CLN Clinical Laboratory News DAILY

Tuesday, August 1, 2017

Section A

AACC

The Official Publication of the AACC Annual Scientific Meeting & Clinical Lab Expo

# Better Outcomes for Young Women Surviving Cancer

By Sarah Wheeler, PhD, NRCC

"Reproductive health is not the same as sex ed," Teresa K. Woodruff, PhD, from the Feinberg School of Medicine, Northwestern University, reminded us in yesterday's plenary session, "Oncofertility: From Bench to Bedside to Babies." The war on cancer has been hard fought, with more young women than ever now surviving cancer but being faced with the possibility of infertility.

We often think of fertility management as an elective treatment for those with the means to seek it, rather than understanding the health risks associated with loss of this important endocrine function. Infertility sometimes leads to premature menopause, which is associated with many long-term health risks including premature death, cardiovascular disease, osteoporosis, neurologic disease, and other disorders. Estrogen treatment doesn't completely mitigate these outcomes. Children with damaged ovaries that don't allow for a normal pubertal transition face compounded risks.


Teresa Woodruff delivers the plenary session "Oncofertility: From Bench to Bedside to Babies."

Woodruff reminded the audience that clinical research is integral to improving fertility management for cancer survivors. Emerging assays provide more options for young women to manage their fertility after cancer treatment. For example, a blot-spot assay for anti-Mullerian hormone (AMH) enables patients to send in a blood spot from home to assess their ovarian reserve, facilitating an estimate of the reserve of growing follicles each month. This knowledge enables physicians and patients to make timely, educated decisions about fertility options that can include embryo or egg banking, surrogacy, and ovarian cryopreservation.

Beyond assessing fertility status, Woodruff's laboratory is working to provide solutions for endocrine and fertility loss in cancer survivors. With a complete understanding of what makes a healthy egg and microenvironment, and how somatic cells and oocytes communicate, the aim of these efforts is to better inform testing, treatment, and functional restoration—and Woodruff and her colleagues are closer to doing so than we might have imagined. She described an in vitro microfluidic system that produced a 28-day menstrual cycle hormone profile in murine ovarian follicles. This technology, named EVATAR, mimics the complex endocrine loops between ovary, fallopian tube, uterus, cervix, and liver by circulating fluidics between each of these tissues. This phenocopy of the female reproductive system provides an accessible system for evaluating the effects of certain treatments on the reproductive system at a personal level.

The introduction of the EVATAR is also opening a new era in reproductive health research where microfluidics carry signals between organs, bring fresh nutrients, and remove metabolic waste products. This seemingly small difference allows researchers to study cycling hormones and

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# Is Laboratory Medicine Ready for Artificial Intelligence?

By Adil Khan, PhD

Some say that the invention of the abacus more than 2,500 years ago was the first step on the long road to artificial intelligence (AI). The reason why this simple calculator made of beads and wires is often called the precursor to the modern computer is because the principle—performing repeated calculations faster than the human brain—is the same. Now scientists are harnessing the speed of modern computers and programming them with cognitive algorithms and sophisticated decision trees to help solve complex medical problems. This rapidly advancing science was the focus yesterday of the Chair's Invited Session, "Is Artificial Intelligence in Genomics Ready for Prime Time?"

Stanley Lo, PhD, chair of the 2017 AACC Annual Meeting Organizing Committee, said he selected the topic because "AI can be considered disruptive technology that significantly changes how we perform laboratory medicine."

The first of three distinguished speakers, Michael Berger, PhD, examined the use of the MSK-IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets) assay to look for mutations in some 468 cancer genes. Gene mutations associated with a particular cancer can sometimes be found in other cancers too, sometimes making it amenable to the same treatment. Berger's team takes DNA samples from the tumor and the patient's blood to help differentiate between germline and somatic mutations and identify the genes causing the cancer. Their technique can more easily identify clinically relevant gene mutations and also pinpoint the pathways affected by the altered gene(s). This targeted gene therapy can potentially cure the cancer and opens up exciting possibilities.

Next, Patrick McNeillie, MD, clinical lead and senior architect of IBM's Watson Health project, discussed how advanced clinical diagnostics algorithms can allow computers to relate diverse clinical literature with patient data to generate an "outcome report." To achieve this, AI systems need to "see" unstructured data, such as radiologic images, graphs, slide

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# Expert Advice on Picking the Correct Genetic Test

By Angela Ferguson, PhD, DABCC, FACB

The amount of information gathered via next-generation sequencing has made the diagnosis of genetic disorders quicker and more accessible to clinicians than ever before, but with expanded testing options come questions about ordering the correct type of testing. Each patient's particular clinical situation is really the most important driver when deciding which type of genetic testing to order, according to experts who spoke during Monday's morning symposium, "Is Bigger Always Better? Pros and Cons of Targeted vs. Comprehensive Genetic Testing."

Linnea Baudhuin, PhD, and Carol Saunders, PhD, led an interactive session that sought to take some of the guesswork out of ordering complex genetic tests by outlining the pros and cons of ordering gene panels, whole-exome, and whole-genome testing. The speakers queried session attendees about the types of genetic testing offered at their institutions and quizzed them on which test should be ordered after learning details of several case studies.

"People should realize that there are benefits to both whole-genome and targeted analyses, and it comes down to ordering the appropriate test in the appropriate clinical setting," Baudhuin said. There are many differences between the two types of tests that people are unaware of, she continued. In reality, whole-exome and whole-genome testing really are more like screening tests, due to limits of sensitivity—a fact not well understood outside clinical laboratories. However, in cases where a patient has a very non-specific phenotype, this type of testing makes more sense, she explained.

Another common misconception about this type of analysis is that it tests for "everything." The truth is, current technologies miss a lot in the genome. "Hopefully most people realize by now that there are poorly covered or under-represented regions, "Saunders said. "As with any test, it's important to realize the limitations."

In spite of these constraints, the information clinicians gain can be very impactful. Saunders discussed several studies that emphasized the utility of rapid whole-genome sequencing. Almost half of the patients in each study had a change in clinical care based on the sequencing results and a similar number of patients received a final diagnosis that had not been considered by the clinical team initially.

Educating clinicians is a key element in effectively utilizing genetic testing. Both speakers also emphasized the importance of genetic counselors in this process. These key players serve as the face of the laboratory, gather additional clinical information about patients, and guide ordering of correct tests or offer alternatives when appropriate. The need for clinician education does not stop once the correct test is ordered. Any type of genetic testing still needs to be interpreted correctly, a challenge that laboratories handle differently. The variant interpretation process is the main bottleneck of the testing process and also factors into the variable quality of results from different laboratories. Clinicians often don't understand these factors, presenting still more opportunities for genetic testing results to be misinterpreted.

Analytics aside, whole-genome sequencing is more expensive to perform than targeted panels and whole-exome sequencing, with low reimbursement. In spite of this, in cases where the sequencing results are able to give a family an answer and halt a diagnostic odyssey, the cost savings could equal years of testing and treatments. "Whole-genome sequencing is an effective, albeit expensive, tool; until sequencing costs decrease, whole-exome sequencing is a good bet for most situations," suggested Saunders.

Speakers Carol Saunders (left) and Linnea Baudhuin prepare to present during "Pros and Cons of Targeted vs Comprehensive Genetic Testing."

# Order This, Not That

By Allison Chambliss, PhD, DABCC

Ambiguity about healthcare reform saturates the news media and is creating a buzz in hospitals. In an age of great expectations for patient satisfaction on top of decreasing reimbursement for laboratory tests, clinical laboratories are forced to cut costs while maintaining overall quality. Some facilities have responded by launching laboratory stewardship programs that seek to ensure appropriate lab test utilization through evidence-based approaches. By eliminating redundant or unnecessary test orders, such programs have the potential to both save money and improve patient care.

Julia Drees, PhD, recognizes that laboratory stewardship programs can be challenging to develop and uphold. In Sunday's AACC University session, "Systems, Stakeholders, and Sustaining: Successful Strategies for Improving Laboratory Stewardship," Drees shared her own experiences from implementing test utilization tools at her regional reference laboratory at Kaiser Permanente. Examples included successful efforts to curb unnecessary vitamin D screening in healthy patients as well as the implementation of a testosterone testing algorithm to ensure that the correct type of testosterone test was ordered depending on patient demographics and the clinical scenario.

Having provided these examples, Drees cautioned that each lab must customize its strategy. "The type of lab and the population it serves, among other variables, dictate which strategies will work best," Drees said. She introduced Patrick Mathias, MD, PhD to provide his perspective from a large academic hospital. Mathias has a background in clinical informatics and spoke about effective tools that labs can build within electronic ordering systems to manage test utilization. Noting that outdated provider order sets can be major drivers of unnecessary ordering patterns, he demonstrated how the revision of combined hepatitis testing panels at the University of Washington proved to be an effective way to decrease redundancy in hepatitis A orders. Additionally, Mathias discussed the value of providing feedback to providers about their lab ordering patterns via "report cards." Such report cards may trend the number of tests ordered per inpatient per day for various locations of the hospital to give providers an idea of how their ordering patterns stack up against those of the other hospital services.

The final speaker, Jane Dickerson, PhD, offered her expertise from a laboratory in a children's hospital. Dickerson discussed a highly-successful program she implemented at Seattle Children's Hospital for high-level laboratory review of complex tests requests. She noted that as many as one-third of genetic send-out tests, in particular, may be inappropriate. Initiatives within her laboratory have included implementing an electronic ordering and tracking system for preauthorization requests for genetic testing as well as case review by expert genetic counselors. Through real clinical case studies, Dickerson illustrated how such laboratory-driven systems can prevent unnecessary orders, provide modifications to semi-appropriate orders, and even elicit a high degree of clinician satisfaction.

Attendees left the session feeling empowered with a better understanding of how test utilization is a critical responsibility of clinical laboratorians. With the variety of perspectives provided at the session, all attendees are likely to identify strategies to help optimize test utilization in their own institutions.



# Data-Mining, Machine Learning, and the Holy Grail of Clinically Actionable Information

By Mark Kellogg, PhD, DABCC, FACB, MT (ASCP)

Clinical laboratories are teaming with data, but transforming that data into information usable by clinicians has been a difficult endeavor. In tomorrow's afternoon short course, "Enhancing the Diagnostic Value of Clinical Laboratory Testing using Data Mining, Machine Learning, Informatics and Clinical Decision Support," attendees will hear success stories from four experts in computational pathology on how they have harnessed data into clinically actionable information.

Clinical laboratories have traditionally focused largely on robust data production, often going to painstaking lengths to ensure accurate test results. However, this leaves the equally important step of transforming this data into clinically actionable information to manual decision-making processes downstream from the laboratory. Now, an ever-growing group of pathologists and laboratorians argue that this traditional approach may fail to extract key diagnostic information.

"In this era in which machine learning and big-data analytics have permeated industries ranging from manufacturing and drug discovery to weather forecasting and computer vision, it is quite likely that computational approaches can add considerable value to laboratory diagnosis as well," explains Jason Baron, MD, a pathologist and computational pathology researcher who will speak at the session. "One goal of computational pathology is to increasingly integrate these computational approaches into the clinical laboratory to augment traditional laboratory test reports with predictive and prescriptive information."

Leaders from Massachusetts General Hospital, Medical College of Wisconsin, University of Washington, and the University of Michigan will describe opportunities to incorporate machine leaning into clinical laboratory practice, discussing fundamentals of clinical analytics as well as practical considerations such as regulation and machine learning's important limitations.

The course moderator, Jason Baron, MD, will lead off by providing an overview of machine learning and key targets for computational pathology. He will describe efforts from his personal experience at Massachusetts General Hospital, including to identify acute kidney injury using a machine learning algorithm. He also will describe an algorithm to detect preanalytical errors associated with improper usage of line draws, and another to predict ferritin test results that he hopes may facilitate iron deficiency diagnosis.

Baron will be followed by Lee Schroeder, MD, PhD. Schroeder's talk will look at processes to mine electronic health records to derive new knowledge. Schroeder will share examples such as an effort to use analytics to derive better personalized reference ranges. He will also discuss a multianalyte assay with algorithmic analysis that uses routine laboratory test results to monitor the response to treatment with thiopurine analogs in patients with inflammatory bowel disease.

Decision support and image analysis in anatomic pathology will be the focus of Christopher Garcia, MD. Garcia will discuss applications of analytics to anatomic pathology including automated image analysis. He will also cover regulatory considerations related to predictive algorithms.

Wrapping up the short course will be Brian Shirts PhD, who will explore the use of clinical decision support in genomics and molecular pathology. Shirts will include several cautionary tales designed to illustrate pitfalls and the importance of proper validation, as well as end-user strategies for the critical assessment of clinical algorithms.

