70TH AACC ANNUAL
SCIENTIFIC MEETING
& CLINICAL LAB EXPO

REGISTER BY JUNE 14 AND SAVE

July 29–August 2, 2018
Chicago, IL USA
www.aacc.org/2018am

As of 4/12/18. For the most up-to-date information, use the session search on www.aacc.org/2018am.
AACC UNIVERSITY

The Conference before the Conference
Sunday, July 29, 2018

Registration fees apply for each course. General conference registration is waived for Sunday only.

The theme for AACC University is “Basics and Beyond.” If you don’t have the time or budget to attend the full conference, AACC University includes 13 courses that you can attend without paying the full registration fee. BONUS: If you take a course on Sunday, you are invited to attend the special session (pg 12), Sunday plenary session and the AACC Opening Mixer.

AACC University Times

SUNDAY
Morning.........................................8:30am–11:30am
Afternoon......................................12:30pm–3:30pm
Full Day..........................................8:30am–11:30am and 12:30pm–3:30pm

PLENARY SESSIONS

Designed for all levels, the plenary sessions feature renowned speakers in clinical practice, research, business and policy who are visionaries on the future of healthcare.

Plenary Session Times

SUNDAY
Late Afternoon .............................. 5:00pm–6:30pm

MONDAY–THURSDAY
Morning.........................................8:45am–10:15am

SCIENTIFIC SESSIONS

Scientific sessions are presented by experts actively involved in the field covering an array of topics in lab medicine and diagnostics. Sessions will be held in either 1.5- or 2.5-hour increments.

Scientific Session Times

MONDAY
Morning........................................10:30am–12:00pm
Mid-Day........................................12:30pm–2:00pm
Afternoon .................................2:30pm–4:00pm or 5:00 pm
Late Afternoon .............................4:30pm–6:00pm

TUESDAY, WEDNESDAY
Morning........................................10:30am–12:00pm
Afternoon .................................2:30pm–4:00pm or 5:00pm

THURSDAY
Morning........................................10:30am–12:00pm

BROWN BAG SESSIONS

Attendance limited to 10 participants per session. Advance registration and fees are required to register.

These small discussion settings provide intimate exchanges between participants and experts. Expect lively discussion, dialogue and debate, as well as Q&As. Brown Bag Sessions are presented twice daily. PLEASE NOTE: No meals are provided; please purchase food in the Convention Center.

Brown Bag Session Times

MONDAY–WEDNESDAY
Morning (40000 Series)...............7:30am–8:30am
Afternoon (50000 Series).............12:30pm–1:30pm
Fee: $25

2018 SESSION DESCRIPTIONS

Each session depicts relevant content levels as Basic, Intermediate or Advanced:

BASIC: For participants who lack previous training or experience in the subject or whose experience is minimal.

INTERMEDIATE: For those with knowledge of the basic theory of the topic, and prior training and education.

ADVANCED: For attendees with specialized content and working knowledge of current theory and practice who want to refine their skills or learn about new principles and techniques.

All session levels are open to all conference registrants.
MEET THE EXPERT SESSIONS
Attendance limited to 75 participants per session. Seating is first come, first served.
These sessions are intense, interactive discussions with plenary speakers.

Meet the Expert Session Times
MONDAY–THURSDAY
Morning ......................................... 10:30am–11:30am

PRESIDENT’S INVITED SESSION
The AACC President has created this special session of particular importance to AACC Annual Scientific Meeting attendees. This year’s presentation is “A View from the Trenches of the Opioid Epidemic: How Do We Win the War?” Details on page 17.

CHAIR’S INVITED SESSION
The chair of the 2018 Annual Meeting Organizing Committee (AMOC) created this special session of particular importance to AACC Annual Scientific Meeting attendees. This year’s presentation is “Clinical Lab 2.0: How Laboratories Can Support Value-Based Care, Optimize Patient Outcomes and Reduce Total Cost of Care in Acute and Chronic Conditions.” Details on page 19.

ORAL ABSTRACT PRESENTATIONS
Selected abstracts identified by the AMOC will be presented. Presenters will give oral presentations and present posters during the poster sessions.

This year, the six topics are:

MONDAY, JULY 30
10:30am–12:00pm
Global Health 32110
2:30pm–4:00pm
Clinical Applications 32219

TUESDAY, JULY 31
10:30am–12:00pm
Mass Spectrometry 33109
2:30pm–4:00pm
Molecular Diagnostics and Genomics 33212

WEDNESDAY, AUGUST 1
10:30am–12:00pm
Emerging Biomarkers and Technologies 34110
2:30pm–4:00pm
Hot Topics in Lab Medicine 34215
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**AACC University Full-Day Course**

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**AACC University Half-Day Course (Morning or Afternoon)**

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**Brown Bag Sessions**

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*Save at least $280 on your registration fee by becoming an AACC member today. To receive your discount, join when you register. **Includes a 1-year AACC Trainee Membership. Proof of current full-time student/trainee status required.
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- ✓ Included with registration type
- 🎟 Ticket required
- $ May purchase ticket
- 🚫 May NOT purchase ticket
- ✗ May NOT attend
### TOPIC TRACK SESSIONS

Eight topic tracks highlight different dynamic areas of clinical laboratory medicine. Check out the sessions that support your area of interest, and make the most of your educational experience in Chicago.

<table>
<thead>
<tr>
<th>TOPIC TRACK</th>
<th>SESSION NUMBER</th>
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<tr>
<td><strong>ENDOCRINOLOGY</strong></td>
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<td><strong>SESSION NUMBER</strong></td>
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<tr>
<td>Refining Measurement of Hemoglobin A1c (HbA1c): Do We Know What It Means?</td>
<td>32130</td>
<td>Monday</td>
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<tr>
<td>Clinical Assay Issues: What Endocrinologists Will Ask You</td>
<td>33107</td>
<td>Tuesday</td>
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<tr>
<td>Current Challenges of PTH Testing and Approaches to Developing a Reference Measurement Procedure</td>
<td>43107/53207</td>
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<tr>
<td>A Team Approach to Reducing Diagnostic Error: Optimizing Care for Patients with Suspected Primary Aldosteronism</td>
<td>34102</td>
<td>Wednesday</td>
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<tr>
<td>Endocrine Disrupting Chemicals in Children and Environmental Health—Emerging Opportunities for the Clinical Laboratory</td>
<td>34212</td>
<td>Wednesday</td>
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<tr>
<td>Measuring Low Estrone and Estradiol Levels in the Clinical Lab: Why, When and How?</td>
<td>44102/54202</td>
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<tr>
<td>Oxytocin Testing: Status and Clinical Applications</td>
<td>44103/54203</td>
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<tr>
<td>Toward Improving Parathyroid Hormone Measurements and Management of the Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD)</td>
<td>35106</td>
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<table>
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<th>GENOMICS/GENETICS</th>
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<tr>
<td>Practical Next-Generation Sequencing: A Toolkit for Laboratorians</td>
<td>193006</td>
<td>Sunday</td>
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<tr>
<td>Quality Control and Quality Assurance in the Era of Next-Generation Sequencing</td>
<td>32103</td>
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<tr>
<td>Emerging Clinical Applications of Circulating DNA Analysis</td>
<td>32415</td>
<td>Monday</td>
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<tr>
<td>TDM and Pharmacogenomics: Complementary Tools for Precision Medicine</td>
<td>32222</td>
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<tr>
<td>Real-Time Next-Generation Sequencing for Infectious Diseases: Challenges and Opportunities</td>
<td>33111</td>
<td>Tuesday</td>
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<tr>
<td>Clinical Cardiovascular Genomics Bootcamp</td>
<td>33219</td>
<td>Tuesday</td>
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<tr>
<td>Sequence Gazing: Somatic Variant Calling and Interpretation for Next-Generation Sequencing</td>
<td>35104</td>
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## TOPIC TRACK

### SESSIONS

#### MASS SPECTROMETRY

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<tr>
<td>The Secrets to Success: Implementing Robust LC-MS/MS Methods in the Clinical Laboratory</td>
<td>193007</td>
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<tr>
<td>Quantitative Protein Mass Spectrometry: A Step-by-Step Guide to Designing Your First Assay</td>
<td>32106</td>
<td>Monday</td>
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<tr>
<td>Quantitative Analysis of Low-Abundance Protein Targets by Immuno-Affinity Enrichment and Multiple Reaction Monitoring</td>
<td>42109/52209</td>
<td>Monday</td>
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<tr>
<td>Next-Generation Clinical Mass Spectrometry Here and Now</td>
<td>42110/52210</td>
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<tr>
<td>Liquid Chromatography Method Development to Enable High-Quality LC-MS assays</td>
<td>33217</td>
<td>Tuesday</td>
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<tr>
<td>A Beginner’s Guide to Developing Clinical Mass Spectrometry Assays</td>
<td>43114/53214</td>
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<tr>
<td>Mass Spectrometry Applications for Monoclonal Antibody Therapeutics: Which Road to Travel</td>
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<td>Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) Analysis of Testosterone and Estradiol in Serum</td>
<td>44123/54223</td>
<td>Wednesday</td>
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<tr>
<td>ICP-MS: Essentials and Interactive Case Studies on Elemental Testing in Clinical Laboratories</td>
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#### PEDIATRIC/MATERNAL-FETAL

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<tr>
<td>Update on Thyroid Disease in Pregnancy</td>
<td>32102</td>
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<tr>
<td>Update on Gestational Diabetes Mellitus: Current National and International Diagnostic Criteria</td>
<td>42122/52222</td>
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<tr>
<td>Inborn Errors of Metabolism: From Newborn Screening to Diagnosis</td>
<td>43125/53225</td>
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<td>New Approaches for Drug Screening in Pediatrics</td>
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<tr>
<td>Accurate Measurement of Thyroid Hormones in Disease and Pregnancy</td>
<td>34107</td>
<td>Wednesday</td>
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<tr>
<td>Endocrine Disrupting Chemicals in Children and Environmental Health—Emerging Opportunities for the Clinical Laboratory</td>
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<td>Jumping the Pediatric Reference Interval Hurdles</td>
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### POINT-OF-CARE TESTING

