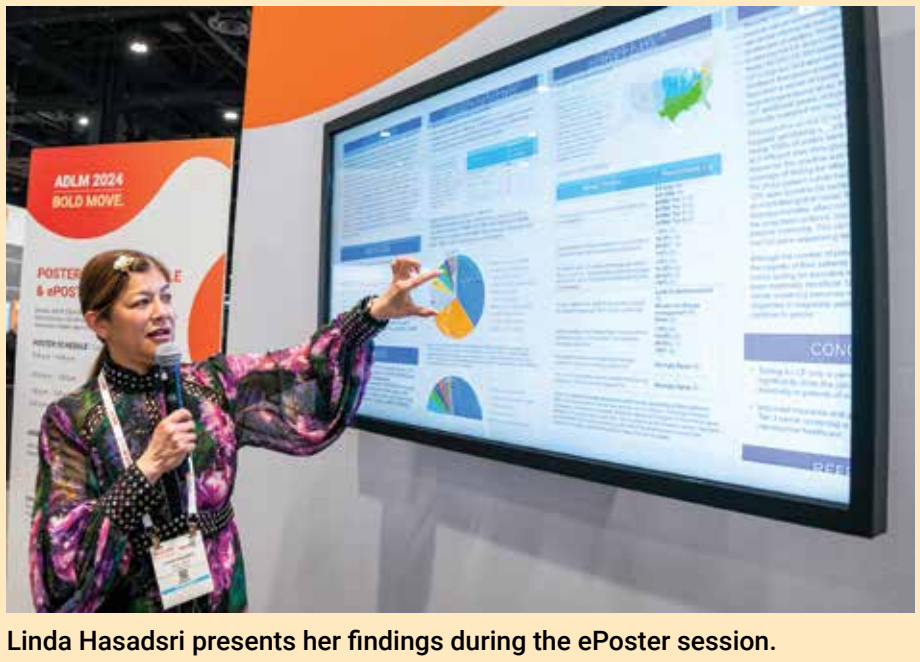
Attendees enjoy some puppy love on the Clinical Lab Expo floor.

Barbara Elli (from left), Kerstin Halverson, Jeanne Mumford, Lilah Evans, Jamie Acero, Kim Skala, Kathleen David, and Peggy Mann have fun in the photo booth at CPOCT AfterGlow.

SYCL celebrates after winning Laboratory Feud: David Shiembob (left), Caroline Nottingham, David Macias, and Yachana Kataria.



Hiroko Shimazaki presents her poster to Lydia Yan (left) during the poster session.



Linda Hasadsri presents her findings during the ePoster session.

Attendees enter the Clinical Lab Expo after the ribbon-cutting ceremony on Tuesday morning.

Molecular diagnostics in the genomic age

By Joel A. Lefferts, PhD

Molecular diagnostics is a unique form of laboratory testing that brings together several clinical specialties — including oncology, genetics, and infectious disease — through a common set of techniques for detecting and interrogating nucleic acids. Over the last few decades, the field has experienced unprecedented growth, with more technologies being used for a greater variety of specimens. This evolution allows lab professionals to provide more complex and detailed test results that assist with patient care in ways previously unimagined.

Earlier this year, a special issue of the *Journal of Applied Laboratory Medicine* (JALM) was published that focused on molecular diagnostics: "Molecular Testing in Medical Practice: Challenges and Triumphs of the Genomic Age." The lead guest editor of that issue, Nikoletta Sidiropoulos, MD, was joined by two of her fellow guest editors on Wednesday for the scientific session, "JALM Hot Topics: Current Challenges and Future Promise in Molecular Diagnostics." Together, they explored themes that emerged in several of the articles featured in the special issue of JALM — namely, diagnostic stewardship, cost-effectiveness, and equitable access.

Erin Graf, PhD, D(ABMM), started the session with a focus on diagnostic stewardship in molecular infectious disease testing. Despite the improved sensitivity of molecular tests over traditional microbiology methods, there is a significant concern about overuse and overinterpretation of multiplexed molecular testing. For example, the difference between colonization and infection is often missed when a result of "positive" is reported for a microbial nucleic acid target. Lab professionals can help avoid this potential confusion through laboratory stewardship that addresses proper test utilization.

Ann Moyer, MD, PhD, then provided an overview of three articles for the special issue. These articles explored the cost of genomic testing, the potential for genetic screening, re-analysis of existing genomic data, and pharmacogenetic testing using NGS instead of the targeted testing traditionally used in pharmacogenetic genotyping. With the promise of decreasing costs and increasing

Erin Graff presents during Hot Topics: Current Challenges and Future Promise in Molecular Diagnosis on Wednesday.

quality of DNA sequencing in the future, it is unclear whether re-analysis of previous sequencing data would be more useful than resequencing patients multiple times throughout their lives.

Sidiropoulos concluded the session by addressing the themes of diagnostic stewardship, cost-effectiveness, and equitable access, with a focus on molecular diagnostic testing in oncology. She shared an example of the implementation of reflexive molecular testing of lung tumors as a way to ensure all patients with a shared diagnosis receive appropriate testing. She shared remarkable data showing an improvement from approximately 50% compliance with test ordering to near 100% of these cases being submitted for testing.

A main takeaway from this session was that the desire to move the field of molecular diagnostics forward with new and exciting technology must be tempered with the need to make sure the testing we offer has clinical utility, does not burden patients or the health care system with excessive costs, and is equitable and accessible to all patient populations who could benefit from such testing.