Clinical laboratorians sit at a key interface between data and reporting. Taking this information and making it easy for clinicians to do the right thing and difficult to do the wrong thing is the driving motivation of these speakers. "We want to convey some practical knowledge that participants can take home and use right away along with some ideas and insights about evolving opportunities," Baron says. "Perhaps we can even get some laboratorians newly interested in computational pathology."

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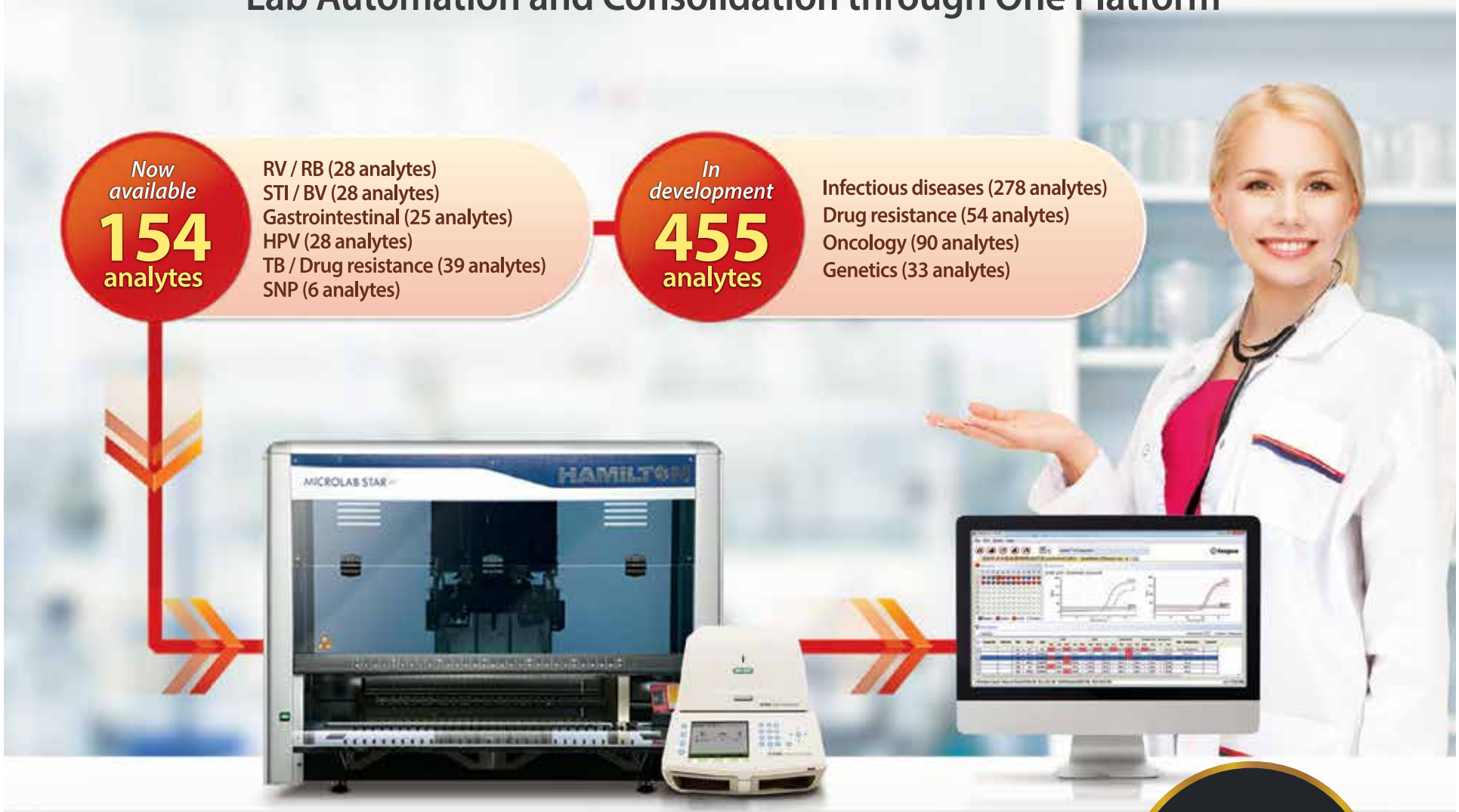


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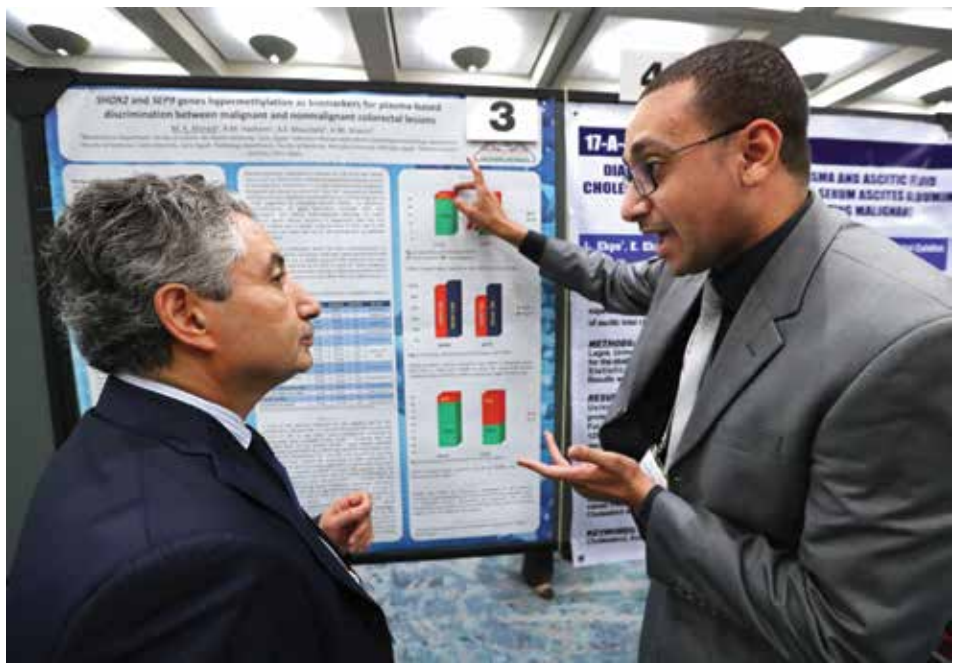
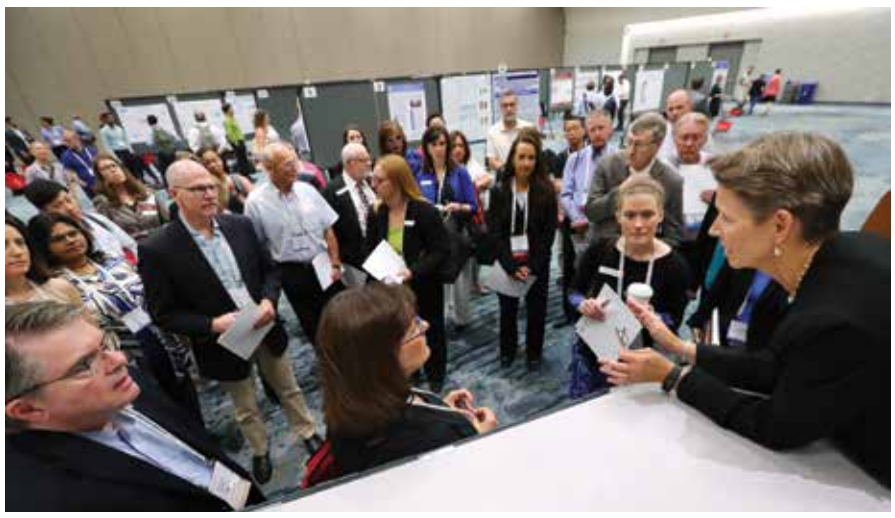
AACC President Michael Bennett presents 2016 AACC President Patricia Jones with the AACC traditional red jacket.



Moustafa Kamel Hassan Abozeid (right) discusses his findings with judge Khosrow Adeli during the student poster contest.

AACC Academy Fellows James Wesenberg (from left) and Kent Dooley visit with Chris Perigard during the AACC Community Opening Mixer.



Contest moderator Ann Gronowski confers with the judges as they prepare to meet with their student poster presenters.

## AACC Student Poster Contest Winners

**Oral Presentations**
1st Place: Lusia Sepiashvili
2nd Place: Melanie Yarbrough
Honorable Mentions: Sarah Delaney and Carmen Ghersaim

**Poster Presentations**
1st Place: Felix Leung
2nd Place: Uvaraj Uddayasankar
Honorable Mentions: Victoria Higgins and Shaw Li Chaw


Frontier Medical Devices—the winner of the Qualcomm Tricorder XPRIZE competition—showed off DxtER, a real-life tricorder, during the Q&A session with XPRIZE finalists.

The Honorable Eric Haner, District Court Judge, Louisville, KY, prepares to hear testimony at "Presenting Expert Testimony in the Courtroom."

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# *CLN Daily* 2017 Editorial Board

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**Octavia Peck-Palmer, PhD**

Dr. Peck-Palmer is a board certified clinical chemist and associate professor at the University of Pittsburgh School of Medicine. She directs three automated testing laboratories and is a member of the AACC Academy, Secretary of the AACC Clinical Translational Science Division, and the AACC Philadelphia Local Section. Her interests include racial disparity in sepsis/infection biomarkers, automation, and test utilization.

**Allison Chambliss, PhD**

Dr. Chambliss is an assistant professor of clinical pathology at the Keck School of Medicine of the University of Southern California in Los Angeles, CA. She is the director of clinical chemistry and point-of-care testing at the Los Angeles County and USC Medical Center. Her current professional interests include clinical lab standardization and fostering clinical collaborations outside of the laboratory.

**Angela Ferguson, PhD**

Dr. Ferguson is the co-director of clinical chemistry at Children's Mercy Hospital in Kansas City, Missouri and an assistant professor of pathology at the University of Missouri-Kansas City. She is a diplomate of the American Board of Clinical Chemistry and serves as a member of its board of directors, and is a Fellow of the AACC Academy, serving as Secretary/Treasurer. She is actively involved in AACC and is currently the Treasurer for the AACC Pediatric and Maternal-Fetal Division.

**Kamisha Johnson-Davis, PhD**

Dr. Johnson-Davis is an associate professor (clinical) at the University of Utah in the department of pathology and medical director for clinical toxicology at ARUP Laboratories in Salt Lake City. She is board certified in clinical chemistry and toxicological chemistry, a diplomate of the American Board of Clinical Chemistry and a fellow of the National Association of Clinical Biochemistry and the Association of Clinical Scientists.

**Mark Kellogg, PhD, MT(ASCP)**

Dr. Kellogg is the associate director of chemistry and director of quality systems in the department of laboratory medicine at Boston Children's Hospital and an assistant professor of pathology at Harvard Medical School in Boston. He is a native of Battle Creek, Michigan, where all good Kelloggs come from.

**Adil I. Khan, MSc, PhD**

Dr. Kahn is an assistant professor at Temple University Lewis Katz School of Medicine in Philadelphia and Director of Point of Care Testing at Temple University and Episcopal Hospitals. He is also director of the Clinical Chemistry Laboratories at Temple University, Episcopal Hospitals, and the Northeastern Ambulatory Care Center. He is a member of the IFCC and Laboratory Medicine Task Force on Point of Care Testing. His research interests include understanding the role of adhesion molecules in leukocyte recruitment in health and disease; novel markers of inflammation; clinical trials of point-of-care testing devices and clinical laboratory instruments; and assay development.

**Veronica Luzzi, PhD**

Dr. Luzzi is the medical director at Providence Health and Services Regional Laboratory in Portland, Oregon. She is also the director of Chemistry at the same institution. Dr. Luzzi supports laboratory stewardship and acts as a liaison between healthcare providers and the clinical laboratory. She is a faculty member for the AACC Global Lab Quality Initiative and often shares her expertise through the Latin-American Working group.

**Sarah Wheeler, PhD**

Dr. Wheeler is an assistant professor of pathology at the University of Pittsburgh School of Medicine. She is also director of UPMC Mercy Clinical Laboratory, Children's Hospital of Pittsburgh Automated Testing Laboratory, and associate director of clinical immunopathology at UPMC Central Laboratory. Her research interests include improving testing for multiple myeloma and HIV, as well as developing assays for novel investigational transplant specimens.