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<tr>
<td>Rise and Shine! The Essential Elements of a Point-of-Care Testing Boot Camp—Part 1</td>
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<td>Afternoon Reveille! Continuing the Essential Elements of a Point-of-Care Testing Boot Camp—Part Two</td>
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<td>Blood Gas Testing: Basics and Beyond</td>
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<td>Challenges of Implementing Rapid HIV Testing into an HIV Testing Algorithm</td>
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<td>Enhancing Patient Care Using POCT: Tackling Current and Future Challenges</td>
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<td>Guidance for Evaluating the Hypoxemic Patient in the Critical Care Setting</td>
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<td>Emergency Department Workflows: Data-Driven Approaches to Common Questions</td>
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<td>There’s No Place Like Home: Exploring Hospital at Home Care Strategies</td>
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<td>Innovations in Body Fluid Testing</td>
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### PRECISION MEDICINE & ONCOLOGY

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<td>Implementing a High(er) Sensitivity Cardiac Troponin Assay: Lessons Learned from One Institution about Analytical Validation and Clinical Protocol Development</td>
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<td>Implementation of a Multidisciplinary Cancer Precision Medicine Program: An Institutional Experience</td>
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<td>TDM and Pharmacogenomics: Complementary Tools for Precision Medicine</td>
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<td>Lipoprotein-Related Precision Medicine—Implications in Risk Stratification and Emerging Therapies of Coronary Heart Disease and Aortic Valve Disease</td>
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<tr>
<td>Gaps in Knowledge and Controversies Surrounding Thyroglobulin Measurement and Interpretation</td>
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<td>Opportunities for Clinical Chemists in Precision Oncology Multi-Omic Clinical Trials (AACC-NCI Symposium)</td>
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<td>Pharmacogenomics in Laboratory Medicine: Moving to an Era of Precision Medicine</td>
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<td>Real Global News: It’s Time to Embrace High-Sensitivity Cardiac Troponin Assays with Cost-Benefit Strategies for Early Rule-Out and Rule-In of Myocardial Infarction and Injury</td>
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### TOPIC TRACK SESSIONS

#### TOXICOLOGY/TDM

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<td>Real-Time Toxicology Testing and Case Discussion for Drugs of Abuse</td>
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<td>The Burden of Proof: Understanding Impacts of Laboratory Testing and Technology</td>
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<td>Therapeutic Drug Monitoring of Anticoagulant Agents by Coagulation Laboratory Tests</td>
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<td>Urine Drug Testing: Debates over Best Practices to Assess Compliance and Manage the Opioid Crisis</td>
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<td>How People Try to Beat Drug Testing and Defend Positive Results</td>
<td>43102/53202</td>
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<tr>
<td>Implementing or Extending Toxicology Laboratory Services—What and How?</td>
<td>44105/54205</td>
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<td>What Is My Patient Using? Facilitating the Accurate Interpretation of Urine Drug Screen Results</td>
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#### UTILIZATION & LAB MANAGEMENT

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<td>The Role of the Clinical Laboratory in Transplantation</td>
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<td>Contributing Factors to Diagnostic Errors in the Clinical Laboratory Identified by Laboratorians: What Can We Fix Right Now?</td>
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<td>Clinical Lab 2.0: How Laboratories Can Support Value-Based Care, Optimize Patient Outcomes and Reduce Total Cost of Care in Acute and Chronic Conditions</td>
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<td>Speed Dating: Navigating Pain Points in the Clinical Laboratory</td>
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<td>Navigating through Go-Live “Hiccups” with Instrumentation, Automation and Informatics: An Application Showcase</td>
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<td>Are Your Lab Tests Viable under PAMA Medicare Reimbursements?</td>
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<td>Better Testing, Better Care—the Role of the Laboratory in Improving Patient Outcomes</td>
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<td>Harnessing the Power of Evidence-Based Medicine to Maximize Laboratory Cost Savings and Effective Test Utilization</td>
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PLENARY SESSIONS

**PLENARY**

5:00pm–6:30pm

**Imatinib as a Paradigm of Targeted Cancer Therapies**

**SPEAKER:** Brian Druker, Oregon Health & Science University Cancer Institute, Portland, OR

This session shows how to translate knowledge of the molecular pathogenesis of cancer into specific therapies and investigate the optimal use of these molecularly targeted agents. Dr. Druker revolutionized the treatment of cancer through research that resulted in the first drug to target the molecular defect of a cancer while leaving healthy cells unharmed. Imatinib (marketed as Gleevec®) turned a once-fatal cancer, Chronic Myeloid Leukemia, into a manageable condition. Imatinib received FDA approval in record time and established Dr. Druker as a pioneer in the field of precision medicine. Most important, his discovery became a new proof of principle for targeted therapies, spurring the development of more than 50 similar precision therapies for other cancers.
MORNING HALF DAY

8:30am–11:30am

Hemoglobin Electrophoresis
Developed in cooperation with Hematology and Coagulation Division
This course will review specialized testing used for the diagnosis of hemoglobinopathies. In addition, this course will also provide an overview of the clinical presentation of patients with hemoglobinopathies.

8:30am–11:30am

Trust, but Verify: Getting the Most Out of Verification Protocols for FDA-Approved Methods
Can laboratories assume that all methods are acceptable? Sadly, no. Labs are responsible for verifying that their methods perform “as advertised.” Participants will learn how to implement and interpret the required verification studies performed when first using an FDA-approved method. It will focus on CLSI guidelines but include additional assessment tools such as Sigma metrics. Participants will learn how to judge method performance objectively to determine whether or not the test is providing results that meet the required quality for good patient care.

AFTERNOON HALF DAY

12:30pm–3:30pm

Afternoon Reveille! Continuing the Essential Elements of a Point-of-Care Testing Boot Camp—Part 2
Developed in cooperation with Critical and Point-of-Care Testing Division
The findings of a recent national survey show a demand for targeted POC education and application of skills. This afternoon session will focus on the important elements of quality indicators, analytics and procedure writing using interactive techniques and audience response. (See Part 1 for focus areas in the morning session.) All sessions will include the importance of building clinical partnerships for successful POCT program delivery.

12:30pm–3:30pm

Using CLSI Guidelines to Meet Quality Requirements Established by FDA, CLIA and ISO throughout the Laboratory Test Life Cycle: A Panel Presentation
Developed in cooperation with CLSI
This AACC University session will explain how to ensure quality through establishment, validation and verification of performance specifications for laboratory-developed tests (LDTs). The test life cycle, related concepts and definitions will be introduced. For each step in the life cycle, speakers will present the FDA, CLIA and ISO requirements. A specific LDT will be used to show how CLSI documents can be used to meet the requirements.
## AFTERNOON HALF DAY

### Protein Electrophoresis Interpretation and Reporting Workshop—Part 2

12:30pm–3:30pm  
**INTERMEDIATE**  
**192011**

This session will provide an interactive set of serum and urine protein electrophoresis and immunofixation cases. Attendees will be provided approaches, examples and advice on how to interpret these results. Results will include capillary electrophoresis and agarose gels. Case examples will include clinical history and context, plus challenging interpretative aspects, such as monoclonal proteins that migrate in the alpha and beta region as well as samples with interferences.

### Blood Gas Testing: Basics and Beyond

12:30pm–3:30pm  
**BASIC**  
**192012**

**Developed in cooperation with Critical and Point-of-Care Testing Division**

Blood gas analyses are essential for the management of critically ill patients. This session will review the basics of blood gas testing, discuss approaches for ensuring quality in blood gas analyses, and provide guidance on overcoming challenges associated with blood gas analyses in different clinical settings.

### ANA IFA: A Workshop for Laboratory Leaders

12:30pm–3:30pm  
**INTERMEDIATE**  
**192013**

**This session will include an overview of ANA IFA recommendations, an introduction to the International Consensus on ANA Patterns (ICAP) and the organization’s role in promoting consensus around ANA pattern nomenclature, an interactive audience session interpreting complex ANA IFA patterns, and management of the laboratory to meet the growing demand for ANA IFA testing.**

## SPECIAL SESSION

### Investigating Startups in the Medical Testing Space: Lessons Learned

3:30pm–4:30pm  
**BASIC**  
**11002**

**SPEAKER: John Carreyrou, Investigative Reporter, The Wall Street Journal**

Since 2016, startups have become increasingly interested in breaking into the medical testing space but have found that doing so is more complex than they realized. This Q&A discussion with *The Wall Street Journal* investigative reporter John Carreyrou will center on his investigative reporting on Theranos and related actions by the Food and Drug Administration, the Centers for Medicare & Medicaid Services, and other regulatory authorities, as well as why it is essential to move carefully when introducing new technologies so that the accuracy of clinical laboratory testing is not at risk.

## FULL DAY

### Practical Next-Generation Sequencing: A Toolkit for Laboratorians

8:30am–11:30am and 12:30pm–3:30pm  
**BASIC**  
**193006**

**Developed in cooperation with Mass Spectrometry and Separation Sciences Division**

Genetic testing using next-generation sequencing is advancing precision medicine. This session will use interactive cases to describe (1) quality control, quality assurance and regulatory considerations for NGS; (2) the relative advantages and limitations of targeted versus comprehensive NGS tests; and (3) NGS data analysis and variant interpretation.

