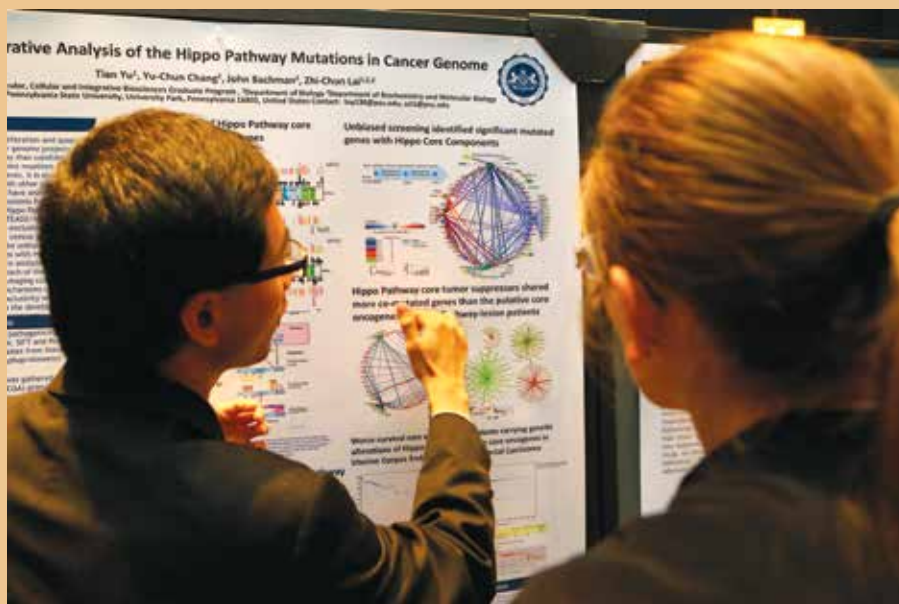




Tian Yu describes his poster on the Integrative Analysis of the Hippo Pathway Mutations in Cancer Genome with M. Laura Parnas, during the Student Poster Contest. See p. 6 for Student Research Awards.

Clinical Applications of miRNAs

A New Frontier in Molecular Diagnostics?

By Melanie Yarbrough, PhD

The discovery that noncoding regions of the genome such as microRNAs (miRNAs) can influence the pathogenesis of cancer has led investigators to consider using these molecules to guide clinical decision making. In a symposium this morning, miRNAs in Practice: Little Molecules With A Lot of Punch, Muller Fabbri, MD, PhD, and Vincent De Guire, PhD, will discuss new research on the biology of miRNAs and explore their potential clinical applications.

miRNAs are endogenous, small RNAs that inhibit gene function by targeting mRNA for either degradation or inhibition of translation. After

transcription, they undergo a series of processing steps that culminate in a small, 22-nucleotide RNA that binds to target mRNAs with imperfect complementarity. miRNAs can bind to multiple targets, precipitating global changes in expression patterns. Consequently, aberrant expression of miRNAs can contribute to the pathogenesis of many human diseases.

There are many potential uses for miRNAs in medicine. For example, global alterations in miRNA expression have been described in a large number of malignancies, giving rise to the idea that miRNAs can serve as biomarkers for detection of cancer and prognostics to

» see page 12

When It Comes to Data, Size Matters

By Christopher McCudden, PhD

Big data refers to massive amounts of raw information that require new paradigms of storage, visualization, and analysis. With the 'datafication' of the world, these datasets are more available than ever, offering extraordinary opportunities to make predictions and discover new connections.

Attendees were taken beyond the hype of big data at Monday's plenary session, where Viktor Mayer-Schönberger offered real examples of how big data analysis has revolutionized traditional analytical approaches. Big data is transforming hypothesis testing, where millions of ideas can be tested simultaneously rather than having to limit focus to a single question due to data sampling restrictions, Mayer-Schönberger explained. With

"small" data, a researcher has to choose just what to focus on. With big data, she does not need to make the choice, and can grapple with everything, "zooming in and out at will," he said. "Letting the data speak."

For evidence-based medicine, algorithms can help make predictions even in the absence of an understanding of causation, and multiple correlations may be enough to derive useful meaning. "If correlations yield insights, then we should use them," Mayer-Schönberger said. "We should go for causality if we can get it, but don't put it on a pedestal as the be all and end all."

Mayer-Schönberger also asserted that, in healthcare, we are over or under-treating all the time. Best practices are based on averages, where no particular treatment or therapy is really optimized for an individual. As our genetic make-up, metabolic state, and disease severity become better known and understood, personalized medicine will rely on big data. With more information from sensor technology, real-time measurements of basic chemistry analytes can lead to remarkable improvements in outcomes. Mayer-Schönberger described an example of real-time monitoring in preemies, where thousands of data points per second can predict a blood stream infection before it is detectable by traditional methods.

Other big-data leaps for healthcare include unusual corporate ventures. Mayer-Schönberger described how FICO, traditionally known as a credit score company, was able to use third party data sources to predict medication adherence. Incredibly, is now possible for a single entity to predict whether you will default on your mortgage, get a car loan, qualify for life insurance, and be compliant with your drug prescriptions.

Of course, big-data predictions are not perfect. Mayer-Schönberger described the Google Flu project, where flu outbreaks are predicted from keyword searches combining known outbreaks with epidemiological data from the Centers for Disease Control and Prevention. The Google Flu project has been criticized recently for apparent inaccuracies in the model. Society will certainly have to tackle difficult questions resulting from big data and predictive analytics. There are many

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Viktor Mayer-Schönberger, Oxford Internet Institute, discusses the limitations and value of "Big Data" at Monday morning's plenary session.

INSIDE

- LDTs A-8
- Test Interpretation A-12
- Big Data Analytics A-14

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What's a Müllerian?

By Ann Gronowski, PhD

There's a new biomarker on the block for assessing ovarian reserve and it's called anti-Müllerian hormone (AMH). But what is a Müllerian? In a mid-day short course yesterday moderated by Alicia Algeciras-Schimnich, PhD—Banking on the Numbers: Laboratory Assessment of Ovarian Reserve—Joely Straseski, PhD, and GERALYN Lambert-Messerlian, PhD, answered this question and many more related to the assessment of a woman's reproductive status. Straseski began the session with an overview of female fertility. "We have to understand fertility before we can understand infertility," she said.

Straseski then quoted current statistics showing that one in seven couples have difficulty conceiving and one-third of couples with female partners over the age of 35 have fertility problems. Simple math tells us that this is a problem affecting a lot of people and it does not appear to be going away anytime soon.

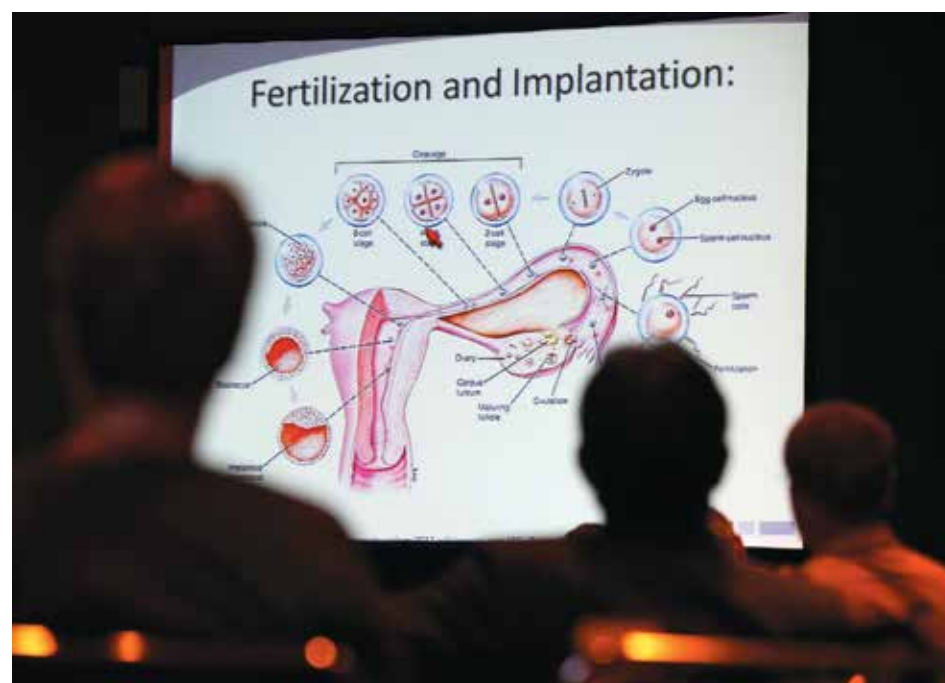
While a woman's age is one of the leading causes of infertility, the ability to predict a woman's reproductive potential, termed ovarian reserve, has the potential to be very helpful in developing treatment plans. Straseski defined ovarian reserve as the quality and size of the follicle pool present in a woman's ovary. "Basically, the more follicles, the

greater the chance for fertilization and pregnancy," Straseski said. "As we age, both the number and quality of those follicles declines." As a result, markers of ovarian reserve have received a lot of attention in reproductive medicine.

Lambert-Messerlian introduced the audience to AMH. "Early studies have shown that AMH concentrations correlate well with antral follicle counts, the gold standard of ovarian function," she said. "It is an excellent marker of ovarian reserve because of its biology. AMH is produced by small follicles of the ovary, those that are not growing in response to follicle-stimulating hormone. This is unlike other markers of ovarian reserve such as estradiol and inhibin B."

AMH plays a role at various stages throughout the lifespan, Lambert-Messerlian explained. First discovered to have an essential role in embryonic development, AMH inhibits the formation of the Müllerian ducts, which develop into the female reproductive tract. Fast forward through those early years, and AMH also helps tell the story of a woman's ovarian function, and may even help predict menopause.

The session also dealt with problems in defining normative data and assay standardization. Lambert-Messerlian emphasized that laboratorians are going to play a crucial role in AMH testing



2014 AACC Annual Meeting & Clinical Lab Expo attendees participate in the Banking on the Numbers: Laboratory Assessment of Ovarian Reserve short course on Monday afternoon.

going forward. "Currently, the assays for measurement of AMH are being developed and refined and efforts to standardize among methods are underway," Lambert-Messerlian said. "Once reliable standards and reference data are available, widespread use of AMH can be expected in the clinical laboratory."

Could this be a game-changer for women, as recent trends show childbirth being delayed to later repro-

ductive years? Will AMH become a common tool to aid in women's reproductive decisions? If menopause could be predicted, could that information accelerate a woman's timetable for having children? As every good research article ends—more studies are needed. One thing that is for certain is that we can expect to hear a lot more about the marker highlighted in this short course in the future.

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The Best Offense Is a Good Defense

New Approaches to Combat Multi-Drug Resistant Microorganisms

By Melanie Yarbrough, PhD

A minor cut or scratch can progress to a life-threatening illness with startling speed if a multi-drug resistant microorganism takes hold. In the 2014 annual antimicrobial resistance global surveillance report from the World Health Organization, the assistant director-general for health security, Keiji Fukuda, MD, warns that “a post-antibiotic era—in which common infections and minor injuries can kill—is a very real possibility for the 21st century.”

In today's afternoon short course, Hot Topics in Clinical Microbiology, three experts will discuss new strategies to combat resistance, including improving diagnostics and novel therapeutics for some of the most common hospital and community-acquired infections. The speakers will make the case that laboratory medicine serves as a hub, providing data to detect emerging resistance phenotypes and facilitating judicious use of antimicrobial therapy.

The first speaker, Christopher Doern, PhD, will highlight trends in the development and mechanisms of resistance among the various resistant pathogens.

Worldwide selective pressure due to misuse and overuse of antibiotics

has contributed to the emergence of resistant strains of bacteria that cause common diseases such as infections of the urinary tract, wounds, and bloodstream. For example, strains of carbapenem-resistant *Enterobacteriaceae* have been isolated that are resistant to almost all antibiotics, including many last-resort drugs. Multidrug-resistance is also found with increasing frequency in strains of *Mycobacterium tuberculosis*, which infects an estimated one third of the world's population, making these infections almost impossible to treat.

These trends threaten to turn back the clock on one of the singular achievements of modern medicine. Infectious diseases had been the leading cause of death until breakthroughs like the discovery of penicillin by Sir Alexander Fleming in 1928. Countless lives were saved by the subsequent antibiotic revolution.

Treatment of infections caused by drug-resistant bacteria creates a vicious cycle in which physicians administer more antibiotics to treat the infection, which can lead to development of even more resistant strains. In addition, the overuse of antibiotics, especially in a hospital setting, can eliminate or disrupt the balance of many of the so-called “good” bacteria in the body, creating a

dysbiosis that allows a hostile takeover by pathogens usually kept at bay by our normal flora. One such pathogen, *Clostridium difficile*, is the number one cause of hospital-acquired diarrhea and rates of community onset of infection are on the rise.

Both diagnosis and treatment of this infection are major challenges. Carey-Ann Burnham, PhD, will discuss the challenges faced in the diagnosis of *C. difficile* infection and strategies for treatment. One novel idea is the use of fecal transplants to restore the normal flora in affected patients. Although not without problems, such alternatives to traditional antimicrobial therapy are a welcome strategy to combat infection.