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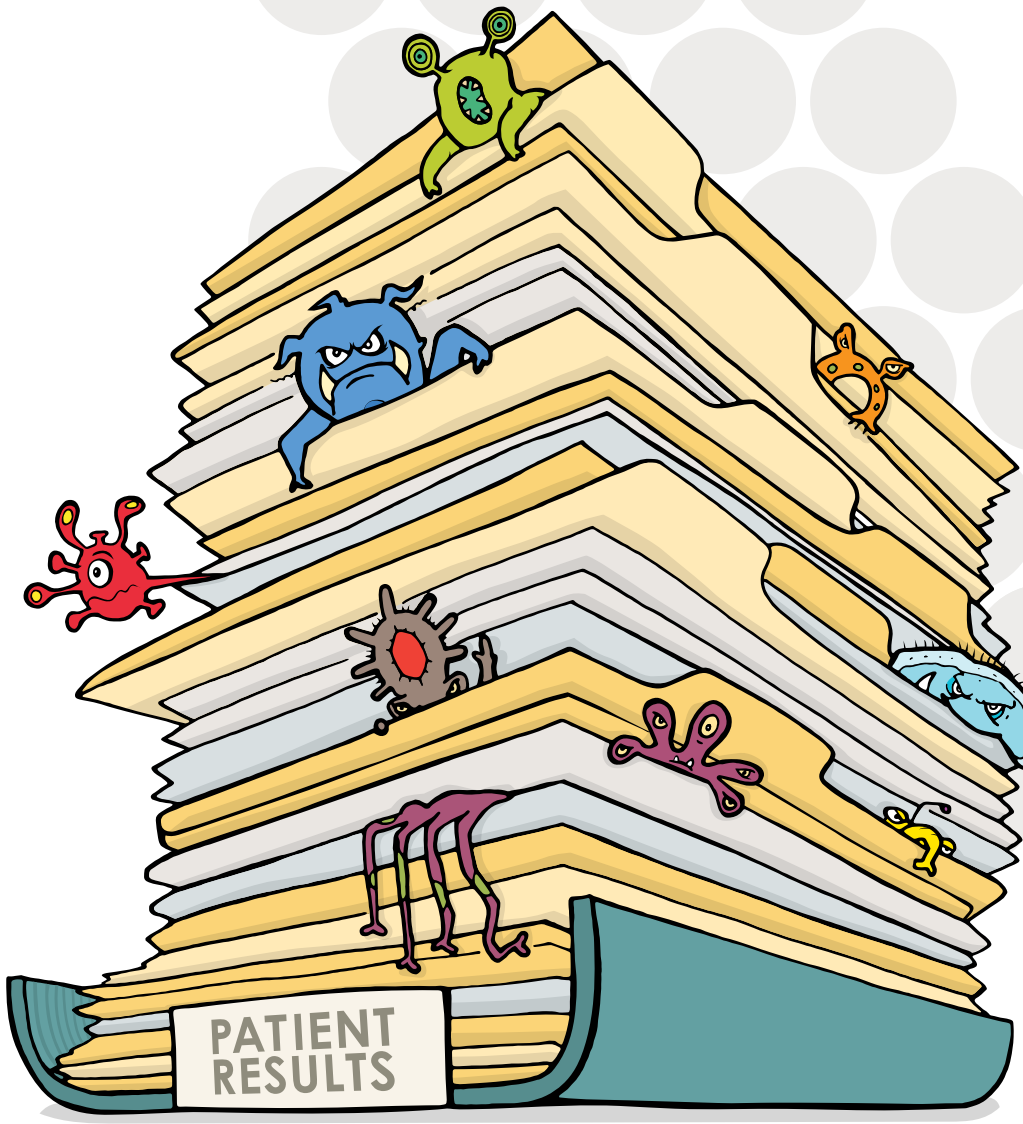


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# The Life Cycle of a Lab Developed Test

By Veronica Luzzi, PhD

If you think you are alone in trying to figure out how to create, validate and verify performance specifications of a laboratory developed test (LDT), think again. Clinical laboratories have struggled to understand the best approach for establishing LDT performance for some time. In fact, understanding the different terminology is a big part of that struggle. In the U.S., clinical laboratories that use LDTs are required by CLIA to establish performance specifications of a newly introduced test system, specifically those that are not subject to the U.S. Food and Drug Administration (FDA) clearance or approval. Laboratories must do the same for any approved/cleared assay that the lab modifies.

While CLIA requires that labs establish these performance specifications, it leaves the "how" up to labs. LDTs have evolved from home-brew tests to more complex assays being manufactured by corporations for the screening of life-changing diseases. Navigating the regulatory terminology and the complexity of the different evaluations required for LDTs can be daunting.

In 2015, stakeholders representing lab professionals, the in vitro diagnostic (IVD) industry, and government, including FDA and the Centers for Disease Control and Prevention, collaboratively created the CLSI Evaluation Protocol 19: "A Framework for Utilizing CLSI Guidelines to Evaluate Clinical Laboratory Assays." This guideline uses standardized terminology that is useful, clear, and consistent with FDA usage.

In the session "Laboratory Developed Tests - What's a Laboratory to Do?" Paula Ladwig, MS, MT(ASCP), Luann Ochs, MS, and Lucia Berte, MA, MT(ASCP), shared their expertise on how and when to establish and implement an LDT using the CLSI EP 19, the FDA's Quality Systems Regulations, and ISO standards for validation and verification of LDTs. Ladwig introduced the idea of the assay life cycle paradigm and discussed its two main stages: establishment and implementation. She clarified the requirements for establishing performance of an LDT, and the steps required for implementation so that laboratories can routinely perform the LDT. She emphasized the milestones common to LDTs and commercially-manufactured assays. She used hypothetical LDT examples to illustrate how CLSI guidelines are used to establish performance claims and illustrated how decisions are made and supporting data documented.

Using the checklists provided in the EP19 labs can strengthen the validation through documenting the work done, Ladwig said. She also mentioned that one important part of establishing method performance is to define acceptability criteria at the beginning before validation begins.

Ochs is currently the senior vice president of operations for CLSI and had a key role in shepherding the EP19 guideline to completion. She has vast experience in the IVD industry and explained the importance of FDA's Quality System Regulation 21CFR820 (QSR) and future expectations.

Ochs introduced the concept of design control or what labs need to do to meet FDA requirements on top of what they need to do to comply with CLIA. Design control is a term that may be unknown to labs but is already frequently practiced by many labs that create LDTs. When LDT requirements are understood before an LDT is developed, the development occurs in a controlled manner, changes are deliberate and controlled, and every step is reviewed and documented, Ochs said.

Finally, Berte demonstrated how useful the CLSI guidelines and the International Organization for Standardization (ISO) 15189 can be for clinical laboratories. Specifically, she used graphics to explain how the plan-do-check-act paradigm applies to ISO standards and to LDTs. Berte emphasized using terminology and steps as described in EP19 and ISO 15189 to facilitate documenting, establishing performance characteristics, and implementing an LDT. She used a picture to describe the life cycle of a test and overlaid the ISO clauses corresponding to each of the steps of test life cycle. The session moderator, Rex Astles, PhD, facilitated lively interactive exchanges between the speakers and attendees.



## Important Correction

Please note that in the Product Showcase section of the *CLN Daily*, on page B-28, the article about the product called ADVIA Centaur® Zika IgM Assay was printed in error. We regret this mistake and apologize for the error.

# Common Rule Changes Favor Researchers

By Angela Ferguson, PhD, DABCC, FACB

The biggest news about changes made to the Common Rule in the federal regulations governing research was in regard to the proposed change that wasn't made. This is the consensus opinion of the experts speaking in a morning symposia today at 10:30 a.m., "Changing the Rules of the Game: Multi-Disciplinary Stakeholder Perspectives on the New 2017 Federal Regulations for Research." Erin Paquette, MD, JD, Danelle Miller, and Mark Sobel, PhD, MD will discuss the proposed changes to the rule, the changes that were put in place in the final version of the Common Rule, and how these changes will affect both academic and industry-based research.

The Common Rule provides protection to human research subjects and had not been updated since 1991. Proposed changes released to the public in 2015 included a provision that would have redefined the term "human subject" to include the unidentified biospecimens found in clinical laboratories. Miller, vice president of global regulatory policy and intelligence with Roche Diagnostics, states, "The final rule maintained the current [Food and Drug Administration] policy allowing the use of biospecimens that are deidentified, but there is a provision requiring review of the policy after one year." She explains that the definition of an identifiable biospecimen will be reevaluated to keep up with advances in technology, which, if changed, could impact researchers in industry and academics.

The panel will discuss the changes that made it into the final rule, including allowing a single institution's Institutional Review Board (IRB) to approve a multi-site research study, and requiring informed consent forms for research studies to state clearly and concisely at the front of the document the risks to study participants. They also will highlight how regulations have the potential to thwart clinical research.

Overall, the changes that were made will be good for research. "From an investigator's standpoint, a number of the changes were aimed to reduce burden," says Paquette, assistant professor of pediatrics at Northwestern University and associate chair of the ethics committee at Ann and Robert H. Lurie Children's Hospital of Chicago. "There are some additional responsibilities placed on IRBs that they will have to work out how to implement." She adds that the informed consent requirement will be the trickiest to implement. It could lead to some misunderstanding about the benefits of participating in a research study. However, as imperfect as this new requirement might be, it is time for an overhaul of the consent process due to research participants' historically poor understanding of giving consent. By the end of the session, Paquette hopes attendees understand that Federal oversight for research balances two priorities: conducting research that is meaningful for the scientific community, and protecting patient autonomy and privacy. Changes to the rule achieved those aims, but time will tell if more tweaks are needed.

Miller believes that the changes to the Common Rule, and the provisions in the 21st Century Cures Act, have created a positive environment for doing clinical research in the U.S. that still protects both patients and the privacy of human research subjects. She hopes audience members involved in research will continue to consider and advocate for policies that assist researchers so that healthcare moves forward with new and innovative products to benefit patients.

## Woodruff

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tease out nuances in signaling that are lost in static culture models.

Woodruff and her colleagues are pursuing possible interventions, including engineering an ovarian bioprosthetic, that will maintain and restore normal autonomous function to follicles. Already, her lab has restored ovarian function in sterilized mice using 3D printed microporous scaffolds to create a bioprosthetic ovary that allowed for pups born through natural mating. This important breakthrough provides new treatment possibilities for endocrine support and infertility in the many premenopausal and prepubertal cancer survivors.

In Woodruff's experience, many oncologists tend to be uninformed about reproductive health. This is an area in which more education about the role of hormones in fertility and endocrine support could produce healthier lives. This rapidly advancing frontier will require our close attention to ensure that cancer survivors achieve the best possible long-term health outcomes. Woodruff closed with a reminder that "when grants and papers meet clinical problems, patient needs are met and we can change a devastating diagnosis into hope for the future."

# New Psychoactive Substances Challenge Detection

By Kamisha Johnson-Davis, PhD, DABCC (CC,TC)

Anyone who walked into Monday's morning symposium, "Novel Psychoactive Substances (NPS) in Emergency Toxicology" thinking that NPS are not a growing threat to public health were quickly disavowed of that notion. Speakers Jennifer Colby, PhD, and Kai Li, MD, described various compounds, including the drug U-47700, which is a synthetic super-opioid that causes extreme euphoria and respiratory depression, frequently leading to adverse effects, including death.

U-47700 is just one of many new psychoactive substances being sold on the street as counterfeit prescription drugs or in combination with prescription and illicit drugs. Various monikers like "legal highs," "research chemicals," and "synthetic drugs" have been applied to NPS owing to the compounds being structural analogs of target drugs that imitate the pharmacological effects of these drugs. However, NPS are structurally unique from target drugs, in order to evade identification and scheduling by the Drug Enforcement Agency, as well as detection in drug testing laboratories.

As Colby explained, "trends in NPS use change quickly and vary in different parts of the country." Some of these compounds were synthesized more than 40 years ago but now have re-emerged and made their way into use. With no regulatory oversight on the manufacturing and purity of these products, consuming them poses grave risks. Colby and Li emphasized that use of NPS in the form of cannabinoids, cathinones, benzodiazepines, opioids, phenethylamines, and more, has led to world-wide adverse drug reactions, hospitalizations, and fatalities. Laboratories face challenges in detecting these compounds because NPS have variable cross-reactivity with existing immunoassays and because laboratories lack access to analytical methods capable of detecting all of the variations of these designer drugs.

Li described the commonality of designer drug intoxications as well as the toxidromes associated with NPS ingestion. "Toxidromes are important symptoms to recognize early in the care of the poisoned patient," Li, noted. The speakers underscored the need for teamwork between medical and clinical toxicologists and clinical laboratories to identify drug compounds in intoxication or poisoning cases. They also described methods that were developed to test for NPS to support patient care. Colby and Li elaborated, through case reports, their success in using broad-spectrum drug screening via high-resolution mass spectrometry to identify the compounds intoxicated patients had ingested. The session was interactive, using the FXP | touch app, and the speakers quizzed the audience on drugs that corresponded to the toxidrome symptoms in the case reports. They also polled attendees to determine which instruments were being used to support testing in attendees' emergency departments.

Speakers Kai Li (left) and Jennifer Colby present at Monday's "Novel Psychoactive Substances in Emergency Toxicology."

"These drugs are not going away. In fact, the number of new drugs continues to increase," Colby said. "Outbreaks of drug substitutions, where users ingest something other than what they expected, continue all across the country. Poison control centers are often the first to hear of these epidemics, yet lack close laboratory collaborators to rapidly identify the causative drug. I think that by working with our medical toxicology colleagues, clinical toxicologists can play an important role in patient care and potentially even in public health."