Uncharted waters: The changing landscape of LDT regulation

By Gabrielle N. Winston-McPherson, PhD

The regulation of laboratory-developed tests (LDTs) has been a topic of much discussion throughout ADLM 2024. The primary focus has been on the changing U.S. regulatory landscape, but yesterday morning's session, "International Regulatory Considerations for Laboratory Developed Tests: Opportunities and Risks for Patient Care," broadened the conversation to include a European perspective.

Session moderator Tina Lockwood, PhD, DABMGG, DABCC, began with an overview of how regulation by the Food and Drug Administration (FDA) has shifted over the years, from the 1976 FDA medical device amendments to the recent final rule, which explicitly states that LDTs are in vitro diagnostic products (IVDs) that must legally adhere to FDA requirements.

Lockwood described two examples of the studies commonly cited by the FDA. Although these studies seem to indicate poor performance of LDTs, in both cases, key methodological details were ignored, she said. Lockwood went on to compare the regulatory roles of the FDA and CMS regarding clinical labs, emphasizing that both bodies have requirements for analytical validity that can be confusing and even contradictory.

Lockwood also provided an evaluation across the U.S., E.U., Australia, and India of the number of risk-based classifications, pre-market evaluation processes, and post-market monitoring, noting that the pre-market evaluation processes were least comparable among these geographic areas.

Next, Patrick Bossuyt, PhD, the 2024 Wallace H. Coulter Lectureship Awardee, provided an overview of the European Union's (E.U.'s) In Vitro Diagnostic Medical Device Regulation (IVDR). He described policy changes initiated in 2017 that shifted IVD oversight from a directive (IVDD) to a regulation (IVDR). In the E.U., a directive requires individual member nations to incorporate certain requirements into their own national legislation, and implementation is nation-specific. Directives, on the other hand, are directly applicable to all E.U. nations and become binding automatically on date of application.

Bossuyt pointed out some of the key changes associated with making the transition from IVDD to IVDR, including adopting a broader definition of what constitutes an in vitro diagnostic medical device. The new requirements also include expanded risk classes. One notable difference between the E.U. and the U.S. is that, in the E.U., the IVDR impacts all IVDs. This is an important distinction because it may restrict access to widely marketed tests. Another major difference is that, in the E.U., some LDTs are not subject to all aspects of the regulation.

Christina Lockwood presents during the International Regulatory Considerations for Laboratory Developed Tests: Opportunities and Risks for Patient Care.

The IVDR states that, "with the exception of relevant general safety and performance requirements, the new regulation does not apply to some in-house tests (E.U. term for LDTs) if specific requirements are met."

Bossuyt also discussed the challenges that have arisen with implementing IVDR. One major hurdle has been the small number of organizations that are designated to assess product conformity (notified bodies) — which is a requirement of IVDR. Another roadblock has been that the database meant to track and catalog IVDs is not ready. Due to these challenges, implementation has been delayed multiple times.

We already knew that many in the U.S. clinical diagnostic community are confused and concerned about how new regulations will impact lab practices and patient care. In Wednesday's session, we learned that the concerns are shared worldwide.

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Anna Merrill (left) and Takara Blamires pick up their bags celebrating 10 years of ADLM Artery during the Artery Happy Hour at the ADLM booth in the Clinical Lab Expo.

Beyond behavioral change: A systems approach to sustainability in clinical labs

By Gabrielle N. Winston-McPherson, PhD

Clinical labs are major contributors to the healthcare industry's impact on the environment. They consume up to 10 times more energy than similarly sized office spaces and are responsible for disposing of large quantities of plastic and shipping materials. This morning's session, "A Pathway Towards Greater Sustainability in Lab Medicine," will highlight how clinical labs can minimize their ecological footprint.

Joe Wiencek, PhD, DABCC, NRCC, FADLM, will host Ilyssa Gordon, MD, PhD, and James Connelly as they discuss their efforts to foster sustainability by leveraging the laboratory partners responsible for waste generation and removal. Both Wiencek and Gordon will point out that clinical labs are not, in themselves, major sources of waste because they use standard operating procedures and regulated workflows designed to ensure the products of their processes are utilized. Thus, the key to change is to focus on the processes that occur both upstream (shipping materials, plastic packaging, inefficient packing) and downstream (waste removal, decontamination procedures) of the laboratory.

Wiencek will begin by outlining how laboratorians can approach sustainability. He wants the audience to "recognize how crucial grassroots efforts are to reduce, reuse, and recycle in their own laboratories," he said. Wiencek will recommend evaluating waste streams to identify opportunities for improvement, presenting examples from his own experience.

Next, Connelly will provide a big-picture perspective on the health industry's impact on the environment, while also discussing specific opportunities that labs can use to make impactful changes. He will stress that the path toward sustainability is not primarily about making behavioral adjustments; instead, it's about implementing systematic changes that engage both suppliers and waste removers. Connelly is CEO of My Green Lab, a nonprofit committed to helping labs create cultures of sustainability.

Gordon will close the session by explaining the implications of environmental waste for human health and underscoring the link between climate and health. She will note that, because "lung disease is related to air pollution, heart failure is connected to heat-related illness, and changing vector geography is linked to climate change ecology," healthcare providers have a responsibility to reduce their environmental footprint for the benefit of their patients.

Wiencek hopes that this session will catalyze laboratory medicine and pathology societies to examine their efforts, identify areas for improvement, and foster discussions with journals, industry partners, and general membership on specific pathways to advance sustainability in our field.