Another problem is that the availability of invasive and indwelling medical devices has created new niches for the proliferation of drug-resistant bacteria. For instance, prosthetic joints provide an ideal access point for bacteria, which can lead to septic arthritis in these patients. Unfortunately, the specific

diagnosis of prosthetic joint infection can be a challenge, and many of the bacteria that cause these infections exist in a biofilm. This makes them difficult to recover in culture. Therefore, the causative agent—and thus best course of treatment—often remains elusive. Susan Butler-Wu, PhD, will review the increasing role of molecular diagnostics and novel culture techniques in the identification of these bacteria, in addition to exploring the potential diagnostic utility of serum and synovial biomarkers of infection.

Today's session on Hot Topics in Clinical Microbiology illustrates that laboratory professionals must continue to develop and implement multiple approaches to deal with the prevention and diagnosis of multi-drug resistant pathogens. Moreover, the emerging technology in this area emphasizes the importance of an interdisciplinary approach—both within laboratory medicine and among our clinical colleagues.

CLN Daily Editorial Board 2014

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Spotlight on Young Scientists

The following AACC Student Research Awards were presented at the joint ABCC-SYCL reception on Monday evening.

Poster Presentations

Garrett Mullins – University of Virginia
Lipolysis Suppresses Insulin Signaling and Glucose Uptake

Maria Willrich – Mayo Clinic
Antibodies-to-Infliximab: Assay Development and Correlation with Infliximab Concentrations in Serum Samples of Treated Patients

Sarah Delaney – University of Toronto
Bupropion Exposure in an Infant: A Case Report

Chris Crutchfield – Johns Hopkins University
Alternative Calibration Strategies for LC-MS Based Analysis of Broad Reportable Range Analytes

Oral Presentation

John Mills – Mayo Clinic
High Sensitivity Detection of Residual Disease in Multiple Myeloma Using Mass Spectrometry

Jeff Meeusen – Mayo Clinic
Analytical and Clinical Validation of an LC-MS/MS Method for Urine Leukotriene E4: a Marker of Systemic Mastocytosis

Trevor Pitcher – University of Louisville
A Urine-Based Immunoassay for Urocortin 3 and Diagnosis of Sleep Apnea

Shuhei Mamiya – Tokyo Medical and Dental University
Lipid Hydroperoxides in Apolipoprotein E-containing High-Density Lipoprotein Abstract Control Number



Brenda Suh-Lailam discusses her poster with William Link, Bio-Rad Laboratories, Hercules, CA, during the Student Poster Contest.



Presenters demonstrate their work to attendees during the Student Poster Contest.



Presenters John Mills (from left), Shuhei Mamiya, and Jeff Meeusen share a light moment before Monday's Student Oral Presentation Contest.



Trevor Pitcher presents his research on antibody development during the Student Oral Presentation Contest on Monday.

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The Wild West of Laboratory-Developed Tests

By David Colantonio, PhD

Most testing conducted in today's clinical laboratories uses commercial reagent kits, manufactured and marketed by in vitro diagnostics companies. However, many new and existing biomarkers do not have commercial reagents available, resulting in the need for labs to develop and validate their own tests. These laboratory-developed tests (LDT) are primarily for internal use and are not distributed or sold to other labs. However, they present unique regulatory and validation challenges.

William Clarke, PhD clarified the evolving regulatory landscape for LDTs during yesterday afternoon's symposium, Understanding and Implementing LDTs: What Should We Know? Clarke reviewed the role that the Centers for Medicare and Medicaid Services and the Food and Drug Administration (FDA) play in LDTs. Although FDA regulates 'primary ingredients' for analyte-specific reagents—such as antibodies, nucleic acids, and enzymes—the agency does so to ensure the quality of these test components: it does not currently regulate LDTs themselves.

However, FDA recently concluded that LDTs should be regulated at some level. In moving towards more oversight, three classes of risk have been established: Class I, low risk (e.g.

spectrophotometer); Class II, moderate risk (e.g. routine chemistry assays); and Class III, high risk (e.g. in vitro diagnostic multivariate index assays for cancer diagnosis). High risk LDTs would require the strictest FDA oversight. Although many in the laboratory community agree that FDA should improve oversight for some LDTs—especially for high risk or direct-to-consumer tests—how FDA regulates LDTs is a big cause for concern, Clarke noted.

Among these concerns are that FDA would end up classifying most LDTs as high-risk; the problem of inconsistent evaluation of analytical and clinical validity between laboratories; and a minimized role for laboratory directors if FDA tries to supplant their scientific and consultative responsibility through regulation. Clarke also mentioned The Modernizing Laboratory Test Standards for Patients Act (HR 3207), introduced this year by representative Michael Burgess, (R-Texas), which removes FDA from the LDT loop. The Burgess legislation proposes oversight of LDTs by the department of Health and Human Services rather than FDA, creation of an LDT test registry, and the requirement that data on analytical and clinical validity be submitted for new LDTs.

Experts will also tackle the need for rigorous validation procedures for LDTs at a Wednesday afternoon short course,



Ross Molinaro, PhD, discusses proposed regulatory approaches for laboratory developed tests (LDTs) at Monday's morning symposia, Understanding and Implementing LDTs: What Should We Know.

Validating Laboratory Developed Tests: Practical Application Examples, from 2:30–5:00 pm. Jason Park, PhD and

Hung Luu, PhD will review practical examples of how to validate LDTs. Park will use the example of gene sequencing to highlight that a minimum level of validation should be conducted for any new or existing technology, as well as how different approaches to validation are related to how test results are interpreted.

Luu will offer his experience with CellaVision, a digital hematology analyzer that uses neural networks to locate, digitize, and pre-classify leukocytes, as well as characterize red blood cell morphology. One of the requirements for evaluating a peripheral blood smear is assessing red blood cell morphology, including identification of intracellular parasites such as malaria. Although it has become widely adopted for performing manual differentials for CBCs, Luu's is the first institution to use this technology for routine screening of malaria.

"In searching the literature, I realized there was no data comparing the sensitivity of CellaVision versus conventional microscopy for routine screening of malaria," Luu said. The last part of his talk will focus on the approach used to validate the use of CellaVision for routine screening of intracellular parasites.

Hidden Gems

By Chris McCudden, PhD

With 873 accepted abstracts representing 21 different areas of laboratory medicine, it's easy to miss some great abstracts. Here I highlight a few hidden gems that did not necessarily win awards, but are worth a look.

Fructosamine and Glycated Albumin with Risk of Coronary Heart Disease and Death, by E. Selvin, et al. Poster A-138

Fructosamine and glycated albumin have long been known as alternate measures of glycemic control. The authors examined long-term cardiovascular (CVD) outcomes as part of the Atherosclerosis Risk in Communities (ARIC) study. The authors measured fructosamine and glycated albumin in >11,000 patients without pre-existing CVD over two decades and found that fructosamine and glycated albumin were both significant independent risks factors for coronary heart disease and mortality. Interestingly, low concentrations of these markers also conferred increased CVD risk.

Suspected Lassa Fever (LF) Case Outcomes: A Comparison to a Non-Febrile Population in Sierra Leone, by B. L. Brown et al. Poster A-143

Lassa fever is an acute viral hemorrhagic disease endemic to Western Africa. Patients with Lassa fever exhibit a variety of non-specific symptoms making diagnosis difficult. The authors examined common

lab and physical findings in patients with Lassa fever, and found that patients with confirmed Lassa fever exhibited elevated creatinine and BUN, with higher respiratory rates. This characterization data may aid in Lassa fever diagnosis and help identify which patients require further workup and treatment.

Iatrogenic Vitamin D Toxicity in an Infant: Clinical Relevance of Vitamin D Metabolic Profiling, by H. Ketha et al. Poster A-190

Vitamin D has been at the forefront of discussions of test utilization, measurement accuracy, and epidemiology. This abstract provides a case report of a vitamin D overdose in a 4 month-old child. The remarkable part of the case is that it was a combination of both gross overdosing of over-the-counter vitamin D and inaccurate vitamin D content in the supplement. The authors highlight how metabolite profiling of vitamin D metabolites can help work up cases of apparent vitamin D toxicity. They also highlight the risk of over-supplementation and the need for better regulation of supplements.

New Instrument Interface Standard to Enable Improved Interoperability with Integrated Information Systems, by J. B. Jones et al. Poster B-009

Existing standards for LIS interfaces are highly flexible and not

» see page 14



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NACB Distinguished Abstracts Highlights

By Mari DeMarco, PhD

Every year the National Academy of Clinical Biochemistry (NACB) selects the most outstanding abstracts accepted to the AACC annual meeting. This year NACB Fellows selected 34 abstracts for their scientific excellence from more than 870 abstracts. "Recognition of excellence in research is a primary goal of the NACB, and the Distinguished Abstracts program is one of the ways we advance that initiative," said Roger Bertholf, PhD, chair of the NACB awards committee.

Attendees can easily identify the winning abstracts by attending the poster sessions held Tuesday and Wednesday from 9:30 am to 5:00 pm, and keeping an eye out for the NACB blue ribbons. Below are just a few of the award winners and highlights from their research studies.

Circulating presepsin (soluble CD14 subtype) in patients with severe sepsis and septic shock. Data from the Albumin Italian Outcome Sepsis (ALBIOS) study, by Roberto Lantini. Poster A-146

"The cornerstone of the emergency treatment of severe sepsis and septic shock is an early, goal-directed therapy," Lantini noted. Toward that end, the

Albumin Italian Outcome Sepsis study was undertaken, whereby blood specimens were collected from septic patients over the course of a week. They then evaluated presepsin concentration, as compared to procalcitonin concentration, as a prognostic biomarker. In their multicenter trial, enrolling 997 septic patients, they identified an incremental role for presepsin in predicting 90-day mortality.

Development and validation of a X-ray fluorescence method for ischemia-modified protein detection, by Yang Luo. Poster B-350

During myocardial ischemia, the N-terminus of albumin can be modified, affecting the binding capacity of transition metals—cobalt in particular—to albumin. To measure ischemia-modified albumin in serum, the authors developed a quantum dot sandwich immunoassay and X-ray fluorescence spectroscopy method. Ischemia-modified albumin concentration was determined by subtracting the intact (unmodified) albumin—determined based on the amount of cobalt bound to albumin—from total serum albumin, which they measured by immunoassay. As there is no gold standard for testing, the authors compared their assay to the FDA-cleared spectro-

photometric Albumin Cobalt Binding test (ACB test). They found some key differences between the two assays when examining specimens from ischemic and non-ischemic patients.

Saturated and unsaturated dietary fat differentially modulate ethanol-mediated changes in gut microbiome, intestinal barrier integrity and liver in an experimental animal model of alcoholic liver disease, by Irina Kirpich. Poster B-120

The authors fed mice either an unsaturated fat or a saturated fat Lieber-DeCarli diet (containing ethanol), and also maintained a control group fed on an isocaloric basis. Stool metabolomics analysis was performed to characterize ethanol and dietary fat mediated changes in the stool metabolome. In addition, the mice were evaluated for liver injury, steatosis, intestinal and hepatic inflammation, intestinal permeability, and blood endotoxin levels. The authors found that both the stool metabolome and intestinal microbiome were differentially modulated by the type of dietary fat in their diet.

hCG candidate epitopes for improving the measurement of hCG: results from the second ISOBM TD-7 workshop, by Philip Hemken. Poster A-64

Poster Tip

To help navigate the many interesting posters presented at the meeting, you can attend one of the Guided Poster Tours. Each 30-minute tour will be led by an expert from one of the AACC Divisions and will highlight a handful of outstanding posters from the event. The tours are free and will run Tuesday and Wednesday during the regular poster sessions. See page B-21 for the full schedule.

The goal of this study was to evaluate the specificity and epitopes recognized by antibodies used for the quantitation of human chorionic gonadotropin (hCG) and its variants. The authors tested 69 different antibodies, provided to the study team by companies and research groups. They used the First WHO International Reference Reagents for six hCG variants (hCG, hCG β , hCG β n, hCG β cf, hCGn and hCG α) in their analysis. They were able to identify the variable specificity of the antibodies for each of the hCG variants, as well as their degree of cross-reactivity with luteinizing hormone.



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Right Test, Right Patient, Right Time...Wrong Interpretation?

By Amy Saenger, PhD

Providing accurate test results is a critical function of the clinical laboratory—but our responsibility doesn't end there. Clinicians depend on the laboratory to provide vital interpretive comments to give meaning to these results. However, there is a fine line between providing helpful information to the end user versus contributing to information overload. Moreover, the end user is no longer only the physician, but extends to other healthcare providers and even to patients themselves who increasingly access their results via patient portals.

A Monday morning interactive short course developed with the Royal College of Pathologists of Australasia (RCPA) Quality Assurance Program (QAP) grappled with this issue, linking the quality of interpretive comments directly to patient outcomes and patient satisfaction.