# Interesting Findings: Unexpected Discoveries Among the Posters

By Octavia Peck Palmer, PhD

The 2017 AACC Annual Meeting Organizing Committee accepted 740 abstracts representing innovative scientific work from more than a dozen countries. Although every abstract will not receive distinguished recognition from the AACC Academy or the various AACC Divisions, highlighted here are several interesting studies that you may want to visit during this year's poster sessions. Posters are located in the upper level of the Sails Pavilion in the San Diego Convention Center.

*Analytical Evaluation of Soluble fms-like Tyrosine Kinase 1 (sFlt-1) and Placental Growth Factor (PlGF) on Brahms Kryptor Automated Immunoassay for the Diagnosis of Preeclampsia (Poster B-017)* presented by S. Chan et al. Although preeclampsia was described more than 2,000 years ago, the etiology of this hypertensive disorder is not clear. Moreover, the diagnosis of preeclampsia has been modified over time and includes factors such as hypertension, proteinuria, impaired liver function, and low platelet count. The acute onset of preeclampsia and delayed detection can lead to both maternal and fetal mortality. Chan et al. examined the analytical performance of the Brahms Kryptor automated immunoassay for measurement of two potential preeclampsia biomarkers, sFlt-1 and PlGF. The assay demonstrated acceptable analytical performance needed to further delineate the diagnostic utility of sFlt-1 and PlGF.

*Changes in Laboratory Testing Turnaround Times at a Major Academic Medical Center After Converting to a Total Laboratory Automation System for Chemistry and Hematology (Poster B-024)* presented by M. R. McGill et al. If you have not already, it's highly likely that in the near future you will experience implementing total laboratory automation (TLA) in your institution, so why not visit a group of colleagues who just completed this arduous task in 2016? McGill et al. focused specifically on the effect of TLA on test turnaround time (TAT). They reported an initial increase in TAT after the implementation of TLA that was reversed after key collaborative efforts with the manufacturer, including hardware and software adjustments. After these changes, TLA significantly decreased TAT for BMP, CMP, CBC, and cTnI.

*Testosterone Content in Hyaluronidase Powder: Evaluation of Commercially-Available Sources for the Pretreatment of Viscous Body Fluid Specimens (Poster A-272)* presented by S. L. La'ulu et al. Many clinical laboratories use hyaluronidase to liquefy viscous body fluids. However, you may not have considered the purity of the hyaluronidase preparation. In this study the authors assessed the relative quantity of testosterone in three commercially available hyaluronidase preparations and the potential effects of testosterone contamination on several assays.

*Unstable Trends in Metabolites Predict Mortality Within 48 Hours Among Long Term Hospitalized Patients (Poster B-036)* presented by A. Momeni Boroujeni et al. Interestingly, the authors retrospectively examined metabolite trends in deceased inpatients (n=110) in their institution over a 2-year period to "evaluate end-of-life laboratory values time trends among deceased long term inpatients." Using the ARIMA and Mann-Kendall trend test, they identified increases in BUN, AST, and ALP, all indicative of end organ damage in the 48 hours that preceded death. They also found that Na, Cl, and K vary significantly from normal values. The authors concluded that, "Perhaps early detection of these changes can allow for timely interventions for the patients."

**Posters are located in the upper level of the Sails Pavilion in the San Diego Convention Center.**

*Comparison of qSOFA (quick SOFA) Score, Presepsin, Procalcitonin and Lactate for Severity Assessment and Mortality Prediction in Patients with Initial Sepsis (Poster B-069)* presented by E. Spanuth et al. Sepsis is a global public health problem. In 2016, the Third International Consensus Definitions for Sepsis and Septic Shock introduced a new sepsis definition, Sepsis-3, and a new risk score, the qSOFA score, in order to predict the risk of mortality in patients with suspected infection. The authors compared the performance of presepsin and procalcitonin with the qSOFA to differentiate sepsis, severe sepsis, or septic shock and the risk of mortality prediction in a cohort of 66 patients. The authors concluded that assessing qSOFA and presepsin together was better than using qSOFA alone.

# Shedding Light on Cannabis-Impaired Driving

By Kamisha Johnson-Davis, PhD, DABCC (CC,TC)

Public support and legislative efforts over the past few decades have led to the legalization of cannabis (marijuana) for medical and/or recreational use in 29 states and the District of Columbia. The medical use of cannabis has expanded from HIV/AIDS wasting disease and glaucoma to epilepsy, cancer, neurological disorders, and chronic pain. Despite its medical benefits, there is growing concern about the dangers of driving under the influence (DUI) of cannabis. The short-term cognitive effects of cannabis include impairments to memory, sensory perception, psychomotor control, and reaction time. The amount of cannabis consumed and the time window relative to use influence the severity of these effects.

Today's afternoon symposia, "Cannabis Impaired Driving: Biological Markers and Behavioral Indicators of Recent Cannabis Intakes," will give attendees a comprehensive overview of cannabinoid pharmacology and cannabis markers typically found in occasional and chronic smokers from four highly regarded investigators. Marilyn Huestis, PhD, a prominent researcher who has been conducting controlled cannabis administration studies for more than 20 years, will moderate and describe the endogenous cannabinoid system, the metabolism of cannabinoids, the disposition of cannabinoids in blood, and markers of recent cannabis use.

Rebecca Hartman, PhD, of the Monroe County (New York) Office of the Medical Examiner, will present findings from studies examining cannabis driving impairment following controlled cannabis administration, while Madeleine Swortwood, PhD, of Sam Houston State University, will describe the disposition of cannabinoids in oral fluid after smoked, inhaled, and oral cannabis administration in chronic, frequent, and occasional cannabis smokers and on-site oral fluid testing to identify recent cannabis use. Meanwhile, Barry Logan, PhD, of NMS Labs, will highlight on-site oral fluid data based on random sample collections from volunteers at a music festival, and minimum blood testing requirements to identify drug-impaired driving.

"Everyone is affected by cannabis-impaired driving, the most important short-term consequence of cannabis medicalization and legalization," says Huestis. Cannabis-related DUI automobile accidents and fatalities have been on the rise, and the general public needs to understand that "driving while under the influence of cannabis approximately doubles your risk for injury or death," she adds.

DUI means a driver is unable to drive safely due to the exposure to drug or alcohol use. The laws governing DUI vary greatly among states. Some have zero tolerance laws, which declare that any concentration of Δ9-tetrahydrocannabinol (THC – the main psychoactive constituent of cannabis) detected in a specimen classifies a driver as DUI. Other states stipulate a "per se" blood concentration of a drug at a specified threshold to characterize the driver as DUI, while still others require documented performance impairment. Roadside screening devices detect cannabis use in oral fluid to assess acute driving impairment. The legal consequences of a DUI violation may include monetary fines, jail time, community service, probation, license suspension, or requirement to enroll in a drug treatment program.

Clinical laboratories—should be prepared to offer blood, plasma, oral fluid, and urine cannabinoid testing for therapeutic drug monitoring of new cannabinoid therapies, to detect recent cannabis use in motor vehicle crashes, workplace or home accident investigations, to identify relapse in drug treatment programs, or to screen applicants and employees for workplace drug testing programs, according to Huestis.

This session will debate the most effective measures to document cannabis-impaired driving. Come and join in the discussion!




## AI

›› from page A-1

images, clinic notes, and literature texts, and then convert this to a knowledge base in a structured format. Software must also associate this with other similar "knowledge banks." For example, cortisol can be either a hormone or drug, and can be differentiated by looking at context clues. So if cortisol is associated with "secretion" it indicates a physiological process, ruling out its use in this example as a drug. This contextual information-based approach helps the system be intelligent.

Complementing these two speakers, Nirali Patel, MD, explained how IBM Watson is helping her institution to help fulfill the promise that "healthcare should be tailored to meet the needs of the individual." However, Patel noted that "AI can be used to aid physicians in making their diagnosis, but not replace them entirely."

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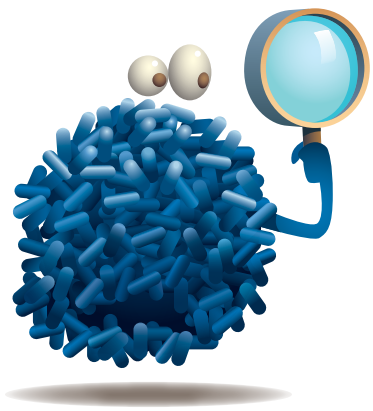

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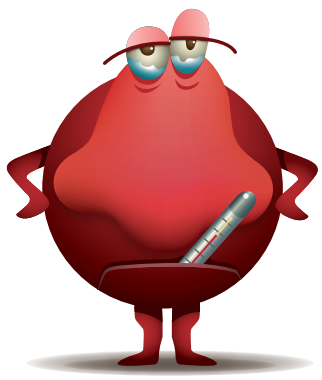

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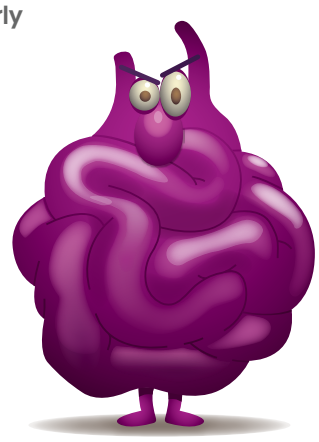

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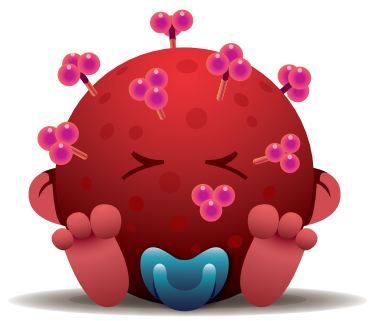

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CLN DAILY
Clinical Laboratory News
Tuesday, August 1, 2017
AACC
The Official Publication of the AACC Annual Scientific Meeting & Clinical Lab Expo
Section B

# AACC's Lab Tests Online Celebrates 300 Million Users

By Dominique Smith

Lab Tests Online recently celebrated a significant milestone by serving an estimated 300 million visitors since the U.S. site launched in 2001. For the past 16 years, AACC's award-winning health information web resource (labtestsonline.org) has been helping patients and caregivers understand the many lab tests that are a vital part of medical care. Laboratory and medical professionals representing AACC and related laboratory and medical organizations develop and review all content, including articles on lab tests, conditions/diseases, screening, clinical laboratory topics, and lab test news. Health professionals and patients alike frequent the website for its comprehensive, peer-reviewed content.

The AACC LTO staff and representatives from European Lab Test Online sites met at the Greek Society Clinical Chemistry Office in Athens, Greece to review new initiatives and discuss editorial planning.

## Raising the Visibility of Lab Medicine Worldwide

Local versions of the site operate in more than 15 countries and in more than 10 languages, including Chinese, Spanish, and French. International partner societies make a valuable contribution to the breadth and quality of the content by developing native language versions of Lab Tests Online in their home countries. This global network of Lab Tests Online websites is committed to the mission of raising public awareness about the importance of laboratory medicine and its contribution to healthcare. AACC acknowledged 10-year anniversaries for sites in Hungary, Italy, Poland and Spain this past June at the Lab Tests Online Global Editors meeting in Athens, Greece that preceded EuroMedLab.

**During the 69th AACC Annual Scientific meeting, the Lab Tests Online team will be at the AACC Member Center (#3539) promoting its free ACCENT CE Reviewer Program.**

In 2009, D. Robert Dufour, MD, FACB, a founding member of AACC's Lab Tests Online Editorial Review Board, became the Executive Editor of the Global Lab Tests Online program. This role has been instrumental in ensuring high-quality content and consistency across all country sites by coordinating the implementation of Lab Tests Online's editorial policies and guidelines. Dufour will retire from the role of Executive Editor but will continue to serve as an AACC member of the Lab Tests Online Editorial Review Board. AACC and the global websites will commemorate Dufour's nearly 20 years of service to the Lab Tests Online program and welcome Shannon Haymond, PhD, DABCC, FACB, as the incoming Executive Editor of Lab Tests Online during the LTO Editors' Meeting here in San Diego, July 31.

During the 69th AACC Annual Scientific meeting, the Lab Tests Online team will be at the AACC Member Center (#3539) promoting its free ACCENT CE Reviewer Program. AACC members with US or Canadian licensure or certification can contribute to lab medicine patient education and earn 4 CE credits by reviewing and updating Lab Tests Online content.

## Looking Forward: Lab Tests Online Launches a New, Modernized Website

As consumers become more proactive about their health and doctor-patient collaboration, the demand for health education websites with advanced, media-rich tools continues to rise. After nearly 17 years, Lab Tests Online will unveil a new, modernized website featuring a user-friendly layout and functionality aimed at optimizing the visitor experience. When the site launches this December, users can anticipate a mobile-friendly website with an expanded repository of interactive, media-rich tools and imagery. Over the next 2 years, Lab Tests Online plans to offer advanced features that provide a more tailored experience for both patients and health care providers that use the website.