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Demystifying the equations: Estimating glomerular filtration rate in children

By Gabrielle N. Winston-McPherson, PhD

The glomerular filtration rate (GFR) is a crucial indicator of kidney function, enabling earlier diagnosis and better management of kidney diseases. However, since direct measurements are difficult to perform, equations were developed to provide accessible and non-invasive methods for calculating an estimated GFR (eGFR).

While most estimations for adult populations use creatinine-based equations, a different approach is needed for children. In the Monday afternoon session, "Implementation of Equations to Estimate Glomerular Filtration Rate at a Pediatric Institution," Angela Ferguson, PhD, DABCC, FADLM, and Darcy Weidemann, MD, MHS, discussed the insights and lessons learned from their experiences validating an LIS-based eGFR calculation in a pediatric hospital.

Ferguson began the session by discussing pediatric eGFR equations from the perspective of a laboratorian, paying particular attention to the CKiD Under 25 (U25) equation, which demonstrated improved performance compared to other equations. She reviewed details about the laboratory testing that provides key values in the calculation: creatinine and cystatin C. She emphasized the importance of using methods with strong analytical performance and conducting robust validation studies.

Through teamwork, they were able to use an LIS-based calculation for pediatric eGFR.

The CKiD U25 equation also incorporates age (years), sex, and height (cm), so successful integration of the equation requires these values to be available. It is critical for the information to be entered with the correct units or the estimation will be incorrect.

Next, Weidemann took to the podium to provide the clinician's point of view. She used cases to underscore the clinical utility of reporting pediatric eGFR. Some uses include early identification of kidney disease and guidance for pharmaceutical dosing of nephrotoxic medications. Weidemann also emphasized that reporting eGFR improves pediatricians' clinical decision-making.

Both speakers emphasized the importance of collaboration. Through teamwork, they were able to use an LIS-based calculation for pediatric eGFR. Their work was a novel implementation in the pediatric setting with unique challenges. They provided several examples throughout the session, highlighting how they overcame unexpected difficulties.

In one example, Weidemann described the struggle to incorporate accurate height data into the equation, a parameter with potentially big changes over a short period of time — and not always measured accurately. To deal with this issue, they made height and length checks default in care plans, in addition to standardizing height and length assessment procedures.

An overall theme of the session was the need for clinicians and laboratorians to partner to improve patient care. Both presenters described instances where they leaned on each other to make the implementation work. "This whole project couldn't have gotten off the ground without the laboratory and the nephrology division working closely together," Ferguson said.

Stronger together: Building strategic collaborations between C-suite and department leaders

By Nichole Korpi-Steiner, PhD, DABCC, FADLM

The senior executives in healthcare organizations are the visionaries and decision-makers who set the organization's strategic objectives. How can laboratory medicine professionals effectively communicate with them to highlight the value of laboratory medicine services and advocate for the resources they need to deliver high-quality patient care? This morning's session, "Effective Communication with C-Suite Executives: A Chief of Operations and a Department Chair Perspective," is the first of its kind at ADLM to engage leaders in the hospital C-suite — or senior executives with titles starting with "Chief" — in discussions pertaining to laboratory medicine. It will provide practical insights on how to develop mutually beneficial collaborations.

ADLM Treasurer Victoria Zhang, PhD, MBA, DABCC, FADLM, will kick off the session with an overview of the structures and functions of the C-suite in healthcare organizations. Zhang hopes this inaugural session will inspire further dialogue on enhancing cooperation between laboratory professionals and healthcare leaders to improve diagnosis and patient care.

These speakers will share multiple real-life collaborative efforts throughout their healthcare enterprise.

Next, Kathy Parrinello, PhD, RN, president and chief executive officer of Strong Memorial Hospital and Highland Hospital, will share suggestions on how lab leaders can engage effectively with the C-suite, emphasizing the need for clear communication to ensure alignment between departmental goals and organizational strategy, optimal decision-making, and efficient resource allocation. Some tips Parrinello will emphasize include providing regular updates to executives, engaging these leaders proactively, fostering collaborative relationships, and demonstrating the lab's critical role in achieving the organization's mission and goals.

Offering another perspective is Bruce Smoller, MD, former chair of the department of pathology and laboratory medicine at the University of Rochester Medical Center, who noted that the C-suite is a critical intermediary for supporting laboratory medicine services and needs. Department leaders need to persuasively convey the value of laboratory medicine, advocate for necessary resources, and underscore the impact that lab results can have on patient outcomes. The alignment of laboratory medicine goals with the organization's strategic objectives is essential for driving innovation, maintaining regulatory compliance, and achieving financial sustainability in healthcare organizations.

Together, these speakers will share multiple real-life collaborative efforts throughout their healthcare enterprise, including consolidating laboratory testing, providing subspecialty sign-outs and high-complexity testing, and establishing and maintaining a laboratory formulary system for appropriate test utilization.

Session attendees will come away with comprehensive perspectives and practical approaches to articulate the value that all stakeholders bring to the table for delivering high-quality patient care.

Visit the ADLM booth, Member Lounge

Exclusively for ADLM members, the ADLM Member Lounge is the place to take a break, network with colleagues, and learn more about ADLM programs and services. Located inside the ADLM booth (#1879), it offers a convenient opportunity to recharge electronics, meet with ADLM representatives, and enjoy complimentary coffee and cookies.