Now that we have improved analytical test results, we need to improve the pre and post analysis, noted Samuel Vasikaran, MD. "If we don't interpret test results right then the effect of testing won't be correct," he said.

Vasikaran explained that most junior doctors feel they only have moderate

or limited confidence in requesting and interpreting results. A recent survey at his institution, the Royal Perth Hospital showed that most junior doctors and general practitioners would like more help with test interpretation. Furthermore, studies have demonstrated that well written interpretive comments improved test utilization and patient outcome.

Vasikaran recommends that laboratorians only add comments to a test result if the results are unexpected, influence decisions on management or treatment, or if the test is fairly esoteric. Ideally, the laboratory should individualize comments in the context of the patient's clinical condition and in conjunction with other test results or clinical parameters. Unfortunately, this is not always feasible.

An interactive survey of the audience showed that 100% of attendees provide some type of interpretive comments to their test results, but 57% had no mechanism to assess the quality of the comments they provide. Until recently, laboratorians did not have mechanisms available for peer reviewed quality assessment (QA) and support for continuous professional education. The RCPA QAP developed its assessment to enable

individuals to objectively examine their practice and approach the assessment as a quality activity, while functioning as a component of a larger QA scheme. The assessment also contains a strong educational component, making it more than just a traditional exam or checklist item.

Graham Jones, DPhil, MBBS, highlighted the lessons learned from the RCPA QAP external quality assessments, one of which focuses on improving deficiencies in the quality of comments in patient reports. Jones walked the audience through several examples of case interpretations which illustrated the difficulty in proper interpretations. According to Jones, desirable comments may include: absence or presence of abnormality; possible clinical implications

and/or diagnosis; degree or severity of abnormality; and suggested follow-up or specialist referral. Undesirable comments may include restating the obvious ("normal" or "elevated"); suggesting obvious clinical interventions (check blood pressure, conduct physical exam); restating the clinical question if known; and suggesting any invasive interventions, such as a biopsy.

Both Jones and Vasikaran predicted that in the future, participating in external QA schemes for interpretive comments will largely become more of a contractual obligation rather than a professional one. They also emphasized that the visibility of the laboratory depends primarily on the results and interpretive comments laboratorians provide to physicians and patients.

Data

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fascinating—and perhaps somewhat frightening—implications to this new world of big data. One safe prediction is that policy makers globally will be at least a few steps behind.

"Big data will help us understand

the world better and make better decisions," Mayer-Schönberger said. "But also brings new challenges and dramatic dangers. We must remain its master. With a vital need to learn from the data, we need to allow for human creativity, and even defiance against the data. Data is a shadow of reality and therefore always incomplete. We must use humility and humanity."

miRNAs

» from page 1

define therapeutic response. Hundreds of studies have found circulating miRNAs in biological fluids such as blood, urine, and many others.

De Guire will discuss different applications for the use of these small RNAs in diagnostics and therapeutics. He will also discuss preanalytical and analytical variables that influence measurement of circulating miRNAs. Reliable measurement of these molecules can be challenging due to the lack of standardization of variables such as collection, processing, and storage of specimens.

Fabbri will explain how profiles of miRNA expression may differentiate normal versus disease tissue. Small

molecule miRNAs are highly stable, abundant, and specific for certain cell types, and research has shown that amounts correlate with several diseases. Fabbri will discuss recent findings showing that dysregulated miRNAs are secreted from tumor cells in small vesicles called exosomes. Intriguingly, Fabbri's research has shown that surrounding immune cells can engulf these vesicles, and the resulting activation is thought to trigger an inflammatory response that promotes cancer cell growth. These changes in expression of tumor-expressed miRNAs can alter the surrounding tumor microenvironment, raising the possibility that a relationship between a primary tumor and circulating miRNAs may serve as useful noninvasive biomarkers for some cancers.

Because miRNAs can regulate entire pathways rather than single targets, their use as therapeutic agents would have a key advantage over currently available selective protein inhibitors that target only one piece of a pathway and are prone to acquired resistance. If miRNAs can be harnessed in this way as tumor suppressors, they will be an appealing target for developing new therapeutics.

At the same time, there are several technical challenges to overcome before miRNAs fulfill their promise, such as finding a non-toxic delivery system and concerns about off-target effects. Ultimately, a better understanding of the contribution of miRNAs to complex biological networks is critical before miRNAs can be applied to clinical therapeutics.

"This field is still in relative infancy," according to the moderator of today's session, Tina Lockwood, PhD. "Although several challenges remain, miRNAs undoubtedly have enormous potential to provide diagnostic, prognostic, and therapeutic information in human disease."

Indeed, if miRNAs continue to show promise as biomarkers, they will be very welcome additions to today's era of personalized medicine.

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Hidden Gems

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entirely standardized, making it difficult to integrate information from different sources. The authors describe a new, plug-and-play interface standard. Rather than requiring unique instrument-interface builds to connect each device to an LIS, this standard promises simpler connectivity and less extensive testing and validation. This abstract provides a window into some of the detailed requirements for integrating health information. Jones describes in his symposium on Wednesday the benefits of such integration in the form of patient outcomes and reduced cost.

Thrombin-Mediated Degradation of Parathyroid Hormone in Rapid Serum Tubes, by S. L. La'ulu et al. Poster A-235

In an effort to reduce turnaround times, some labs have turned to special serum collection tubes designed to increase the speed of clot formation. The authors describe the potential unintended consequence

of using thrombin-containing rapid serum tubes for blood separation. They report that the tubes cause an apparent thrombin-mediated degradation of PTH. This serves as a cautionary tale and a template for additional studies where labs may employ rapid serum tubes.

Development and Validation of a High Performance Liquid Chromatography Tandem Mass Spectrometry 9 Steroid Panel using Minimal Sample Volume B. Stolze, et al. Poster A-408

Soldin's group has a rich history of developing multiplex HPLC-MS/MS assays for steroids. Here he and collaborators at NIH describe an improved method for simultaneous detection of 9 steroids using small sample volume and limited preparation time. This third generation assay offers 11.5 minute run times and 50 uL sample volumes while achieving an order of magnitude greater limit of detection. Performance characteristics are also improved. The new generation assay is particularly amenable to steroid measurement in children where detection limits and sample size requirements are demanding.

Big Data Analytics

By Chris McCudden, PhD

Effective data analytics promise to save costs, improve processes, and achieve better patient outcomes. But how can laboratorians play a role in this emerging area of research and practice? At today's afternoon symposium, Big Data: Applying Analytics to the Practice of Laboratory Medicine, Jay Jones, PhD, Brad Brimhall, MD, and Nicole DeHoratius, PhD, offer a tour de force that explains in practical terms how big data can translate into measurable quality improvements. From health system-wide data integration to improved operational efficiency in a busy emergency department (ED), this session will provide a plethora of examples from the cutting-edge of laboratory data analysis.

This session is divided into three parts: integrated big data, new value propositions, and ED performance. The first of these, presented by Jones, will relate the journey of data integration across a regional healthcare system that has demonstrated improved patient outcomes. Jones will discuss how Geisinger Health System relies on a single laboratory information system (LIS), standardized instrumentation, and an in-house clinical decision intelligence system (CDIS) to implement system-wide standards of best practice. At Geisinger, physicians implement best practices by using technological support from the CDIS to integrate care using data from the laboratory, pharmacy, diagnostic imaging, and electronic health records (EHR).

One of the many remarkable aspects of this data integration system is the outcome data Jones says is now being yielded. After nearly a decade of collecting data and implementing standardization and best practices, there is evidence that patients participating in this system are healthier. This is real delivery on the promise of big data. Jones also says that better outcomes naturally lead to economic benefits, stating that "improved outcomes are

good business." He also points out that current federal reimbursement incentives mesh well with this data-driven approach to integrated care.

In the second session, Brimhall will provide further examples of the benefits of using data to direct laboratory strategies. Discussing the combination of LIS and EMR data with accurate financial information, he will provide examples laboratorians can use to identify savings due to inappropriate test utilization. For example, he describes how physician-level analysis identified patterns of ineffective test use, such as physicians either always ordering TSH and FT4 at the same time or never—of course, both practices can't be right. These kinds of data analyses require both an analytical skillset and domain expertise. Laboratorians who produce data will have a better understanding of its provenance, limitations, and value than a third party or non-laboratorian would.

In the third part of the session, DeHoratius will talk about process redesign using point-of-care (POC) test strategies to improve the efficiency of an ED. She will describe a unique study of the impact of POC on hospital emergency departments. DeHoratius's work is motivated by emergency overcrowding and uses a branch of operations research known as queuing theory. Queuing theory is used to generate hypotheses about ED performance, which is then tested using data from a large urban tertiary care center. Results from the study show reductions in service time in patients who receive tests as well as a small, but significant improvement in service time for patients who do not get lab tests. This fringe benefit of POC has not previously been reported, but makes sense from an operational standpoint where the workload for laboratory staff is reduced, enabling them to produce results on a smaller number of patients more efficiently.

Collectively these speakers offer tremendous insight into the benefits of data analytics using real-world examples.

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Alk Phos	Primidone
ALT	RF
Amikacin	Salicylate
Ammonia	Sodium
Amylase	Theophylline
APO A1	Thyroxine (T4)
APO B	TIBC-direct
ASO	Tobramycin
AST	Total Bile Acids
BUN	Total Bilirubin
C3	Transferrin
C4	Triglycerides
Calcium	T-Uptake
Carbamazepine	Uric Acid
Chloride	Valproic Acid
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Cholinesterase	Vitamin D-direct™†
CK	UDTs
CK-MB	Amphetamine
CO2	Barbiturates
Creatinine	Benzodiazepines
CRP	Buprenorphine
CRP wide-range	Cannabinoids (THC)
Cystatin C	Carisoprodol*
D-dimer	Cocaine Metabolite (benzoylecgonine)
Digoxin	Cotinine* (nicotine metabolite)
Direct Bilirubin	Ecstasy (MDMA)
Fibrinogen	Ethanol
Fructosamine	Ethyl Glucuronide (EtG)*
Gentamicin	Fentanyl*
GGT	Heroin (6-AM)
Glucose	Hydrocodone
Glucose, urine	K2* (synthetic marijuana)
Haptoglobin	Methamphetamine
HDL-direct	Meperidine*
HbA1c-direct	Methadone
Homocysteine	Methadone Metabolite (EDDP)
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IgA	Oxycodone
IgG	Phencyclidine (PCP)
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Guided Poster Tours Offer Inside Look at Latest Science

By Elizabeth Grisham

Attendees of the 2014 AACC Annual Meeting & Clinical Lab Expo have many opportunities to explore the latest innovations in laboratory medicine, but experts say this week's guided poster tours are among the best such occasions.

"I believe the guided tour is a unique opportunity to review and discuss among a peer group and colleagues the work accomplished by authors in a casual and collegial

environment," said Vincent Ricchiuti, PhD.

Ricchiuti, who also served as a poster tour leader last year, is one of several volunteers from each AACC division who choose abstracts that they think exemplify the best scholarship for that specialty. They select abstracts based on several criteria: science, study design, experimental approach, methods used, and translational medicine relevance and clarity, according to Ricchiuti. From there, the volunteers assign a score to each abstract using a scale of one to five for each criterion, with one being poor and five being outstanding.

Next, "a first round of abstracts is narrowed down to the six best abstracts with the highest average scores," Ricchiuti said. "A second round of selection leads to the best abstract out of the six initially selected abstracts."

During guided poster tours, tour leaders discuss the posters from the top six abstracts, including the one with the abstract deemed the best. "The concept is to review posters from abstracts that are considered relevant



Expert guides from AACC Divisions will be on hand to help attendees make the most of the poster sessions.

by division experts," Ricchiuti said. "I am convinced that by the end of a guided tour, the attendee participants may have learned as much from the division leaders as they have from the attendees themselves, especially if the topic or methods used in the posters are new to the viewers."

For new members of AACC or first-time attendees, Ricchiuti said guided poster tours are important opportunities for learning and interaction. "I consider that the guided tour for a new AACC member or a new

» see page B-21

"I am convinced that by the end of a guided tour, the attendee participants may have learned as much from the division leaders as they have from the attendees themselves."

Plug Into the Digital Pulse of #AACC2014

By Bill Malone

With hundreds of exhibitors and myriad symposia, brown bags, and other educational sessions to choose from, the AACC Annual Meeting & Clinical Lab Expo has more to offer every year. To help capture all the excitement of the meeting, this year AACC is making it easier than ever to follow events and share your own #AACC2014 stories via social media.

In the registration area in the convention center attendees will find the first of two social media walls—large screens showing photos and messages from across the various social media platforms. The second screen is at the AACC booth in the exhibit hall. Want to see your own photo or message on the social media wall? Just be sure to use the official hashtag, #AACC2014.

This year, attendees can also share messages and photos on the

social media wall using SMS texting from cell phones and even email. Send messages and photos to 87884 and include the #AACC2014 hashtag. For email, attach a photo to your message and send it to AACC2014@wiffiti.com with the #AACC2014 hashtag.