Stop by the AACC booth (#3539) for a free memento and to learn more about the new Lab Tests Online site.

# Making a Match at the AACC Clinical Lab Expo

By April Banks and Anne Novak

With many companies seeking to increase business around the world, making the right connections at the show can make a big difference. The U.S. Department of Commerce is taking a leading role in facilitating those connections under Commerce's International Buyer Program (IBP), which the AACC Clinical Lab Expo is part of this year. The IBP facilitates approximately $1b in new business at major industry trade shows each year.

Commerce Trade Specialists from U.S. offices will be onsite at the International Trade Center, located in the Sails Pavilion on the top level of the San Diego Convention Center, to assist attendees in meeting with international companies that are interested in their products and services.

Commerce Commercial Specialists from Argentina, Brazil, Kenya, Malaysia, Mexico, Pakistan, the Philippines, Saudi Arabia, Singapore and Taiwan will meet with U.S. exhibitors at the meeting to counsel them on export prospects in their countries. They also can offer country-specific market advice.

In addition to matchmaking with U.S. companies, the ITC offers a host of services with international visitors in mind, including private meeting rooms, a lounge area, refreshments, and computer capabilities with internet access. Companies can meet with delegation leaders, U.S. companies, or just relax.

For those interested in setting up appointments with U.S. suppliers attending the show, visit the ITC to find out more.

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## See what's new—visit CAP Booth #3727.

**AGENDA**

**Tuesday, August 1**

***Learn. Discuss. Advance.***

**Half-hour Sessions**

**10:00 AM–4:30 PM, CAP Booth #3727**

- Personnel: Ensuring You Have the Right Person in the Right CLIA Role
- Accidental PT Referral: Best Practices for Prevention
- Root Cause Analysis: Getting to the Bottom of It
- Calibration Verification and Analytic Measurement Range Verification: Case Studies Highlight Requirements and Solutions



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# Posters On Display

All posters accepted for the 69th AACC Annual Scientific Meeting will be on display Tuesday, August 1 and Wednesday, August 2 from 9:30am – 5:00 pm in the Sails Pavilion, Upper Level, San Diego Convention Center. Presenting authors will be in attendance from 12:30 – 1:30 p.m.

Attendees can also download a complete PDF book and search abstracts online at www.aacc.org. Click on Meetings and Events > 2017 Annual Meeting > Call for Abstracts.

The critical and point-of-care testing division poster walk group listens as Kerstin Halverson (left), 2016 point-of-care coordinator of the year, answers questions about her poster at the 2016 AACC Annual Scientific Meeting in Philadelphia.

## Division Poster Walks Today

Led by AACC Division subject matter experts, poster walks highlight posters selected by the division for further discussion. Poster walks are free, limited to 20-30 participants, and last about 30 minutes. Participants must have a full or daily conference registration and are asked to line up next to the tour signs outside the entrance to the poster display. All poster tours begin at 12:30 pm.

| *Division* | *Tour Leader* |
|---|---|
| Biomarkers of Acute Cardiovascular Disease | Alan Wu |
| Clinical & Diagnostic Immunology | Maria A. Willrich |
| Clinical Translational Science | Zhen Zhao, Vincent Ricchiuti, and Octavia Palmer |
| Endocrinology | Bill Winter |
| Mass Spectrometry and Separation Sciences | Frederick Strathmann |
| Hematology and Coagulation | John V. Mitsios |
| Nutrition | Elizabeth Frank |
| Tumor Markers and Cancer Diagnostics | Joshua Hayden |

# Product Showcase


### Abbott ARCHITECT B·R·A·H·M·S PCT (Procalcitonin)

The ARCHITECT B·R·A·H·M·S PCT assay is now available in the US! The assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of procalcitonin (PCT) in human serum and plasma.

**Abbott Diagnostics**
**Booth 3916**


### Abbott ARCHITECT Syphilis TP

Abbott's ARCHITECT Syphilis TP has launched in the US! The assay is intended to be used as an initial diagnostic test or in conjunction with a nontreponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection. Warning: The ARCHITECT Syphilis TP assay is not intended for use in screening blood, plasma, or tissue donors.

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### Advanced™ Anoxomat® III System

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**Advanced Instruments**
**Booth 4951**


### GloCyte® Automated Cell Counter for CSF

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### OsmoPRO® Multi-Sample Micro-Osmometer

OsmoPRO®, the newest addition to the Advanced Instruments family of freezing point osmometers. Designed specifically for mid- to high-volume laboratories wanting to automate osmolality testing to improve laboratory efficiency, throughput, and workflow.

**Advanced Instruments**
**Booth 4951**

### 6545XT AdvanceBio LC/Q-TOF

The Agilent 6545XT AdvanceBio LC/Q-TOF system is designed to handle multiple workflows in biopharmaceutical characterization.

**Agilent Technologies, Inc.**
**Booth 4807**

### PathFinder 350D Decapper/Sorter

Designed specifically for small to medium labs, Aim Lab's new PathFinder 350D is a compact pre-analytical workstation to decap and sort incoming specimen tubes into various analyzer racks ready for testing. Throughput is 350 tubes/hr. The flexibility in design can expand throughput to 600 tubes/hr, double the deck space and align tube barcodes.

**Aim Lab Automation Technologies Pty Ltd.**
**Booth 5457**

### Alere™ i Influenza A & B, Strep A, RSV

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**Alere, Inc.**
**Booth 2931**

### Alere Afinion™ AS100 Analyzer

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# Product Showcase

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**BD**
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The BioPlex 2200 Syphilis Total & RPR (Rapid Plasma Reagin) Assay offers laboratories the first fully automated Treponemal/Non-Treponemal dual assay, which simultaneously detects antibodies to T. pallidum and reagin antibodies as well as RPR titer determination.

**Bio-Rad Laboratories**
**Booth 3339**

### NEW BioPlex 2200 ToRC IgM Assay

The BioPlex 2200 ToRC IgM Assay is a fully automated, multiplex flow immunoassay for the simultaneous identification and differentiation of IgM antibodies to T. gondii, Rubella and CMV, which are antibodies commonly tested in individuals suspected of having one of the respective disease states including women of child bearing age.

**Bio-Rad Laboratories**
**Booth 3339**


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**CompuGroup Medical**
**Booth 5931**

### Simplexa® C. difficile Direct Assay

DiaSorin recently launched the Simplexa® C. difficile Direct assay for detection of Clostridium difficile tcdB gene present in liquid or unformed stool samples without the need for nucleic acid extraction. The assay redefines workflow and performance with simple direct detection, less processing steps, excellent performance and low invalid rate.

**Diasorin Inc.**
**Booth 4407**


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**Eurotrol, Inc.**
**Booth 1947**

## Clinical Lab Expo Hours

Tuesday
9:30 am – 5:00 pm

Wednesday
9:30 am – 5:00 pm

Thursday
9:30 am – 1:00 pm

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# Special Event Tomorrow

**Winning Organization-wide Support for Laboratory Proposed Acquisitions**

*Marriott Marquis San Diego Marina*
*Marina Ballroom, Salon D*
*Wednesday, August 2*

While you're at the 69th AACC Annual Scientific Meeting & Clinical Lab Expo, be sure to attend this free educational event to learn how to win the support of your organization's stakeholders to purchase new laboratory equipment and technology that will improve operations and patient care. Registration is free, although space is limited. Attendees may register online at www.aacc.org/conferences, or onsite before the event.

## Event Program

5:30 pm to 5:45 pm
Check in and Reception

5:45 pm to 6:05 pm
Welcome and Brief Overview
Omai Garner, PhD; Assistant Professor, Pathology & Laboratory Medicine, Associate Director, Clinical Microbiology, and Director; Point of Care Testing University of California Health System, Los Angeles, California.

6:05 pm to 6:30 pm
How our Lab Purchased a Cutting-Edge Robotic Specimen Processor
Karissa Culbreath, PhD, Assistant Professor, Pathology, University of New Mexico Health and Science Center Scientific Director, Infectious Diseases, Research and Development, TriCore Reference Laboratories Albuquerque, New Mexico.

6:30 to 6:50 pm
Panel Discussion and Q&A

6:50 to 7:30 pm
Reception and Networking

AACC designates this activity for a maximum of 1.0 ACCENT® credit hours towards the AACC Clinical Chemist's Recognition Award.

This educational activity has been made possible by an educational grant from Roche Diagnostics.

Roche

# Today's Exhibit Hall Theater Industry Workshops

**10:15 am – 11:15 am**

**Improving Quality and Turnaround Time of Clinical Chemistry Plasma Specimens with a Mechanical Separator**
Sponsored by BD
*Exhibit Hall, Theater 1*

**11:30 am – 12:30 pm**

**Integrating Innovation: Paving the Way to TnT Gen 5 Adoption**
Sponsored by Roche Diagnostics
*Exhibit Hall, Theater 2*

**12:45 pm – 1:45 pm**

**A New, Accessible Point-of-Care Molecular System for Physician Offices**
Sponsored by Mesa Biotech
*Exhibit Hall, Theater 1*

**3:15 pm – 4:15 pm**

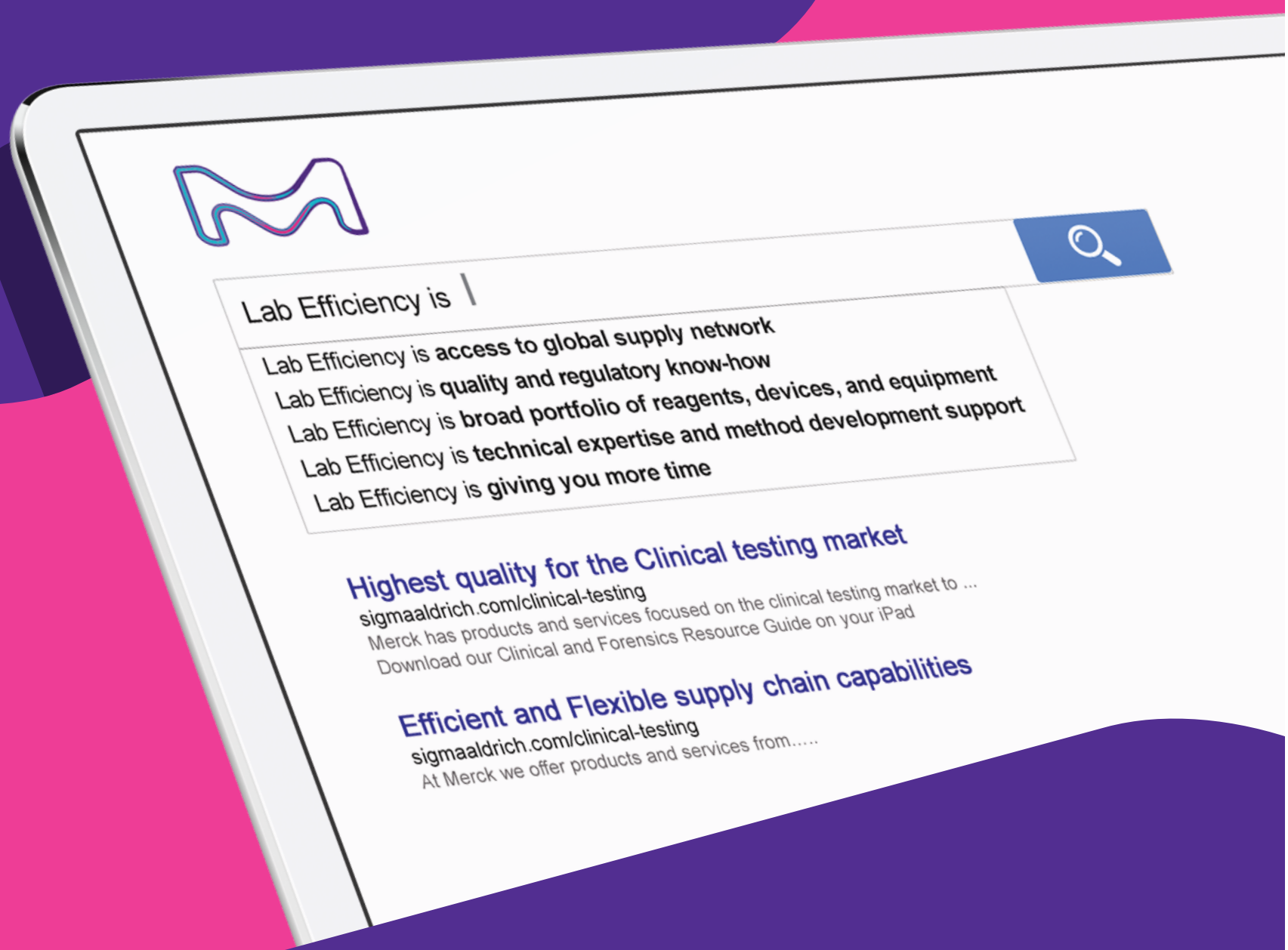
**Heparin-Induced Thrombocytopenia (HIT) from Clinical Suspicion to Rapid Diagnosis, Lab Testing and Implementation of a HIT Testing Protocol**
Sponsored by Instrumentation Laboratory (IL)
*Exhibit Hall, Theater 1*

**2:00 pm – 3:00 pm**

**Controversies in CTD Testing**
Sponsored by Inova Diagnostics
*Exhibit Hall, Theater 2*

Visit AACC booth #3539

# anticipating your needs for better lab efficiency




EMD Millipore and Sigma-Aldrich come together to solve the toughest problems in life science.