### The Secrets to Success: Implementing Robust LC-MS/MS Methods in the Clinical Laboratory

8:30am–11:30am and 12:30pm–3:30pm  
**BASIC**  
**193007**

**Developed in cooperation with Mass Spectrometry and Separation Sciences Division**

This session aims to assist clinical laboratories interested in implementing mass spectrometry. It will cover the fundamentals of liquid chromatography and tandem mass spectrometry, a discussion of available sample preparation techniques; and essential considerations and effective approaches for method development, validation, post-implementation monitoring and troubleshooting.

### How to Truly “Excel” at Data Analysis and Visualization: An Introduction to the R Programming Language

8:30am–11:30am and 12:30pm–3:30pm  
**BASIC**  
**193008**

**R is a freely available statistical programming language that supports the complex data manipulation and analysis activities needed for efficient clinical laboratory practice. In this session, we will introduce basic concepts of R programming as well as more generalizable best practices in working with laboratory data.**
**PLENARY & EDUCATION SESSIONS**

**PLENARY**

8:45am–10:15am

**Genetic Defects in Bile Acid Synthesis Causing Liver Disease—Diagnosis and Treatment—Translational Medicine from Mass Spectrometry Discovery to the Bedside**

**SPEAKER: Kenneth Setchell, PhD, Cincinnati Children’s Hospital Medical Center, Cincinnati, OH**

This session highlights how mass spectrometry was successfully applied to define new genetic defects in the bile acid biosynthetic pathway. Bile acid synthesis disorders caused by single enzyme defects often present in infancy or early childhood with a progressive cholestatic hepatitis that, unchecked, leads to cirrhosis, liver failure and death. Prior to the seminal work of Dr. Setchell and colleagues in identifying six genetic diseases as discrete entities and conceiving an effective therapy, children with these autosomal recessive diseases either underwent liver transplantation or, more commonly, were given supportive care until they died of liver failure of unknown origin. The session describes the use of mass spectrometry techniques that led to the elucidation of the biochemical basis of these diseases, the development of an international screening program, and the evaluation of therapeutic responses that served to ultimately gain regulatory approval from the FDA for a life-saving therapy based on oral administration of cholic acid. This application of mass spectrometry to clinical chemistry is a noteworthy example of the transition from bench to bedside.
MONDAY | JULY 30

BROWN BAG SESSIONS

7:30am–8:30am (40000 Series) or 12:30pm–1:30pm (50000 Series)

The Use of Radio Frequency Identification (RFID) in In Vitro Diagnostic Applications
SPEAKER: Chuck Barber, JADAK, Syracuse, NY

Next-Generation Clinical Mass Spectrometry Here and Now
SPEAKER: Steven Wong, PhD, DABCC (TC), FAACC, Wake Forest University School of Medicine, Winston-Salem, NC

The Pyramid and the Policies—Safety Controls in the Lab
SPEAKER/MODERATOR: Dan Scungio, BS, MT(ASCP), SLS, COA (ASQ), Sentara Healthcare, Hampton, VA

Risk Management: Practical Implementation in a Clinical Laboratory
SPEAKER: Saswati Das, MBBS, MD, Quest Diagnostics, Gurgaon, Haryana, India

ANA Testing: The Renaissance of Indirect Immunofluorescence Assay (IFA)
SPEAKER: Vincent Ricchiuti, PhD, Laboratory Corporation of America Holdings, Dublin, OH

CDC Exploration of Opportunities and Challenges in Supporting Clinical Laboratory Workforce Development
SPEAKER: Renee Ned-Sykes, MMSc, PhD, Centers for Disease Control and Prevention, Atlanta, GA

Practical Applications of Biological Variation Data from Clinical Diagnostic Tests
SPEAKER: Paul Johnson, PhD, MBA, MT(ASCP), Upstate Medical University, Syracuse, NY

Going beyond LDL Cholesterol: Clinical Indications and Methodologies for Advanced Lipid Testing
SPEAKER: Valentinias Gruzdys, PhD, University of Utah, Salt Lake City, UT

Critical Test Results Boot Camp
SPEAKER: Qian Sun, MD, PhD, National Institutes of Health, Bethesda, MD

Rule-Based Strategies for Improving Laboratory Utilization Management
SPEAKER: Ron Schifman, MD, Southern Arizona VA Healthcare System, Tucson, AZ

Therapeutic Drug Monitoring of Anticoagulant Agents by Coagulation Laboratory Tests
SPEAKER: Yifei Yang, PhD, University of Chicago, Chicago, IL

Integrating Moving Average of Normals and EQA
SPEAKER/MODERATOR: Tony Badrick, PhD, FAACC, RCPA QAP, Sydney, Australia

What Does the Physician Need from the Laboratory?
SPEAKER: Eugenio Zabaleta, PhD, OhioHealth Mansfield Hospital, Mansfield, OH

Building Strong Communications between Laboratory and IT Staff
SPEAKER: Abbey Vangeloff, MS, Yahara Software, Madison, WI

Quantitative Analysis of Low-Abundance Protein Targets by Immuno-Affinity Enrichment and Multiple Reaction Monitoring
SPEAKER: Wenfang Wu, PhD, Berg LLC, Framingham, MA

The CDC Lipids Standardization Programs—Ensuring the Quality of Cardiovascular Disease Biomarker Measurements
SPEAKER: Uliana Danilenko, PhD, Centers for Disease Control and Prevention, Atlanta, GA
MONDAY | JULY 30

BROWN BAG SESSIONS

7:30am–8:30am (40000 Series) or 12:30pm–1:30pm (50000 Series)

Laboratory Assessment of Anemia
SPEAKER: Jaime Noguez, PhD, DABCC, University Hospitals Case Medical Center and Case Western Reserve University, Cleveland, OH

Discrepancies in Electrolyte Measurements between Direct and Indirect Ion-Selective Electrodes
SPEAKER: Sudip Datta, MBBS, MD, Dip Hosp Mgmt, All India Institute of Medical Sciences, New Delhi, Delhi, India

Update on Gestational Diabetes Mellitus: Current National and International Diagnostic Criteria
SPEAKER/MODERATOR: Hans Guenther Wahl, PhD, MD, MBA, Philipps University Marburg, UKGM Marburg, Marburg, Germany

What’s beyond PSA: Novel Biomarkers for Detection of Prostate Cancer
SPEAKER: Bernard Cook, PhD, DABCC, FAACC, Henry Ford Hospital, Detroit, MI

The Challenges of Distinguishing In Vivo from In Vitro Hemolysis
SPEAKER: Merih Tesfazghi, PhD, Washington University School of Medicine, St. Louis, MO

The CDC Hormone Standardization (HoSt) Program—Improving Clinical Measurements of Testosterone and Estradiol
SPEAKER: Krista Poynter, Centers for Disease Control and Prevention, Atlanta, GA

The Impact of the Jaffe and Enzymatic Methods on Evaluation of Renal Function
SPEAKER: Neval Akbas, PhD, Medpace Reference Laboratories, Cincinnati, OH

Developed in cooperation with Endocrinology Division

Do You Trust Your Measurements? NIST’s Health Assessment Measurement Quality Assurance Program (HAMQAP)
SPEAKER: Carolyn Burdette, National Institute of Standards and Technology, Gaithersburg, MD

Strategies to Improve Rapid Diagnosis of Ethylene Glycol Poisoning in the Emergency Department
SPEAKER: Sheng-Ying Lo, Geisinger Medical Laboratories, Danville, PA

Emerging Challenges in Protein Electrophoresis Interpretation
SPEAKER: Kwabena Sarpong, PhD, University of Virginia Health System, Charlottesville, VA

Updates and Challenges Regarding Diagnostic Testing for and Utilization of Beta-lactam/Beta-lactamase Inhibitor Combinations
SPEAKER/MODERATOR: Amanda Harrington, PhD, Loyola University Medical Center, Maywood, IL

Viral Hepatitis: Advances and Current Challenges
SPEAKER: Patricia Slev, PhD, DABCC, University of Utah/ARUP, Salt Lake City

Ionized or Albumin-Adjusted Calcium?
MODERATOR/SPEAKER: Tahir Pillay, MD, PhD, University of Pretoria, Pretoria, Gauteng, South Africa

Ethnic Variation: A Challenge for Different Common Laboratory Parameters
SPEAKER: Asmita Hazra, MBBS, MD, Assistant Professor, Christian Medical College Vellore, Vellore, Tamil Nadu, India

High-Sensitivity Troponin I: Did Adam and Eve Bite into a Forbidden Apple?
SPEAKER: Barnali Das, MD, DNB, PGDHHM, Corresponding Member, IFCC C-RIDL, Kokilaben Dhirubhai Ambani Hospital, Mumbai, Maharashtra, India
**MONDAY | JULY 30**

**MEET THE EXPERT**

10:30am–11:30am

**Genetic Defects in Bile Acid Synthesis Causing Liver Disease—Diagnosis and Treatment—Translational Medicine from Mass Spectrometry Discovery to the Bedside**

**SPEAKER: Kenneth Setchell, PhD, Cincinnati Children’s Hospital Medical Center, Cincinnati, OH**

This session provides an excellent opportunity for a limited number of attendees to meet with Dr. Kenneth Setchell to discuss his discovery of six genetic defects that cause liver disease in infants and children and the development of a treatment for reversing what are otherwise fatal conditions. Dr. Setchell demonstrated that oral bile acid therapy successfully reversed the biochemical and histological abnormalities and avoided the need for liver transplantation, the only alternative treatment. Dr. Setchell will discuss his application of mass spectrometry to clinical chemistry as a notable example of translational medicine.