Attendees can also stop by the AACC booth (1531) to get their photo posted on the AACC Facebook photo album and Twitter. At the AACC photo booth, you can take your own picture with some fun props, add a quote, and it will post to AACC media galleries automatically. Attendees can also tag photos and share them with friends. The photo booth is open Tuesday and Wednesday, 9:30



The AACC Pathfinder App is available for Apple and Android devices.

a.m. to 5 p.m. and Thursday, 9:30 a.m. to 2 p.m. The person whose photo receives the most likes on Facebook will win a \$200 gift card.

AACC is also once again offering the popular digital companion for the meeting—the AACC Pathfinder App. Available for smartphones and tablets

from the Apple iTunes store and on Google Play for Android devices, the app allows users to keep track of educational sessions, plan each day with a built-in calendar, map out a path through the expo, and even check off visits to exhibitors.

If you're still a social media novice, AACC is now offering a free, members-only webinar, The Risks

and Rewards of Social Media for Laboratory Professionals. In this webcast, Tiffany Roberts, PhD, makes the case that social media is, in fact, a great way to enhance your career and become known for your expertise, whether it's connecting with other laboratorians or helping spread the word more broadly about the value of laboratory medicine in healthcare. As she says in the webcast, "you will

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New Product Showcase



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Booth 442



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Applied Biocode, Inc.
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Awareness Technology, Inc.
Booth 1814



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Access 2 and Dxl

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Booth 2812



OVA1

ASPiRA LABS offers a continuum of care with personalized reporting for the ovarian mass, applying innovative methods to detect and monitor the treatment of ovarian cancer.

For the Women's Healthcare Provider, OVA1 is the first FDA-cleared blood test to help evaluate an ovarian mass for cancer prior to a planned surgery. The OVA1 result may help determine whether consult or referral to the Gynecologic Oncologist is the best course of action.

For the Gynecologic Oncologist, Longitudinal CA125 is offered in a multi-point graphing system to monitor ovarian cancer once it has been diagnosed. When OVA1 has been ordered through ASPiRA LABS, the Longitudinal CA125 report will include the pre-surgical CA125 baseline value from the original OVA1 result.

ASPiRA LABS
Booth 663

sive prospective clinical trial that enrolled over 1,900 subjects, and confirmed that our assay provides the clinical performance you need for optimal patient management. The AccuTnI+3 assay delivers the precision, and the clinical sensitivity and clinical specificity that are necessary to assist physicians with the diagnosis of MI.

Beckman Coulter
Booth 2812

#AACC2014

» from page B-1

be Googled!" An AACC member and active social media user, Roberts offers expert advice on how to craft a personal brand on social media, how to assess the benefits of different social media platforms for your content, and how to start using Twitter in a few simple steps.

Confused, stressed about, or afraid of taking the plunge into social media? You're not alone. Many scientists, including laboratory professionals, feel uneasy about sharing on

social media—or don't see a reason why they should in the first place.

In this two-part webcast, Tiffany Roberts, PhD, explains why laboratory professionals should explore social media as part of their professional life, as well as how novices can get started if they're not sure where to begin.

The program also includes access to a curated collection of peer-reviewed research on social media for scientists, getting started guides, and articles from around the web.

Tiffany Roberts, PhD, explains her approach to social media in a members-only AACC webcast.



AACC offers 1 ACCENT continuing education credit for this program.

Access the webcast on the AACC website, <http://tinyurl.com/AACCSocial>.

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- Send photos to AACC2014@wiffigi.com.

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- Live tweeting of the Wednesday plenary by @mcervinski
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New Product Showcase



Immunosuppressant Drug Monitoring Assays for AU Series

Beckman Coulter offers a new comprehensive menu of immunosuppressive drug monitoring kits designed to work across multiple AU chemistry system platforms. Thermo Fisher Scientific Immunoassays – QMS® Tacrolimus, QMS® Everolimus, CEDIA® Cyclosporine Plus and CEDIA® Mycophenolic Acid – distributed by Beckman Coulter, Inc., are now available on the AU480/680/5800 series.

The new assays offer:

- Proprietary Quantitative Microsphere System technology (Tacrolimus/Everolimus)
- Cloned Enzyme Donor Immunoassay technology (Cyclosporine Plus, Mycophenolic Acid)
- Correlation to well established (LC-MS/MS, HPLC) reference methods.

QMS® is a registered trademark of Thermo Fisher Scientific Inc.

CEDIA® is a registered trademark of Roche Diagnostics.

**Beckman Coulter
Booth 2812**



Alifax Roller 20PN

The Alifax Roller 20PN Erythrocyte Sedimentation Rate System, available from Beckman Coulter, is designed to fit all workloads, including small hospitals, large reference laboratories, core laboratories and satellite locations.

Alifax's technology measures the kinetics of red blood cell aggregation by capillary photometry and reads aggregation over a ten second period. With this patented technology, Alifax Roller 20PN provides a fully automated, hands-off operation that processes the same whole blood tubes from the hematology analyzer, resulting in ESR analysis in 35 seconds*, which reduces turnaround times and helps improve patient outcomes and physician satisfaction. *7 minutes to first result with other results following every 35 seconds.

**Beckman Coulter
Booth 2812**



BioPlex® 2200 25-OH Vitamin D Kits*

BioPlex® 2200 25-OH Vitamin D kit is a fully-automated, random access method for the quantitative measurement of total 25-hydroxyvitamin D in human serum. The kit features a broad reportable range, internal quality control flags, and equimolar measurement of 25-OH Vitamin D2 and D3 as an aid in the assessment of Vitamin D sufficiency. Enhance your laboratory workflow efficiency with a convenient 200 test kit, 30-day calibration curve stability, and long open vial stability for reagents, calibrators and controls. The BioPlex® 2200 system now offers menu consolidation of specialty autoimmune, infectious disease serology and 25-OH Vitamin D all on one platform. *Pending FDA clearance.

**Bio-Rad Laboratories
Booth 2031**



BioPlex® 2200 HIV Ag-Ab Kit* Bio-Rad Laboratories' BioPlex 2200

HIV Ag-Ab kit simultaneously screens and differentiates antibodies to HIV-1 (Groups M & O) and HIV-2, and HIV-1 p24 antigen. This 5th generation kit offers enhanced performance over 4th generation kits, with the lowest Limit of Detection available for screening. Using proprietary multiplex technology, the kit simultaneously detects and reports up to 3 individual HIV results plus a traditional screen. Differentiating HIV-1 from HIV-2 antibodies and detecting HIV-1 p24 antigen can save time and resources by directing supplemental testing and potentially detecting acute HIV infections sooner. The kit expands the BioPlex 2200 System's infectious disease menu. *Pending FDA Approval. Available outside the U.S.

**Bio-Rad Laboratories
Booth 2031**



UniCel DxH Connected Workcell Solution

With the UniCel DxH Workcells*, labs can streamline workflow management while delivering comprehensive and accurate patient results. With the ability to connect up to three DxH 800 analyzers with one DxH Slidemaker Stainer, labs can create a scalable workflow solution that builds on Beckman Coulter's innovative cellular science.

Performance, low review rates and first past accuracy are all driven by Beckman Coulter's exclusive Automated Intelligent Morphology (AIM), a multidimensional, flow cytometric technology that improves analysis of abnormal specimens. Workflow is managed efficiently through the DxH Workcell's automated sample routing and increased data management capabilities. *Not available in the U.S. for in vitro diagnostic use.

**Beckman Coulter
Booth 2812**



Powerful, Dependable 10-Color Flow Cytometry

The Navios flow cytometer delivers highly sensitive detection, unsurpassed data interrogation, more information per event, and exceptional workflow efficiencies. The Navios enables seamless transition from lower complexity assays to advanced applications. You can trust the Navios to deliver consistent results, with software tools that ensure robust quality control and audit capabilities, as well as hardware features such as single tube vortex capability, built-in thermoregulation, and 1,048,576 channel resolution for high quality results. Backed by the proven expertise of Beckman Coulter, the Navios gives your lab powerful, worry-free performance along with reduced costs and a highly streamlined workflow.

**Beckman Coulter Life Sciences
Booth 3417**



Power Express Automation System

Designed to meet the needs of the most demanding laboratories, Power Express is a high-throughput automated sample handling system that processes Chemistry, Immunochemistry, Hematology and Coagulation tubes. Utilizing a high speed 4-lane track and an intelligent sample handling system, Power Express performs centrifugation, decapping/recapping, aliquoting, and refrigerated/ambient storage to give labs the ability to offer rapid and predictable turn-around times, reduced errors, and improved overall laboratory productivity.

**Beckman Coulter
Booth 2812**



REMISOL Advance Data Manager

With 3,000 installations worldwide, REMISOL Advance is an enterprise data management solution that helps manage lab workflow, improve quality of patient care, standardize operations across multiple sites and increase productivity. It provides critical results faster to help enable labs to empower clinicians to make more informed decisions.

REMISOL Advance features virtualization capability to help reduce failure points, increase uptime and enhance patient data security. It offers an integrated visual management system to track and trace transported samples from the draw site to the lab assisting your lab to become ISO15189 compliant. It is a key to helping you develop a comprehensive lab management solution. Not available in all geographies.

**Beckman Coulter
Booth 2812**

Liquichek™ Cardiac Troponins Control

Liquichek™ Cardiac Troponins Control is now available to monitor the precision of Troponin I and Troponin T. Values are assigned for Roche platforms. For laboratories outside the U.S., values are also assigned for Troponin T hs.

Liquichek™ Cardiac Troponins Control is human based, has tri-level utility and is available in 6 x 3 mL (two per level) as well as 3 x 3 mL (one per level) packaging.

**Bio-Rad Laboratories
Booth 2031**

New Product Showcase



Liquichek™ Immunology Control with Anti-CCP

Liquichek™ Immunology now includes Anti-Cyclic Citrullinated Peptide (Anti-CCP) along with Rheumatoid Factor (RF), to assist clinical laboratories in their QC for rheumatoid arthritis markers. Liquichek Immunology Control is human serum based, offers trilevel utility and is available in 1 mL as well as 3 mL vials.

Bio-Rad Laboratories
Booth 2031



Lyphocheck® Allergen sIgE Controls

Bio-Rad, the QC market leader, introduces Lyphocheck® Allergen sIgE Controls, Negative and Panel A. These independent quality control products are assayed for 15 frequently tested allergen specific IgE's providing quantitative insert values for up to three of the major automated test systems commonly used for in-vitro allergy diagnostics. Lyophilized for maximum stability, the control offers a three year shelf life and reconstituted open-vial stability of 28 days when stored at 2°C to 8°C. Lyphocheck® Allergen sIgE Controls offers a superior option for routine quality control and will allow participation in Bio-Rad's Unity™ Interlaboratory Program, the worldwide peer group comparison program.

Bio-Rad Laboratories
Booth 2031



Lyphocheck® Hemoglobin A1C Linearity Set, Six (6) Level

The new Lyphocheck® Hemoglobin A1C Linearity Set from Bio-Rad provides six levels for HbA1c assay linearity verification. Assayed values are available for popular analyzers from Bio-Rad, Siemens, Roche, Beckman Coulter®,

Abbott, Ortho®, Tosoh, Trinity, and Pointe Scientific with target values ranging from 3.3% to 19.5% (NGSP). Customers can compare their results with both target values and peer group data through Bio-Rad's Linearity Web tool which can be accessed from QCNet™ (www.qcnet.com) under "LabTools™". Reports with useful graphics for linear regression and percent bias are available instantly and provide an easy to use solution to meet CLIA and CAP requirements for Calibration Verification and AMR Verification.

Bio-Rad Laboratories
Booth 2031



BioPlex® 2200 25-OH Vitamin D Kits* BioPlex® 2200 25-OH Vitamin D kit is a fully-automated, random access method for the quantitative measurement of total 25-hydroxyvitamin D in human serum. The kit features a broad reportable range, internal quality

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Bio-Rad Laboratories
Booth 2031

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Ravi Oruganty, PhD
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New Product Showcase



Access AccuTnI+3 troponin I for Access 2 and Dxl

The AccuTnI assay has a long history of proven clinical performance in the diagnosis of myocardial infarction (MI). The new Access AccuTnI+3 assay was evaluated through an extensive prospective clinical trial that enrolled over 1,900 subjects, and confirmed that our assay provides the clinical performance you need for optimal patient management. The AccuTnI+3 assay delivers the precision, and the clinical sensitivity and clinical specificity that are necessary to assist physicians with the diagnosis of MI.

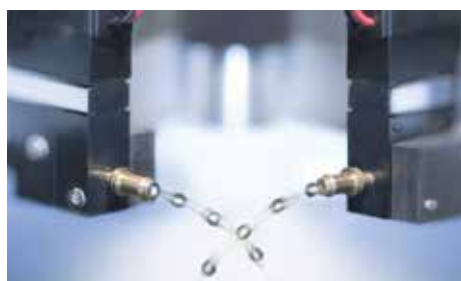
**Beckman Coulter
Booth 2812**



CLC6410™ High Volume Modular Chemistry Analyzer

The new, FDA-cleared CLC6410™ from Carolina Liquid Chemistries is a high volume, modular clinical chemistry analyzer capable of meeting the needs of large hospitals and clinical reference laboratories. The CLC6410™ has an economical, modular design that allows laboratories to expand its throughput as their needs grow. A single module can run up to 1600 tests/hr, while four modules can be joined to achieve 6400 tests/hr. All configurations include a 300 sample loader and intuitive software that automates numerous operational and quality control procedures. The CLC6410™ also features technological advances that save time, water, and energy. For more information, visit carolinachemistries.com/clc6410.