Law and order, ADLM edition: Clinical chemists as expert witnesses

By Hannah Brown, PhD

At yesterday afternoon's session, "Clinical Toxicology in the Courtroom: How to Serve as an Expert Witness," attendees could easily mistake the conference room for a courtroom. Judge Eric Hunter, JD, brought the room to order. Opposite him were two tables with diametrically opposed lawyers and expert witnesses.

Representing the prosecution, Bo Bolus, JD, scribbled furiously in a notebook. To his right sat his expert toxicology witness, Saeed Jortani, PhD, DABCC, FADLM, who was lost in thought about the case on his mind. On the defense, Matthew Gay, JD, prepared to give his opening statement and present his witness, Alan Wu, PhD, who maintained a calm demeanor. Attendees waited eagerly to witness the trial of a case involving a 25-year-old man who died from a methadone overdose.

This session, an encore of a similar gathering at the 2016 ADLM annual meeting, was intended to highlight the critical role that clinical chemists and toxicologists play in the criminal justice system. Laboratory experts are often summoned to testify, either as factual or expert witnesses who can provide scientifically sound interpretations of pivotal toxicological data. However, many in the clinical laboratory community lack formal training or education in this area. To address this gap in knowledge, speakers illustrated the types of questions often asked in court, the style of expert testimony, and the nature of discussions that take place between opposing sides.

Speakers illustrated the types of questions often asked in court, the style of expert testimony, and the nature of discussions that take place between opposing sides.

Jortani and Wu opened the session by explaining that laboratorians can serve as two kinds of witnesses: factual and evidential. Regardless of the type of witness one serves as, he reminded audience members of the importance of not stepping outside of one's field of expertise when testifying and remaining calm and collected when cross-examined. Wu continued, "Experts need to stay true to the science and practice irrespective of which side the science falls on," highlighting the importance of letting the science be the loudest voice in the room.

Next, Judge Hunter explained the rules for evidence guiding what expert witnesses can and cannot discuss, pointing out the differences between lay opinion, expert opinion, and other categories. While it is imperative for lawyers to prepare their witnesses for trial, it is critical that expert witnesses heed these rules when delivering their testimony so they don't jeopardize the integrity of the trial.

Finally, Bolus and Gay shared how lawyers select and prepare expert witnesses. Attorneys typically look at the area of expertise that is needed for the field in question. Next, they consult publications and presentations to identify experts who may be suitable. They then review the qualifications and experience of the potential witness.

Once they select their witnesses, lawyers prepare them by asking them to review pertinent materials, depositions, and testimony guidelines. They also meet with witnesses to discuss their testimony and remind them to stay in their lane.

Following these educational discussions, the presenters carried out a mock trial of the methadone overdose case. Audience members observed the importance of properly preparing expert witnesses. Toxicology laboratory directors have a responsibility to ensure that test results are not misused in a court of law. While not all laboratorians will be called on to testify, all attendees of this session left with the knowledge they will need if they are.

Plenary

›› from page A-1

is built to span a physical obstacle without blocking the path underneath, HIV-prevention options should help patients to avoid infection without blocking their normal routines, experiences, and desires.

Thus, the best options for HIV prevention should act as bridges. While current alternatives, such as abstinence, condom usage, knowing a partner's HIV status, and PrEP, may all be documented to be effective to varying degrees, in practice they could be completely ineffective for individuals for whom those choices are unavailable or unrealistic.

Injectable PrEP is a recent option that holds promise to become more popular for some patients, Hillier noted, as are drug-containing vaginal rings, which are currently available in Africa but not the United States.

Different people have different preferences. Thus, the key to ensuring people at risk of HIV infection are most protected is to create more options. Hillier shared exciting results published just last week from the PURPOSE 1 trial of lenacapavir, an antiretroviral used for PrEP. This study demonstrated a complete absence of HIV infections among 2,134 women treated with the new long-acting lenacapavir (LEN-LA) PrEP option.

But she cautioned the audience to remember that compliance is critical to prevention, and LEN-LA requires precise timing of both oral loading doses and sub-cutaneous injections, which might limit access or acceptance for many.

Hillier concluded by emphasizing that the best approach for stopping the HIV pandemic is to provide a full arsenal of effective PrEP options available to people from all geographic, ethnic, gender, and identity backgrounds.

Abortion law

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In the 2007 decision of Gonzales v. Carhart, Chief Justice Anthony Kennedy wrote that the choice to have an abortion could lead to "severe depression and loss of esteem," while also acknowledging a lack of reliable data to support this assertion. In response, Foster and her team collected those very data. "Although I originally started this work to rigorously examine possible mental health harm from receiving abortions, I have found that there is greater physical, socioeconomic, and even mental health harm associated with denial [of abortions]," she said. "As health care professionals, it is important to understand the science and evidence."

In addition to sharing information relevant for all healthcare professionals, Foster will also highlight direct impacts to the clinical laboratory. For example, how should laboratory professionals respond when they are asked to perform testing for abortion medications in regions where abortion is criminalized?

This plenary promises to be a compelling examination of the current state of abortion access and its broader implications on patients and the field of laboratory medicine. It is not one to miss!

LDT oversight

›› from page A-4

perspective. Sharing the story of her daughter, Olivia, Braswell detailed the critical role LDTs have played in ensuring the highest quality of care in diagnosing and managing Olivia's Down Syndrome. Since individuals with Down Syndrome are at increased risk of developing health conditions such as cancer, Braswell regularly advocates for timely testing for Olivia. Many of those tests are LDTs.