**MONDAY | JULY 30**

**SCIENTIFIC SESSIONS**

**MORNING**

10:30am–12:00pm

**Implementing a High(er) Sensitivity Cardiac Troponin Assay: Lessons Learned from One Institution about Analytical Validation and Clinical Protocol Development**

Despite widespread use worldwide, high-sensitivity cardiac troponin tests are just now becoming approved for use in the U.S. This session will cover issues specific to analytical validation required for U.S. laboratories, as well as other topics such as clinical protocol development, analytical outliers and interferences that are applicable worldwide.

**Update on Thyroid Disease in Pregnancy**

*Developed in cooperation with Pediatric and Maternal-Fetal Division*

Pregnancy has profound effects on the thyroid gland and its function. As a result, assessment of thyroid status during pregnancy can be complicated, confusing and even controversial. This session will present information on the diagnosis and management of thyroid disease during pregnancy and postpartum, including important new published guidelines.

**Quality Control and Quality Assurance in the Era of Next-Generation Sequencing**

The session will discuss quality control and quality assurance standards and practices for current clinical applications of NGS, limitations, challenges and possible solutions. The first part will focus on current practices and challenges. The second part will discuss current limitations and emerging practices and technology to assure quality of patient results.
**MONDAY | JULY 30**

**SCIENTIFIC SESSIONS**

**MORNING**

**10:30am–12:00pm**

**Challenges of Implementing Rapid HIV Testing into an HIV Testing Algorithm**

New generations of HIV point care and immunoassays for screening and confirmation are now available. This discussion will center on the challenges that we faced using HIV POC assays, as well as their integration into an HIV testing algorithm in clinical situations where the turn-around time may be crucial for patient care.

**10:30am–12:00pm**

**Clinical Laboratory’s Role in the Care of Transgender Patients**

Proper care for transgender patients can be particularly difficult for hospitals and clinical laboratories at many levels. This session will provide an overview of hormone therapy for transgender adolescents and adults, its impact on laboratory values, and challenges in clinical informatics.

**10:30am–12:00pm**

**Quantitative Protein Mass Spectrometry: A Step-by-Step Guide to Designing Your First Assay**

*Developed in cooperation with Mass Spectrometry and Separation Sciences Division, Proteomics and Metabolomics Division*

This session uses a participatory approach to introduce practical quantitative investigation of peptides and proteins by mass spectrometry. This session will focus on hands-on training (attendees must bring a WiFi-enabled laptop) in setting up a quantitative protein mass spectrometric method.

**10:30am–12:00pm**

**Developing Standards in Antinuclear Antibody Indirect Immunofluorescence (ANA IFA) Interpretation and Reporting**

*Developed in cooperation with Clinical and Diagnostic Immunology Division*

Laboratory practices in ANA IFA pattern interpretation and reporting are variable. The International Consensus of ANA Patterns (ICAP) group has defined criteria for identifying currently 30 defined ANA IFA patterns, and has categorized patterns into those interpretable by competent or expert laboratories. This session will review the processes for consensus development, define nuclear patterns and introduce cytoplasmic pattern testing.

**10:30am–12:00pm**

**The Quantified Self and Wellness Monitoring: Actionable Data or Harmful Information?**

Quantifying what constitutes wellness, illness or a transition between the two is the goal of broad, large-scale efforts to map human health. Proponents believe that leveraging longitudinal health data will demystify disease. Opponents are concerned that frequent monitoring will cause harm. This session will present both perspectives and engage the audience in a robust dialogue of the issues.

**10:30am–12:00pm**

**President’s Invited Session: A View from the Trenches of the Opioid Epidemic: How Do We Win the War?**

Efforts to control acute and chronic pain in the late 20th century spurred rapid prescribing of potent synthetic analogs. Presently, millions of individuals misuse and abuse prescription opioids. Although laboratory testing plays a key role in promoting proper use and detecting misuse of these drugs, it will not end this epidemic alone. This session will explore the tactics being deployed to combat an epidemic that is responsible for the first drop in U.S. life expectancy since the early 1990s.

**10:30am–12:00pm**

**Invited Oral Abstracts: Global Health**


**10:30am–12:00pm**

**Refining Measurement of Hemoglobin A1c (HbA1c): Do We Know What It Means?**

*Developed in cooperation with American Diabetes Association (ADA), Clinical Societies Collaboration Committee*

The standardization of hemoglobin A1c (HbA1c) has substantially enhanced its clinical value. The improvement in analysis has resulted in identification by clinicians of a subset of patients in whom HbA1c results appear discordant with the clinical impression. The major concerns relate to the contribution of HbA1c to complications of diabetes and the effect of different lifespans of red blood cells and hemoglobin variants on HbA1c measurements.
MONDAY | JULY 30

SCIENTIFIC SESSIONS

MID-DAY

12:30pm–2:00pm  INTERMEDIATE  32411

Real-Time Toxicology Testing and Case Discussion for Drugs of Abuse

Developed in cooperation with TDM and Toxicology Division
This session will present a real toxicology case from Poison Center toxicologists and will include live comprehensive serum and urine testing. Both groups will be blinded to the drugs involved. Speakers will discuss tox needs and present the case while toxicologists will discuss a drug differential diagnosis as testing is being conducted and watched by the audience. When testing has been completed, the results will be discussed by the toxicology panel. Moderators will then discuss the challenges in providing real-time testing (reporting, billing, regulatory approvals and sample delivery from outside hospitals).

12:30pm–2:00pm  BASIC  32412

The Role of the Clinical Laboratory in Transplantation
Participants will be provided with a broad overview of the clinical laboratory testing performed to support the field of transplantation. Testing to evaluate donors and recipients pre-transplant, as well as to monitor recipients perioperatively and post-transplant, will be discussed. The critical role of the clinical laboratorian as a member of transplant team will be explored.

12:30pm–2:00pm  BASIC  32413

AACC Goes Platinum: 70 years of the AACC Annual Meeting
Developed in cooperation with History of Clinical Chemistry Division, Industry Division
Presentations will highlight notable advances in the profession and its technology over the past 70 years, from the first AACC Annual Meeting in 1949 in Atlantic City to the present day. Key disruptive technologies central to the evolution of clinical laboratory testing from that 1949 meeting onward will be surveyed. Projections will also be made about the clinical laboratory 30 years in the future, at the time of the 100th AACC Annual Meeting in 2048.

12:30pm–2:00pm  INTERMEDIATE  32414

Contributing Factors to Diagnostic Errors in the Clinical Laboratory Identified by Laboratorians: What Can We Fix Right Now?
The goal of the session is to probe the audience (using an audience feedback system requiring only an iPhone) with questions to identify major sources of diagnostic error they have witnessed in the clinical laboratory. This will involve the presentation of responses to 40 to 60 questions that extend from the pre-pre-analytical steps to the post-post-analytical steps, which will follow a brief introduction of the topic. It is hoped that audience members will help quantify the number of times that they, as individuals knowledgeable about diagnostic testing, have experienced a diagnostic error personally or have observed such a mistake in regard to a family member or loved one. The data obtained from these responses could provide the basis for a report in an AACC-sponsored newsletter.

12:30pm–2:00pm  INTERMEDIATE  32415

Emerging Clinical Applications of Circulating DNA Analysis
Much recent progress has been achieved in the analysis of circulating graft-derived and tumor-derived DNA. Some of these new applications have been or soon will be implemented clinically for organ transplantation monitoring and cancer screening/diagnosis. In this session, details of the clinical studies, technological and molecular approaches, and new biological understanding of circulating DNA will be shared.

12:30pm–2:00pm  INTERMEDIATE  32416

Implementation of a Multidisciplinary Cancer Precision Medicine Program: An Institutional Experience
Developed in cooperation with Molecular Pathology Division
A viable precision medicine program addresses challenges from sample to answer, including impact on patient care. This session will present Columbia’s experience in implementing a multidisciplinary precision medicine program, including assay choice, institutional workflows, billing, interpretation and reporting, molecular tumor boards, and utility review.
MID-DAY

12:30pm–2:00pm

**Harmonized Education: Use of Surrogate Samples in IVD Development and Regulatory Submission**

Surrogate samples, when properly used, decrease the time needed for analytical testing and reduce costs for test development and submission. A framework collaboratively developed by industry and the FDA establishes a foundation for surrogate use to support innovation and product submissions. Educational materials were developed to speed patient access to innovative technology.

12:30pm–2:00pm

**Enhancing Patient Care Using POCT: Tackling Current and Future Challenges**

Developed in cooperation with Critical and Point-of-Care Testing Division

This session will focus on current and future challenges facing the clinical laboratory as a result of healthcare reform and provide guidance on how to tackle current challenges and prepare for future challenges using POCT.

LATE BREAKING SESSION

12:30pm–2:00pm

**Cervical Cancer Screening as an Example of a Global Health Strategy in Resource-Limited Countries**

This session will describe the challenges of implementing and sustaining a cervical cancer screening and HPV testing program in low- and middle-income countries. Lack of adequate facilities and trained staff, cost-prohibitive therapeutics, patient access to healthcare, and remote practice will be discussed, as will laboratory challenges regarding developing an operational testing process. Findings from HPV genotype studies will be presented that challenge the current strategies for vaccination programs in low- and middle-income countries.

AFTERNOON

2:30pm–5:00pm

**Clinical Lab 2.0: How Laboratories Can Support Value-Based Care, Optimize Patient Outcomes, and Reduce Total Cost of Care in Acute and Chronic Conditions**

Population health management is emerging as a method to aggregate clinical data and produce actionable insights. Laboratories can leverage historical and longitudinal test results to develop targeted population health management tools integrated into clinical workflows. Results of these efforts can lead to improved patient outcomes and reduced total cost of care for conditions such as prenatal care and diabetes.

2:30pm–5:00pm

**Antibiotic Stewardship: Keeping Up with the Mandates**

The Centers for Medicare & Medicaid Services and the Joint Commission have mandated that hospitals have infection prevention and control and antibiotic stewardship programs for the surveillance, prevention and control of healthcare-associated infections and other infectious diseases, and for the appropriate use of antibiotics. This session will clarify these mandates, discuss best practices, identify caveats in unique populations and discuss how diagnostics can be utilized by institutions to support these mandates.