**Carolina Liquid Chemistries
Booth 1019**



Burkert Pneumatic Dosing Unit

The unique Pneumatic Dosing unit from Burkert – ultra precision and repeatability of fluid dosing come together with a flexible, customizable design giving you precisely the results that matter to you.

Features you can rely on:

- Defined volumes with high precision and repeatability up to +/- 2%
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- Highly integratable technology
- Media separation with high quality materials
- Single use wetted parts
- Easy to use robust system and less maintenance

Your customization options:

- Variable dosing volume to fit your application
- Different materials to fit your needs
- With or without internal pressure supply to fit your device
- Flexible design to fit your package

**Burkert Fluid Control Systems
Booth 3848**



Lyphocheck® Specialty Immunoassay Control

Lyphocheck® Specialty Immunoassay Control is a perfect companion for Liquichek™ Immunoassay Plus, Lyphocheck® Immunoassay Plus, and Liquichek™ Specialty Immunoassay controls. It offers specialty analytes such as Procalcitonin (PCT), 25-OH Vitamin D, intact PTH, Sex Hormone Binding Globulin (SHBG), and Erythropoietin (EPO). Lyphocheck® Specialty Immunoassay Control has a 3-year shelf life when stored at 2–8°C. Once reconstituted, most analytes are stable for 30 days (at 2–8°C). Lyphocheck® Specialty Immunoassay Control is part of the Unity™ QC program for benchmarking laboratory performance.

**Bio-Rad Laboratories
Booth 2031**



Vitamin D-direct™ Moderately Complex, No Pre-Treat

Vitamin D-direct™ is a moderate complexity assay for the CLC720 chemistry analyzer that requires no manual pre-treatment of the sample or reagent. A sample can run in 20 minutes (up to 400 tests/hr) and can be run in random access mode with other chemistries, eliminating the need for batch testing.

Vitamin D-direct™ measures total 25-Hydroxy (sum of D3 + D2), is traceable to NIST standard reference material, features wide dynamic range, improved precision, eliminates washing steps, and eliminates inaccurate results caused by “matrix effects.”

Competitively priced reagents and the economical CLC720 make Vitamin D-direct™ a great choice for laboratories seeking to reduce costs. For more information, visit carolinachemistries.com/vitaminD.

**Carolina Liquid Chemistries
Booth 1019**

UniPOC

UniPOC, the new CONWORX POC data management system successfully organizes the daily Point of Care Testing (POCT) operations of hospitals. In a single system it manages all accreditation requirements, presents data in a clear and structured format. Utilizing our core expertise in POCT interface development gained over 15 years, UniPOC guarantees a secure connection for more than 100 various POCT device models. The benefit of complete manufacturer independence and POCT experience allows you full flexibility in the selection of the appropriate Point of Care Testing devices. With extensive know-how in implementing over 1700 systems worldwide, we would be pleased to assist you in the organization of all your POCT in accordance with your exact requirements.

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**Conworx Data Solutions America, Inc.
Booth 1375**



Theater Slim PCR Cycler

<http://www.coyotebio.com/en/> Theater Slim PCR Cycler is the thinnest PCR cycler and is the only portable PCR cycler in the market, which makes the transition of PCR cycler from Desktop to Laptop. The operation of the Slim PCR Cycler is extremely simple and beats any other cyclers. This cutting-edge product will open new markets in education and molecular diagnostics.

Features:

- 12V DC Powered for field applications
- From Desktop to Laptop
- Touch Screen & EASY Operation
- Precise Temperature Control
- And Quiet

**Coyote Bioscience
Booth 2655**



Homogenous Assay for HDL Subfraction (HDL3)

Denka Seiken introduces a homogenous, direct assay for the fast and easy quantification of HDL3. The test does not require any off-line manual process such as for sample pretreatment but can run fully automated on routine clinical chemistry analyzers. The test employs two liquid, ready-to-use reagents and consists of two steps: the 1st step to selectively decompose chylomicron and VLDL, and the 2nd step to specifically measure cholesterol in HDL3 particles. HDL2 is also quantified by a simple subtraction of HDL3 from total HDL. Not for use in diagnostic procedures, for research use only.

**Denka Seiken Co., Ltd.
Booth 2052**



Homogenous Assay for Triglycerides in LDL Particles (LDL)

Denka Seiken introduces a homogenous, direct assay for the fast and easy quantification of triglycerides in LDL particles. The test does not require any off-

line manual process such as for sample pretreatment but can run fully automated on routine clinical chemistry analyzers. The test employs two liquid, ready-to-use reagents and consists of two steps: the 1st step to selectively decompose chylomicron, VLDL,

HDL and the 2nd step to specifically measure triglycerides in LDL particles. Not for use in diagnostic procedures, for research use only.

**Denka Seiken Co., Ltd.
Booth 2052**

See how we're shaping the lab of the future at AACC, booth 412

At Tecan, we believe that the most valuable assets in any lab are the scientists. By starting with people rather than experiments, we're developing equipment that not only improves performance but also ignites imaginations.

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 **TECAN.**

New Product Showcase



Ultra-sensitive TIA for Ferritin

Introducing a latex-enhanced turbidimetric immunoassay for the fast and easy determination of ferritin levels in blood samples with ultra-sensitivity. The new assay does not require off-line sample pretreatment or presample dilution, and it can give results in 10 minutes. The new test uses polystyrene particles coated with anti-human ferritin that form a complex with ferritin present in blood samples (serum or plasma) and can be measured with routine clinical chemistry analyzers. Available only outside the U.S.

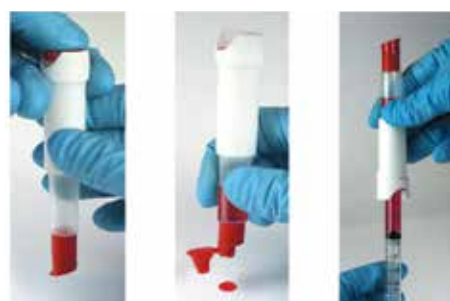
Denka Seiken Co., Ltd.
Booth 2052



25-OH Vitamin D Assay for Chemistry Analyzers

Diazyme's 25-OH Vitamin D Assay is intended for use in clinical laboratories for the quantitative determination of 25-hydroxyvitamin D (25-(OH)D) in human serum and plasma on automated chemistry analyzers. The tests provides rapid results with calibrator traceability to NIST 972a. The assay has excellent correlations to LC-MS/MS and leading 25-OH Vitamin D Immunoassays. Furthermore, the cost effective assay does not require dedicated immunochemistry analyzer. The test is based on the principle of α -complementation of the enzyme β -galactosidase and the competition between an enzyme donor-25-OH Vitamin D conjugate, an anti-Vitamin D antibody and the 25-OH Vitamin D content of a serum sample. For in vitro diagnostic use only.

Diazyme
Booth 1238



CueSee® Glucose

CueSee® Glucose is the new generation for validating precision and accuracy of glucose meters. Its real blood matrix makes it highly commutable and compatible with all glucose devices with minimal matrix effects. Its low imprecision makes it comparable with that of human whole blood.

ACU-Drop II is the packaging form key to deliver this control in a dual-chambered device keeping the various fractions separated to prevent reactions between components of the desired matrix. Push a button to allow fractions to combine, mix, and the sample is ready to use either from the built-in dropper bottle or by attaching a syringe.

Ideal for QC, calibration verification, proficiency testing, competency assessment, method validations and lot comparisons.

Eurotrol, Inc.
Booth 1144



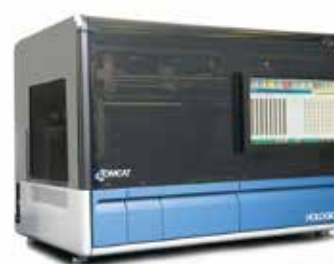
CueSee® VeriSTAT with CueSee® Online

CueSeeVeriSTAT all-in-one quality control and linearity product for use with Abbott i-STAT analyzers contains hematocrit, blood gases, electrolytes, and chemistries with a blue dye for visibility. It has optimal target ranges, longest shelf life and longest room temperature stability.

The product eliminates the need to use two separate cartridges with each control check, cutting time and costs. Meet regulatory requirements with three levels of quality control and the five level AMR/calibration verification panel.

Also included is CueSeeOnline, a free web-based data submission program for peer comparison, statistics and graphical presentations. Enhancement of the quality control program is further simplified via the data import tool.

Eurotrol, Inc.
Booth 1144



Tomcat™ Instrument

The Tomcat general purpose instrument performs a full range of processing activities for liquid-based cytology samples including:

- Barcode validation
- Vortexing
- De-capping
- Re-capping
- Aliquoting
- Reagent dispensing
- Incubating

The Tomcat instrument accommodates multiple sample types concurrently, with the ability to continuously load and unload samples, waste and consumables. By eliminating manual aliquoting steps, the Tomcat instrument can help laboratories improve workflow, free skilled labor for other tasks, improve confidence in positive sample ID/chain of custody, reduce the risk of cross-contamination, standardize the aliquoting process and reduce the risk of repetitive motion injuries.

Hologic, Inc.
Booth 4012



HRDR 200: Holomic Rapid Diagnostic Reader

The Smartphone based Holomic Rapid Diagnostic Reader or HRDR-200, is an economical, handheld, quantitative reader for lateral flow immunoassay tests. The reader features instant access to electronic health records, and real-time, wide area diagnostic data collection via a secure CLOUD service. It provides exceptional sensitivity and accuracy for your tests. The reader is ideal for point-of-care, telemedicine, public health monitoring, as well as for lab and factory needs. Available in both chromatographic and fluorescent versions, the reader also features Test Developer software for R&D and manufacturing of rapid tests. Reader customization to your requirements is fast, easy, and low cost.

Holomic LLC
Booth 2043



EasyCell Assistant Cell Image Analysis for Hematology

EasyCell Remote software can increase staffing efficiency in reviewing slides by physicians remotely.

Improve productivity by automatically locating white cells and pre-classifying them on a display, grouped by cell type. Red cells and platelets are also displayed for morphology and platelet estimates.

Lowers costs by reducing technologist time required to perform manual differentials.

Automates data access by providing convenient access to previous cell images to track patient status storing up to 10,000 slides on-board the system.

Assures accurate performance with built-in quality control software that verifies that nucleated cells are presented to the technologist for review. Checks for acceptable slide preparation and ensures quality results.

HORIBA Medical
Booth 2063



Moderately Complex Vitamin D assay for Pentra 400

Moderately Complex Vitamin D assay for Pentra 400 Chemistry System. This innovative Vitamin D assay enables clinical laboratories of virtually all sizes to run Vitamin D tests in house without the need for expensive specialized instruments. The high-throughput liquid stable assay provides precise test results, is user friendly, cost effective and has excellent correlation to the existing commercial methods. The HORIBA Medical Pentra 400 Vitamin D assay can help clinical laboratories improve their workflow and reduce their turnaround time for test results. This assay also eliminates the need for a customer to purchase expensive and highly complex instruments. This method of Vitamin D measures total 25-hydroxy Vitamin D (sum of 25-(OH)D3 + 25-(OH)D2) levels.

HORIBA Medical
Booth 2063



Hypoxic QC

Report pO2 results as low as 15 mmHg on any blood gas analyzer with the world's only available extremely low pO2 control, Eurotrol's Hypoxic QC. Critical for Analytical Measurement Range validation, it is now recommended by many instrument manufacturers and regulatory

inspectors. With its active hemoglobin buffering and real O2 saturation curve, Hypoxic QC has a 10 minute open ampule stability time and precision comparable to that of real patient blood.

It is ideal for the laboratory, point of care sites, respiratory departments and critical care areas such as ICU, OR,

ER or NICU. Also included with Hypoxic QC is CueSee®Online, a free web-based data submission service used for peer comparisons and to generate statistics, graphs and reports.

Eurotrol, Inc.
Booth 1144

New Product Showcase



Interferon-Omega Autoantibody RIA Test Kit†

KRONUS® is proud to offer the Interferon-Omega Autoantibody (IFN-ωAb) RIA Kit† for the accurate determination of autoantibodies to interferon-omega (IFN-ω) in serum. Please visit the KRONUS exhibit booth at number 1931 to learn more about our innovative product line. †For Research Use Only. Not for use in diagnostic procedures.

KRONUS, Inc.
Booth 1931

ARIES

ARIES™ – Available Soon. Revolution-izing Molecular diagnostics with a system that integrates seamlessly into the lean laboratory workflow, right out of the box.



