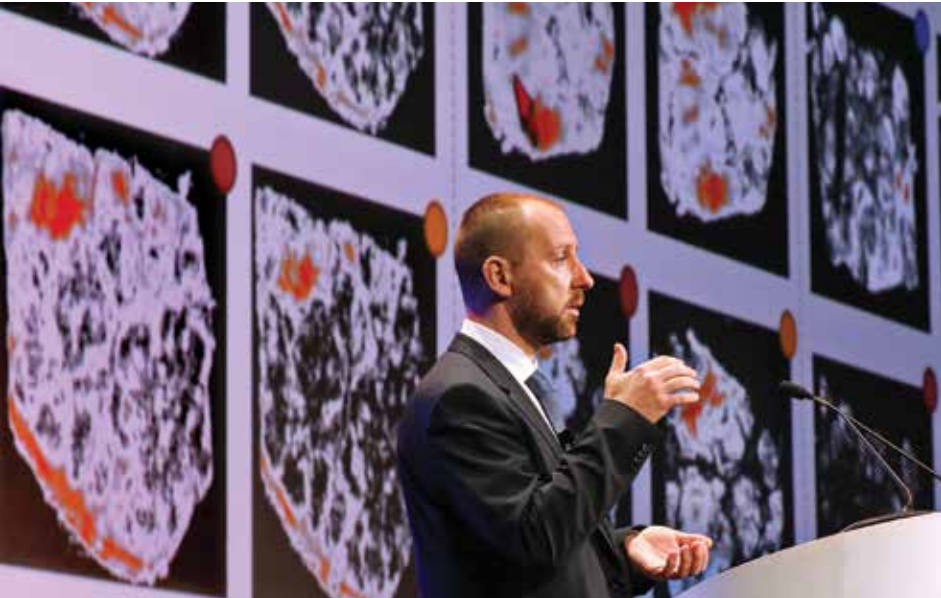


Going Under a Sharper Knife



Zoltan Takats discusses direct mass spectrometric profiling of biological tissue.

By Anna Merrill, PhD

Instantaneous and unequivocal differentiation of malignant from benign tissue during tumor resection is the Holy Grail of surgical oncologists, pathologists, and innovators of biomedical technology. In yesterday's plenary session, "Direct Mass Spectrometric Profiling of Biological Tissues – A New Paradigm in Histology," Zoltan Takats, PhD, presented how cutting-edge advances in applied mass spectrometry are making rapid, intraoperative tissue profiling a reality.

Takats directs pioneering work in the field of ambient ionization, which enables mass spectrometry to seek new applications outside the traditional laboratory, such as the surgical suite. Surgical excision remains the standard

of care for most solid tumors, but the frozen section tissue histology used for intraoperative assessment of tumor margins requires at least 15 minutes for results, thus limiting the number of sampling points and overall precision of the resection.

Certain biomolecules, such as phospholipids, are highly tissue-specific and produce "spectacular differences" in molecular fingerprints, according to Takats, making them excellent candidates for tissue diagnostics. Takats recounted how he set out to develop a technology for in situ chemical characterization of tissues as a valid alternative to frozen sections that would enable real-time intraoperative decision-making. His most significant discovery

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The Great Cannabis Experiment

By Jaime Noguez, PhD

Cannabis sativa, or marijuana, long one of the most popular illicit drugs in the world, has recently been legalized in the U.S. for medical use in 23 states and the District of Columbia. Additionally, four states have legalized its use recreationally. Legalization of cannabis has quickly become a subject of contentious debate. Supporters of cannabis law reform cite its perceived health benefits and that it is no more dangerous than alcohol and tobacco. Opponents argue that legalization will increase its use and people will become desensitized to its dangers—that they will infer that because it is legal it must also be safe. The truth is that the short- and long-term effects of the drug remain poorly understood, and the increased accessibility of cannabis may cause serious health and public safety problems that policymakers have

not predicted.

In today's plenary session, "The Great Cannabis Experiment: Medical Miracle? Harmless High? Civil Consequences?" renowned toxicologist Marilyn Huestis, PhD, will discuss recent developments in the science and use of cannabis. Huestis's groundbreaking research has used controlled human drug administration studies to investigate the disposition of drugs and their metabolites. She also has created new tools for interpreting drug concentrations in many matrices, generated scientific data for evidence-based drug policy and legislation, and provided valuable insights into our understanding of drug abuse and its dangers. As an author of more than 400 publications, she continues to advance the field of toxicology through her research, consultation, and inspiring lectures.

Huestis will open the session with a review of recent cannabis legalization

efforts as well as the epidemiology of its use and abuse in the United States. She will follow with a discussion of the cannabinoid receptors and how smoking cannabis affects the brain, referencing her research that has elucidated cannabinoids' mechanisms of action. She will also discuss her work documenting the effects of acute and long-term cannabis exposure on the nervous system and in utero, including recently published data demonstrating decreased CB1-cannabinoid receptors in the brain of chronic cannabis smokers using imaging studies.

The session will continue with a discussion of the social consequences of cannabis legalization, focusing on the impact on driving and how impairment can be detected. Research has shown that cannabis use can cause a number of mild cognitive deficits that pose potential safety risks, such as increased weaving between lanes and slowed re-

action time, which are not accounted for in most new regulations. Investigators are still deliberating on the blood cannabinoid concentration necessary to cause these cognitive impairments and at what point they translate to more traffic accidents.

Huestis also will share epidemiologic evidence for driving impairment

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The (Hu)man Element Live

By Joesph R. Wiencek, PhD

Like it or not, for many of us science and chemistry are a way of being. From atomic weights and chemical symbols to biological reactions, we spend a considerable portion of our lives learning the intricacies of science. All around us, scientific discoveries continue to happen every day, but do we ever truly stop to consider the driver of scientific and creative discovery?

In Monday afternoon's Meet the Expert session, "Clinical Chemistry's Inspiring Minds... Live!" the audience got a full overview of the single most important part of innovation—the human element. This unprecedented session, developed in conjunction with *Clinical Chemistry* and the Society for Young Clinical Laboratorians (SYCL), featured a panel of renowned clinical laboratory professionals including Steven Soldin, PhD, Fred Apple, PhD, and Carl Wittwer, MD, PhD.

Misia Landau, a senior science writer at Harvard Medical School, asked each panelist about the personal stories and internal motivations that helped define their scientific careers. During this exciting and nontraditional session, panelists answered questions in a round robin format. "This session, was intended to put a human face on science—to explore firsthand the life stories of some of the most renowned clinical laboratorians working today," Landau said. "We hope that in hearing these stories, students and established scientists were educated, entertained, and most of all, inspired."

Soldin, a senior scientist at the National Institutes of Health, explained that his career developed by "optimizing creativity" and "seeing things others tend to miss." He also observed that "we all have job choices in life and seem to thrive on challenges. However, being aware that creativity can be fostered through what British philosopher Alan Watts termed 'the wisdom of insecurity'

... can often bring out the best in us." Soldin added that his success also has been bolstered by avoiding what was comfortable and focusing on diseases that are not managed well.

A highlight of the session came when the panel was asked if they could discuss a specific moment that impacted their life. Apple, medical director of clinical laboratories, clinical chemistry, toxicology, and point-of-care testing at Hennepin County Medical Center, related a moment back in 1979 when he was in Miami, Florida at his uncle's pool. That day he received a call from Jack Ladenson from Washington University

asking if he would be interested in taking a look at the clinical chemistry program. "I told him that I was pretty busy at the moment, but I would get back to him in a week," Apple said. "I will never forget Jack's response, he said 'I think you're sitting around a pool drinking a beer,' which I was. I started looking around and I thought to myself was he in the bushes?" Apple explained. "The rest was history."

Wittwer, who is a professor of pathology at the University of Utah School of Medicine, offered personal advice about overcoming obstacles. "We should be careful on what we trust to be true," he

said. He added that in our daily life "we must not let authority get in the way of our rationality" and that we need to have a hobby to maximize creativity. Fortunately for those in attendance, Wittwer gave a special performance of the juggling ability he developed as an outlet in medical school.

For many of us, the human element defines our love for science, and indeed, we wonder if there would be any science at all without passion and self-sacrifice. Hearing Monday's Inspiring Minds talk reminds us that those who pursue the scientific art will always have a story to tell.

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Cannabis

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after smoking marijuana and point out inconsistencies in research due to differences in study designs. She will present her most recent research on developing tests and legislation to assess cannabis-impaired driving. For example, Huestis and colleagues conducted a controlled drug administration study using an advanced driving simulator. Using this clever tool, Huestis worked to define the blood cannabinoid concentration necessary to create the same impairment of driving skills as seen with the legal blood alcohol concentration limit for driving under the influence (0.8%).

Be sure to come to today's plenary for a timely discussion of how scientific research and policy intersect in "The Great Cannabis Experiment." This is sure to be an exciting session that you won't want to miss.



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Speakers Steven Soldin, left, Fred Apple, and Carl Wittwer, share a laugh during “Clinical Chemistry’s Inspiring Minds....Live!”