2:30pm–5:00pm

**TDM and Pharmacogenomics: Complementary Tools for Precision Medicine**

This session will discuss how pharmacogenomics and TDM can be utilized to optimize treatment therapies. This session will focus on pre-emptive pharmacogenomics and well-established gene–drug pairs, as well as scenarios in which genetic information may not predict therapeutic responses. Further, using case studies, drug–drug and drug–herb interactions will also be discussed, along with strategies to combine different types of laboratory data to optimize clinical outcomes.

2:30pm–5:00pm

**Hemostatic Disorders That Can Kill You**

Dangerous bleeding and thrombotic disorders will be covered in depth, including hemophilia, venous thromboembolism (large vessel thrombosis) and thrombotic thrombocytopenic purpura (TTP), which involves thrombosis of the microvasculature. These conditions should be recognized early because they are all amenable to treatment with a good chance of excellent recovery.
AFTERNOON

2:30pm–5:00pm

Using R for Method Validation Studies: The Good, the Great and the Beautiful

This session will demonstrate the versatility and power of the R statistical programming language in applications for clinical laboratory medicine by showcasing tools that have been built and implemented by session speakers. Applications will include topics of method evaluation, automated report generation and establishing reference intervals.

2:30pm–5:00pm

Overdiagnosis and Overmonitoring—Can We Do Better?

Developed in cooperation with Evidence-Based Laboratory Medicine Committee

This session, presented by laboratorians, clinicians and epidemiologists, focuses on what needs to be done to avoid patient harm related to overdiagnosis/overmonitoring. The drivers and solutions to overdiagnosis/overmonitoring and approaches to the redefinition of diseases due to the availability of new and more sensitive tests will be discussed.

2:30pm–5:00pm

Lipoprotein-Related Precision Medicine—Implications in Risk Stratification and Emerging Therapies of Coronary Heart Disease and Aortic Valve Disease

Developed in cooperation with Lipoproteins and Vascular Diseases Division

Lipoproteins are becoming the focus of precision medicine in the management of highly prevalent cardiovascular diseases in the U.S. population. This session covers the topics of apolipoprotein assay utilization, methodologies of lipoprotein(a) assays and novel dyslipidemia treatment targeting lipoproteins, and it will discuss the advances in the field of lipoproteins and vascular complications.

LATE AFTERNOON

SPECIAL SESSION

4:30pm–6:00pm

AACC Disruptive Technology Award Session

AACC’s Disruptive Technology Award recognizes innovative testing solutions that improve patient care through diagnostic performance or access to high-quality testing. Three diagnostic developer finalists will present their technology. During this session, a panel of expert judges will evaluate all presented testing solutions based on feasibility and performance. The winner will be chosen at the end of the session.
PLENARY & EDUCATION SESSIONS

TUESDAY
JULY 31

PLENARY

8:45am–10:15am

HPV-Associated Cancers and the HPV Vaccine

SPEAKER: Denise Galloway, PhD, Fred Hutchinson Cancer Research Center, Seattle, WA

This session highlights the discovery that human papillomaviruses (HPVs) cause cervical and other cancers. In just 25 years, this discovery has led to the development of HPV vaccines (Gardasil 9® and Cervarix®). Dr. Galloway will review the history of HPV vaccine development, especially the work needed to meet U.S. FDA regulations and the importance of achieving herd immunity. Future work includes improving efficacy, assessing the adequacy of initial vaccination, vaccinating males, assessing the need for boosters, reducing cost and improving international availability.
### BROWN BAG SESSIONS

**TUESDAY | JULY 31**

**7:30am–8:30am (40000 Series) or 12:30pm–1:30pm (50000 Series)**

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<tr>
<th>OSHA Safety Programs You Need to Know</th>
<th>INTERMEDIATE</th>
<th>43101 or 53201</th>
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<tr>
<td>SPEAKER/MODERATOR: Dan Scungio, BS, MT(ASCP), SLS, CQA (ASQ), Sentara Healthcare, Hampton, VA</td>
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<th>How People Try to Beat Drug Testing and Defend Positive Results</th>
<th>BASIC</th>
<th>43102 or 53202</th>
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<tr>
<td>SPEAKER: Amitava Dasgupta, PhD, DABCC, NRCC, University of Texas at Houston Medical School, Houston, TX</td>
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<th>Integrating Preanalytical Quality Indicators for Laboratory Testing Efficiency</th>
<th>INTERMEDIATE</th>
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<td>SPEAKER: Aparna Ahuja, BD Diagnostics, Franklin Lakes, NJ</td>
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<th>The Quest for Quality through Competency Assessment</th>
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<td>SPEAKER/MODERATOR: Elia Mears, MS, MT(ASCP)/SM, Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL</td>
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<th>How to Select and Utilize an Appropriate Method for Testosterone Testing</th>
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<tr>
<td>SPEAKER: Yusheng Zhu, PhD, DABCC, FAACC, Pennsylvania State University Hershey Medical Center, Hershey, PA</td>
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<th>Emergency Department Workflows: Data-Driven Approaches to Common Questions</th>
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<tr>
<td>SPEAKER: Christine Snozek, PhD, DABCC, FAACC, Mayo Clinic, Scottsdale, AZ</td>
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<th>Current Challenges of PTH Testing and Approaches to Developing a Reference Measurement Procedure</th>
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<td>SPEAKER: Candice Ulmer, Centers for Disease Control and Prevention, Atlanta, GA</td>
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<th>There's No Place Like Home: Exploring Hospital at Home Care Strategies</th>
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<td>SPEAKER: Michelle Parker, PhD, University of Toronto, Toronto, ON, Canada</td>
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<tr>
<th>HIV Diagnostics: Past, Present and Future</th>
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<tr>
<td>SPEAKER: Vincent Ricchiuti, PhD, Laboratory Corporation of America Holdings, Dublin, OH</td>
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*Developed in cooperation with Clinical Translational Science Division*

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<th>Pharmacogenomics in Laboratory Medicine: Moving to an Era of Precision Medicine</th>
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<tr>
<td>SPEAKER: Mahesheema Ali, PhD, Baylor College of Medicine/Texas Children's Hospital, Houston, TX</td>
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<th>Method Validations: Plan Development and Data Evaluation</th>
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<td>SPEAKER: Stephanie Inman, Atrium Health, Rock Hill, SC</td>
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<th>Overview and Recent Recommendations for Bone Turnover Markers</th>
<th>BASIC</th>
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<tr>
<td>SPEAKER: Jennifer Powers, PhD, ABCC, Core Lab for Clinical Studies, St. Louis, MO</td>
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<tr>
<th>Emerging Trends in Autoimmune and Paraneoplastic Encephalopathy Testing</th>
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<tr>
<td>SPEAKER: Christopher Farnsworth, Washington University in St. Louis, Maplewood, MO</td>
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<tr>
<th>A Beginner's Guide to Developing Clinical Mass Spectrometry Assays</th>
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<tr>
<td>SPEAKER: Pratistha Ranjitkar, PhD, DABCC, Medical College of Wisconsin, Milwaukee, WI</td>
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<th>Measurement of Steroid Hormones by Mass Spectrometry</th>
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<tr>
<td>SPEAKER: Lumi Duke, MS, Centers for Disease Control and Prevention, Atlanta, GA</td>
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*Developed in cooperation with Endocrinology Division, Mass Spectrometry and Separation Sciences Division*

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<tr>
<th>Flow Cytometry for Beginners: Basic Principles and Applications in the Clinical Laboratory</th>
<th>BASIC</th>
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<td>SPEAKER: Ashton Brock, PhD, University of Virginia, Charlottesville, VA</td>
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TUESDAY  |  JULY 31
BROWN BAG SESSIONS
7:30am–8:30am (40000 Series) or 12:30pm–1:30pm (50000 Series)

Designing a Successful Point-of-Care Testing Program: Survival Guide for New Laboratory Directors
SPEAKER: Rob Nerenz, PhD, DABCC, Dartmouth-Hitchcock Medical Center, Lebanon, NH
*Developed in cooperation with SYCL*

The PSA Screening Controversy: History, Guidelines and Future Outlook
SPEAKER: Claire Knezevic, PhD, Johns Hopkins Medical Institutes, Baltimore, MD

Hemophagocytic Syndromes
SPEAKER: Carlos Lemos, MD, CHLN, Lisbon, Portugal

Revving Up the Contact System: The Interface between Anaphylaxis, Complement Activation and Thrombosis
SPEAKER/MODERATOR: Neil Harris, MBChB, MD, DABCC, FCAP, FAACC, University of Florida College of Medicine, Gainesville, FL

Topics in Coagulation—Clinical Case Vignettes
SPEAKER: Lindsay Bazydlo, PhD, DABCC, University of Virginia, Charlottesville, VA

Ferritin: Should We Use Reference Intervals or Medical Decision Thresholds?
SPEAKER: Paul Yip, PhD, FCACB, DABCC, University Health Network, Toronto, ON, Canada

Heterophile Antibodies: An Interference You Can’t Afford to Miss
SPEAKER: Anu Maharjan, PhD, University of Utah/ARUP Laboratories, Salt Lake City, UT

Setting and Evaluating Quality Metrics
SPEAKER: Joshua Bornhorst, PhD, DABCC, Mayo Clinic, Rochester, MN
*Developed in cooperation with Management Sciences and Patient Safety Division*

Inborn Errors of Metabolism: From Newborn Screening to Diagnosis
SPEAKER: Khushbu Patel, PhD, DABCC, UT Southwestern, Dallas, TX