Come by the Luminex® booth 738 to learn how ARIES™ can help maximize laboratory productivity with:

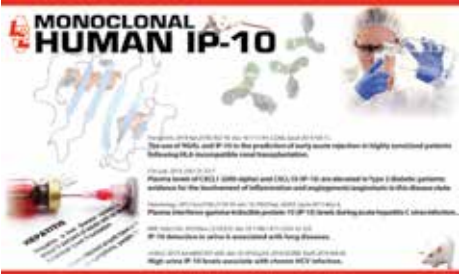
- Minimal footprint
- Menu consolidation
- Open platform and LDT capable
- Laboratory efficiency
- Improved healthcare

Ask about our growing IVD menu! The launch menu includes:

- ARIES HSV 1&2 Assay
- ARIES C. difficile Assay
- ARIES Norovirus Assay
- ARIES Flu A/B and RSV Assay
- ARIES GBS Assay

ARIES is the next generation of sample-to-answer testing, providing simplified workflow and accurate, rapid results. www.Luminexcorp.com.

Luminex
Booth 738



Mouse Monoclonal to Human IP 10

A monoclonal antibody specific to human IP10 was generated at Lampire through a rapid, efficient, hybridoma development program. All aspects of antibody generation were performed in-house in less than 8 weeks. The IP-10 antibody is available for purchase or license from Lampire. Lampire offers custom, reliable, antibody development to meet any client specification.

Lampire Biological Laboratories, Inc.
Booth 746



xTAG® CYP2D6 Kit v3 & xTAG® CYP2C19 Kit v3

Adverse Drug Reactions (ADRs) are a leading cause of morbidity and mortality in the U.S. One of the reasons attributed to the occurrence of ADRs is the prescription of more drugs per patient and an increase in the combination of drugs being used.

Identification of CYP2D6 & CYP2C19

genotypes may help clinicians tailor drug treatment to patients by selection of appropriate therapies.

The xTAG® CYP2D6 and xTAG CYP2C19 assays are IVD tests that allow detection of major alleles associated with variant drug metabolism. Both assays have reported high reproducibility and accuracy providing confidence in results.

These assays are not indicated for stand-alone diagnostic purposes, nor intended to be used to predict drug response or non-response.

Luminex
Booth 738

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Diagnostics—it's at the heart of decision making. Every day, clinicians depend on the power of science to make better and more informed decisions. And every day, their patients depend on timely, accurate test results to live longer, healthier lives. That's why clinical excellence isn't optional. It's a requirement.

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2014 AACC Annual Meeting & Clinical Lab Expo

EXHIBITING AS BOOTH NUMBER
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Zinexts Life Science Corp.	3873
Zyomyx, Inc.	4163

—List as of 7/1/14

New Product Showcase



Zinc Transporter 8 Autoantibody ELISA Test Kit[†]

KRONUS[®] is proud to offer the Zinc Transporter 8 Autoantibody (ZnT8Ab) ELISA Kit[†] for the accurate determination of autoantibodies to zinc transporter (ZnT-8). Please visit the KRONUS exhibit booth at number 1931 to learn more about our innovative product line. [†]For research use only. Not for use in diagnostic procedures.

KRONUS, Inc.
Booth 1931



LeadCare Ultra

The LeadCare[®] Ultra[™] Blood Lead Testing System is designed to provide clinical laboratories unmatched ease of use with prepackaged reagents and electronic calibration. Offering both barcode scanning and LIS compatibility in a compact footprint, it provides rapid, cost-effective results for labs of all sizes and complexity.

Bring rapid, cost-effective lead testing to your lab with LeadCare Ultra

Easier to set up, run and maintain than GFAAS

- Electronic calibration: Seconds to complete, no standards, no drift.
- Simple interface: Easy to use with no experience needed
- FDA cleared: No method development required

More cost-effective and flexible than send-outs

- Faster turn around time:
- No batching needed and results in 3 minute
- Simplified workflow: Barcode reader and LIS connectivity

Magellan Diagnostics, Inc.
Booth 4252



IS 1200 Automatic Chemiluminescence Analyzer

IS 1200 Automatic Chemiluminescence Analyzer and the companion reagents are the combination of the advanced precision analytic instrumentation and magnetic microparticle based enhanced immunoassay technology. The assay dynamic range is widened and the sensitivity of detection is also increased. The assay speed is improved by the patented technologies. The flexibility of assay choices and reliability of measurement are the characteristics of IS 1200 system. Quality-Assured Disposable sample tips and reaction cuvettes avoid cross-contamination. High-quality reagents guarantee the reliability of test results. Better Performance/Cost IS 1200 system not only ensure the reliability of test result, but also meets the requirements of reducing costs.

MAKER Biotechnology
Booth 859



SE4710 Scan Engine

Empower your smallest devices with next generation imaging performance. In clinical lab applications, speed and accuracy of scanning are of paramount importance. The new SE4710 scan engine from Motorola Solutions provides the highest levels of speed while maintaining scanning accuracy, all in the smallest form factor available.

Your product designs can offer the sleek lines today's customers demand. And with our patented, proprietary PRZM Intelligent Imaging technology, industry leading decoding algorithms and advanced focusing, optical and illumination systems, your customers can count on class-leading high-performance data capture they need.

Motorola Solutions Inc.
Booth 2678



Hemoglobin A1c Reagent, Stabilized R2 Component

Pointe Scientific, A MedTest Company, introduces an improved reagent for the direct determination of Hemoglobin A1c on general chemistry analyzers.

The methodology uses a highly specific monoclonal antibody to HbA1c with HbA1c determined by immunoturbidimetric analysis. The R2 has been stabilized so that it is now ready to use. Mixing two separate R2 components is no longer necessary.

Automated sample preparation (RBC lysing) can be performed on many chemistry analyzers providing a totally automated test system.

The Pointe Scientific Hemoglobin A1c reagent is NGSP certified, liquid-stable, and has been shown to be accurate and precise.

Liquid Calibrators and Controls are also available.

MedTest
Booth 3517



Stat Profile Prime[®] CCS

Nova Biomedical announces the latest in critical care blood gas analyzers—the Stat Profile Prime[®] CCS, featuring ZERØ[™] maintenance cartridges and MicroSensor technology for exceptional value in a critical care whole blood analyzer. Stat Profile Prime's ZERØ maintenance cartridge technology consists of individual cartridges for biosensors, calibrators, and liquid quality control. This design optimizes the life of each cartridge; improves analyzer uptime; and eliminates the waste, downtime, and higher costs of older combined calibrator/sensor cartridge systems. Stat Profile Prime delivers a full 10-test profile in just 60 seconds including pH, PCO₂, PO₂, Na, K, iCa, Cl, Glucose, and Lactate.

Nova Biomedical Corporation
Booth 2618



Orchard[®] Sequoia[™] Enterprise-class LIS

Orchard[®] Sequoia[™] is a new enterprise-class LIS designed to be scalable to accommodate large volumes of laboratory testing across multiple laboratories and departments performing clinical, microbiology, molecular, and pathology testing.

- Enterprise-class LIS utilizing Microsoft[®] SQL[®] Server Enterprise Edition Architecture
- Single Application with a Segmental Design, including Clinical, Anatomic Pathology, & Molecular
- Analytics Support Business Intelligence & Population Health Management
- Rules Enhance Productivity & Reduce Errors
- Sample Tracking & Supply Management
- Sophisticated Image Management Automation
- SQL Server AlwaysOn technology for High-availability & Disaster Recovery
- Big Data Archival Storage for Mining Unstructured Data

Orchard[®] Sequoia[™]
Booth 4422



cobas u 601* Urine Analyzer

Roche introduces the cobas u 601 urine analyzer, a fully automated solution for urine strip testing in mid- to high-volume labs. Designed to automate all manual steps and deliver high-quality results using proven reagent test strips based on 50 years of experience and innovation. *Not available for sale in the US. A 510(k) submission is pending.

Roche Diagnostics
Booth 1209



Cystatin C Liquid Stable Reagent*

Pointe Scientific, A MedTest Company, introduces a new reagent for the determination of Cystatin C in serum or plasma.

The reagent is liquid stable and ready to use with a shelf life greater than 1

year. This latex enhanced immunoturbidimetric method is ready to use on your clinical chemistry analyzer.

The Cystatin C reagent has a linear range of 0.2 – 8.0 mg/L and obtains excellent precision: Within Run precision is less than 5.6 %, Between Run

precision is less than 4.5%.

Calibrators and controls for the assay are also available. *Not FDA Cleared; Not for sale in the United States.

MedTest
Booth 3517

MuDT™ Technology

One Channel, Multi-C_t in Real-time PCR

2014 AACC
Visit us at Booth

435

The world first Real-time PCR technology for both high multiplexing and quantification in a single channel

1. Multi-C_t (threshold cycle) values in a single channel

- Accurate measurement of both amount and number of multiple pathogens present in a specimen
- Shorter turnaround time (TAT) because melting curve analysis after amplification is not necessary

2. Simultaneous detection and quantification of multiple targets in a single reaction

- Comprehensive information for improved patient care
- Reduction in healthcare costs and labors

3. Each C_t value of co-infected pathogens equals to that of single target amplification

- High sensitivity even in co-infected specimens

4. SNP genotyping in a single channel

- Wild type or mutant type homozygous, or heterozygous results in a single reaction with short TAT

5. Multiple channels not necessary for detection and quantification of multiple targets

- Easy to select fluorescent dyes regardless of real-time PCR instrument types
- No more crosstalk between channels by selecting channels distanced from each other
- Free from well-to-well and instrument-to-instrument variations



○ Multi-C_t in a single channel for detection & quantification of multiple targets

Clinical sample No.	Current Tm-based Assay								MuDT™-based Assay (C _t value)							
	FAM		HEX		Cal Red 610		Quasar 670		FAM		HEX		Cal Red 610		Quasar 670	
	UU	UP	MG	MH	NG	CT	TV	IC	UU	UP	MG	MH	NG	CT	TV	IC
1	+	+	-	+	-	-	-	+	35.8	29.8	-	32.7	-	-	-	28.5
2	-	-	+	+	-	-	-	+	-	-	28.3	35.9	-	-	-	29.0
3	-	+	-	-	-	+	-	+	-	26.2	-	-	-	28.6	-	29.1
4	-	+	-	-	-	+	-	+	-	36.7	-	-	-	26.3	-	30.2
5	-	+	-	+	-	+	-	+	-	28.1	-	37.7	-	32.5	-	28.7
6	+	+	+	-	-	-	-	+	35.1	32.6	32.1	-	-	-	-	32.1
7	-	+	-	-	-	+	-	+	-	29.4	-	-	-	31.9	-	28.5
8	+	+	-	+	-	-	-	+	37.2	35.5	-	31.9	-	-	-	31.2

► UU : *U. urealyticum*, UP : *U. parvum*, MG : *M. genitalium*, MH : *M. hominis*, NG : *N. gonorrhoeae*, CT : *C. trachomatis*, TV : *T. vaginalis*, IC : Internal Control



www.seegene.com

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E-mail: eu@seegene.com

New Product Showcase



Acrodisc® WBC Premium Syringe Filter

Pall Life Sciences New Acrodisc® white blood cell (WBC) premium syringe filter is a key sample prep tool for the laboratory. Pall Life Sciences Acrodisc WBC filter contains Pall's patented Leukosorb® media. Leukosorb is a fibrous matrix that uses a multimodal approach to capture and recover leukocytes from whole blood samples while allowing RBCs and platelets to flow through the membrane. This filter provides a simple and easy method to separate blood cells for a variety of research applications including: cell receptor analysis, antigen specificity, antigen modulation studies, cell therapy and stem cell research. To learn more about our WBC Acrodisc Filter please visit our booth 3540 or visit our website at www.pall.com.

Pall Life Sciences
Booth 3540



A2 Multiplex IA Slide

QuantiScientific's new A2® Multiplex IA slide represents a unique approach for creating custom antibody or antigen microarrays without the need to print. Based upon the company's Oligo-Link-it technology, the slide contains 14 unique capture oligos in each of its 8 sub-arrays. Complementary activated oligos are provided in a spin column-based conjugation kit enabling the preparation of up to 14 unique oligo-antibody conjugates. A hybridization kit is used to assemble the antibody or antigen arrays for use in multiplex immunoassays. The preparation of a quantitative multiplex immunoassay can be completed in 2.5 days. The slides may be read using a variety of microarray imaging readers or scanners.

QuantiScientifics LLC
Booth 3553



Sofia hCG FIA

Sofia hCG FIA (Fluorescent Immunoassay), with Kinetic Check™ technology detects human Chorionic Gonadotropin (hCG) in urine specimens. In addition to excellent performance and accuracy, the Sofia hCG FIA provides distinct advantages over conventional rapid hCG tests. The test uses monoclonal antibodies specific to the beta subunit of hCG to ensure greater specificity. The Kinetic Check technology gives the user greater flexibility, up to 5 minutes, before placing the Cassette into Sofia for analysis. Quick, objective and automated results help eliminate operator to operator variability and reduce transcriptional and billing errors. Sofia also prints and/or sends results to the LIS, allowing for easy transfer of patient records.