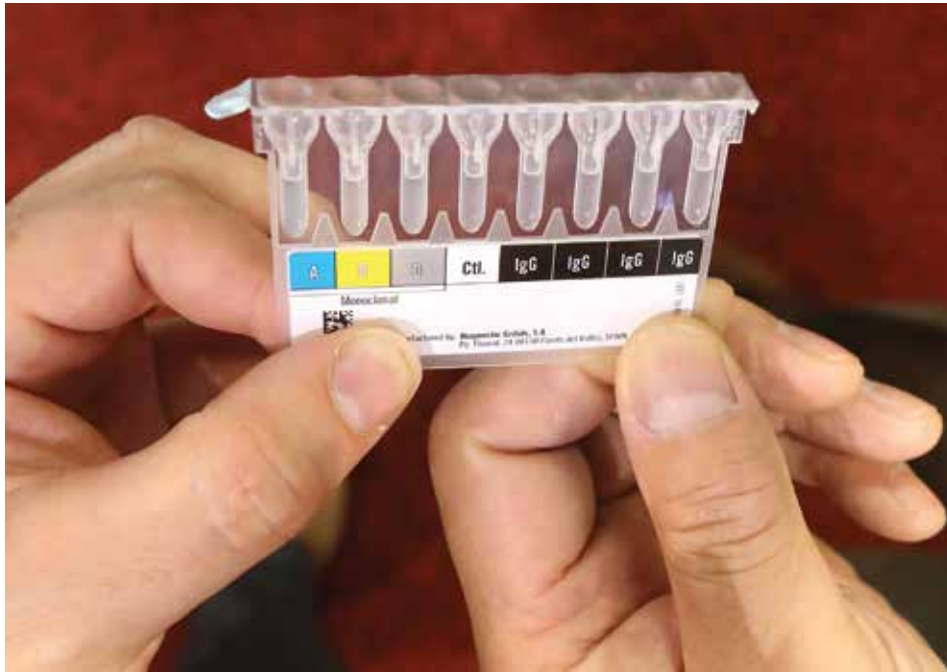
Bing Shi stops by the New Product Showcase display before entering the Clinical Lab Expo.



An attendee passes by Judy Pfaff’s celebratory sculpture CIRQUE made of steel, aluminum, glass, cable, urethane, and lacquer paints suspended across the Grand Hall.



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.



Ed Eng looks over an ABO RH forward type with IG for blood typing with exhibitor Neil Oliver at the Grifols booth.



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The ABCs of LDTs: Practical Guidelines for Lab Developed Tests

By Jaime Noguez, PhD

A laboratory developed test (LDT) can be defined as an assay that is developed

and used within a single laboratory without Food and Drug Administration (FDA) clearance or approval. Unlike standard diagnostic tools, LDTs have

flowed under the regulatory radar for years and were rarely subjected to strict regulatory oversight to ensure their acceptability for clinical use. This is because LDTs have traditionally been relatively simple assays designed to detect rare conditions in a local patient population and were perceived to be of low risk to patient safety. However, as technology has advanced and business practices have changed, LDTs have evolved as well. They have diverged from simple "home brew" tests to include more complex assays being manufactured by large corporations for broader use—such as screening for common or serious diseases—in patients throughout the world.

Recognizing the increased risk to patient safety, all major laboratory accreditation bodies in the private sector now require that laboratories offering such testing comply with rigorous quality control, proficiency testing, and personnel requirements, as well as documentation of analytical validity. In addition, FDA has recently shifted its position on LDTs from exercising enforcement discretion to plans for increased regulatory oversight by implementing premarket review to confirm the performance of these tests.

As a result, performing LDTs in today's regulatory environment is a whole new ball game for clinical laboratories. Many laboratorians may find that they lack the knowledge or experience to appropriately establish and implement such testing. So who can laboratory medicine professionals turn to for guidance? The Tuesday afternoon short course, "Current Guidelines for Laboratory Developed Tests: ISO 15189, CLSI EP19-A, and Practical Guidance to FDA's Quality System Regulation (QSR) for LDTs," provided participants with a



Speaker Lucia Berte watches the tabulation of attendee answers on the screen during "Current Guidelines for Establishment and Implementation of Laboratory Developed Tests."

better understanding of the regulatory requirements surrounding LDTs, as well as practical tips on how to meet them with confidence.

Paula Ladwig, MT (ASCP), Luann Ochs, MS, and Lucia Berte, BS, MA, led the session. Ladwig opened by introducing the concept of the two-stage assay life cycle: establishment and implementation. She described the critical elements of assay validation and explained how the same Clinical and Laboratory Standards Institute (CLSI) protocols that commercial manufacturers use to produce reliable test methods are also useful to clinical laboratories developing LDTs. Ladwig highlighted key components of CLSI EP19-A that laboratories can use to improve documentation of acceptable performance throughout the life of the LDT, such as tailored checklists.

Ochs followed with an explanation of FDA's Quality System Regulation (QSR) and how labs can use the CLSI QSR for LDTs document as a practical guide when FDA publishes the final LDT guidance. According to Ochs, the CLSI document focuses on what laboratorians need to do above and beyond their current practices. It is especially helpful in situations where the regulatory language seems open to interpretation.

Berte closed the session with a high-level overview of the International Organization for Standardization (ISO) 15189 document and how it can help medical laboratories demonstrate acceptable evaluations and performance of LDTs during establishment and implementation. She used graphic representations of the guidelines with the aim of "helping laboratorians understand them in a way that makes sense for the environments they are used in." She also offered a comprehensive summary of all three presentations, emphasizing the differing regulatory requirements for labs that manufacture LDTs versus those that only purchase and use them.

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Helpers and Hurters: The Duality of Antibodies

By Pradip Datta, PhD

We all know how the antibodies of our immune system protect us from microbial harm and pathology. We also know the history of immunoassays, and how this technology makes very specific and sensitive detection possible. The highly specific and strong reaction between antigens and their corresponding antibodies enables laboratories to measure biomarkers in many kinds of biological fluids. Because of immunoassays, we can detect biomarkers quickly and efficiently diagnose many diseases, making them a cornerstone of modern medicine.

But at the same time, antibodies also have a dark side. One example of this is the way in which heterophilic antibodies and paraproteins present in patient samples. These interact with assay reagents—not only immunoassays, but many chemistry assays as well—to give erroneous results, resulting in misdiagnosis and compromising patient care. Sutirtha Chakraborty, MD, and Bernard Cook, PhD, explored these trouble-



Bernard Cook discusses the hows and whys of endogenous antibody detection.

some interferences and their results in yesterday's short course, "Endogenous Antibody Interferences in the Chemistry Laboratory: Trouble from the Inside."

Chakraborty described how the interference of monoclonal proteins

in clinical chemistry assays could be detected and solved. Such interference may often be detected when the lab result does not match the clinical picture. He also talked about false positive inorganic phosphorous (IP) results in serum samples from patients with monoclonal gammopathy. IP is commonly analyzed by molybdate reaction under acidic condition. Monoclonal paraproteins may precipitate under such condition, generating false positive results. Chakraborty described a method for removing the serum proteins first, either by PEG-6000 precipitation or by ultrafiltration. In his studies, the protein-free supernatant had the correct IP results.

Such interference may happen for many other chemistry assays—bilirubin, HDL-cholesterol, calcium, uric acid, electrolytes, glucose, albumin, C-reactive protein, ferritin, urea, creatinine, and thyroxine, for example. Laboratories can deal with this interference by removing proteins before analysis or by alternate methods.

For his part, Cook explained how heterophilic antibodies can interfere

in immunoassays. He gave examples where false positive serum hCG led to unneeded surgery and/or chemotherapy for suspected choriocarcinoma. In these examples, the serum samples gave different results in other hCG assays and did not dilute linearly. Also, urine samples from these patients did not show hCG or its degradation products. The conclusion, Cook explained, was that protocols for diagnosis and treatment of choriocarcinoma must include a compulsory test for hCG in urine. Cook also elucidated the use of antibody fragments and other blockers to neutralize serum heterophilic interference.

The take home message from this short course was that laboratorians must watch for lab results that do not agree with the clinical picture. Laboratories can take steps that can remove or minimize the interferences from heterophilic antibodies or monoclonal proteins in serum or plasma samples. Yes, when it comes to immunoassays, laboratories face "trouble from within." However, with the right knowledge, laboratories can still succeed against such troubles.

Bringing on Mass Spec? Consider This

By Joe El-Khoury

What century-old technique is revolutionizing clinical laboratories worldwide? Yes, we're talking about mass spectrometry. In the last two decades alone, mass spectrometry (MS) has grown from being a large, expensive, and highly complex platform that is restricted to academics, to an indispensable tool for routine clinical chemistry testing.

This rapid advancement is largely due to the advent of electrospray ionization (ESI) and matrix-assisted laser desorption ionization (MALDI), for which a joint Nobel Prize was awarded in 2002. This allowed coupling of mass spectrometry to liquid chromatography. These improvements have expanded the limited scope of application for this technology from drugs of abuse confirmation and newborn screening to microbiology, anatomic pathology, pharmacogenetics, immunology, endocrinology, metabolomics, proteomics, and more.

With significantly broadened applications and reduced instrument size and cost, MS has become a very attractive testing platform for clinical laboratories. However, it remains a high-complexity test that requires many considerations before implementation.

In Monday morning's session "Building New or Adding On: Fundamentals for Overcoming Challenges in Operationalizing Clinical Mass Spectrometry," Deborah French, PhD, discussed the fundamental principles and major applications of clinical liquid chromatography and mass spectrometry. It is important to recognize that there are many different types of

liquid chromatography techniques and mass spectrometers that may be used for a variety of applications, French noted. French discussed the most commonly used combination of these to provide optimum sensitivity and specificity for the desired analysis. Measurement of total testosterone was used as an example to describe the development and validation process. Fortunately, help is available to new users through published methods, CLSI documents, and of course colleagues. "You can call us, we will be nice to you," French said.

Shannon Haymond, PhD, described ways to facilitate operational quality and sustainability. She discussed staff skill requirements and offered guidance on the development of training and competency plans. Often, the most

difficult aspect of the implementation process is finding or training qualified staff, Haymond noted. Successful implementation of any clinical MS program relies on successful training and retention of testing personnel.

Haymond shared experiences from her own clinical laboratory. She has developed CLSI GP21-A3 compliant extensive training checklists for LC-MS/MS, published by *Clinical Laboratory News* and available from www.aacc.org. There are also a number of training resources available through national conferences and mass spec vendors, Haymond said. But thanks to her efforts, directors and managers of mass spec labs now have access to CLSI-compliant training checklists to make their lives easier. "I know it's overwhelming to think about

transitioning everything over to the new CLSI format, but I urge you to start somewhere and use these templates to move forward," Haymond said.