Minimum Retesting Intervals: Importance, Determination, Advantages, Challenges of Enforcement
SPEAKER: Asmita Hazra, MBBS, MD, Assistant Professor, Christian Medical College Vellore, Vellore, Tamil Nadu, India

Common Auto-Verification Rules and Their Exceptions in an Automated Testing Laboratory
SPEAKER: Yifei Yang, PhD, University of Chicago, Chicago, IL

Can You Substitute Diesel with Gas in Your Car? The Story of Active Vitamin B12 and Total Vitamin B12
SPEAKER: Barnali Das, MD, DNB, PGDHHM, IFCC C-RIDL, Kokilaben Dhirubhai Ambani Hospital, Mumbai, Maharashtra, India

Common Pitfalls in Testing and Interpretation of D dimers
SPEAKER: Saptarshi Mandal, AlIMS Jodhpur, Jodhpur, Rajasthan, India

Promoting the Clinical Laboratory to Patients, Students and the General Public
SPEAKER: Alan H.B. Wu, PhD, DABCC, FAACC, Professor of Laboratory Medicine, University of California, San Francisco, and Chief, Clinical Chemistry Laboratory, Zuckerberg San Francisco General Hospital and Trauma Center, San Francisco, CA
HPV-Associated Cancers and the HPV Vaccine

SPEAKER: Denise Galloway, PhD, Fred Hutchinson Cancer Research Center, Seattle, WA

This session provides an excellent opportunity for a limited number of attendees to meet with Dr. Denise Galloway, an expert in pathogen-associated malignancies. Her fascination with the idea that a virus could lead to cancer by sparking changes within cells led her to study the human papillomavirus, or HPV, and to make breakthrough contributions to a vaccine that prevents HPV and averts tens of thousands of cervical cancer cases each year. Dr. Galloway will discuss her role in these discoveries and her ongoing efforts to understand, treat and prevent cancers caused by other pathogens.

TUESDAY | JULY 31

SCIENTIFIC SESSIONS

10:30am–12:00pm

Urine Drug Testing: Debates over Best Practices to Assess Compliance and Manage the Opioid Crisis

Two ongoing debates on best practices for urine drug testing to determine compliance with prescribed medications and manage the opioid crisis will be discussed: (1) what the critical components of a definitive testing panel are, and (2) whether detecting drugs in urine is superior to oral fluid. First, the utility of quantitative definitive testing by mass spectrometry, the required components of the panel and necessary cutoffs will be debated using illustrative clinical cases. Recommendations on implementation of mass spectrometry in clinical laboratories and the role of interpretative comments will also be made. Second, there will be a debate on the clinical utility of urine and oral fluid matrices, and an optimal testing algorithm will be provided.

10:30am–12:00pm

Gaps in Knowledge and Controversies Surrounding Thyroglobulin Measurement and Interpretation

Thyroglobulin (Tg) and anti-Tg autoantibody (TgAb) measurements are central to long-term follow-up for thyroid cancer. The introduction of mass spectrometry-based methods has revealed limitations of current assays. This session will discuss pros and cons of Tg and TgAb methods. Clinical scenarios involving TgAb-positive and negative patients will be discussed.

10:30am–12:00pm

Emerging Strategies for Value-Based Laboratory Stewardship Aimed at Improving Outcomes and Reducing Diagnostic Errors

This session will describe advanced concepts and emerging strategies that improve patient outcomes and reduce errors. Topics will include the benefits of forming partnerships to directly manage patient testing, the laboratory's role in population health, the use of patient registries, the value of inter-institutional benchmarking, cost-effective analysis and techniques for designing utilization studies.
**MORNING**

10:30am–12:00pm  
**INTERMEDIATE**  
33105

**Standardization of Traditional and New Cardiovascular Disease Biomarkers—Addressing Cholesterol and Beyond**

*Developed in cooperation with IFCC Scientific Division, IFCC Apolipoproteins by Mass Spectrometry Working Group*

This session will examine the current state of standardization of traditional and new cardiovascular disease biomarkers by focusing on advanced lipoprotein testing.

10:30am–12:00pm  
**INTERMEDIATE**  
33106

**Surviving the Regulatory and Accreditation Landscape: The “Must-Know” Secrets for Success!**

*Developed in cooperation with College of American Pathologists*

This session will be an interactive, case-based session for new and experienced laboratory directors, managers, supervisors and quality personnel focusing on regulatory and accreditation issues that put laboratories at risk. Participants will get practical tips for handling challenging issues such as proficiency testing, competency assessment, delegation of duties and others.

10:30am–12:00pm  
**INTERMEDIATE**  
33107

**Clinical Assay Issues: What Endocrinologists Will Ask You**

*Developed in cooperation with Endocrine Society, Clinical Societies Collaboration Committee*

Endocrinologists frequently contact the clinical lab for guidance on test selection and interpretation. An informal survey of clinicians attending the 2017 Endocrine Society Conference revealed their concerns as problems with interpretation of thyroid function tests, the increasing prevalence of biotin interference in immunoassays, and factors that alter hemoglobin A1c independent of glycemia. This symposium will address these topics to help clinical laboratorians to face such issues.

10:30am–12:00pm  
**INTERMEDIATE**  
33108

**Clinical Chemistry’s Hot Topics of 2018**

Cardiovascular disease (CVD) biomarkers for risk prediction and therapy optimization are the subjects of numerous frequently cited articles published in *Clinical Chemistry* and will be discussed in this session.
2:30pm–4:00pm  
Invited Oral Abstracts: Molecular Diagnostics and Genomics  

2:30pm–5:00pm  
Leadership Strategies: Cultivating Engagement through Leadership  
Inherent in management positions is the responsibility to lead, but what’s often lacking are the critical attributes of a great leader. “Responsibility” without “ability” clearly distinguishes the not-so-good leaders from the exceptional ones. Session attendees will take away new leadership skills to unlock their employees’ true engagement potential.

2:30pm–5:00pm  
Solving Laboratory Diagnostic Challenges with Technology, Automation and Innovation—Closing the “Brain-to-Brain” Loop  
This scientific session will focus on the application of technologies throughout the testing process. Highlights include (1) heuristic and machine learning approaches to figuring out who to test; (2) applications of mass spectrometry in rapid analysis techniques, novel multiplexing strategies, untargeted analyses and the leveraging of resultant data; and (3) pre-analytical problems and emerging technologies applied to reduce the risk of erroneous results.

2:30pm–5:00pm  
Bridging the Gaps between Laboratory Medicine and Clinical Decision Making: Challenges and Conundrums  
A mix of theory and practical case examples will illustrate a number of important laboratory topics and how these can be communicated to clinicians. Laboratory topics will include different types of interferences, clinical cut-points/reference intervals, standardization, traceability and uncertainty of measurement, and external quality control to establish bias/accuracy.

2:30pm–5:00pm  
Why Are Harmonized Results Difficult to Achieve?  
Developed in cooperation with International Federation of Clinical Chemistry and Laboratory Medicine Working Group for Standardization of Albumin in Urine, International Consortium for Harmonization of Clinical Laboratory Results, Joint Committee for Traceability in Laboratory Medicine  
Non-harmonized laboratory results can lead to misclassification of disease conditions and erroneous patient care decisions. Reference systems can be difficult to implement due to technical limitations of reference measurement procedures and reference materials, as well as to regulatory requirements. This session addresses how to develop a reference system, the role of a harmonization protocol and how to address regulatory challenges.

2:30pm–5:00pm  
Liquid Chromatography Method Development to Enable High-Quality LC-MS Assays  
Method development of liquid chromatography-tandem mass spectrometry encompasses a variety of esoteric techniques that may be difficult to apply cohesively. This session will focus on scientific approaches to optimize and enhance the LC component—the workhorse—of LC-MS/MS. The course will describe rational method development techniques, focusing specifically on solvent system selection (empirical screening) for improved detection limits, including use of additives and modifiers; column screening for and step-wise optimization of both reverse phase and hydrophilic interaction LC; 1D versus 2D LC setups (when and how to use); gradient versus isocratic LC (benefits and pitfalls); cycle time optimization (throughput); and techniques to enhance overall ruggedness for targeted diagnostic LC-MS/MS workflows.
AFTERNOON

2:30pm–5:00pm  BASIC
Navigating through Go-Live “Hiccups” with Instrumentation, Automation and Informatics: An Application Showcase
This session will present “hiccups” that occur when going live with front-end automation, middleware-information systems, automated chemistry analyzers and mass spectrometers. Real-life case studies will be presented to highlight challenges and solutions during such go-lives. Problem-based learning will be used to provide recommendations and strategies for successful implementation of these systems.

2:30pm–5:00pm  INTERMEDIATE
Clinical Cardiovascular Genomics Bootcamp
Developed in cooperation with Molecular Pathology Division
Genomic medicine is transforming healthcare; however, many healthcare professionals receive limited genomics training [1–5]. Lab workers can play an important role in improving patient care in genomics [5]. Using cardiovascular disease cases and an interactive small-group approach, participants will learn introductory principles related to applying and interpreting genomic testing.

2:30pm–5:00pm  INTERMEDIATE
The Good, the Bad and the Ugly: Opportunities and Challenges for Harmonization of Autoantibody Testing
Developed in cooperation with Clinical and Diagnostic Immunology Division
Experts from the laboratory, from the IFCC Committee on Harmonization of Autoimmune Tests (C-HAT) and the U.S. Food and Drug Administration (FDA) will discuss the current status of autoantibody assay standardization in this interactive session, and will address the following questions:
• Standardization or harmonization?
• Why do we need it?
• (How) Can we achieve it?