Quidel Corporation
Booth 445



cobas® CT/NG v2.0 Test

This highly sensitive and specific test for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae DNA in symptomatic and asymptomatic patients is FDA-cleared for use with six specimen types. It may be used with male or female urine, self-collected vaginal (collected in a clinical setting), clinician-collected vaginal, and endocervical swab specimens, all collected in cobas PCR media, and with cervical specimens collected in PreservCyt® solution. The fully automated, real-time PCR-based test is performed on the cobas 4800 system and includes an automatic internal control and the AmpErase® enzyme, providing laboratories with accurate, efficient results.

Roche Diagnostics
Booth 1209



cobas® HPV Test

Clinically validated in the landmark ATHENA trial, this DNA-based human papillomavirus test is now FDA-approved for first-line primary screening for cervical cancer in women 25 and older. It is the first HPV test approved for this expanded indication in the U.S. The cobas HPV Test provides three results in one test: individual results for HPV 16 and 18—the genotypes responsible for 70 percent of cervical cancer—and a pooled result for the 12 other high-risk types, all in one run, from one patient sample. The test is performed on the cobas 4800 System, which offers walk-away automation of nucleic acid purification, PCR set-up and real-time PCR amplification and detection.

Roche Diagnostics
Booth 1209



cobas® 8100 Automated Workflow Series

The cobas® 8100 automated workflow series delivers automation without compromise by providing multilevel, bidirectional sample transport lines that maintain predictable TAT during peak testing hours with two-story system architecture that separates full sample holders from empty ones. The workflow your way feature enables the instrument to conform to the individual needs of the lab by allowing users to conduct workflows using primary samples, aliquoting, or a mixture of both. Add-on buffers allow for flexible mid-term storage that automates the entire add-on/repeat testing process.

Roche Diagnostics
Booth 1209



Elecsys® Calcitonin Immunoassay

Roche introduces the Elecsys® Calcitonin immunoassay, which is intended for use as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism in combination with other clinical and laboratory findings. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Roche Diagnostics
Booth 1209



Elecsys® CMV IgG Assay

The Elecsys® CMV IgG assay, which is an in vitro qualitative test for the detection of IgG antibodies to CMV in human serum, lithium-heparin plasma, K2-EDTA plasma and K3-EDTA plasma, is used as an aid in determining the serological status to CMV in individuals in which a CMV IgG test was ordered, including pregnant women.

Performance characteristics have not been evaluated in immunocompromised or immunosuppressed individuals. It is not intended for use in neonatal screening, point-of-care facilities or screening of blood and plasma donors.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Roche Diagnostics
Booth 1209



Elecsys® HBeAg Immunoassay

Roche introduces the Elecsys® HBeAg immunoassay, which is intended for the in vitro quantitative determination of Hepatitis B e antigen in human serum or plasma (K2-EDTA, lithium or sodium heparin, and sodium citrate) in adult

patients with symptoms of Hepatitis or at risk for Hepatitis B virus (HBV) infection. Combined with other serological and clinical information, this test may be used for lab diagnosis of acute or chronic Hepatitis B or recovery from Hepatitis B infection.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the MODULAR ANALYTICS E170 analyzer.

Roche Diagnostics
Booth 1209



Miniature Solenoid Valves
Light Weight, Low Power and Small Footprint



Miniature Diaphragm Isolation Valve
Particulate and Crystallization Resistant



Parker Smart Syringe Pump
High Accuracy and Precision Non Pulsatile Flow



Miniature Diaphragm Liquid Pumps
Highly Inert Waste Pumps



Inert Isolation PTFE Valves
Harsh Reagents/ Bleach/Cleaning

Together, we can build smarter, more efficient assays.

Parker Precision Fluidics is a leading supplier of miniature fluidic components and system solutions integral to the world's clinical chemistry instrumentation. Whether the system is moving the sample, reagents, bleach or waste, Precision Fluidics valves and pumps can solve your problems. More equipment manufacturers turn to Parker when quality and reliability are critical to their instrument.

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New Product Showcase

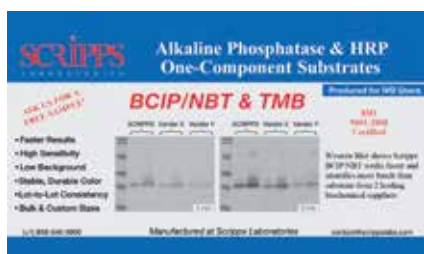


Product Name: A1c iGear

A1c iGear is an HbA1c analyzer for diabetes. This system offers results as accurate as lab tests just like its predecessor, A1c GEAR (k130014) and has more advanced features. Its all-in-one cartridge is ideal for point-of-care settings. The key features include:

- Compact and simple design
- Result available approximately in 6 minutes
- Easy and simple operation by the touch panel
- Only 1µL of whole blood required
- Excellent correlation with established methods
- 3 samples can be loaded with results being available sequentially
- Patient ID registration capability
- Bidirectional communication port (RS232) and USB external port

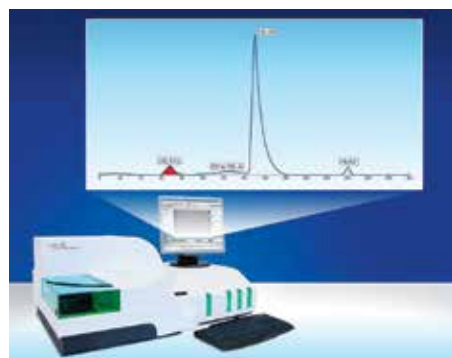
Sakae Corporation
Booth 2345



Alk Phos & HRP Substrates from Scripps Labs

Scripps Laboratories has developed high quality, one-step chromogenic substrates for alkaline phosphatase (BCIP/NBT) and HRP (TMB). These ready-to-use solutions are designed for membrane-based assays like western blot, PCR and dot blot. Results appear quickly, within 3-5 minutes, and color development is stable, with negligible fading over time. In a side-by-side comparison, Scripps BCIP/NBT worked faster and identified more bands than did substrate from 2 leading biochemical suppliers. And when you buy from Scripps, you enjoy the benefits of working directly with the manufacturer: ISO Certification, controlled production procedures to avoid back-orders, and stringent quality control for lot-to-lot consistency. Contact us for a FREE SAMPLE.

Scripps Laboratories
Booth 3954



Capillary HbA1c Assay

The next generation of HbA1c testing, based on the principle of capillary separation, provides high resolution and clear-cut and precise separation of HbA1c and HbA0 fractions. Capillary separation allows the elimination of direct interferences on the A1c fraction (carbamyated, acetylated, and labile hemoglobins, plus common Hb variants, such as, HbS, HbC, HbD, HbE) as well as the analytical exclusion of HbA2 and HbF from the measurement. It also allows for high accuracy of results and low CVs. Capillary 2 Flex Piercing and Minicap Flex Piercing systems, with whole blood-closed tube capacity, offers HbA1c testing with the best balance in precision, robustness, and throughput, along with the ability to run protein, immunotyping, hemoglobinopathy, and CDT testing.

Sebia
Booth 317



Minicap Flex Piercing Instrument

The Minicap Flex Piercing has been FDA cleared for HbA1c and protein testing. The Minicap Flex Piercing instrument uses proven capillary separation technology to provide clear-cut and precise results for the newest generation in HbA1c testing. The system's small footprint is able to offer flexibility, scalability and full automation to the low to mid volume laboratories. Place a primary tube on the system and walk away; whole blood samples are automatically inverted prior to analysis, continuous access sample wheel allows for the addition of samples at any time. True positive sample ID is achieved with full traceability. A complete test menu also includes whole blood hemoglobinopathy* testing, immunotyping* and CDT*.

*Under development for U.S. market.

Sebia
Booth 317



Sekisui Diagnostics SK™500 Chemistry System

The SK™500 is a new chemistry system from a global leader in clinical chemistry reagents. A high-efficiency system combined with Sekure™ assay performance, it is ideal for moderate-volume laboratories. The SK500 provides exceptional throughput with minimal use of space and low water consumption. The system delivers up to 580 tests per hour in a small footprint. The intuitive user interface enables simple operation. For more information, visit booth #4025 or email us at questions@sekisui-dx.com. The SK logo and Sekure are trademarks of Sekisui Diagnostics, LLC

Sekisui Diagnostics LLC
Booth 4025



Sias AG
Booth 2454

CAL 8000 Cellular Automation Line

CAL 8000 Cellular automation line integrates the BC-6800 hematology analyzer and SC-120 slide maker & stainer into one line. There are two tracks in the system automatically deliver the samples to different analyzers for rerun and reflex according to the pre-defined criteria by users. After users input the review criteria, the tracks deliver the abnormal samples to the SC-120 for slide making and staining as well.

All reagents as well as the pneumatic unit could be set in the trolley below respective BC-6800 or SC-120. The CAL 8000 is a scalable system, 1-4 units of BC-6800 and 0-2 units of SC-120 could work together to fit different sizes of labs.

Shenzhen Mindray Bio-Medical Electronics
Booth 3618



PCR Setup Solution

Are you looking for a small pipetting robot to combine with your PCR reagents to create a tailored package? Get to know Xiril's PCR Setup Solution! – a small liquid handling workstation for automated PCR setups. This ideal fusion of liquid handling and dedicated software leaves you enough flexibility to be composed the way you need it. The risk of cross-contamination during PCR setups is highly reduced and process safety is given due to the built-in decontamination features and the use of robotic filter tips. The PCR Setup Software fully "speaks PCR": serial dilutions, calculations of quantities and complete workflow data processing from input- to output file. Let us support your OEM project configuring a comprehensive PCR Setup Solution!



4500MD

The AB SCIEX Triple Quad™ 4500MD LC/MS/MS system is a high performance, easy to use, bench top triple quadrupole mass spectrometer designed for routine in vitro diagnostic testing laboratories. This instrument provides superior quantitative performance, excellent robustness, and long term stability, enabling laboratorians to develop tests for even the most demanding clinical applications.

AB SCIEX Diagnostics
Booth 3418

Viva-ProE™ System*

The Viva-ProE™ System* with Emit® technology is a dedicated drug-testing platform that provides drug-testing performance on a reliable, next-generation benchtop system. It is engineered to meet the demands of laboratories by offering a self-contained design with onboard waste and water storage, compact footprint, and intuitive software in a touchscreen-command center. * Under development. Not available for sale. Future



availability may vary by country.
Siemens Healthcare Diagnostics
Booth 509

Guided Poster Tours Schedule

Tuesday

10:00 am

Tour Leader: Melissa Snyder
Organized by: Clinical & Diagnostic Immunology Division

10:00 am

Tour Leader: William Winter
Organized by: Endocrinology Division

2:00 pm

Tour Leaders: Mike Stocum; Peggy Robinson
Organized by: Personalized Medicine Division

3:00 pm

Tour Leader: Yan Zhang
Organized by: Clinical & Diagnostic Immunology Division

Wednesday

10:00 am

Tour Leader: Sarah Brown
Organized by: Critical & Point-of-Care Testing Division

10:00 am

Tour Leaders: Kris Kulkarni; Sridevi Devaraj; Ping Wang
Organized by: Lipoproteins & Vascular Diseases Division

10:00 am

Tour Leader: Sharon Geaghan; Sihe Wang
Organized by: Pediatric & Maternal-Fetal Division

11:00 am

Tour Leader: Vincent Ricchiuti
Organized by: Clinical Translational Science Division

11:00 am

Tour Leader: Jennifer Snyder
Organized by: Industry Division

2:00 pm

Tour Leaders: Joshua Bornhorst; Dan Chen
Organized by: Management Sciences & Patient Safety Division

2:00 pm

Tour Leaders: Mark Kellogg; Qing Meng
Organized by: Nutrition Division

2:00 pm

Tour Leaders: Jim Ritchie; Patrick Kyle
Organized by: Therapeutic Drug Management & Toxicology Division

3:00 pm

Tour Leader: Alan Wu
Organized by: Biomarkers of Acute Cardiovascular Diseases Division

Posters

» from page B-1

attendee is an opportunity to practice explaining a scientific paper to AACC members, exchanging knowledge, and fostering new collaborations between AACC members," he said. "The guided poster tour during the poster presentation session is a fabulous chance to make a difference by having some posters in the [spotlight]."

James Ritchie, PhD, is also participating in the poster tours for

the second year. The sessions are of particular benefit to student attendees because tour leaders offer detailed explanations of the projects. After each session, tour participants have the opportunity to ask questions and engage in a lively discussion with the tour leader and one another. "It's especially good for students," he said. This year, annual meeting attendees can choose from among 13 guided poster tours, which will take place on Tuesday and Wednesday in the Exhibit Hall of the convention center. In order to participate in a guided poster tour, division leaders

and attendee participants should assemble outside the entrance to the poster session in McCormick Place about 10–15 minutes prior to their walk. "The guided tour usually takes less than an hour and occurs when the poster presenter is not supposed to be at the poster," Ricchiuti said.