Both speakers highlighted the enormous potential of this technology and how they rely on it everyday for generating high-quality patient results. This was further supported by the overflowing number of attendees to this session, of which 79% reported (using an automated polling system) that they currently use this technology. Fortunately, an overflow room was setup nearby to accommodate all attendees, with moderator Yan Victoria Zhang, PhD, taking questions from that room via text messages. Mass spec is going strong: Is your lab ready to embrace it?

Tissue Diagnostics

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was that many longstanding surgical instruments relying on thermal ablation produce a large amount of tissue-originated gaseous ions, an irritating by-product that happens to be the exact input needed for mass spectrometric analysis. By slightly modifying standard surgical equipment, the aerosol produced during electrosurgery was processed using mass spectrometry and multivariate spectral analysis to create a tool known as the intelligent knife (iKnife).

Engineered for translation into routine clinical use, the iKnife has been used to evaluate tissue margin status during a wide range of

oncosurgical procedures, including breast cancer lumpectomy, which has the highest reoperation rate (25%) of all cancers in the UK. Overall, it has demonstrated greater than 95% concordance with classical, post-interventional histological analysis and mis-identifies malignant tissue as healthy in less than 1% of cases. Undoubtedly the most intriguing and transformative aspect of the iKnife is "the apparent rapidity with which one can get an answer," noted Virginia LiVolsi, MD, who presented a brief history of frozen sections during the plenary session.

In fact, the entire process from aerosol delivery to mass analysis and result interpretation can be performed in 50-100 milliseconds. Within the next decade, LiVolsi said he envisions the promising iKnife technology taking over the work of anatomical patholo-

gists evaluating intraoperative frozen sections. Currently, the iKnife instruments are in operating rooms at three hospitals throughout the UK, just a few meters away from patients undergoing procedures in a variety of specialties. The up-front cost of the instrument is a challenge barring its widespread use, though Takats speculated that, with time, popularization of the technology would reduce overall costs. A far more problematic issue discussed was how surgeons accustomed to frozen sections will accept the iKnife as an alternative tool for intra-operative decision making.

After learning more about the iKnife during this plenary lecture, attendees can certainly imagine many ways such advances will continue to impact patient care in the future.

"V" is for Value, Not Volume

Audience members listen while Mike Hallworth discusses a patient-centered laboratory.



and results are interpreted, according to Freedman. "Clinicians face many challenges in accurately, efficiently, and safely ordering and interpreting diagnostic tests," she said. "We, in the laboratory, owe it to our patients and our clinicians to help support them in this process."

Freedman offered clinical examples of how the laboratory adds value to the post-analytical testing phases to impact patient outcomes and reduce harm. She provided examples where reflective add-on testing motivated by abnormal results directly facilitated diagnosis. Crucial to this process is

» see page A-14

By Anna Merrill, PhD

Medical error is estimated to be the third most common cause of death in the U.S. and may be responsible for approximately 10% of all deaths in 2013, according to recent research. And missed, delayed, or incorrect diagnoses can be part of the problem that puts patients at risk for adverse events. But while the laboratory's potential to help minimize diagnostic errors is undeniable, it requires a transformation in the way laboratorians view the services they provide, according to experts who spoke during yesterday's short course, "Towards Patient-Centered Laboratory Medicine – Using Lab Testing to Reduce Diagnostic Error and Improve Patient Outcomes."

Michael Hallworth, MA, MSc, MCB, FRCPath, and Danielle Freedman, MB, BS, FRCPath, EuSpLM, encouraged laboratorians to shift their focus from only high-quality results to high-quality outcomes by emphasizing approaches to measure and improve the value of laboratory services. The value of the laboratory extends beyond providing quality results in an operationally efficient manner. Everyone can agree that even the highest quality result will not benefit anyone if it isn't used appropriately or at all, they noted.

Hallworth, like many laboratorians who witness the practical value of laboratory testing on a daily basis, was frustrated at the lack of systematic evidence to support the value of laboratory medicine. "Past evidence of laboratory value has focused on efficiency and not on clinical effectiveness," Hallworth explained. This is no longer adequate, he argued, especially given the contributions of laboratory testing to diagnostic error. We must shift our focus from "doing things right" to "doing the right things," Hallworth said. He revealed deficiencies in the current delivery of laboratory medicine services that impact patient outcomes. One strategy he described was how to evaluate all tests—old and new—using evidence-based principles, much akin to phases of drug evaluation, to ensure that clinicians are utilizing clinically valuable tests.

The value of the laboratory must be most apparent at the clinician/laboratory interface, where tests are ordered

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Walk this Way

By Erin Kaleta, PhD

Taking a stroll through the poster presentations at the AACC Annual Scientific Meeting is always a daunting task. Each year, the posters presented at the meeting showcase the newest and most exciting research in the field of laboratory medicine, and there is no better way to take in as many posters as you can, than to walk through the posters with subject matter experts. This year, 10 AACC Divisions offer guided tours of pre-selected posters lead by fellow colleagues.

On Tuesday, the Biomarkers of Acute Cardiovascular Disease, Clinical & Diagnostic Immunology, Clinical Translational Science, and Endocrinology Divisions gave their poster walks. These are concurrent presentations, so I attended the Clinical and Diagnostic Immunology poster tour, led by Maria Willrich, PhD.

The poster tour kicked off with two AACC Academy Distinguished abstracts presented by Lusia Sepiashvili, PhD, and Katherine Turner, a PhD candidate from Cleveland State University. Sepiashvili discussed serum free light chain (sFLC) measurement using MALDI-TOF/MS. sFLC was extracted from the patient serum using affinity capture beads traditionally used in nephelometric assays,

and was analyzed by mass spectrometry to look for abnormalities in the sFLC ratio. She demonstrated detection of sFLC in patients who were immunofixation electrophoresis negative, demonstrating clear clinical utility for sFLC measurement.

Turner discussed the quantitation of programmed cell death receptors to identify which patients suffer from resistance to TRAIL, a chemotherapeutic agent that had shown effectiveness in Phase I clinical trials, but failed in Phase 2. She demonstrated that two of three cell lines were resistant to the TRAIL therapy due to reduced death receptors by quantifying these receptors using flow cytometry. The amount of resistance to TRAIL was correlated with reduced quantity of receptors, a finding which can be used to pre-screen patients prior to chemotherapy.

We then traveled to see a poster by Lee Schroder, PhD, who discussed using immunosubtraction with capillary electrophoresis to quantify monoclonal protein. When these proteins co-migrate with β -migrating proteins, quantifying the M-protein can be difficult, and is often reported as the total amount of protein in that fraction. Using immunosubtraction, the immunoglobulin can be selectively immunoprecipitated from the sample, and the initial amount of monoclonal protein can be inferred



Sarah Brown (left) leads the critical and Point-Of-Care testing division poster walk while Kerstin Halverson (right), 2016 Point-Of-Care Coordinator of the Year, answers questions about her poster.

from the difference between those two samples. Lee showed us that his method was sensitive down to 0.1 g/dL of monoclonal protein, sufficiently sensitive compared to traditional electrophoresis methods.

We ended the tour with a stop by a poster given by Alex Cook from The Binding Site. He showed us studies to measure a specific subset of IgG4 which undergoes Fab-arm exchange, leading to molecules that do not crosslink an-

tigen or elicit lymphoid cell activation. These hybrids are believed to dampen the inflammatory process, and are often reduced in patients in IgG4 diseases, leading to over activation of the immune response. Less hybrid is seen in a decreased ratio of hybrid/total IgG, and can be a useful diagnostic marker for IgG4 disease.

This was an excellent poster tour, demonstrating the superior academic performance of our field's researchers.

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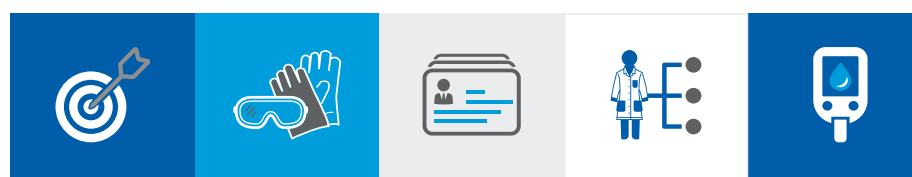
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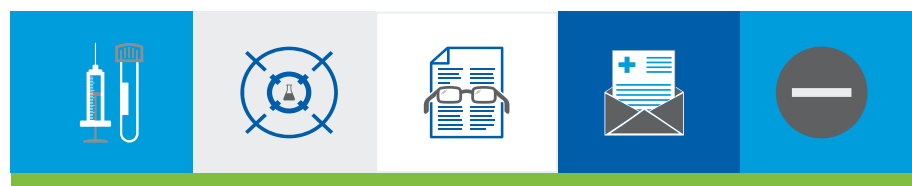
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New Approaches to HIV Screening and Management

By Erin Kaleta, PhD

Over 1.2 million people in the U.S. are currently infected with HIV, and 1 in 8 are unaware of their infection. Despite introduction of antiretroviral therapy, there are still approximately 50,000 new infections each year. At the same time, researchers still are making new progress around the gaps in the diagnosis and treatment of HIV. Experts in HIV explored these efforts during Tuesday afternoon's short course "New Approaches to HIV: Recommendations on How to Test and Treat." Between new CDC guidelines for testing, recent FDA-approved pre-exposure prophylaxis (PrEP) treatment options, and research on antiviral drug resistance, the session was chock full of cutting edge information.

Bonny Bukaveckas, PhD, offered insight into the revised CDC guidelines, pointing toward 4th generation HIV testing to shorten the eclipse phase between HIV transmission and detection by including the HIV-1 p24 antigen. This improves upon 3rd generation assays, which only measured IgG and IgM antibodies indicative of seroconversion. The p24 antigen is high in early HIV infections due to viral burst, and measuring p24 allows for earlier identification of patients with HIV.