The session concluded with panel discussion questions submitted by the audience. Joined by Dennis Dietzen, PhD, DABCC, representing ADLM's Policy and External Affairs Core Committee, the speakers agreed that if the ruling remains unchanged, it will severely reduce patient access to quality healthcare. Dietzen implored us all to amplify this message. The highlight of the session was when participants were joined by Olivia on stage, smiling and waving at the audience.

Undeniably, LDTs play a vital role in fulfilling specific and unmet medical needs. However, the FDA's final rule and the prospect of heightened regulatory oversight may jeopardize the ability of laboratory professionals to utilize their expertise to meet patient care needs. Moreover, it will negatively affect our patients.

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ADLM

Global Lab Quality Initiative hosts workshops in Ethiopia, Ecuador

By Yaakov Zinberg

Effective medical care depends on laboratory quality, the guarantee that lab results are accurate, reproducible, and reliable. Lab quality itself, however, depends on the resources and expertise of a particular lab, as well as local regulations and laboratory practices, all of which can vary by country and region of the world.

Since its inception in 2010, the Association for Diagnostics & Laboratory Medicine (ADLM, formerly AACC) Global Lab Quality Initiative (GLQI) has partnered with the national societies of low- and middle-income countries to offer interactive workshops on lab quality control and method verification. Supported by a generous endowment from the Walter H. Coulter Foundation, GLQI has to date hosted 34 workshops in more than 20 countries, which together have been attended by nearly 5,000 people.

ADLM supports three working groups that serve GLQI, each with a distinct geographical focus: the Africa Working Group, the Asia-Pacific Working Group, and the Latin American Working Group. The working groups consist of ADLM members with laboratory expertise and strong ties to the region, who are well equipped to foster partnerships between ADLM and local societies and collaborate with laboratorians to advance the quality of laboratory testing in diverse local and national settings.

As part of ADLM's continued efforts to serve the entire global laboratory medicine community, the GLQI working groups are as busy as ever, educating, learning from, and engaging with laboratorians across the world.

Recent workshops in Ethiopia and Ecuador

Two recent GLQI workshops illustrate the impact GLQI has had in laboratories across diverse settings.

In April 2024, the Africa Working Group hosted a workshop in Ethiopia

›› see page B-5

A treasure trove of research from the ADLM COVID-19 Immunity Study

By Jen A. Miller

At the 2021 annual meeting, members of the Association for Diagnostics & Laboratory Medicine (ADLM, formerly AACC) rolled up their sleeves and got to work — literally. Members volunteered to give blood samples that have led to four major study publications related to SARS-CoV-2, and a sample bank that can be used by other researchers for years to come.

"We have contributed scientifically to a very timely and stressful moment, but we made a significant dent in the universe of COVID-19," said Y. Victoria Zhang, PhD, MBA, chair of the study's scientific committee, "We also have a very well-characterized sample bank available to the community. It's an outstanding effort."

Initially, 975 members filled out the project's first survey, and 698 of those participants gave blood samples. Of those, 531 took a second survey. Those are all large sample sets, said Zhang, and came at a time when vaccine distribution was still new.

The first study, published in *Frontiers in Public Health* in September 2022, looked at the differences in the side effects between Moderna, Pfizer, and Johnson & Johnson vaccines (*Front Public Health* 2022; doi: 10.3389/fpubh.2022.975781). They found that younger people, females, and those receiving the second dose of Moderna reported they had more vaccine side effects.

The increase in side effects from Moderna may be explained by higher viral mRNA concentrations but may be associated with additional protective immunity. These findings "confirmed and validated a lot of existing publications but with a much bigger data set," Zhang said. "It really added value to the community, and the confidence in the information, which was really needed at the time."

ADLM CEO Mark Golden and members of the association's Board of Directors at the 2021 annual meeting.

In March 2023, the group published their second paper in *Viruses* on neutralizing antibody levels and T-cell memory response per type of vaccine given (*Viruses* 2023; doi: 10.3390/v15030709). They found that neutralizing antibody levels were highest in people who took vaccines by Moderna, followed by Pfizer and then Johnson & Johnson.

The data also showed that people with low levels of neutralizing antibodies were more likely to have breakthrough infections, indicating that neutralizing antibodies might be useful in predicting who might have breakthrough infections in the future. The study also found that T-cell memory responses may protect vaccinated individuals against severe disease symptoms if they get

›› see page B-13

INSIDE SECTION B

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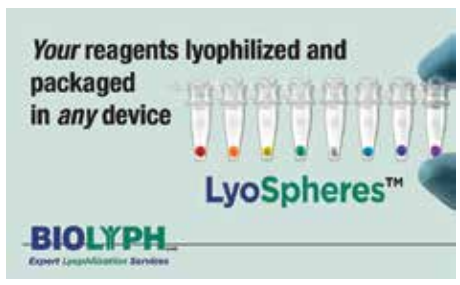

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Diasorin Inc
Booth 1424

LIAISON® MeMed BV®
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Diasorin Inc
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Eurotrol, Inc.
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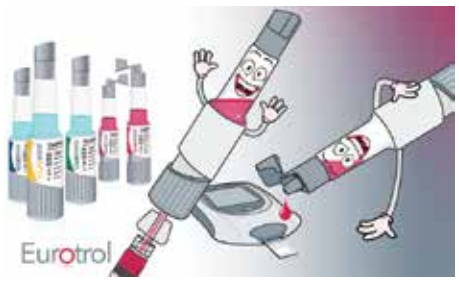
Booth 1017



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MeMed
Booth 4816

GLQI

›› from page B-1

in partnership with the Ethiopian Medical Laboratory Association and Ethiopian Society of Pathology. Merih Tesfazghi, PhD, DABCC, director of core laboratory services at Rush University Medical Center and member of the Africa Working Group, attended the workshop and shared insights into quality assessment programs and quality strategies.