2:30pm–5:00pm  INTERMEDIATE
Opportunities for Clinical Chemists in Precision Oncology Multi-Omic Clinical Trials
Developed in cooperation with Clinical Translational Science Division, Mass Spectrometry and Separation Sciences Division, Proteomics and Metabolomics Division
Precision medicine aims to improve the diagnosis and treatment of cancer. However, research now shows the integration of genomics with proteomics (proteogenomics) and reveals new knowledge previously inaccessible by NGS. This session will discuss mass spectrometry in therapeutic drug monitoring, discuss proteogenomic tests in clinical trials and review the FDA’s approach to ‘omics tests.

2:30pm–5:00pm  INTERMEDIATE
Capillary Samples and Best Practices for Blood Glucose Monitoring in Critical Care and Hospitalized Patients
Developed in cooperation with IFCC and CLSI
Serious errors and performance concerns involving blood glucose meters used in critical care and other hospital settings, especially with capillary samples, will be addressed. Variables affecting BGM, ideal performance, testing options, and strategies for ensuring best technical and clinical practice will be included. Information from a recent IFCC document and FDA Advisory Committee meeting, along with the CLSI white paper POCT17, will be presented.
PLENARY & EDUCATION SESSIONS

PLENARY

8:45am–10:15am

Nucleic Acid Detection Using CRISPR-Dx

SPEAKER: James Collins, PhD, Massachusetts Institute of Technology and Wyss Institute at Harvard University, Cambridge, MA

This session reports on the discovery that CRISPR-Cas13a/C2c2 can be used for the rapid, reliable, inexpensive detection of nucleic acid sequences. This technique achieves single-base specificity in detection of specific RNA or DNA variants. The proof of concept experiment used fragments of the Zika virus genome spliced into a lentivirus and achieved detection down to 1,000 copies per mL (2 attomolar). Dr. Collins and his colleagues have coined the technique “SHERLOCK” (Specific High-Sensitivity Enzymatic Reporter unLOCKing).
BROWN BAG SESSIONS

WEDNESDAY | AUGUST 1
7:30am–8:30am (40000 Series) or 12:30pm–1:30pm (50000 Series)

Strategies for Collaboration with Departments Outside of the Laboratory to Achieve Quality Improvements and Enhance Patient Outcomes
SPEAKER: Vickie Trace, Mayo Clinic Florida, Jacksonville, FL

Measuring Low Estrone and Estradiol Levels in the Clinical Lab: Why, When and How?
SPEAKER: Run Zhang Shi, PhD, Stanford Medical Center Clinical Laboratories, Palo Alto, CA

Oxytocin Testing: Status and Clinical Applications
SPEAKER: Damien Gruson, PhD, Cliniques Universitaires Saint Luc, Brussels, Belgium

CLIA Roles, Qualifications and Responsibilities: A Roadmap for Laboratory Compliance
SPEAKER/MODERATOR: Elia Mears, MS, MT(ASCP)SM, Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL

Implementing or Extending Toxicology Laboratory Services—What and How?
SPEAKER: Alina Sofronescu, MSc, PhD, NRCC-CC, FAACC, University of Nebraska Medical Center, Omaha, NE

Embracing Pathology’s Stepchild: A Practical Guide to Clinical Chemistry Education
SPEAKER: Joesph Wiencek, PhD, University of Virginia School of Medicine, Charlottesville, VA

Getting Started with Machine Learning in the Laboratory
SPEAKER: Dustin Bunch, PhD, Yale University School of Medicine, New Haven, CT

Changing the Culture to a Culture of Change: Case Studies and Approaches to Empowering Change and Improvement
SPEAKER/MODERATOR: Jack Zakowski, PhD, FAACC, IVD Consulting LLC, Yorba Linda, CA

Developed in cooperation with Management Sciences and Patient Safety Division

Laboratory Screening for Cancer: Beyond Test Results
SPEAKER: Shahram Shahangian, PhD, DABCC, FAACC, Centers for Disease Control and Prevention, Atlanta, GA

Developed in cooperation with CDC

Coagulation Factor VIII—Evolution, Biosynthesis, Biology and Monitoring in the Clinical Laboratory
SPEAKER/MODERATOR: Neil Harris, MBChB, MD, DABCC, FCAP, FAACC, University of Florida College of Med, Gainesville, FL

What Is My Patient Using? Facilitating the Accurate Interpretation of Urine Drug Screen Results
SPEAKER: Allison Chambliss, PhD, DABCC, FAACC, Keck Medicine of the University of Southern California, Los Angeles, CA

Controversies and Solutions in Body Fluid Testing
SPEAKER: Darci Block, PhD, Mayo Clinic, Rochester, MN

Markers of Metabolic Bone Disease, Their Prognostic Value and Novel Approaches
SPEAKER: Christopher Farnsworth, MD, Washington University in St. Louis, Maplewood, MO

Planning for Downtime
SPEAKER: Yachana Kataria, PhD, Boston Children’s Hospital, Boston, MA

BASIC
44101 or 54201

INTERMEDIATE
44106 or 54206

BASIC
44102 or 54202

INTERMEDIATE
44103 or 54203

INTERMEDIATE
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44114 or 54214

INTERMEDIATE
44115 or 54215
BROWN BAG SESSIONS

7:30am–8:30am (40000 Series) or 12:30pm–1:30pm (50000 Series)

LOINC Adoption for Both Medical and Clinical Trials Laboratories
SPEAKER: Pamela Banning, MLS(ASCP)CM, PMP(PMI), 3M HIS, West Linn, OR

Clinical Relevance of Emergency Laboratory Tests
SPEAKER: Carlos Lemos, MD, CHLN, Lisbon, Portugal

The CDC Vitamin D Standardization-Certification Program Improving the Clinical Measurement of Total 25-Hydroxyvitamin D
SPEAKER: Otoe Sugahara, Centers for Disease Control and Prevention, Atlanta, GA
Developed in cooperation with Endocrinology Division

HIV Testing Diagnostic Algorithm: Reporting Recommendations and Updates
SPEAKER: Jessica Colon-Franco, PhD, DABCC, Medical College of Wisconsin, Milwaukee, WI

Pharmacogenomics and Opioid Addiction: Can SNPs Reveal Susceptibility?
SPEAKER: Grace Williams, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Prevalence of Biotin Use in the United States and Its Broad Impacts on Clinical Lab Test Accuracy
SPEAKER: Danni Li, PhD, DABCC, FAACC, University of Minnesota, Minneapolis, MN

Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) Analysis of Testosterone and Estradiol in Serum
SPEAKER: Hui Zhou, PhD, Centers for Disease Control and Prevention, Atlanta, GA
Developed in cooperation with Endocrinology Division

A Dirty Assay: Challenges of Parathyroid Hormone Estimation and Progress in Harmonization
SPEAKER: Asmita Hazra, MBBS, MD, Assistant Professor, Christian Medical College Vellore, Vellore, Tamil Nadu, India

Control Your Data Before It Controls You: Establishing and Monitoring and QC in the Clinical Laboratory
SPEAKER: Stefani Thomas, Johns Hopkins University, Baltimore, MD

Serum vs. Plasma: Which Specimen Should You Use?
SPEAKER: Jeffrey Chance, PhD, BD Life Sciences—Preanalytical Systems, Franklin Lakes, NJ

Are You a Leader or Manager in the Clinical Laboratory?
SPEAKER: Kenneth Hoekstra, PhD, FAACC, Quest Diagnostics, Sedro-Woolley, WA

Paraneoplastic Panel Utilization for Better Patient Care and Test Effectiveness
SPEAKER: Rongrong Huang, Houston Methodist Hospital, Houston, TX

How Blood Tests Are Affected by Transfusion or Apheresis
SPEAKER: Saptarshi Mandal, AllIMS Jodhpur, Jodhpur, Rajasthan, India

Therapeutic Drug Monitoring: Immunoassays vs. LC-MS/MS
MODERATOR/SPEAKER: Kamisha Johnson-Davis, PhD, DABCC, FAACC, University of Utah/ARUP Laboratories, Salt Lake City, UT
**Nucleic Acid Detection Using CRISPR-Dx**

**SPEAKER:** James Collins, PhD, Massachusetts Institute of Technology and Wyss Institute at Harvard University, Cambridge, MA

This session provides an excellent opportunity for a limited number of attendees to meet with Dr. James Collins, one of the founders of the field of synthetic biology. His recent efforts have focused on the adaptation of a CRISPR protein that targets RNA for use as a rapid and highly sensitive diagnostic tool with the potential to transform research and global public health. This new molecular tool, dubbed “SHERLOCK” (Specific High-Sensitivity Enzymatic Reporter unLOCKing), can detect extremely low amounts of nucleic acids and, in turn, can be used as a diagnostic test for viral and bacterial infections. Dr. Collins will discuss this groundbreaking work and its potential to fundamentally change the diagnosis of common and emerging infectious diseases.

**MORNING**

**10:30am–12:00pm**

**Biological Variation: Improved Interpretation of Lab Results and Reduced False Rejections for QC**

The biological variation of a laboratory test is a determination of the “assay” analytical imprecision, and variances within and between individuals. From these data, the index of individuality, reference change value, homeostatic set points, and establishment of performance goals for quality control can be determined.

**SCIENTIFIC SESSIONS**

**WEDNESDAY | AUGUST 1**

**10:30am–12:00pm**

**A Team Approach to Reducing Diagnostic Error: Optimizing Care for Patients with Suspected Primary Aldosteronism**

*Developed in cooperation with Endocrinology Division*

The Institute of Medicine (IOM) called for a team approach to reduce diagnostic error. Diagnostic management teams (DMTs), composed of clinical and laboratory experts, are a solution to this charge. In this session, we highlight the clinical, analytical and interpretive aspects of a DMT dedicated to the diagnostic work up of suspected primary aldosteronism.
**MORNING**

**10:30am–12:00pm**  
**INTERMEDIATE**  
**34103**

**Mass Spectrometry Applications for Monoclonal Antibody Therapeutics: Which Road to Travel**  
*Developed in cooperation with Clinical and Diagnostic Immunology Division*

The clinical laboratory can make critical contributions to the management of patients receiving treatment with therapeutic monoclonal antibodies (t-mAbs) through quantitation of the t-mAbs concentration and assessment of anti-drug antibodies. However, these drugs can also pose challenges by interfering in existing tests. Mass spectrometry has been an essential tool in providing solutions for these challenges and broad applications of t-mAbs.