Other updates to the CDC guidelines include dropping the Western Blot assay, and instead recommending an alternative antibody differentiation assay, as well as inclusion of HIV-1 RNA assays for discordant results. Overall, this revised algorithm significantly improves the sensitivity of HIV testing, and allows for earlier intervention with HIV treatment regimens, according to Bukaveckas. With the new recom-

mendations, it is important "to balance speed and complexity" when deciding which HIV strategy to use, Bukaveckas said, comparing POCT devices and automated central lab analyzers described in the guidelines.

But improved earlier detection isn't the end of the line for HIV. The major modality for the management of HIV is antiretroviral treatment; however, over the last decade, there have been shifts in recommended regimens in treatment-naïve patients. Mark Marzinke, PhD, highlighted current treatment recommendations, including factors that guide therapeutic selection, as well

as the shifting trend of recommended regimens away from protease inhibitor-based therapies and toward integrase-strand transfer inhibitors.

Marzinke also discussed preventative treatment options approved by FDA in 2012 that allow for PrEP in high-prevalence/high-risk groups. However, for both treatment and prevention, the major driver to therapeutic success is treatment adherence. Lack of compliance with drug treatment regimens can allow for selective growth of mutated virus, increasing the risk of antiviral resistant strains of HIV.

To wrap up the session, Mary Fowler,

MD, discussed the importance of HIV testing and treatment in pregnancy and in infants. "Guidelines are in line with a Test and Treat approach," for pregnant women, Fowler noted, using NRTI backbone drugs, NNRTI, and Integrase inhibitors. Fowler also discussed when to test in pregnancy: If detected and treated early enough, transmission rates in pregnancy between the mother and child can reduce to <1%. Otherwise, testing should be performed in the third trimester or at L&D for high risk pregnancies. This can allow physicians to initiate newborn prophylaxis immediately and avoid breastfeeding.



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Amanda Paulovich, shares her findings during "The Next Frontier in Precision Medicine-Targeted Peptide Diagnostic Mass Spectrometry Assays."

Striving for a Harmonized World

By Pradip Datta, PhD

As the world becomes more mobile and connected, interpretation of biomarkers is becoming more challenging

for laboratory medicine professionals and clinicians. Many assays may be available for a biomarker. But do they all give the same result? Not necessarily. This is especially a problem

for immunoassays because they are so complex. While international standardization and harmonization efforts have improved this situation for some tests, challenges remain that impact patient care. These topics were covered in yesterday's short course, "Challenges and Clinical Impacts of Standardization of Immunoassays," by Bernard Cook, PhD, Catherine Sturgeon, PhD, and Dina Greene, PhD.

Cook described the challenges and successes in standardizing cancer antigen assays. Found in healthy subjects as well as in those with disease, these analytes are poorly defined and are mainly peptides measured by immunoassays. Depending on antibody selection, epitope recognition, and standards used, the assays give widely different results. The solution is international harmonization, by which assay manufacturers try to coordinate so that all assays give the same results for a recognized international reference material. Cook said, that if harmonization succeeded for endocrine and cardiac markers, it should work for cancer markers too. He cautioned about the challenges—how commercial assay manufacturers find it difficult to change standardization because of regulatory burdens.

It is true that international reference materials have improved harmonization for cardiac troponin I (cTnI). Across multiple assays, imprecision reduced

from a median 88% to 15.5% because of harmonization. But commutability of reference material and analyte heterogeneity makes further improvement difficult. Now as the marker is increasingly used in assessing cardiac health, what analytical cutoffs need to be used? The Third Universal Definition of Myocardial Infarction includes a rise or fall in cardiac biomarkers with at least one value above the 99th percentile upper reference limit. But the difficulty of immunoassay standardization is amplified in these very low analytical results. Greene demonstrated how the interpretation of cTnI test results in the low ranges can lead to misdiagnosis and adverse patient outcomes.

Finally, Sturgeon described standardization of endocrine, and especially steroid assays. Even though steroids are available as pure compounds, harmonization has been difficult. One challenge is the availability of a reliable reference range. On the other hand, thyroid analytes are examples of a successful harmonization program. Sturgeon noted recent successes for vitamin D and testosterone testing.

The success stories were inspiring. Leaders in laboratory medicine have initiated global harmonization efforts for many analytes. We may not remove interassay variability completely, but the situation is definitely improving.



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Patient-Centered

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being able to directly engage end-users of laboratory services. Laboratorians should seek to influence physician behavior by providing minimum retesting intervals, incorporating clinician

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decision support tools, and vetting testing requests, argued Freedman. Furthermore, patients should be looped in to laboratory testing so that they feel empowered to participate in their own care. Designed for patient education, AACC's Lab Tests Online has proven to be a useful resource for patients and healthcare providers alike.

The conversation on promoting value-based laboratory services continues today during this morning's symposium "Diagnostic Errors and Clinical Laboratories." Mark Graber, MD, a national leader in the field of patient safety, will approach medical error from the perspective of internal medicine. Laboratorians will be called to action by Michael Laposata, MD, PhD, who contends that laboratory directors must move beyond the logistics of laboratory operation and re-direct their efforts toward counseling clinicians on test selection and result interpretation. Mario Plebani, MD, FRCPATH, FNACB, will close the session by summarizing the nature of laboratory-associated diagnostic errors encountered and by proposing quality indicators to reduce the risk of errors throughout the total testing process.

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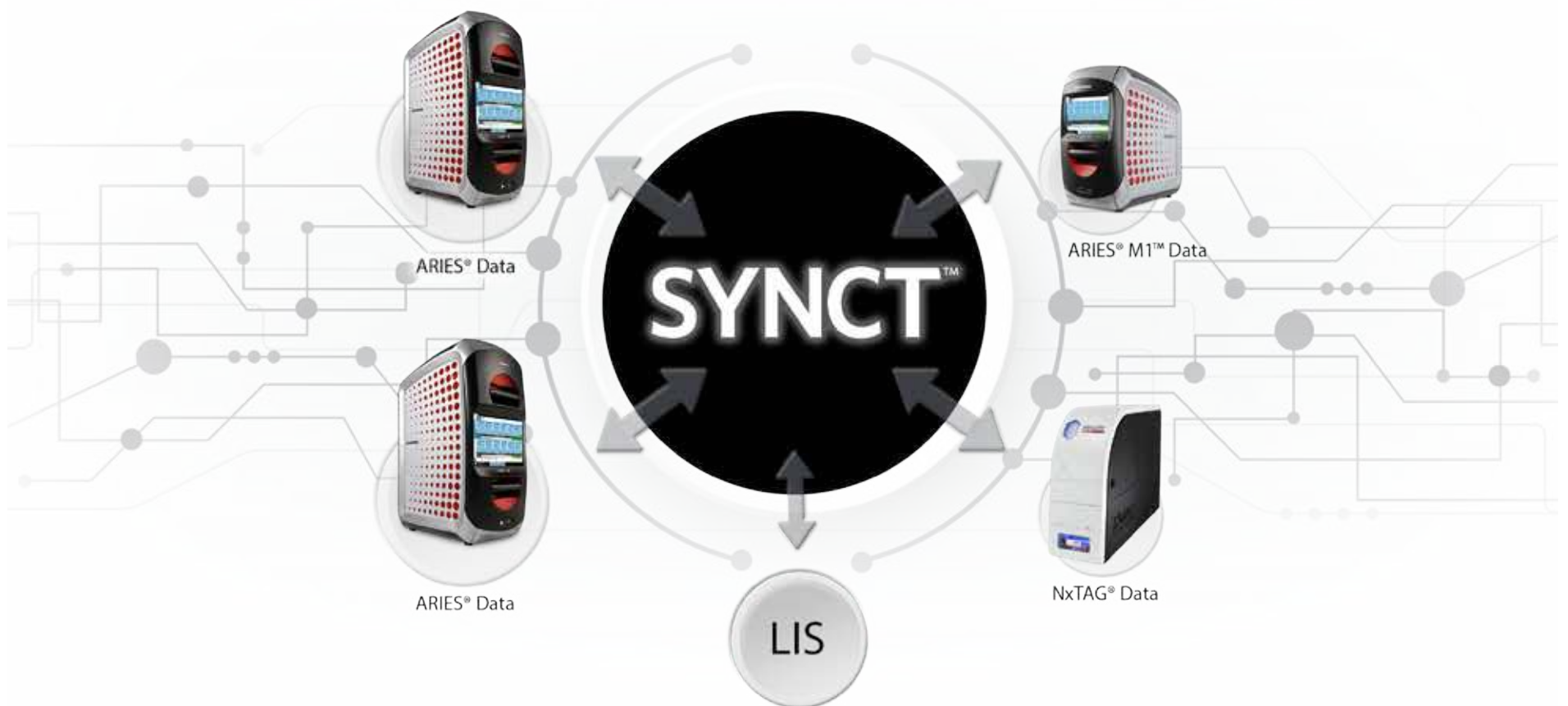
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AACC Unveils the Global Lab Quality Initiative

By Liezl Perez Schewe

Funded by a generous endowment from the Wallace H. Coulter Foundation, the AACC Global Lab Quality Initiative (LQI) provides essential training and education in countries throughout the world. Formerly known as the Emerging Countries program, LQI develops workshops for laboratory medicine students and practicing professionals under cooperative agreements with local host associations and societies. With the goal of sharing best practices in laboratory medicine, LQI presents interactive programs featuring didactic lectures and practical exercises. In addition to a new name for this program in 2016, AACC released a new logo that strengthens the initiative's identity and name recognition across the globe.

LQI beyond the Latin America and Caribbean region with the formation of an Asia-Pacific Working Group (APWG), tasked with launching a program in China in 2016. The first APWG workshop, "Laboratory Medicine from Education to Practice: West Meets East," will take place 21-22 September 2016 in Chongqing, China.

"This move across geographic regions signals AACC and Wallace H. Coulter Foundation's commitment to fostering laboratory best practices and supporting students and lab professionals across the globe, all in collaboration with local societies and experts," said AACC CEO Janet B. Kreizman. "We are thrilled to partner with the Chinese Society of Laboratory Medicine and the Chinese Association for Clinical Laboratory Management in delivering



Workshops in 2016

Planning began in 2015 for expanding

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The LQI will launch its first program in China this September.