He also helped raise awareness about clinical pathology programs. Ethiopia currently does not offer a clinical pathology rotation as part of residency programs, and the Ethiopian societies that partnered with ADLM were interested in learning more about this area.

"This is a request that came from them," Tesfazghi said. "They wanted us to talk about the role of clinical pathology in healthcare."

Tesfazghi emphasized, however, that GLQI workshops are bidirectional: when ADLM members meet with local laboratorians, there is always a two-way exchange of knowledge.

"It is a collaboration," Tesfazghi said of the workshops he's been a part of. "We work together to identify areas of interest," and workshops often involve everyone "sharing their practice and day-to-day life in the lab," which allows all involved to learn from one another, Tesfazghi added.

Jessica Colón-Franco, PhD, current member and incoming Chair of the Latin American Working Group, echoed these sentiments.

Supported by a generous endowment from the Walter H. Coulter Foundation, GLQI has to date hosted 34 workshops in more than 20 countries, which together have been attended by nearly 5,000 people.

"There's momentum that comes with a gathering of laboratory professionals," she said. "When they all get together to talk about quality, they realize the challenges they're encountering and they can exchange notes and experiences, and hopefully it plants the seed to start something locally."

Colón-Franco recently spent a week in Ecuador, a high-priority country for GLQI activities. She visited eight different laboratories, worked with local laboratorians to conduct a needs assessment, and gave talks on quality control and method verification. She found that, though some laboratories in Ecuador lack certain resources, they have strengths compared to some better-resourced labs, such as fewer staffing shortages.

"They don't seem to experience shortages the same way we [in the U.S.] seem to experience personnel challenges," Colón-Franco noted.

These events were organized in partnership with the national societies Latin American Confederation of Clinical Biochemistry (COLABIOCLI), with which ADLM signed a memorandum of understanding in July 2023. The agreement established a collaborative relationship between the two organizations whereby ADLM will consult with COLABIOCLI when developing academic and training activities for the latter's member countries.

Supporting laboratory medicine around the world

In addition to GLQI's educational portfolio, an increasingly large aspect of its activities are efforts aimed at improving laboratory medicine funding and resources in diverse national contexts. For instance, as part of a 2023 GLQI workshop in Cameroon, Tesfazghi and fellow Africa Working Group member Anne Tebo, PhD, met with directors of several Cameroonian laboratories to help them define ways in which more administrative support can be provided. The conference was organized in partnership with the Cameroon Ministry of Public Health.

"Lab medicine requires advocacy, and it requires us to join hands in achieving it," Tesfazghi said. In Ethiopia, Tesfazghi and others met with an administrator of one of the country's biggest hospitals to discuss the role of the lab in patient care. He hopes these conversations will continue to remain a priority in future GLQI events.

The next GLQI workshop will take place in Zambia, with Nigeria and Brazil in sight for future GLQI events. The continued growth and success of GLQI exemplify ADLM's leadership in the global laboratory medicine community and its work towards improving health for patients across the world.

"As we become a more global organization, GLQI becomes a greater part of our identity," Colón-Franco said.

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Thermo Fisher Scientific
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See floor plan on page B-9 >>

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Product Showcase

Ion Torrent™ Genexus™ System

The Ion Torrent Genexus System is a two-instrument next-generation sequencing (NGS) platform that automates the main steps in the NGS workflow, including sample purification and quantification, library preparation, sequencing, bioinformatics analysis, and reporting.

Thermo Fisher Scientific
Booth 2213

TSQ Altis™ Plus Triple Quadrupole Mass Spectrometer

The VeriSpray™ PaperSpray Ion Source is a fully automated, high-throughput, direct ionization technique used with the latest Thermo Scientific™ TSQ triple quadrupole mass spectrometers.

Thermo Fisher Scientific
Booth 2213

Applied Biosystems™ HIV-1 Genotyping Kit with Integrase

The Applied Biosystems™ HIV-1 Genotyping Kit with Integrase is designed to detect HIV genomic mutations in the Protease (PR) codons 6-99, Reverse transcriptase (RT) codons 1-251, and Integrase (IN) codons 1-288 regions of the pol gene in RNA isolated from human immunodeficiency virus type 1 (HIV-1). For Research Use Only. Not for use in diagnostic procedures.

Thermo Fisher Scientific
Booth 2213

Applied Biosystems Diomni Enterprise Software

Diomni software is an IVDR-compliant, innovative workflow solution that makes routine modular testing more efficient in every aspect.

Thermo Fisher Scientific
Booth 2213

Applied Biosystems™ TaqMan™ Custom QSY2-based Probes

The Applied Biosystem's TaqMan Custom QSY2-based Probe is an extension of the existing QSY probe portfolio. The new QSY2 probes are developed for higher order multiplexing of 5 and 6 targets leveraging Cyanine 5 and Cyanine 5.5 dyes. For research use only.

Thermo Fisher Scientific
Booth 2213

TaqPath™ DuraPlex™ 1-Step RT-qPCR Master Mix

Applied Biosystems™ TaqPath™ DuraPlex 1-Step RT-qPCR Master Mix is a benchtop-stable, single-tube master mix optimized for rapid, sensitive, and reproducible detection of viral and bacterial pathogens even in the presence of PCR inhibitors.