**SigmaAldrich.com/clinical-testing**

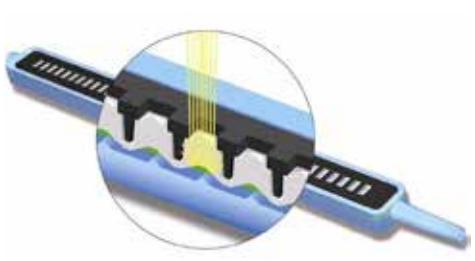
**The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.**

# Product Showcase


### HemaPRO Automated Slide Stainer by QuickSlide

The HemaPRO™ Automated Slide Stainer represents a significant advancement in automated blood smear staining. It is a valuable addition to any laboratory, whether it is the primary stainer used by small hospitals, physicians labs, stat labs, or used as a stat/backup instrument in larger labs.

**Hardy Diagnostics**
**Booth 1518**



### OPTIGEN® Allergen-Specific IgE Assay

Hitachi Chemical Diagnostics OPTIGEN® technology is a next generation in vitro test that provides clinicians with a front-line solution leading to early diagnosis of allergy conditions. OPTIGEN® results are accurate, reliable and reproducible, and correlate well with skin testing and single allergen systems.

**Hitachi Chemical Diagnostics**
**Booth 6139**


### Product name: GEM® Premier™ 5000 with iQM®2

New GEM Premier 5000 Critical Care testing system with Intelligent Quality Management 2 (iQM2) assures quality before, during and after sample analysis by providing automated real-time error detection, correction and documentation. The all-in-one GEM PAK requires no maintenance and offers advanced simplicity at the point-of-care.

**Instrumentation Laboratory (IL)**
**Booth 2223**


### GEMweb® Plus 500 Custom Connectivity

New GEMweb Plus 500 Custom Connectivity provides customizable connectivity and automated functionality for complete control of GEM® Premier™ Critical Care testing systems and their operators at the point-of-care. Now, non-IL devices can be connected too and data accessed from tablet devices for true flexibility.

**Instrumentation Laboratory (IL)**
**Booth 2223**


### HemoCell™ Specialized Lab Automation

New HemoCell Specialized Lab Automation solution is the world's first lab automation solution specifically for Hemostasis Testing.

Combining the analytical capabilities of ACL TOP® Family 50 series systems, HemosIL® assay accuracy, HemoHub™ centralized control on a Thermo Fisher™ track, HemoCell optimizes workflow, throughput and turnaround times.

**Instrumentation Laboratory (IL)**
**Booth 2223**


### HemosIL® HIT-Ab(PF4-H) Assay

The first, fully automated, on-demand assay for Heparin-Induced Thrombocytopenia (HIT) on a Hemostasis testing system, new HemosIL HIT-Ab(PF4-H) detects antibodies associated with HIT. This liquid, ready-to-use assay delivers results in minutes, allowing timely, well informed therapeutic decisions.

**Instrumentation Laboratory (IL)**
**Booth 2223**

IntrinsicDx™
The BioIron Laboratory™

### Intrinsic Hepcidin IDx™ Test

Intrinsic LifeSciences proudly announces the Intrinsic Hepcidin IDx™ Test for serum and plasma hepcidin in clinical samples. Hepcidin, a key hormone regulating iron is useful to aid in diagnosis of iron deficiency. The Intrinsic Hepcidin IDx Test is offered by IntrinsicDx, The BioIron Laboratory™, a CLIA certified and CAP accredited clinical lab.

**Intrinsic LifeSciences**
**Booth 2662**

### ADVANTAGE CHIKUNGUNYA IgM CARD

Advantage Chikungunya IgM Card is a visual, rapid, sensitive, qualitative immunoassay for the detection of Chikungunya specific IgM antibodies in human serum or plasma.

**J. Mitra & Co. Pvt. Ltd.**
**Booth 2463**

## Get to Know the AACC Universal Sample Bank

AACC's Universal Sample Bank contains screened and characterized samples from more than 700 healthy individuals. The sample sets can be used in a variety of clinical studies, including assay development, standardization, and reference range development. Key features include:

- Ethnically and geographically diverse adult population (18+)
- IRB-approved collection protocol
- Comprehensive donor data with health screening information
- Results of HbA1c, Creatinine, and NT-proBNP screens
- Available in serum, EDTA plasma, or lithium heparin plasma

To learn more, *visit www.aacc.org/samplebank*

### ADVANTAGE MALARIA PAN+PF CARD

ADVANTAGE MALARIA PAN +Pf CARD is a rapid, visual and sensitive immunoassay for the qualitative diagnosis of infection with P.falciparum and other Plasmodium species (P.falciparum /P.vivax/P.malariae/P.ovale) in human whole blood only.

**J. Mitra & Co. Pvt. Ltd.**
**Booth 2463**

### DENGUE DAY 1 TEST

Dengue Day 1 Test is a rapid solid phase immuno-chromatographic test for the qualitative detection of Dengue NS1 Antigen and differential detection of IgM and IgG antibodies to Dengue virus in Human serum/plasma.

**J. Mitra & Co. Pvt. Ltd.**
**Booth 2463**


### 21-Hydroxylase Antibody (21-OHAb)

The KRONUS® 21-Hydroxylase Autoantibody (21-OHAb) ELISA Assay Kit is for the detection of 21-OH autoantibodies in human serum. †For Research Use Only. Not for Use in Diagnostic Procedures.

**KRONUS, Inc.**
**Booth 5222**

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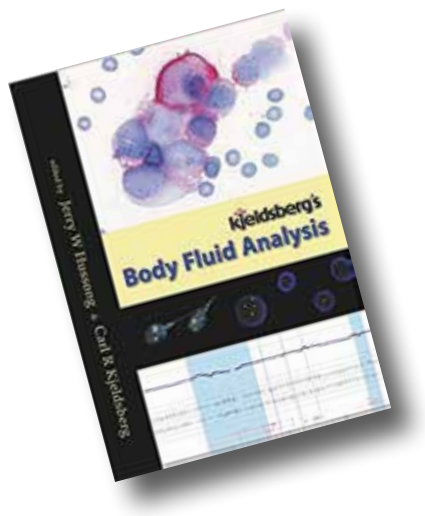
A laboratory test is more than a number; it is a person, an answer, a diagnosis.®

# PATIENTS ANSWERS RESULTS®

## Visit ARUP, booth #2445

Join our featured speakers at the ARUP Mini-Lecture Series.
**Attend a lecture and enter to win an autographed copy of *Kjeldsberg's Body Fluid Analysis*—1st Edition!***
We are giving away four text books—one at every lecture.

*One entry per attendee per lecture; must be present to win.




**Wednesday, Aug. 2, 10 a.m.**

### Earning Customer Loyalty through Tough Love

"Labs and clinical providers share a common goal: high quality patient care. So why are we afraid to hold providers accountable in order to improve the testing process?"

**Brian Jackson, MD, MS**

**Wednesday, Aug. 2, 2 p.m.**

"Appropriate test utilization for diagnosing and monitoring treatment response for various viral hepatitis etiologies is critical for both cost savings and improved patient care."

### Advances in Viral Hepatitis Testing

**Patricia Slev, PhD**

# Product Showcase


### 3-Screen Islet Cell (GAD/IA-2/ ZnT8) Autoantibody Screen

The KRONUS® 3-Screen Islet Cell Autoantibody ELISA Assay Kit is for the simultaneous and non-differential detection of GAD and/or IA-2 and/or ZnT8 autoantibodies in human serum.

†For Research Use Only. Not for Use in Diagnostic Procedures.

**KRONUS, Inc.**
**Booth 5222**


### ARIES® C. difficile Assay

The ARIES® C. difficile Assay is a rapid method for the detection of toxigenic C. difficile from a stool sample, using the sample to answer ARIES® Systems. The assay detects toxins A and B, with built-in controls to ensure accurate results. For research use only. Not for use in diagnostic procedures.

**Luminex Corporation**
**Booth 1838**


### VERIGENE® Respiratory Pathogens Flex Test

The VERIGENE® Respiratory Pathogens Flex Test (RP Flex) detects 16 viral and bacterial respiratory targets in a cost-effective manner—one platform, one comprehensive panel, and the flexibility to use and pay for only what you need. For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions.

**Luminex Corporation**
**Booth 1838**

MediaLab INCORPORATED

### MediaLab's Document Control

Manages policies and procedures in an easy-to-use online system to help meet CAP, CLIA, Joint Commission, ISO 15189, and 21 CFR Part 11 standards. A robust resource for viewing documents and provides a tracking system to maintain versions and revisions, lab director and other approvals, employee signoffs, controlled copies, and reports.

**MediaLab, Inc.**
**Booth 1717**

# Rapid. Engineered. Solutions. It's about time.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Turbocharge your timelines! Get the industry's fastest turnaround of customized fluidic solutions for analytical and medical devices. Our new Rapid Engineered Solutions program collaborates with OEM designers, offering superior miniature valves and assemblies — tailored with specified features, and delivered at unprecedented speeds.

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# Product Showcase

### Milli-Q® IQ 7000 water purification system

The Milli-Q® IQ 7000 water purification system is intelligent, intuitive and designed to make your work as pleasant and comfortable as possible, maximizing lab productivity. The IQ 7000 will change the way you work in the lab with its breakthrough ergonomic design, mercury free UV technology and precision drop by drop dispensing.

**MilliporeSigma**
**Booth 2039**


### Quantimetrix Introduces Dipper POCT® Liquid UA QC

Dipper POCT® Urinalysis Dipstick Control is a 2-level single-use control in a unique slim plastic pouch with a 1.5mL fill of liquid control. The kit contains 62 pouches (31 of each level). Extended RT stability of 3 months & 3 years refrigerated from date of manufacture, exceeding all other urinalysis controls formulated with native ketones.

**Quantimetrix Corporation**
**Booth 4326**




### My Inspection Software

My Inspection Software helps make meeting CLIA and COLA requirements for your lab easier and more efficient. Now you can create, store and retrieve information with the click of a mouse and be inspection ready. If you need a Compliance Manual or need to ask a technical question, ask My Expert.

**My Inspection**
**Booth 4257**


### Acusera 24.7 Live Online

Following extensive development based on customer feedback, Acusera 24.7 Live Online is faster, with a simplified user interface & enhanced user experience. In addition to our existing unrivaled range of features, we have developed new, innovative tools to speed up the review process & provide at-a-glance performance assessment for your lab.

**Randox Laboratories Ltd**
**Booth 3839**


### Tina-quant® Hemoglobin A1cDX Generation 3 Assay

The Tina-quant® Hemoglobin A1cDX Gen 3 is intended for use as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes. It is an in vitro diagnostics reagent intended for the quantitative determination of % hemoglobin A1c (DCCT/NGSP) in hemolysate or whole blood.

**Roche Diagnostics**
**Booth 4606**


### Onestep Laboratories QuickBlu® TMB Substrate

Onestep Laboratories Inc.'s QuickBlu®one component TMB substrates have been proven to be highly sensitive and consistent, and remarkably stable for up to 4 years at 2 - 8°C. The solution can be concentrated up to 10 times for easy transportation and has been patented in the United States.

**ONESTEP LABORATORIES**
**Booth 2057**

### cobas® e 801 module

Roche is pleased to introduce the cobas® e 801 immunoassay module, the newest innovation in the cobas® 8000 modular analyzer series.

**Roche Diagnostics**
**Booth 4606**


### Elecsys® AMH Assay

The automated Elecsys® AMH assay is intended for the assessment of ovarian reserve in woman presenting to fertility clinics in conjunction with other clinical and laboratory for fertility evaluation. Designed to offer excellent performance, the assay enables clinicians to provide patients with accurate results in only 18 minutes.

**Roche Diagnostics**
**Booth 4606**


### Quantimetrix Introduces CHROMASCOPICS Liquid UA QC

CHROMASCOPICS™ UA Control is a combined urinalysis and sediment control specifically designed for the Siemens Clinitek Novus, other Siemens UA test strips, confirmatory tablet tests, and βhCG methods. CHROMASCOPICS may also be used to validate the microscopic analysis of urine sediment.