New AACC Governance Structure Brings More Opportunities for Members

By Bill Malone

The value of AACC membership has always been a tradition of members offering their best to the profession and their peers, and in return building new relationships and advancing science. But building professional networks and tackling big projects like advocacy, practice recommendations, conferences, and more requires a strong structure—one that supports an evolving and growing organization with global impact.

For a leading professional association like AACC, the organization's governance provides this essential structure, undergirding all of the work that members do. However, with a history spanning nearly 7 decades, AACC's governance structure has grown organically over the years. This resulted in some groups with overlapping charges or even committees without a clear purpose. In order to accomplish the association's strategic goals, the AACC Board of Directors realized they needed to create a governance structure where committees had clear responsibilities and that covered the breadth of AACC program areas, while also representing the diversity of AACC membership.

In November 2015, the board approved a bold new governance plan that creates new opportunities for members to get involved and ensures a strong foundation for future growth. The new



The new AACC governance includes five new core committees.

governance plan, available in full on www.aacc.org, ensures that every committee or other governance body has clear roles, as well as direct reporting relationships to association leadership (Figure 1). This ensures that the hard work members put into numerous projects retains the same cohesiveness and focus even as AACC grows. The new structure also promotes cross-committee collaboration to ensure that member ideas and insights will have maximum impact across a multifaceted operation.

New Committees, Terms

For AACC members ready to translate their experience into shaping new and existing AACC programs, five new core committees will work to ensure that the organization provides the highest quality programs and services in the field of laboratory medicine. Committee appointments will now be 3 years, with staggered terms to ensure both continuity and new ideas. The new core committees include: Science and Practice, Education, Publications, Policy and External Affairs, and the Society for

Young Clinical Laboratorians (SYCL). Other committees and governance bodies, including divisions, will report to these core committees. In turn, the core committees report directly to the AACC Board of Directors (Figure 1).

A Stronger AACC Academy

As part of the new governance transition, the National Academy of Clinical Biochemistry (NACB) will be rebranded as the AACC Academy. Launched in 1976, AACC members created NACB to elevate the science and practice of laboratory medicine by promoting research, education, and professional development. NACB's first guideline, Laboratory Support in Assessing and Monitoring Nutritional Status, published in 1994, was the first of a long

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INSIDE

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Philadelphia Center City MapB-20



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Giving Back: Getting to Know the AACC Access Program

By Caroline Eggers

At the AACC Annual Scientific Meeting & Clinical Lab Expo, laboratory medicine professionals dig into the latest research, technology, and best practices. They also network with peers from around the world. These opportunities can help transform or launch careers in laboratory medicine. However, for many international or early-career laboratorians, traveling to this annual event can be a challenge.

For more than 30 years, AACC has supported travel grants for international and early-career laboratory professionals or students, under what is

now called the AACC Access Program. Contributions to such programs is one way the laboratory community can give back to their profession.

AACC's Access Program is fueled by donations from corporate sponsors or individuals, as well as from AACC Local Sections and Divisions. In addition to providing travel grants, individual AACC members or groups also mentor the international visitors.

This year, AACC awarded 33 International Travel Grants to people from across the globe, including Turkey, Nepal, India, Gambia, Thailand, Nigeria, Egypt, Ghana, Russia, China, Ethiopia, South Korea, Mexico,

Donations of any amount can be made at the AACC Booth (#2627). Contributions also can be submitted directly at www.aacc.org.

Argentina, Singapore, Saudi Arabia, Sudan, Pakistan, Japan, France, the United Kingdom, and Brazil.

In addition, AACC selected 10 individuals at various stages in their careers or studies from the Society for Young Clinical Laboratorians (SYCL) for domestic travel grants. The need-

based grants are given to applicants who demonstrate promise in their respective fields, with preference given to those who present during poster sessions.

In a challenging, ever evolving area of medicine, budding laboratory professionals rely on relationships with their peers to create fruitful, enduring careers. Each year, this gathering of clinical laboratory professionals, both seasoned and nascent, permits an occasion of collaboration, support, and discovery.

During the AACC Annual Scientific Meeting, donations of any amount can be made at the AACC Booth (#2627). Contributions can also be submitted directly on www.aacc.org.

Thanks to the 2016 AACC Annual Scientific Meeting Organizing Committee

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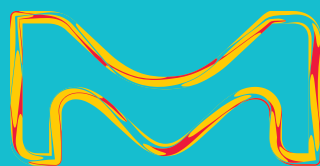
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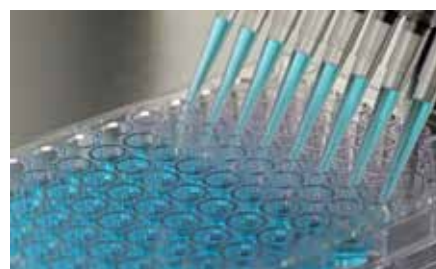
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Global LQI

» from page B-1

the first Global LQI workshop in the Asia-Pacific region.”

The Chongqing workshop aims to open a dialogue between laboratory practitioners from the United States and China to share experiences on laboratory training, employee competency evaluation, and laboratory reporting. The Chinese Society of Laboratory Medicine and the Chinese Association for Clinical Laboratory Management worked closely with AACC to identify and develop the workshop topics.

AACC also will continue to deliver its successful workshops in the Latin America and Caribbean region with a workshop in Cordoba, Argentina in early October. This workshop will build on the success of a previous event in March, when five members of AACC’s Latin American Working Group traveled to Havana, Cuba to deliver a well-received workshop to more than 120 participants.

The Cordoba workshop, “Verifying Assay Performance: Steps to Follow to Verify Manufacturer’s Claims,” will focus on how to verify accuracy, precision, linearity and reference range.

To learn more about the Global LQI and other international AACC initiatives, visit www.aacc.org/global-health-outreach.

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In order to best reflect the essence and intent of the Emerging Countries Program, its name was recently changed to the Global Laboratory Quality Initiative (LQI). Along with this new moniker comes a brand new logo that strengthens the initiative’s identity and overall name recognition across the globe.

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Axxin T8-ISO Instrument

Axxin provides diagnostic products for biomedical applications. Axxin's advanced isothermal instrument enables the next generation of diagnostic DNA/RNA amplification in a compact, low cost, stand alone, sensitive instrument suitable for field based and point of care diagnostic applications.

Axxin
Booth 2015/2044



TANGO infinity® Automated Blood Group Serology

The TANGO infinity® combines simplicity and convenience without sacrificing accuracy for immunohematology testing. It features innovative volume verification of every sample and reagent for every assay, and proven Solidscreen® II and Erytype® S methodologies. The system offers lean automation with intuitive software and minimal operator steps.

Bio-Rad Laboratories
Booth 1427/1462



Apex 6

The Apex 6 is preprogrammed to provide high performance STAT processing of BD Barricor™ tubes to meet the needs of lean laboratories. With the Drucker Dash approach to centrifugation, the Apex 6 improves turnaround time for chemistry samples and coags. Its High G-force capability provides 3-minute sample separation to make labs even more efficient.

Drucker Diagnostics
Booth 3606



Ultra Rapid Clinical AST of Positive Blood Culture

Alifax Clinical Susceptibility Test (CAST) is the unique ultra rapid IVD giving results in only 3 hours directly from blood culture. Performed with Alifax patented systems based on light scattering technology, CAST provides clinical useful results for the improvement of Critically ill patient management and antibiotic resistance reduction.

ALIFAX S.r.l.
Booth 3317



Amplichek™ II – QC for Healthcare Associated Infections (HAI)

Bio-Rad now offers Amplichek™ II a quality control product to monitor the performance of in vitro laboratory nucleic acid testing procedures for the detection of HAI. This control allows laboratories to be more confident with their assay performance since it contains inactivated bacteria to control both extraction and amplification steps with just one control.

Bio-Rad Laboratories
Booth 1427/1462



Dispensette® S Bottletop Dispenser

NEW BRAND Dispensette® S bottletop dispensers from BrandTech® Scientific, Inc. bring even more safety and convenience to dispensing of virtually any laboratory liquid. Dispensette® S dispensers mount directly on reagent bottles for faster, more convenient dispensing, and are autoclavable for use with sterile reagents.

BrandTech Scientific
Booth 3258



CueSee® CO-OX

COOX controls with real Hb derivatives in 1 sample. Packaged in ACU-Drop II-innovative, dual-chambered device keeps O2Hb separated from MetHb for long shelf-life. Clinically relevant levels, compatible with and identical results on all common CO-oximeters, it's ideal for quality control, method comparisons, AMR validations and proficiency testing.

Eurotrol, Inc.
Booth 2533



Pipette Calibration System (PCS)

Artel's new Pipette Calibration System (PCS®) allows you to take full control of your pipette calibration program, assess and document operator skills, and fulfill your laboratory's regulatory requirements. Start performing state-of-the-art metrology with an ergonomic and easy to use system. Stop by booth 3733 to learn more.

Artel
Booth 3733



D-100™ Hemoglobin Testing System

D-100™ is the future of HbA1c testing. The D-100™ is fully automated and designed to meet the needs of medium and high volume clinical laboratories, for greater throughput, high quality results, and simplified workflow for A1c testing.

Bio-Rad Laboratories
Booth 1427/1462

Exhibit Hall Hours

Thursday
9:30 am – 1:00 pm

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New Product Showcase



LUMIPULSE® G1200

Fujirebio presents the LUMIPULSE G1200. A robust mid-sized fully automated immunoassay instrument. The LUMIPULSE G1200 is based on CLEIA (chemiluminescent enzyme immunoassay) technology. The unique and user friendly system offers multiple features to simplify your workload.

Fujirebio Diagnostics, Inc.
Booth 501



TEG® 6s analyzer

The TEG® 6s analyzer is new thrombelastography technology that significantly improves ease of operation while measuring the same viscoelastic properties of blood coagulation. It can be readily deployed in either lab or near patient settings. The all-in-one cartridge system simplifies and automates preparation to reduce time and operator variability.