Thermo Fisher Scientific
Booth 2213

Applied Biosystems QuantStudio 5DX Real Time PCR System

Designed to simplify workflows and minimize training needs, the Applied BioSystem™ QuantStudio 5 Dx Real-Time PCR System can help you get to your clinical answers quickly by fitting seamlessly into your established workflow. For In Vitro Diagnostics Use.

Thermo Fisher Scientific
Booth 2213

Applied Biosystems QuantStudio 7Pro Dx Real Time PCR

The QuantStudio 7 Pro Dx Real-Time PCR System is the qPCR platform for the future, combining modern hardware and software in a compact footprint, enabling customers in molecular diagnostics to achieve maximum efficiency, smarter productivity, and higher accuracy from their workflow. For In Vitro Diagnostics Use.

Thermo Fisher Scientific
Booth 2213

Thermo Scientific™ MAS™ Omni Quality Controls

The Thermo Scientific™ MAS™ Omni controls offer highly consolidated solutions to help you simplify QC routine with fewer bottles. Our long shelf life and open vial stability helps streamline QC management and reduce waste.

Thermo Fisher Scientific
Booth 2213

Thermo Scientific™ MAS™ Diabetes Max Control

The Thermo Scientific™ MAS™ Quality Controls portfolio now includes a new Max option, offering Load-and-Go barcoded* tubes to help automate your QC workflow and maximize productivity. *Refer to product package for available barcodes. Not all products are CE marked. Availability of products in each country depends on local regulatory marketing authorization status.

Thermo Fisher Scientific
Booth 2213

Thermo Scientific™ Indiko™ Plus Analyzer

The Thermo Scientific™ Indiko™ Plus Analyzer is low to medium fully-automated random access benchtop analyzer for drugs of abuse and clinical chemistry is a reliable, efficient, and cost-effective solution that can run over 20 drugs using high-quality DRI and CEDIA system reagents. Availability of products in each country depends on the local regulatory marketing authorization status.

Thermo Fisher Scientific
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B·R·A·H·M·S™ sFlt-1/PlGF KRYPTOR™ Test System

The Thermo Scientific™ B·R·A·H·M·S™ sFlt-1/PlGF KRYPTOR™ Test System is the first and only FDA-cleared blood test for risk assessment and clinical management of severe preeclampsia, a life-threatening blood pressure disorder that occurs during pregnancy and the postpartum period.

Thermo Fisher Scientific
Booth 2213

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List as of July 11, 2024

Congratulations 2024 ADLM Award winners

The Association for Diagnostics & Laboratory Medicine (ADLM, formerly AACC) and its Academy recognize individuals around the world for outstanding research and service in the field of laboratory medicine and strive to raise awareness of the vital contribution made by all lab professionals to patient care.

To learn more about individual awardees, visit meeting.myadlm.org/about/awards

Wallace H. Coulter Lectureship Award

Patrick M. Bossuyt, PhD
University of Amsterdam

Outstanding Lifetime Achievement Award in Clinical Chemistry and Laboratory Medicine

Thomas Annesley, PhD, DABCC
University of Michigan

Outstanding Contributions Through Service to the Profession of Clinical Chemistry

David G. Grenache, PhD, D(ABCC)
TriCore Reference Laboratories

Outstanding Contributions to Education in Clinical Chemistry

James H. Nichols, PhD, DABCC, FADLM
Vanderbilt University School of Medicine

Outstanding Scientific Achievements by a Young Investigator

Mark A. Zaydman, MD, PhD
Washington University School of Medicine

Clinical Laboratory Scientist Achievement Award

David Shiembob, MBA, C(ASCP)
ARUP Laboratories

ADLM Past President Award

Shannon Haymond, PhD, MSPA, DABCC, FADLM
Ann & Robert H. Lurie Children's Hospital of Chicago
Northwestern University Feinberg School of Medicine

ADLM General Research Grant Recipient

Cristina Andrea Figueroa Villalba, MD
Yale School of Medicine

Helen Free Travel Grant Recipient

Kaitlyn Bolte, MS, MLS(ASCP)CM
The Children's Hospital of Philadelphia

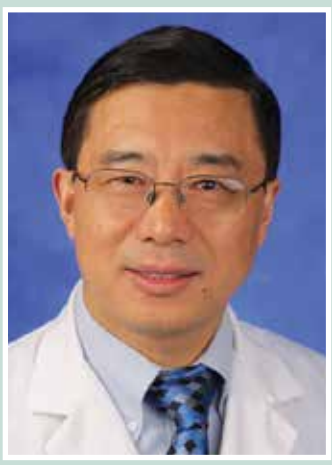
2024 Academy Award winners

The Academy Award for Outstanding Contributions to Clinical Chemistry in a Selected Area of Research

Amitava Dasgupta, PhD, DABCC, FADLM
University of Kansas Medical Center

Professor Alvin Dubin Award for Outstanding Contributions to the Profession and the Academy

Yusheng Zhu, PhD, MS, DABCC (CC, TC, MB), FADLM, FACSc
Penn State University Hershey Medical Center and College of Medicine