**Quantimetrix Corporation**
**Booth 4326**


### cobas® c 513 analyzer

This dedicated, high-volume HbA1c testing solution features high-quality components and offers functionalities designed to fulfill the needs of high-volume laboratories, while also meeting the new requirements for HbA1c testing.

**Roche Diagnostics**
**Booth 4606**


### Elecsys® Troponin T Gen 5 STAT

The automated Elecsys® TnT Gen 5 assay is intended to aid in the diagnosis of myocardial infarction (MI). As the only high-sensitive Troponin assay in the U.S. and designed to offer excellent precision, the assay delivers accurate results in only 9 minutes, enabling clinicians to accurately diagnose patients with a suspected heart attack.

**Roche Diagnostics**
**Booth 4606**



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# The science of uninterrupted productivity.

LUMIPULSE® *G*1200

With a MTBF>300 days, the LUMIPULSE *G*1200 is a reliable, market-proven choice for automated immunoassay systems in clinical laboratories.

The LUMIPULSE *G*1200 from Fujirebio is now FDA cleared and for sale in the United States.

GET TO KNOW US

While visiting AACC, drop by for a friendly cup of freshly-brewed java.

**Booth #2917**

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# 69th AACC Annual Scientific Meeting & Clinical Lab Expo

SAN DIEGO CONVENTION CENTER • SAN DIEGO, CA • EXHIBIT HALLS A – H


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9:30 am – 5:00 pm

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9:30 am – 5:00 pm

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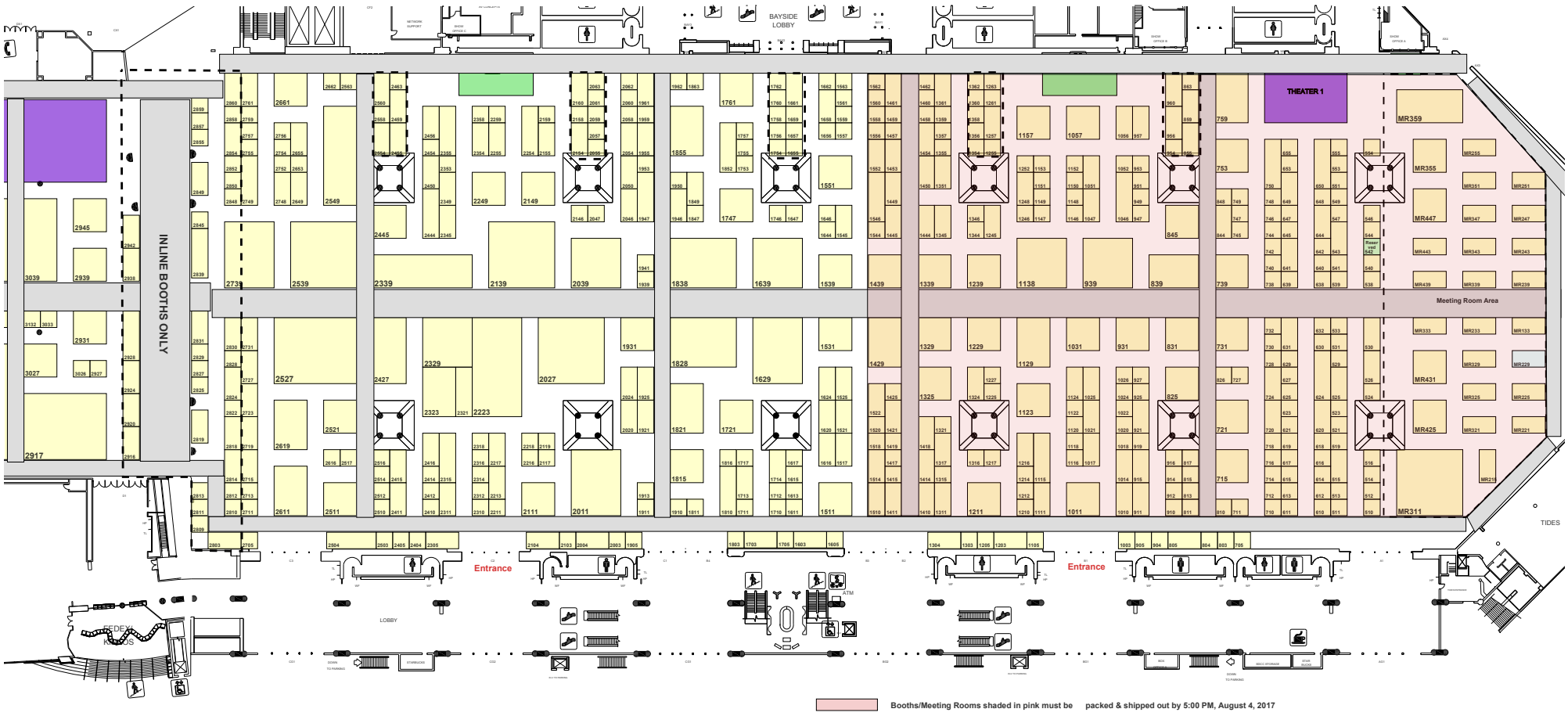
9:30 am – 1:00 pm

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*– As of June 30, 2017*

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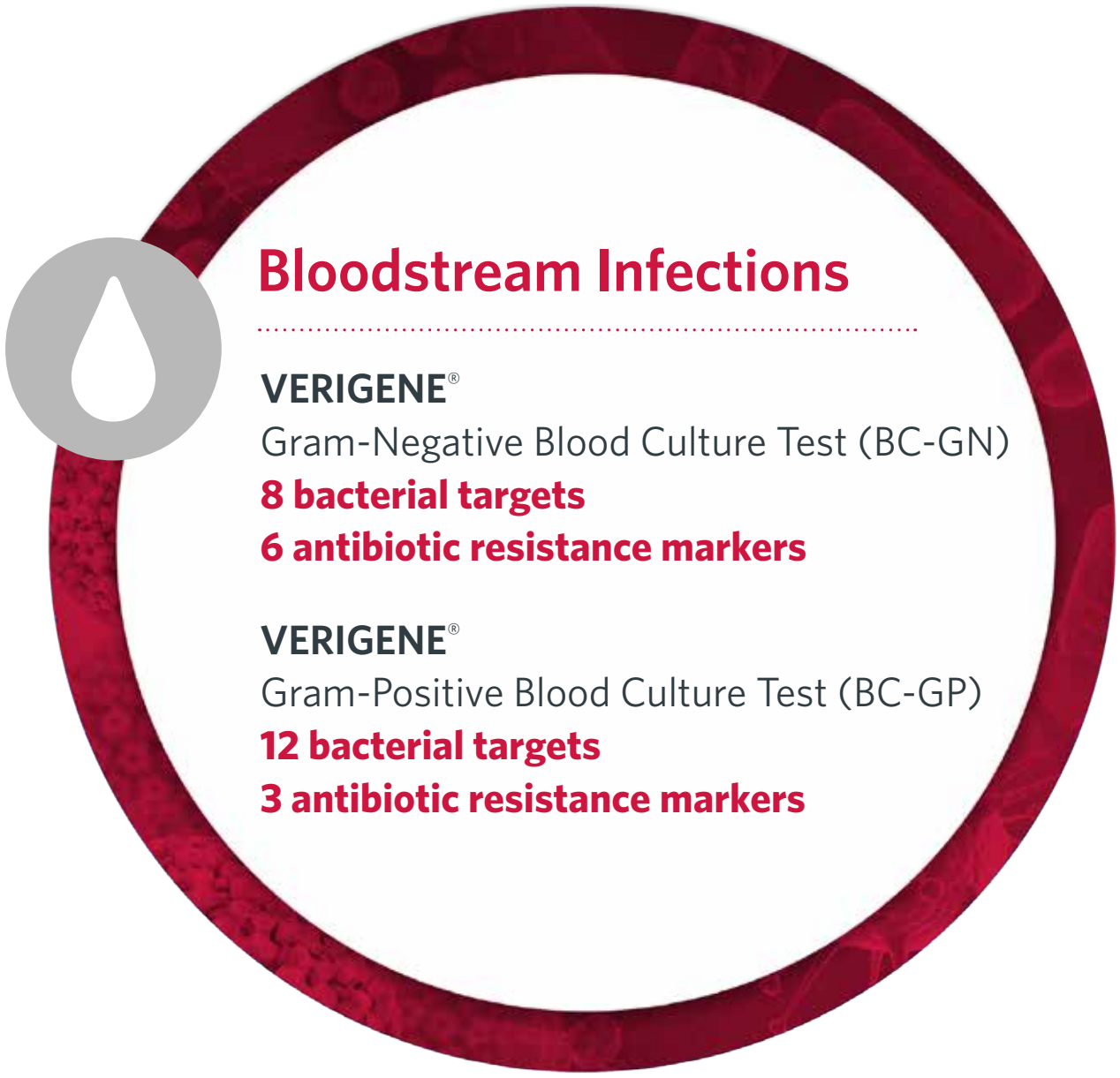
Our VERIGENE® bloodstream infection solutions provide cost-effective bacterial identification and antibiotic resistance determination directly from positive blood culture bottles up to 48 hours faster than conventional methods,[1] producing improved patient clinical and economic outcomes, and better antimicrobial stewardship.[2]




## Visit Luminex at booth 1838 to learn more about our rapid and accurate bloodstream infection tests.

[1]Buchan BW, Ginocchio CC, Manii R, Cavagnolo R, Pancholi P, et al. (2013) Multiplex Identification of Gram-Positive Bacteria and Resistance Determinants Directly from Positive Blood Culture Broths: Evaluation of an Automated Microarray-Based Nucleic Acid Test. PLoS Med 10(7): e1001478. doi:10.1371/journal.pmed.1001478.

[2]Walker T, Dumadag S, Lee CJ, et. al. Clinical impact of laboratory implementation of VERIGENE BC-GN microarray-based assay for detection of gram-negative bacteria in positive blood cultures. J Clin Microbiol 10.1128/JCM.00376-16.

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# Today's OEM Lecture Series Theater Presentations



**10:00 am – 10:20 am**

**Next Generation for Enzymes of Gene Amplification & Sequencing**
Sponsored Pharmozyme Inc.
*Exhibit Hall, Theater 3*

**10:30 am – 10:50 am**

**Novel Antibody Generation Platforms**
Sponsored by Abcam Inc.
*Exhibit Hall, Theater 3*

**11:00 am – 11:20 am**

**Speeding Immunoassay Development - Key Parameters for Optimizing LodeStars Magnetic Beads. Properties and Performance in CLIA Automated Platforms that Improve Performance**
Sponsored by Agilent
*Exhibit Hall, Theater 3*

**11:30 am – 11:50 am**

**Biological Drug Monitoring in IBD and RA: Grifols Experience**
Sponsored by Grifols
*Exhibit Hall, Theater 3*

**12:00 pm – 12:20 pm**

**INTELLIGENT LYOPHILIZATION: Providing Years of Room Temperature Stability for Your Reagents and Simplifying User Experience for Your Customers**
Sponsored by BIOLYPH
*Exhibit Hall, Theater 3*

**12:30 pm – 12:50 pm**

**Providing Comprehensive Solutions to Help You Prevail in Diagnostic Development and Commercialization**
Sponsored by Thermo Fisher Scientific
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**1:00 pm – 1:20 pm**

**Supporting Your Molecular Diagnostics Assay Development with OEM Commercial Supply Partnerships**
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**2:00 pm – 3:00 pm**

**Supply Chain Savings: Opportunities for Labs**
Sponsored by Health Industry Distributors Association (HIDA)
*Exhibit Hall, Theater 3*

# Today's Hotel Industry Workshops

*All at Marriott Marquis San Diego Marina*

**7:00 am – 8:30 am**

**Mobilizing data to build insights and unlock your laboratory's health potential through Business Intelligence.**
Sponsored by Abbott Laboratories
*Grand Ballroom 3, 4, 6*

**Procalcitonin Guided Therapy and How Rapid Diagnostics Support Antimicrobial Stewardship**
Sponsored by bioMerieux, Inc.
*Grand Ballroom Section 11*

**Connecting the Dots: Improving QC Strategy & Return On Investment**
Sponsored by Bio-Rad Laboratories
*Grand Ballroom Section 8*
(Please note: this industry workshop starts at 6:30 AM with the program starting promptly at 7:00 AM)

**Fast Forward Your Lab Productivity and Drive Precision Medicine**
Sponsored by Thermo Fisher Scientific
*Grand Ballroom Section 5*

**6:00 pm**

**Building Heathier Hospitals through world class quality and six sigma optimization with innovative instrumentation and informatics solutions.**
Sponsored by Abbott Laboratories
*Grand Ballroom 3, 4, 6*

**IFA Automation and Improvements in Autoimmune Testing**
Sponsored by Grifols
*Grand Ballroom Section 5*

**LDL Particle Measurement by Electrophoresis**
Sponsored by Helena Laboratories
*Cardiff/Carlsbad*

Evaluation of the FDA cleared Vitamin D Assay using the SCIEX Topaz™ LC-MS/MS System
Sponsored by Sciex
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# Product Showcase


### Elecsys® BRAHMS PCT Assay

Procalcitonin (PCT) is a sensitive and specific biomarker that provides insights into the severity of a bacterial infection both on presentation and during the course of treatment of sepsis patients. The Elecsys® BRAHMS PCT provides industry-leading precision and turnaround time as the only fully automated and integrated PCT solution in the U.S.