Haemonetics Corporation
Booth 3306



The Aptima® Zika Virus Assay on the Panther® System

The Aptima® Zika Virus assay on the Panther® system is a qualitative nucleic acid assay with FDA issued Emergency Use Authorization (EUA) for the detection of the Zika virus RNA. The assay is compatible with plasma/serum specimens and offers excellent sensitivity and specificity with fast turnaround time on the Panther system.

Hologic, Inc.
Booth 1649



IDS-iSYS 17-OH Progesterone

An automated assay for the quantitative determination of 17-OH Progesterone in human serum or plasma. The assay is intended for use as an aid in the diagnosis and treatment of various disorders of the adrenal glands or ovaries.

Immunodiagnostic Systems
Booth 137



Aquaporin-4 Autoantibody ELISA Assay

KRONUS is proud to offer the Aquaporin-4 Autoantibody (AQP4Ab) ELISA Assay Kit for the accurate determination of autoantibodies to aquaporin-4 (AQP4) in human serum. Please visit the KRONUS exhibit at booth 1548 to learn more about our innovative product line.

KRONUS
Booth 1548



Glutamic Acid Decarboxylase Autoantibody ELISA Assay

KRONUS is proud to offer the Glutamic Acid Decarboxylase Autoantibody (GADAb) ELISA Assay Kit for the accurate determination of autoantibodies to glutamic acid decarboxylase (GAD) in human serum. Please visit the KRONUS exhibit at booth 1548 to learn more about our innovative product line.

KRONUS
Booth 1548



ARIES® System

The ARIES® System is a real-time PCR sample to answer platform designed with the modern lean lab in mind. The ARIES® software is intuitive and easy to use, yet powerful and flexible. Visit Luminex at booth 426 to learn more. For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions.

Luminex Corporation
Booth 426



NxTAG® Respiratory Pathogen Panel

Syndromic Testing made easy – The NxTAG® Respiratory Pathogen Panel is a comprehensive assay that detects 20 respiratory pathogens in an easy to use, single well, closed tube system. Visit Luminex at booth 426 to learn more. For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions.

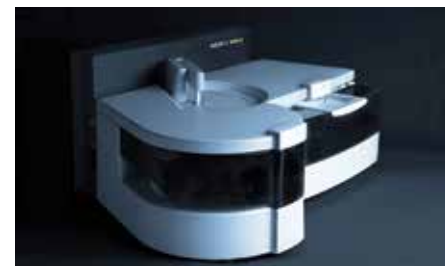
Luminex Corporation
Booth 426



ARIES® M1 System

The ARIES® M1 System is a real-time PCR system crafted to increase laboratory efficiency, ensure result accuracy, and fit seamlessly into today's lean laboratory. The ARIES® M1 software is intuitive and easy to use, yet powerful and flexible. Visit the Luminex booth 426 to learn more. For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions.

Luminex Corporation
Booth 426



EasyRA® Chemistry Analyzer

Medica's EasyRA® clinical chemistry analyzer has been upgraded to enhance workflow efficiency by 50% or more. EasyRA 'smart' reagent wedges automate inventory management, are liquid, stable, and ready to use. The EasyRA is a fully automated, compact benchtop chemistry analyzer that meets the diverse needs of small to medium laboratories. The intuitive touch screen user interface, unsurpassed reliability and modular design for easy maintenance make EasyRA the EASY choice for laboratories.

Medica Corporation
Booth 141



Nova StatStrip® Xpress2 Glucose Hospital Meter System

StatStrip Xpress2 is designed for applications that don't need connectivity capability and joins StatStrip Glucose as the only glucose meters cleared by the FDA for use with critically ill patients. Xpress 2 features a color screen and modern shape for easier use and utilizes the same interference-free measurement technology as StatStrip Glucose.

Nova Biomedical Corporation
Booth 1627

Download the AACC App

With hundreds of exhibitors to navigate and dozens of educational sessions to attend, planning your busy days at the 68th AACC Annual Scientific Meeting & Clinical Lab Expo is essential to make the most of this dynamic event.

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New Product Showcase



Epi proColon®

Epi proColon® is the first FDA approved minimally invasive blood test for colorectal cancer screening for patients who are unwilling or unable to be screened by recommended methods. The molecular DNA test detects methylated Septin 9 DNA, a differential blood biomarker that is methylated in colorectal cancer.

Polymedco, Inc.
Booth 3401



New Zealand Bovine Serum Albumin

Proliant is proud to announce the opening of its new Bovine Serum Albumin (BSA) manufacturing facility. Located in Feilding, New Zealand, it is Proliant's second manufacturing location. With the original site located in Boone, Iowa, the Feilding location enables Proliant to provide BSA to countries that are closed to "Non GBR I" sourced material.

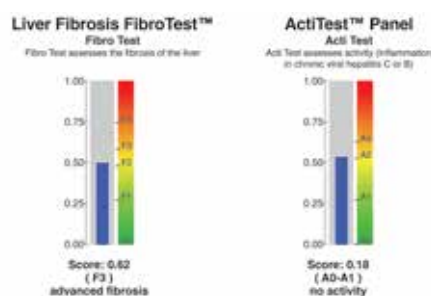
Proliant Biologicals
Booth 1662



Quantimetrix® Complete D® 25-OH Vitamin D Control

The Complete D® 25-OH Vitamin D Control is a 2 level serum control that is compatible, without dilution, on major immunoassay and LC-MS/MS methods (JCTLM #C8RMP3/4). It has a 3 year 2-8°C shelf life and open vial stability of 1 year @ 2-8°C and 30 days @ RT. Values for 25-OH Vitamin D2 and D3 are provided for research or international use only.

Quantimetrix Corporation
Booth 4001



HCV Resistance Tests and Fibrotests

Quest Diagnostics provides extensive diagnostic and prognostic screening options and seamless results reporting needed to successfully manage patients with hepatitis C virus (HCV). We offer a full range of tests for resistance to direct-acting antiviral agents, along with FibroTest™ for non-invasive evaluation of liver fibrosis in patients with HCV.

Quest Diagnostics
Booth 3927



Acusera Linearity Sets

Our Acusera Linearity sets have been developed with convenience in mind, helping you meet CLIA requirements for calibration verification and assessment of linearity. The liquid ready-to-use verifiers are available in varying levels & multiple configurations designed to challenge your instruments complete reportable range.

Randox Laboratories
Booth 2927



CoaguChek® XS mPOC App Kit*

Designed to operate on iOS devices, including iPhone and iPad, the CoaguChek® XS mPOC App works together with a patient's CoaguChek XS meter and SmartClip to automatically transfer his or her PT/INR results to CoaguChek Link, where a physician is able to review the results.

*Currently in development. Not available in the U.S.

Roche Diagnostics
Booth 1301



cobas HIV

The new cobas HIV-1 test is a dual-target, real-time PCR assay that provides precise, quantitative HIV-1 RNA results with exceptional correlation to the COBAS® Ampliprep/COBAS® TaqMan® HIV-1 Test v2.0 that targets two unique, non-drug target regions of the genome. The test runs on the fully automated cobas 6800/8800 Systems that transform molecular workflow, delivering leading throughput and flexibility.

Roche Diagnostics
Booth 1301



cobas® Flu A/B & RSV Assay*

The cobas® Flu A/B & RSV assay is a multiplex test that is designed to detect influenza A, influenza B and RSV concurrently. This real-time PCR-based assay provides definitive, lab-quality test results in about 20 minutes, enabling healthcare providers in all settings to provide patients with prompt, efficient and confident diagnosis and treatment.

*510 (k) pending. Not available in the U.S.

Roche Diagnostics
Booth 1301



c 513 analyzer*

This new, 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.

*510(k) pending. Not available in U.S.

Roche Diagnostics
Booth 1301

Roche Elecsys AMH Assay

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 delivers accurate results in only 18 minutes, enabling clinicians to provide patients with accurate results during their office visit.

*510(k) pending. Not available in U.S.

Roche Diagnostics
Booth 1301

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Plug in and contribute

AACC
ARTERY
AACC Online Community

Visit <https://community.aacc.org> and connect on AACC Artery

- Create conversations about a session that interested you
- Respond to questions from other members
- Expand your network before the meeting ends
- Continue the conversation from home

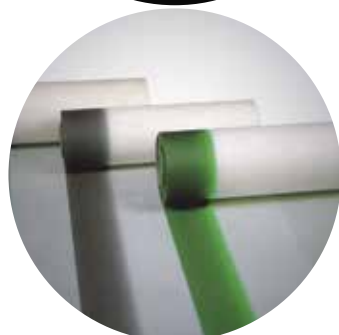
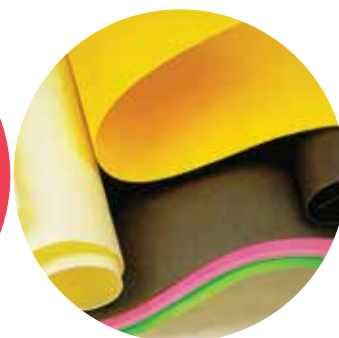
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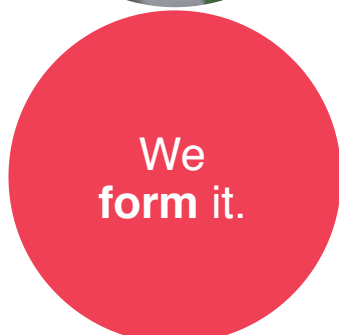
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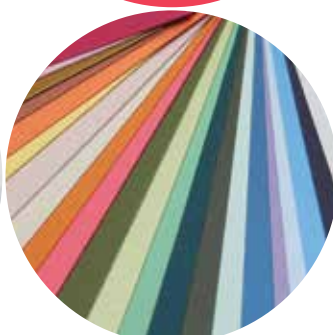
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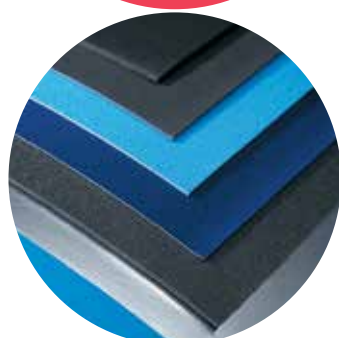
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protect it.