George Grannis Award for Excellence in Research and Scientific Publication

Mary Kathryn Bohn, PhD
University of Toronto

2024 Academy Distinguished Abstract Award winners

A-086 – Bradley Collier, Burlington, NC
A-157 – Tushar Sehgal, Delhi, India
A-167 – Brody Foy, Seattle, WA
A-210 – Thando Gcingca, Bethesda, MD
A-211 – Benjamin Andress, Rochester, MN
A-227 – Heather Melson, Salt Lake City, UT
A-268 – Tina Bui-Bullock, Saint Louis, MO
A-288 – Soraya de Andrade, São Paulo, Brazil
A-310 – Eros Qama, Bronx, NY
A-320 – Kuldeep Dhillon, Richmond, CA
B-052 – Danting Liu, Rochester, MN
B-060 – Tomas De Haro, Spain
B-102 – Fay Stewart, Birmingham, United Kingdom
B-116 – Laura Puigví, Vilafranca del Penedès, Spain
B-123 – Hunter Miller, Louisville, KY
B-137 – Raj Gopalan, Durham, NC
B-149 – Yifei Yang, Rochester, MN
B-153 – Rong Yi, Vancouver, Canada
B-200 – Tonya Jagneaux, Baton Rouge, LA
B-232 – Michelle Dina, Rochester, MN
B-240 – Matthew Baker, Glasgow, United Kingdom
B-247 – Ievgen Motorykin, San Juan Capistra, CA
B-251 – Manan Vij, New York, NY
B-255 – Zoi Sychev, Minneapolis, MN
B-288 – Mellia Bennett, Calgary, Canada
B-304 – Amy Theriault, Birmingham, AL
B-308 – Brendan Manning, Waltham, MA
B-318 – Álvaro González, Pamplona, Spain
B-337 – Cristina Agulló, Salamanca, Spain

Posters of accepted abstracts are on display in the Poster Hall on the Expo show floor on Tuesday, July 30 and Wednesday, July 31. All posters will be posted from 9:30 a.m. - 5:00 p.m. Presenting authors will be in attendance from 1:30 - 2:30 p.m.

Immunity Study

›› from page B-1

SARS-CoV-2, but that those T-cells didn't fight the initial infection. The T-cell memory responses were roughly the same for all vaccine types and remained stable 10-12 months after vaccination.

Like with the first paper, this one was unique because of the large data set, said Zhang. They had close to 700 samples measuring T-cell response, and neutralizing antibodies early in the pandemic — which at the time was not universally available.

In February 2024, the group published another paper in *Viruses* evaluating and comparing the performance of three anti-S and one anti-N assays that were available at the time to detect antibody levels after SARS-CoV-2 vaccination from Moderna, Pfizer, and Johnson & Johnson (*Viruses* 2024; doi: 10.3390/v16020292). They found performance variations among different anti-S assays, both among themselves and when analyzing individuals with different SARS-CoV-2 vaccines. From these results, they advised exercising caution when conducting large-scale studies to ensure that the same platform and assays are used for the most effective interpretation of the data.

In March 2024, the group published a special report in ADLM's *Journal of Applied Laboratory Medicine* about their experiences conducting such a large study at a scientific meeting (*J Appl Lab Med* 2024; doi: 10.1093/jalm/jfad089). In it, they described the formulation and execution of this work, best practices, and insights gained throughout the endeavor.

While Zhang said that they are not anticipating any new papers at this time, that doesn't mean the work is done, because the data set is available for public use. The samples are "from a very healthy population and are very well-characterized," she said. "We have their demographic information and are measuring some basic markers for that population so that people can know a little bit more beyond COVID-19." As a result, "we have another normal population sample bank for the community to take advantage of."

Zhang also pointed out that these studies wouldn't have been possible without two groups: the 22 volunteers who made the sample collection happen only 6 months after the idea was hatched for it, and who then shepherded the research through to publication. And study participants who volunteered time during their busy schedules at the annual meeting.

"I want to thank them because, without them, we couldn't have gotten it done," she said.

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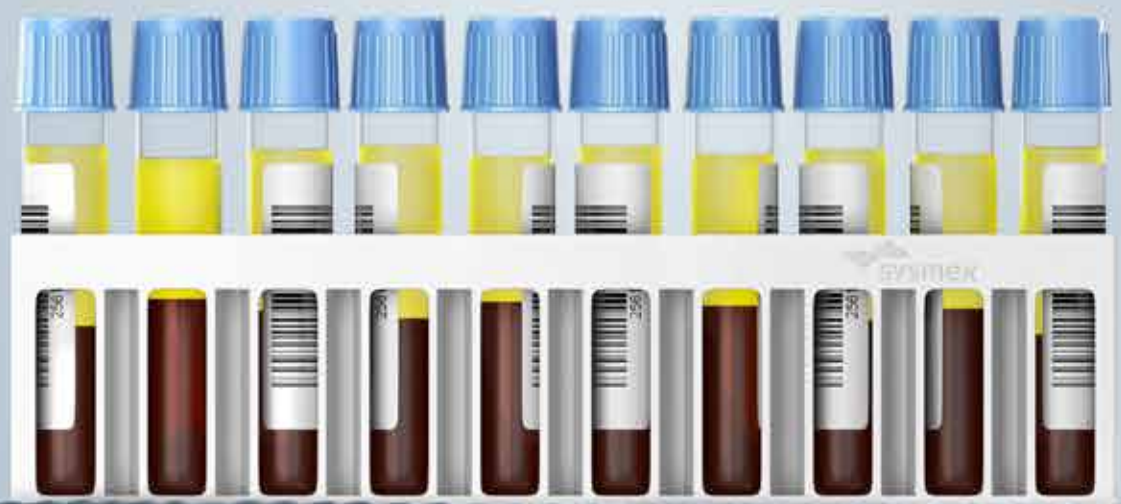

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