Ricchiuti will lead a tour of the Clinical Translational Science division on July 30 at 11 a.m. Ritchie, meanwhile, will lead a tour for the Therapeutic Drug Management & Toxicology division on July 30 at 2 p.m.

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The *First* and *Only* Vitamin D Assay for Clinical Chemistry Analyzers

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New Product Showcase



RAPIDComm® Data Management System*

Siemens offers an ecosystem approach to point-of-care testing (POC) with RAPIDComm® Data Management System software version 5.0. The new version of Siemens' informatics solution for managing POC testing introduces key enhancements to help satisfy compliance requirements and efficiently manage operator training and certification. It includes support for a web application and an interface to PEP Administrator, Siemens' web-based learning-management system. *Product availability varies by country.

**Siemens Healthcare Diagnostics
Booth 509**



ELITE Grade Enzymes from Sigma-Aldrich

Introducing our ELITE grade enzymes designed specifically for IVD manufacturers. As part of our Enhanced Quality Profile program, these enzymes cater to the stringent needs of today's diagnostic manufacturing environment for supply chain transparency, design control and change control notification. Why not source from the original biotechnology manufacturer with the experience and resources to provide you with the product quality, documentation of Supply Chain Transparency and change control parameters you need. To learn more about ELITE grade enzymes such as Proteinase K, Thrombin, γ-Globulins, Thymidine phosphorylase and Pepsin visit sigma-aldrich.com/diagnostics or contact your Sales Rep to learn about our offer for ELITE products.

**Sigma-Aldrich
Booth 460**



DBS Autosampler™

The new DBS Autosampler™ from Spark Holland comprises two main elements: The FTD™ system and a card handling robot. Flow-Through Desorption (FTD™) is an innovative patented technology for extraction of Dried Blood Spots without punching discs out of the DBS filter card. FTD™ enables automation of the entire workflow for Dried Blood Spot (DBS) analysis by LC-MS/MS. A uniquely designed high pressure clamp allows desorption of the sample from the clamped spot directly into a (SPE)/LC/MS/MS system – or other analytical systems. The system also features: clamp size range of 2 - 8 mm, camera for bar-code reading and spot location, automated internal standard addition and DBS card capacity ranging from 96 (standard) up to 350, and more.

**Spark Holland B.V.
Booth 4463**



CD-Chex CD117™ Plus Flow Cytometry Control

CD-Chex CD117 Plus is the first and only commercially available positive procedural control for CD117, CD25 and CD71. It was developed with characteristics similar to the abnormal peripheral blood leukocytes often found in a hematolymphoid neoplastic patient sample. The product possesses surface CD117, CD25 and CD71 that are detectable with fluorescent monoclonal antibodies by flow cytometry. CD-Chex CD117 Plus monitors reagent staining, erythrocyte lysis, sample preparation and instrument performance. For research use only. Not for use in diagnostic procedures.

**Streck, Inc.
Booth 1920**



CD-Chex Select™ Immuno-phenotyping Control

CD-Chex Select is the first and only commercially available flow cytometry control with the selected group of CD markers used for immunophenotyping. It is an assayed positive procedural control for reagent staining, erythrocyte lysis, sample preparation and instrument performance. CD-Chex Select eliminates the need for labs to hold and validate patient samples to use as a control for the evaluated markers, saving lab time and money. CD-Chex Select is available in 3.0ml plastic cap-pierceable vials and is compatible with automated sample preparation instruments. Open-vial stability is 30 days. For Research Use Only. Not for use in diagnostic procedures.

**Streck, Inc.
Booth 1920**



UA-Cellular® Complete Urinalysis Control

UA-Cellular Complete is a comprehensive urinalysis control containing both chemistry analytes and cellular components to more closely mimic a patient sample. Designed for the Siemens CLINITEK Atlas® and Sysmex® UF-1000i™ combined urinalysis system, technologists can use one control to test both instruments. Packaged in a convenient 120ml squeeze bottle with a flip-top cap that accurately dispenses the amount of control needed into sample tubes without waste. Open-vial stability is 30 days.

**Streck, Inc.
Booth 1920**



StabilZyme® Protein-Free AP Stabilizer*

Eliminate interference and cross-reactivity with SurModics StabilZyme® Protein-Free Stabilizers, now available for AP conjugated proteins. New StabilZyme Protein-Free AP Stabilizer delivers performance comparable to the original StabilZyme Protein-Free Stabilizer (SZPF; retained activity of 86% for more than 2 years). Both of these breakthrough solutions offer performance similar to the market-leading StabiZyme HRP Conjugate Stabilizer, only in protein-free formulations. Manufactured in ISO 13485:2003 and 9001:2008 certified facilities, SurModics stabilizers meet your stringent quality and manufacturing requirements. Rely on SurModics for stabilization success. (*For further processing.)

**SurModics IVD
Booth 1938**



Cavro® Omni Robot OEM Liquid Handling System

The Cavro Omni Robot is a general purpose liquid handling component designed to offer reliable pipetting for a wide range of applications. Its flexible, modular construction makes the Cavro Omni Robot easy to integrate into almost any instrument design, allowing the user to choose any combination of X-Y, Y-Z or XYZ axes, plus a range of options to suit their pipetting needs. The robot's new Embedded Command Processor Mode allows direct, OS-independent communication for precise control and coordination of axis movements and liquid handling operations, helping to simplify system integration. These latest updates further extend the versatility of the Cavro Omni Robot, providing exceptional flexibility for OEM liquid handling applications. www.tecan.com/omnirobot.

**Tecan
Booth 421**



POCkit

Siemens POCkit™ is a new web based education solution designed for healthcare professionals performing point-of-care testing. It provides immediate access to the latest topics, videos, and links to access information on how to use Siemens POC

testing solutions. Siemens POCkit connects people to knowledge, with just-in-time performance support, anytime, anywhere from any device. Navigate to www.siemens.com/pockit to learn more.

**Siemens Healthcare Diagnostics
Booth 509**

New Product Showcase



LPM Inert Solenoid Pump

The Lee Company's new LPM Series Inert Solenoid Pump was designed to offer greater design flexibility, and significant cost savings to the medical and scientific industries.

The LPM Pump features a revolutionary port head design that allows tubing connections and manifold mounting. This enables the designer to test the fluidic system using connections to soft 1/16" tubing, and then once the system design has been finalized, the same pump can be manifold mounted using standard O-rings.

Available in 10 μ L and 25 μ L models, the LPM Pump features low power consumption and a contoured end cap which provides secondary connector retention and is compatible with standard AMP connectors.

The Lee Company
Booth 3745



Thermo Scientific™ iRC Pro 1.0 Meta Calculation Software

Thermo Scientific™ iRC Pro software is an automated data processing software for SRM based data. It calculates the concentration of target analytes using mass ion ratios and performs meta calculations using user-defined formula; removing common errors in post-analytical data processing. iRC PRO software saves data processing time and eliminates transcription errors from manual calculations to ensure quick, efficient and accurate data processing results.

Thermo Scientific
Booth 1221



Thermo Scientific™ TraceFinder™ 3.2 software

Thermo Scientific™ TraceFinder™ 3.2 software is an easy-to-use, workflow-driven software for laboratories performing quantitation and targeted screening using GC-MS and LC-MS. TraceFinder software increases productivity with powerful method development, simplified data acquisition and comprehensive data review. TraceFinder software is a single software for nominal mass and HRAM data analysis for screening and quantitation. You can do quantitation with full scan and confirmation with MS2 spectra, forward and reverse library searches, rapid data review and customizable reporting.

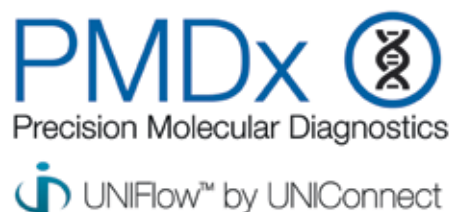
Thermo Scientific
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Thermo Scientific™ Q Exactive™ HF Benchtop Orbitrap Mass Spectrometer

The Thermo Scientific™ Q Exactive™ HF mass spectrometer is the next generation HR/AM bench top system with an ultra-high-field Orbitrap detector, providing greater speed, productivity and confidence for both qualitative and quantitative workflows. It takes identification and quantitation to a new level, making it possible to identify, quantify, and confirm in a single analysis with a single instrument.

Thermo Scientific
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ciconnect

UNICONnect's PrecisionMDx (PMDx) is for lab professionals seeking a focused solution for their CAP/CLIA certified molecular laboratory operations. Ideal for MDx, CDx and PGx pursuits. Standalone software or integrated with existing LIS/LIMS and billing infrastructure. PMDx will support your molecular requirements from sample entry to final report. Designed to manage the depth and complexity of "omic" science, adaptable to accommodate change in this dynamic field, PMDx scales from single lab to global network. Installed locally or hosted on the Cloud. Based on the powerful UNIFlow™ Laboratory Process Management Platform, UNICONnect specializes in rapid implementation. See PMDx at Booth 2078. Or request an appointment at info@uniconnect.com.

Uniconnect
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UTAK reveals NEW Steroids Control in SMx® Serum

UTAK proudly announces the launch of our Steroids Control manufactured with UTAK's proprietary SMx® Serum. This revolutionary Steroids Control product is offered in individual packs for Levels 1, 2, 3, 4 and a Negative Control. There are seven analytes of interest: Corticosterone, Cortisol, Cortisone, Dehydroepiandrosterone (DHEA), Progesterone, 17 α -Hydroxyprogesterone, and Testosterone at clinically relevant levels for most testing methodologies.

UTAK - beyond measure, goes beyond the status quo. UTAK has developed Specialty matrices for Oral Fluid, Hair, Sweat, Urine, and now Serum is added to the UTAK SMx® line to help Laboratories with their most unique testing requirements.

UTAK, it's time to take a closer look, at booth 4314.

UTAK Laboratories, Inc.
Booth 4314



ZEUS Borrelia VlsE1/pepC10 IgG/IgM Test System

ZEUS Scientific's new Borrelia ELISA Test System uses a combination of VlsE1 & pepC10 antigens to test for Lyme Borreliosis simultaneously in the same assay. It's an approach that increases specificity & sensitivity, & allows you to test with greater confidence at all stages of Lyme disease according to R.M. Bacon et al. Improved Serological Testing for Lyme Disease. JID 2003; 187:1187-1199. The Test System also helps to reduce lab costs for unnecessary confirmatory tests, such as Western Blot. The test is capable of being run in a manual, semi-automated, or fully automated capacity. Go to www.zeusscientific.com/lyme to sign up for our trial evaluation program for qualified customers and to learn more information. Test with confidence.

Zeus Scientific
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ZEUS Scientific Broad Menu for HSV Test Systems

ZEUS Scientific offers HSV Test Systems on 3 platforms, ELISA, IFA, & AtheNA Multi-Lyte®. Our ELISA & AtheNA Multi-Lyte® Test Systems feature many universal protocols & reagents, simple automation capability, & a patented SAVe Diluent® to assure no well has been missed. Our ELISA Test Systems also utilize breakaway, removable test wells in a microplate format to allow the most efficient workflow for the laboratory. Our broad menu offers several FDA cleared Test Systems, HSV gG-1, HSV gG-2, HSV-1 IgG, HSV-2 IgG, & HSV-1&2 IGM. Our newest addition to the HSV family includes a CE & Health Canada approved HSV gG1&2 IgG Test System. For our complete list of HSV products, please visit our website at www.zeusscientific.com/products to learn more.

Zeus Scientific
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Please visit us at
Booth #1931



Autoimmune Diagnostics

For nearly 30 years, KRONUS has provided specialized immunoassay test kits to medical professionals at the world's most respected laboratory facilities. Our current product offering encompasses test kits for measurement of the following:

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Acetylcholine Receptor Antibody (AChRAb):

- Binding Antibody
- Blocking Antibody

Voltage-Gated Calcium Channel Antibody (VGCCAb)

ISLET CELL AUTOIMMUNITY

Glutamic Acid Decarboxylase Antibody (GADAb)

IA-2 Autoantibody (IA-2Ab)

Insulin Autoantibody (IAA)

THYROID

Thyroglobulin Antibody (TgAb)

Thyroid Peroxidase Antibody (TPOAb)

TSH Receptor Antibody (TRAb)

Serum Thyroglobulin (Tg)

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21-Hydroxylase Antibody (21-OHAb)

ALSO AVAILABLE FOR RESEARCH APPLICATIONS

Interferon-Omega Autoantibody (IFN- ω Ab)[†]

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Aquaporin-4 Autoantibody (AQP4Ab)[†]

Voltage-Gated Potassium Channel Antibody (VGKCAb)[†]

Titin Antibody (TitinAb)[†]

Zinc Transporter 8 Antibody (ZnT8Ab)[†]

GAD/IA-2 Antibody Screen[†]

[†] For Research Use Only. Not for use in diagnostic procedures.

To obtain additional information on **KRONUS'** unique line of laboratory test kits, please call us toll-free at **800 4 KRONUS** or email us at **kronus@kronus.com**.



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