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form it.



We
rehabilitate it.



We
dream it.



We
make it.

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We are an \$11 billion global chemical and plastics manufacturing company with ten individual businesses in North America. As part of the Sekisui family of companies, Sekisui Diagnostics continues to strengthen their global presence and their deep diagnostics expertise.

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Booth #1337

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Governance

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series of highly regarded monographs reflecting the latest scientific evidence. Recommendations from the most recent guideline in development, on pain management testing, are being presented at the 68th AACC Annual Scientific Meeting here in Philadelphia.

Through this governance transition and rebranding, the AACC Academy will continue to elect its own leadership and induct its own fellows according to criteria set by Academy members. This rebranding not only aids in repositioning the Academy within AACC, but also provides clarity to external stakeholders, reinforcing the Academy's connection to AACC.

The vision for the Academy is that it will be even more integrated into the association, with a closer connection to AACC leadership and a clear direction. This will be a collaborative process among AACC elected leadership and the elected leadership of the Academy.

The core role of the Academy remains intact, with its functional processes essentially unchanged but with refinements to solidify its alignment with AACC. The elected leadership body of the AACC Academy will be known as the AACC Academy Council, and the Academy president will chair the Council. Importantly, the Council chair

has a designated seat on the AACC Board of Directors, ex officio with vote.

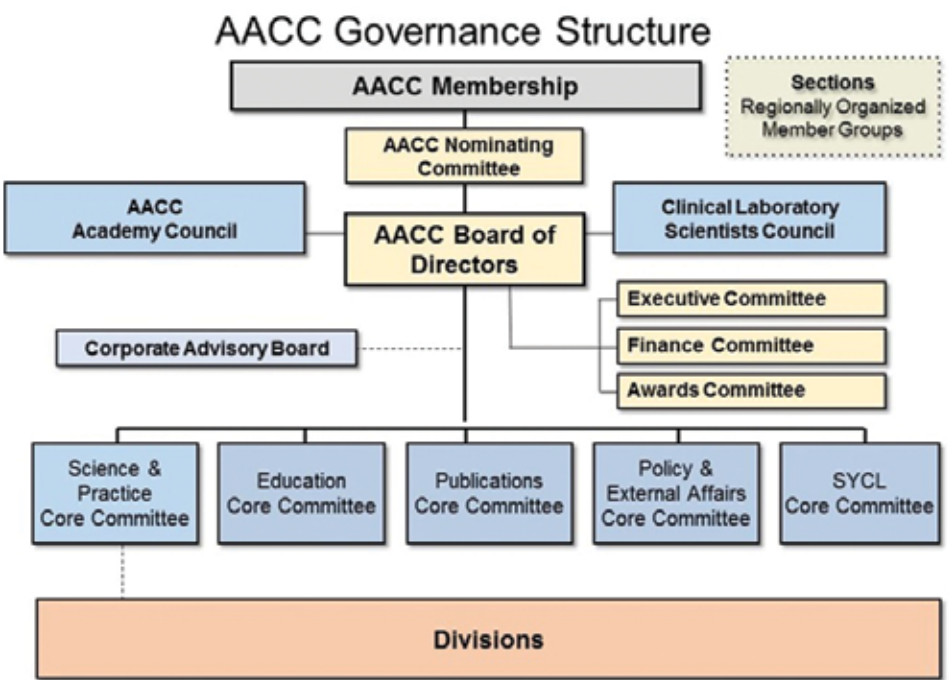
The Clinical Laboratory Scientists Council

The governance plan also puts a strong emphasis on enhancing representation of all areas of laboratory medicine in AACC programs and services. One of the most significant innovations of the new governance is the Clinical Laboratory Scientists (CLS) Council. Established to gain the insights and perspectives of AACC members who hold non-director positions in the laboratory, the CLS Council will include 11 such members, and the CLS Council Chair will have a designated seat on the AACC Board of Directors, ex officio with vote. After appointment by the AACC President in 2016, the inaugural CLS Council will create a process for subsequent Councils to be elected from and by those AACC members who qualify as CLS members.

How to Get Involved

Members have a lot of options for getting more involved, whether by serving on new committees or connecting to their local section or division. A great way to start is by speaking up on AACC Artery, the association's members-only online community. Members also can use AACC Artery to reach out to colleagues who are already involved and seek their advice.

Overall, the nominations process for officers and board members will remain



Under the new AACC governance structure, all governance bodies will have clear roles and responsibilities, objectives, and well-defined reporting relationships. The new governance framework also is designed to involve a larger number of member volunteers, and to engage a greater diversity of the membership.

essentially the same. Calls for nominations will go out to the entire membership via email, and the Nominating Committee will consider the nominees and may suggest additional individuals. The Nominating Committee will have the additional charge of developing the leadership pipeline, using a more robust process for identifying AACC committee members. The AACC President-Elect will continue to make committee appointments.

Members who would like to serve on AACC committees can volunteer in several ways. AACC will issue regular calls for volunteers, similar to calls for nomination. In addition, sitting committee members and chairs will be asked to suggest individuals to be appointed to committees. Members also can email governance@aacc.org to express interest in serving.

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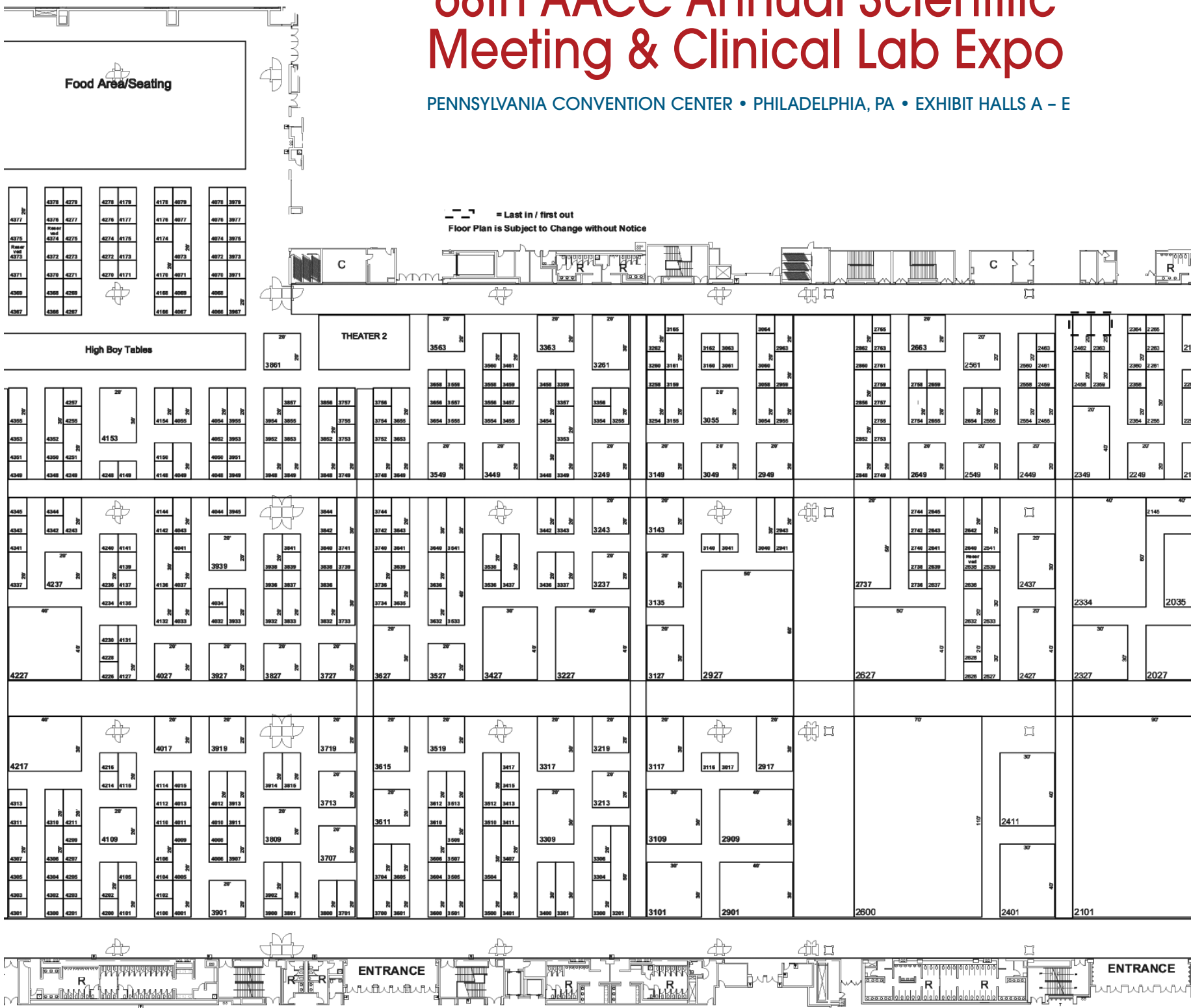
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68th AACC Annual Scientific Meeting & Clinical Lab Expo