**Roche Diagnostics**
**Booth 4606**

### Roche Inventory Solution

This new inventory management application from Roche is designed to address the specific needs of laboratories, optimizing supply chain processes and providing real-time management insights.

**Roche Diagnostics**
**Booth 4606**


### Elecsys® Syphilis Assay

The Elecsys® Syphilis assay is intended for use as an aid in the diagnosis of syphilis infection in conjunction with clinical signs and symptoms.

**Roche Diagnostics**
**Booth 4606**

Elecsys® HIV combi PT

### Elecsys® HIV Combi PT Assay

The Elecsys® HIV Combi PT assay is intended for use as an aid in the diagnosis of HIV-1 and/or HIV-2 infection, including acute and primary HIV-1 infection.

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**Booth 4606**


### CoaguChek® XS Plus System

The CoaguChek® XS Plus system delivers CLIA-waived testing with enhanced connectivity for professional use.

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### ROMA Calculation Tool

The ROMA (risk of ovarian malignancy) calculation tool combines the results of the Elecsys® CA125 II, the Elecsys® HE4 assay and menopausal status into a numerical score used to determine the likelihood of finding cancer upon surgery in women presenting with an adnexal ovarian mass.

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### cobas® 6800/8800 System

The cobas® 6800/8800 systems are fully automated solutions designed for both clinical and donor screening molecular testing. These moderate complexity systems provide unprecedented automation, high throughput, and onboard refrigerated reagent storage to drive transformative efficiency gains in a wide variety of laboratory environments.

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### Accu-Chek® Inform II

The Accu-Chek® Inform II system is a total solution designed to help healthcare professionals provide the best care possible, delivering accurate results in 5 seconds. The system includes a wireless meter, patented test strip technology and easy-to-use lancing devices, which provide users with fast, reliable results, greater efficiency and support.

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Elecsys® Vitamin D total II

### Elecsys® Vitamin D total II Assay

The Elecsys® Vitamin D total II assay is intended for use as an aid in the assessment of vitamin D sufficiency in adults.

**Roche Diagnostics**
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### cobas® Liat® PCR System

The cobas® Liat® PCR system is the only real-time PCR testing platform that's CLIA-waived for Influenza A/B, Influenza A/B & RSV and Strep A, delivering results in 20 minutes or less. The system offers a simple workflow and definitive results that do not require interpretation. Confirmation of negative test results is not required at visit.

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### Accu-Chek® Safe-T-Pro Plus lancet

With the Accu-Chek® Safe-T-Pro Plus lancet, you're able to provide patients comfort and your staff improved workflow efficiencies. This lancet is designed to reduce the spread of infection and meets the latest safety requirements, while minimizing pain for patients.

**Roche Diagnostics**
**Booth 4606**

### BL 1200 ID

The BL 1200 ID accessions and sorts up to 1,200 sample tubes per hour without pre-racking for walk-away pre-analytical processing. Capped tubes are poured into the Bulk Loader, singularized for identification, and sorted into racks, centrifuge adapters, or bulk bins based on customizable rules. Multiple tube sizes are accepted.

**SARSTEDT**
**Booth 2139**

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As of date of June 2, 2017. For more information on partnering with AACC, please visit www.aacc.org/partnerships

# Product Showcase

### S-Monovette® POC Collect Kit

The S-Monovette® POC Collect Kit is an innovative, easy-to-use Point-of-Care solution for venous sampling. It provides healthcare professionals a controlled and precise collection and dosing system that helps reduce test cartridge rejection while minimizing the risk of blood aerosols and exposure.

**SARSTEDT**
**Booth 2139**

### ADVIA Centaur® High-Sensitivity Troponin I Assay*

Provide fast, accurate, and actionable test results with a new high-sensitivity cardiac troponin I assay (hs-cTnI) on ADVIA Centaur® Immunoassay System(s). Meet new clinical practice guidelines with greater sensitivity and precision at the low end, providing the ability to measure slight, yet critical, changes in serial troponin I values. *Not available for sale in the U.S.

**Siemens Healthineers**
**Booth 4439**

### Atellica™ Solution*

Atellica™ Solution*—flexible, scalable, automation-ready immunoassay and chemistry analyzers with integrated sample management—features bi-directional magnetic sample-transport technology, the flexibility to create over 300 customizable configurations, and a broad assay menu** with proven detection technologies. * Not CE marked. Not available for sale. Future availability cannot be guaranteed. **All assays are under development. Not available for sale. Future availability cannot be guaranteed.

**Siemens Healthineers**
**Booth 4439**

### CAPILLARYS 3 MC2

CAPILLARYS 3 MC2, the first automated capillary separation system with work cell capabilities. The CAPILLARYS 3 MC2, combines two CAPILLARYS 3 instruments with a tube loader, capacity of 712 samples, for maximum walk away time. The system can a dedicated or multi-assay system with up to three CAPILLARYS 3 instruments connected to one tube loader.

**Sebia, Inc.**
**Booth 4419**

### ADVIA Centaur® Intact PTH (iPTH) Assay

Intact PTH measurements are used to assess iPTH status in many clinical conditions, including the differential diagnosis of hyperparathyroidism or hypoparathyroidism. The ADVIA Centaur® iPTH assay can also be used to assess and manage other metabolic bone disorders, including osteoporosis and renal osteodystrophy, and can be used intraoperatively.

**Siemens Healthineers**
**Booth 4439**

### ADVIA Centaur® Testosterone II Assay*

The ADVIA Centaur® Testosterone II assay is for in vitro diagnostic use in the quantitative determination of total testosterone (bound and unbound) in human serum and plasma. The assay includes newly established pediatric reference ranges by age group and Tanner stage for more accurate interpretation of pediatric results. *Product availability varies by country.

**Siemens Healthineers**
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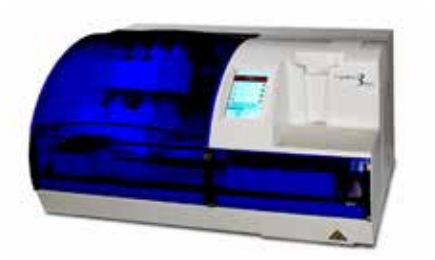

### CAPILLARYS 3 TERA

CAPILLARYS 3 TERA is an automated, high-throughput, proven technology solution for HbA1c testing and protein electrophoresis. Suitable for both core labs and special chemistry, CAPILLARYS 3 is able to provide high volume throughput using capillary technology. HbA1c testing provides accurate and precise results that can configured for auto-release.

**Sebia, Inc.**
**Booth 4419**

### ADVIA Centaur® NT-proBNP Assay*

Provide clinicians with the confidence to accurately diagnose and assess heart failure, no matter which natriuretic peptide you choose: BNP and/or NT-proBNP. Siemens Healthineers has the NP solutions you need, all on one system. *Not available for sale in the U.S.

**Siemens Healthineers**
**Booth 4439**

### ADVIA Centaur® Herpes-1 IgG and Herpes-2 IgG* Assays

The ADVIA Centaur® Herpes-1 and Herpes-2 IgG* assays qualitatively detect IgG antibodies to herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2), respectively. The laboratory can potentially reduce hands-on labor and increase productivity by running these type-specific herpes tests on automated ADVIA Centaur systems. *Not available for sale in the U.S. Product availability may vary from country to country and is subject to varying regulatory requirements.

**Siemens Healthineers**
**Booth 4439**

### ADVIA Centaur® HBsAg Quantitative Assay

The new ADVIA Centaur® HBsAg Quantitative (QHBs) assay provides your lab with accurate results and increased lab efficiency. Consolidate your infectious-disease testing onto one platform with the QHBs assay, which offers automatic dilution and the ability to detect rare a-determinant mutations. *Not available for sale in the U.S.

**Siemens Healthineers**
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# Product Showcase

### IMMULITE® 2000 XPi TSI Assay

Thyroid stimulating antibodies are the hallmark of Graves' disease (GD). Their detection in the blood, along with other clinical and laboratory findings, are important diagnostic tools for GD diagnosis. The IMMULITE TSI assay can measure thyroid stimulating antibodies with a high clinical sensitivity and specificity of 98.3% and 99.7% respectively.

**Siemens Healthineers**
**Booth 4439**

### Dimension EXL Vitamin D Total Assay

The LOCI Vitamin D Total assay for use on the Dimension® EXL™ chemistry system provides highly accurate total 25(OH) vitamin D results (~100% D2 and D3) with a fast turnaround time. Vitamin D testing can now be consolidated with routine testing on a fully automated, high-throughput integrated chemistry system.

**Siemens Healthineers**
**Booth 4439**


### LabTurbo AIO SP-qPCR Automation System

The LabTurbo All-in-One SP-qPCR System fully integrates all the functions of a PCR lab into one compact system, providing a non-stop automation from DNA/RNA extraction, PCR setup, qPCR to the final report. The AIO system is your reliable and intelligent robotic expert in molecular diagnostics with excellent sensitivity and result consistency.

**Taigen Bioscience Corporation**
**Booth 954**

### Phadia™ Lab Systems and Prime Software

Phadia Prime software optimizes operation of Phadia Laboratory Systems for ImmunoCAP™ and EliA™ assays to aid in the diagnosis of allergic and autoimmune diseases. Experience intuitive management of reagent inventory, requests, reflex testing, QC, runs and result reporting with the new Phadia 1000 system from Thermo Fisher Scientific-booth #4039.

**Thermo Fisher Scientific**
**Booth 4039**

### Thermo Scientific™ CW3 Cell Washer

Precise, automated performance – designed to provide thorough, reproducible blood cell washing, up to 24 tubes per run.

**Thermo Fisher Scientific**
**Booth 4039**

### Thermo Scientific™ Prelude LX-4 MD™ HPLC

The Thermo Scientific™ Prelude LX-4 MD™ HPLC is listed with the FDA as a Class I medical device for general clinical use. The device features four parallel channels, which can deliver up to four different separations to a single mass spectrometer with identical or different methods to enhance sample throughout. Photo Disclaimer: For in vitro diagnostics use. Not available in all countries.

**Thermo Fisher Scientific**
**Booth 4039**

### Thermo Scientific™ TSX505 undercounter refrigerator

Redundant cooling technology enables the TSX505 to protect storage while delivering less energy, less noise and more storage capacity.

**Thermo Fisher Scientific**
**Booth 4039**

### Thermo Scientific™ Samco™ Clicktainer™ vials

Samco Clicktainer vials are leakproof specimen containers used in a wide variety of applications: urine, feces, sputum, etc. to capture and contain samples for clinical, diagnostics, and research use.

**Thermo Fisher Scientific**
**Booth 4039**


### Ion Torrent™ Oncomine™ Dx Target Test

The Ion Torrent™ Oncomine™ Dx Target Test is the first targeted next-generation sequencing (NGS) in vitro diagnostic test for non-small cell lung cancer (NSCLC), simultaneously delivering multiple biomarker results for multiple targeted therapies from one sample within four days.

**Thermo Fisher Scientific**
**Booth 4039**

### Sentosa® SQ HIV Genotyping Assay

The Sentosa® SQ HIV Genotyping Assay simultaneously identifies HIV-1 genotype and drug resistance mutations (DRMs). This assay is a part of a fast, automated sample-to-answer workflow that delivers results in just days and with a high level of sensitivity (< 1,000 copies of viral load per mL).

**Vela Diagnositics USA, Inc.**
**Booth 6157**

### Vivafree Filters for Therapeutic Drug Monitoring

VIVAFREE™ centrifugal filters from Vivaproducts separate free drug and hormone samples. They are used for therapeutic drug monitoring of phenytoin, immunosuppressants and antibiotics as well as free hormones such as testosterone, insulin and cortisol. Labs report cost reductions of 35% by replacing other ultrafilters with VIVAFREE filters.

**Viva Products, Inc.**
**Booth 5406**

### ZeptoMetrix™ Respiratory Verification Panel (KZMC037)

ZeptoMetrix™ Respiratory Verification Panel (KZMC037) is a 6 member RUO panel (Influenza A, Influenza B, RSV, Adenovirus, Rotavirus & Negative) intended for use with in vitro rapid tests for the determination of viral presence or absence.

**ZeptoMetrix Corporation**
**Booth 5420**

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