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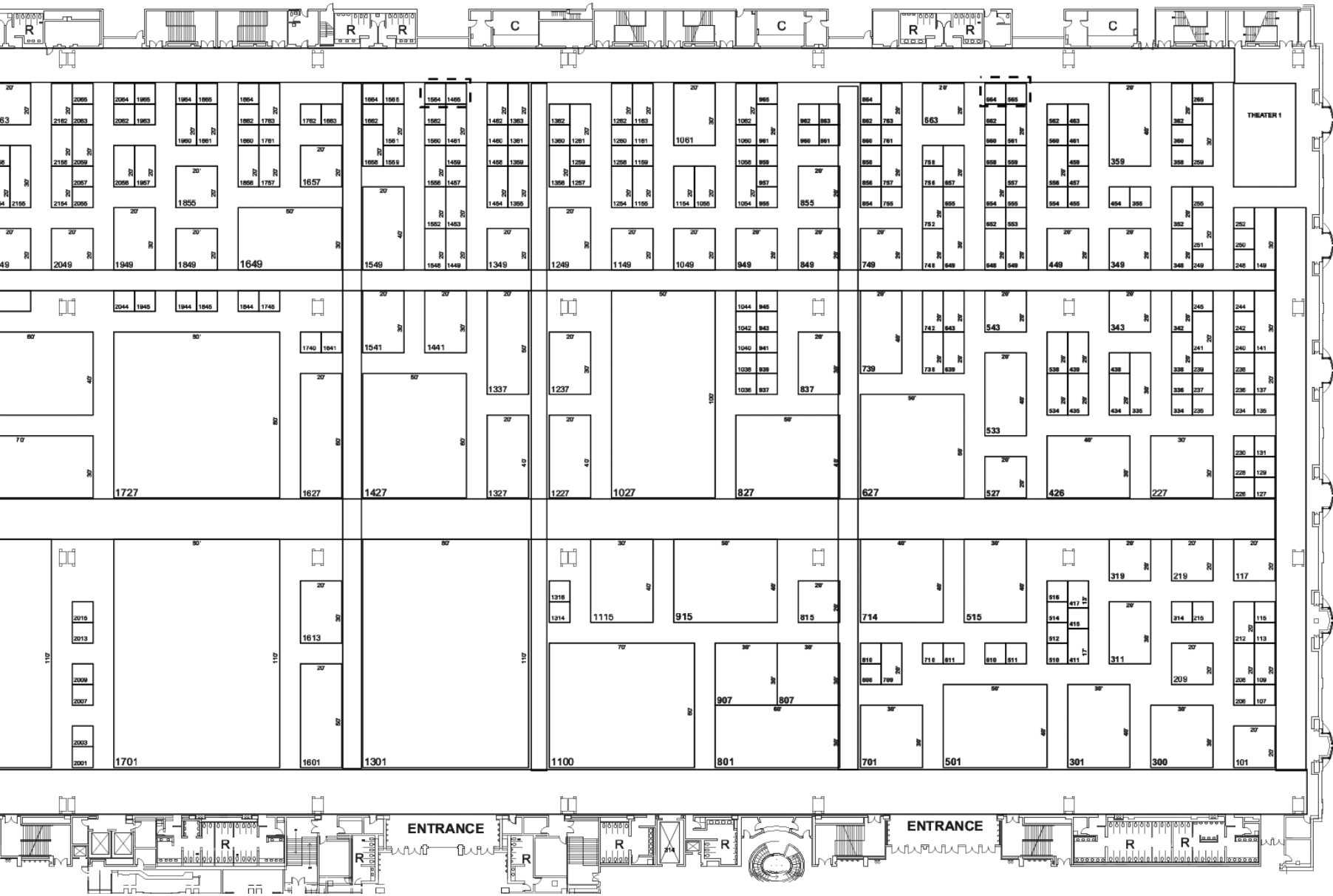
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9:30 am - 1:00 pm



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Roche Elecsys BRAHMS PCT*

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*510(k) pending. Not available in U.S.

Roche Diagnostics
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*Not available for sale in the U.S.

Siemens Healthineers
Booth 2101



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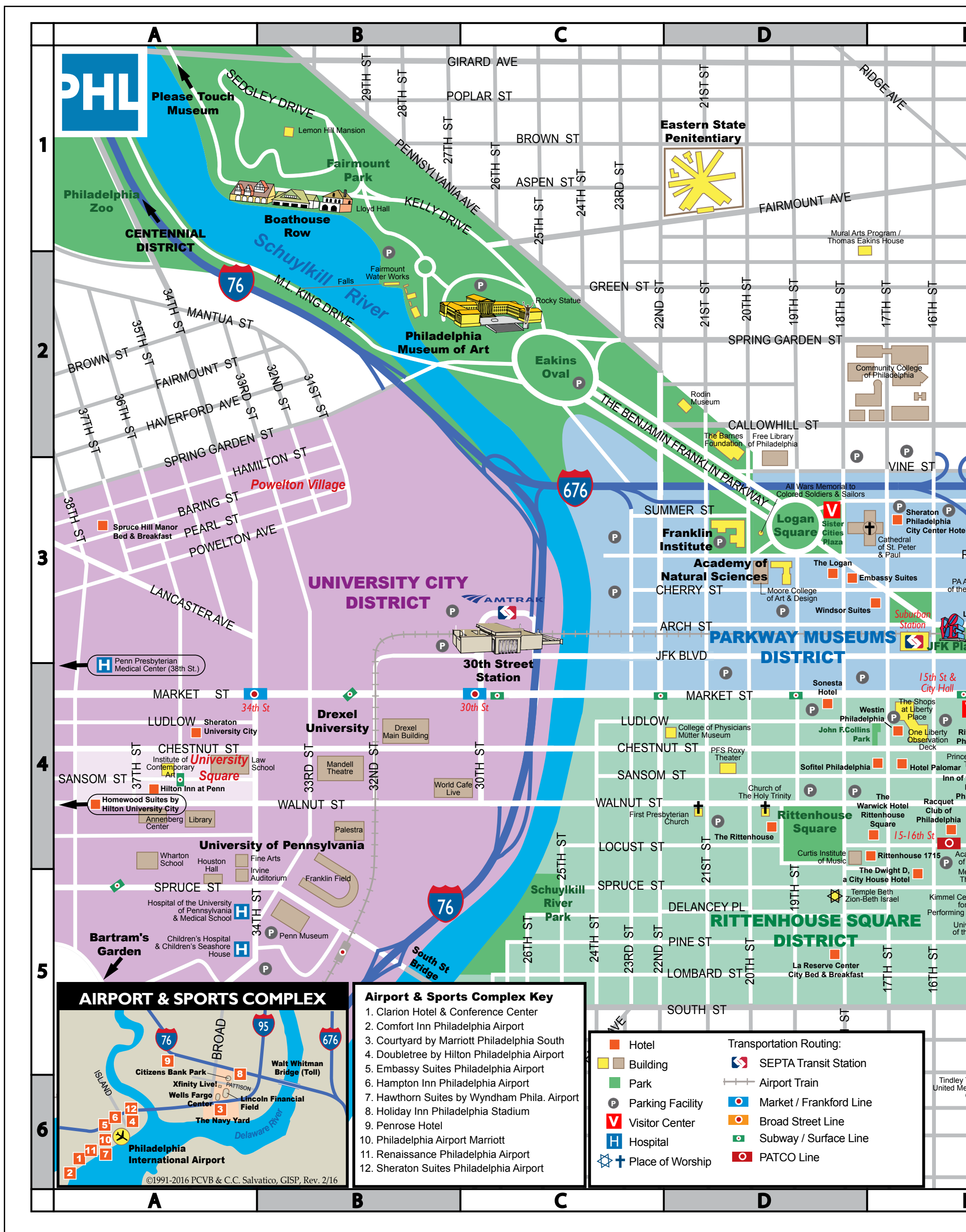
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As you attend sessions, write them down in the Continuing Education Session Recording Form (found at the back of the Program Guide). At the end of each day, go online to: www.aacc.org/AMcredits and follow the instructions to evaluate each session you attended and then print (or save) your Verification of Participation (credit) certificate.

Will I need to record the CE code at the end of each session?

No, continuing education (CE) codes are no longer being used for continuing education credit.

Do I need to take any additional steps for my ACCENT® credit if I am a clinical laboratory scientist in Florida?

Yes, if you would like AACC to report your credits to CE BROKER, enter your Florida Department of Health license



number when you go online to obtain your ACCENT® credits. You must obtain your credits within 30 days of the AACC Annual Scientific Meeting.

Do I need to take any additional steps for my ACCENT® credit if I am a clinical laboratory scientist in California?

Yes, you must sign your ACCENT® Verification of Participation certificate(s) before submitting to the California state licensing agency.

How do I get ACCENT® credit for Poster Sessions?

To obtain ACCENT® credit for Poster Sessions, go to www.aacc.org/AMcredits and follow the same steps as you would for claiming credits for other scientific sessions. There will be two poster sessions (Tuesday and Wednesday). Each session will offer 2.0 ACCENT® credits.

What's the difference between ACCENT® credit and AMA PRA Category 1 Credit™?

ACCENT® credit is for clinical laboratory

professionals, and AMA PRA Category 1 Credit™ is for physicians only.

Is ACCENT® credit available for the 2016 AACC Clinical Expo?

No, ACCENT® credit is not awarded for the AACC Clinical Lab Expo attendance.

Can I obtain my continuing education credits on-site?

Yes, there will be a computer at the ACCENT/CME booth, located in the Grand Hall. Or you may use your own computer, laptop, tablet, or mobile device.

How do I get my Certificate of Attendance for the 68th AACC Annual Scientific Meeting?

Go to www.aacc.org/AMcredits and follow the instructions to obtain your Certificate of Attendance.

Who can answer additional questions about continuing education credit?

The AACC staff at the ACCENT/CME booth (located in the Grand Hall) will be glad to answer your questions, or you may send an email to education@aacc.org.

Visit the AACC Member Center
Located in the main concourse just outside the expo hall, the AACC Member Center is an information hub for new members and those interested in joining the association. Get updates on member benefits, meet with AACC staff, enter one of our raffles, and tell us your story about your career in laboratory medicine.

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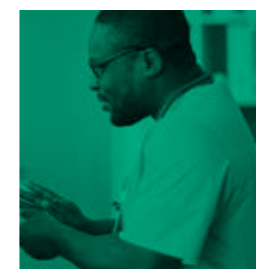
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FDA-Clearance of EliA anti-Thyroglobulin and EliA anti-Thyroid Peroxidase Autoimmunity Assays!

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Samsung LABGEOPT10 Chemistry Analyzer

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