**10:30am–12:00pm**  
**INTERMEDIATE**  
**34104**

**Are Your Lab Tests Viable under PAMA Medicare Reimbursements?**  
*Aligning a test’s cost with its reimbursement is one of the core competencies that a laboratory leader must have in their skill set for the laboratory to survive and thrive in today’s ever-changing and competitive healthcare marketplace. This session will provide a method of analysis for determining a test budget that is aligned with the new PAMA Medicare reimbursement plan, and for creating a plan to bring the actual test cost into alignment with the budget.*

**10:30am–12:00pm**  
**BASIC**  
**34106**

**New Approaches for Drug Screening in Pediatrics**  
*Developed in cooperation with Pediatric and Maternal-Fetal Division*

Immunoassay drug screens are commonly used for their convenience. However, these report qualitative results based on quantitative cutoffs designed for workplace testing, and their use in a medical setting may be inappropriate. Detection of drug exposure, even at low concentrations, is critical in pediatrics to guide treatment. This session discusses novel approaches and experiences of two labs in addressing these issues.
SCIENTIFIC SESSIONS

MORNING

LATE BREAKING SESSION

10:30am–12:00pm

Precision Medicine: From Novel Biomarkers to Blockbuster Drugs
This session explores how to successfully identify novel protein biomarkers for unmet clinical needs and translate them into diagnostic assays for routine use. To drive this point, we will present key diagnostic advances in the areas of immuno-oncology, fibrillary glomerulonephritis and immunoglobulin light chain amyloidosis. On the topic of immune-oncology, the rapid clinical development of pembrolizumab for non-small cell lung cancer required even more rapid development of a programmed cell death 1 ligand (PD-L1) immunohistochemistry assay. This lead to the first FDA-approved companion diagnostic in cancer immunotherapy and accelerated approval of pembrolizumab. We will also explore how tissue-based diagnoses for fibrillary glomerulonephritis and amyloidosis have recently evolved, based on proteomics approaches, to include non-invasive serum-based markers.

AFTERNOON

2:30pm–5:00pm

Endocrine Disrupting Chemicals in Children and Environmental Health—Emerging Opportunities for the Clinical Laboratory
Developed in cooperation with Mass Spectrometry and Separation Sciences Division, Pediatric and Maternal-Fetal Division
Exposure to endocrine disrupting chemicals (EDCs) affect human health and development. To reliably assess the impact of these chemicals on diseases, analytical measurements need to meet the same standards as those used in clinical laboratories. This creates unique opportunities for clinical laboratories to help improve EDC measurements and human health.

2:30pm–5:00pm

AACC/ASCLS Healthcare Forum
This session will discuss CDC efforts to improve the quality of laboratory testing, Office of Inspector General investigations of laboratory billing practices and strategies to comply, recent cuts in Medicare reimbursement and how they will affect laboratories, and an overview of healthcare reform and how it is affecting clinical laboratories.

2:30pm–5:00pm

Protein Electrophoresis Reporting: Multinational Recommendations and Perspectives on Standardization
Protein electrophoresis reporting varies significantly among laboratories and individuals. This session will present international recommendations for reporting protein electrophoresis. The session will also include interactive case presentations using standardized approaches, as well as a multinational panel discussion following the lectures and interactive session.

2:30pm–5:00pm

Innovations in Body Fluid Testing
Non-invasive body fluids show promise in population-based screening studies and point-of-care, decentralized testing. Tests in saliva, cerebral spinal fluid and body fluids will improve diagnostic interpretation and permit biomarker analysis for management and treatment decisions. This session will provide a roadmap to non-invasive clinical testing (NIT).
### SCIENTIFIC SESSIONS

#### AFTERNOON

**2:30pm–5:00pm**

### Advances in Allergen Testing Diagnostics

**Developed in cooperation with Clinical and Diagnostic Immunology Division**

Diagnosis of Immunoglobulin E (IgE)-associated disorders is challenging. Increasing availability of laboratory tests based on clinically relevant allergen components and cell-based functional assays has the potential to change the way allergen-specific IgE antibody diagnostics are performed. In this scientific session, current advances in allergy diagnostics, its advantages and challenges will be discussed.

**2:30pm–5:00pm**

### Real Global News: It’s Time to Embrace High-Sensitivity Cardiac Troponin Assays with Cost-Benefit Strategies for Early Rule-Out and Rule-In of Myocardial Infarction and Injury

In this interactive session, audience members will consider evidence-based case studies to communicate and discuss how to implement utilization of high-sensitivity cardiac troponin (hs-cTnl, hs-cTnT) for early rule-out and rule-in of myocardial infarction in clinical practice. The audience will discuss international guidelines for defining normality, 99th percentiles and decision cutoff concentrations to optimize patient safety outcomes.

**4:00pm–5:00pm**

### AACC Laboratory Feud: Academy vs. CLS Council

This event will use the “Family Feud” game show-style format. Two teams (five members of the AACC Academy Council versus five members of the CLS Council) will compete in an educational challenge covering various laboratory medicine topics. It will be educational and will give everyone an opportunity to learn a little bit more about AACC members in key leadership positions.

*This session is held in Exhibit Hall A and offers no CE credit.*

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### 2:30pm–5:00pm

**Better Testing, Better Care—The Role of the Laboratory in Improving Patient Outcomes**

The shift from volume to value, the need to demonstrate improved patient outcomes, and the reduction of diagnostic error and unnecessary or harmful procedures are key themes of 21st-century medicine, and the clinical laboratory has a central role in all of these areas. However, laboratory medicine has failed in the past to maximize its contribution to healthcare for reasons including perverse reimbursement incentives and lack of education in the proper use of testing. This session will explore the changing external environment and its effects on laboratory medicine and will indicate new approaches to delivering patient-centered laboratory medicine.
PLENARY & EDUCATION SESSIONS

THURSDAY
AUGUST 2

PLENARY
8:45am–10:15am

Essential Diagnostics: Meeting the Needs of a Global Population

SPEAKERS: Timothy Amukele, PhD, MD, Johns Hopkins University, Baltimore, MD; Lee Schroeder, MD, PhD, University of Michigan, Ann Arbor, MI

While medicines treat disease, diagnostics find disease. Yet in global health initiatives, diagnostics receive much less attention. The WHO’s Model List of Essential Medicines has been critical to the efficient delivery of medicines. This session will describe how a Model List of Essential Diagnostics will help strengthen laboratory capacity in resource-poor settings.
MEET THE EXPERT

10:30am–11:30am

Essential Diagnostics: Meeting the Needs of a Global Population

SPEAKERS: Timothy Amukele, PhD, MD, Johns Hopkins University, Baltimore, MD; Lee Schroeder, MD, PhD, University of Michigan, Ann Arbor, MI

This session provides an excellent opportunity for a limited number of attendees to meet with Drs. Timothy Amukule and Lee Schroeder, leaders in ongoing efforts to improve the quality and impact of clinical laboratories in developing countries. Together, they have been strong voices on the need for a list of essential diagnostics to fulfill the healthcare needs of populations. Drs. Amukule and Schroeder will discuss their vision of how an essential diagnostics list will help strengthen laboratory capacity in resource-poor settings and improve outcomes for a global population.

THURSDAY | AUGUST 2

MEET THE EXPERT

10:30am–11:30am

SCIENTIFIC SESSIONS

MORNING

10:30am–12:00pm

Why Negative and Bidirectional Interferences Including Biotin Interferences Cause More Clinical Errors Than Positive Interferences: Case Reports and Mechanisms of Negative Interference

It is accepted that the majority of clinical diagnoses are based on clinical laboratory test results. Immunoassays are widely used in clinical laboratories, which may suffer from interferences from endogenous substances such as heterophilic antibody, hyperbilirubinemia, hyperlipidemia, etc., as well as from exogenous substances such as drug metabolites, biotin interference (if biotinylated antibody is used in assay design), and components of non-prescription, nutraceutical supplements. In general, a false elevation in test results is more likely to prompt recognition and a call to the laboratory for further clarification than is the case when test results are falsely lowered. In this scientific session, case reports will be presented to demonstrate the dangers of negative and bidirectional interferences in clinical laboratory test results, including bidirectional interference of biotin (negative interference with sandwich immunoassays but positive interferences with competitive immunoassays), and especially in assays used for endocrine testing and therapeutic drug monitoring. Although the mechanism of positive interference is straightforward, mechanisms of negative interference can be more complicated. Results of mathematical modeling to explain negative interference will also be discussed in the scientific session.

10:30am–12:00pm

Clinical Applications of Established and Emerging Multi-Analyte Testing Approaches

Developed in cooperation with Tumor Markers and Cancer Diagnostics Division

Implementing multi-analyte tests that combine biomarkers, patient demographics and clinical information into an algorithm to generate a disease risk score is becoming increasingly common in clinical laboratories. This session will center on the clinical utility and implementation considerations of established multi-analyte strategies and will highlight emerging multi-analyte testing approaches. A Q&A session will provide a forum for discussing experiences and perspectives.

10:30am–12:00pm

AACC Artery Hot Topics of 2018

Using AACC’s online forum, Artery, as a metric, we have identified four of the most common pain points and areas of ambiguity facing today’s clinical laboratorians. Relevant to each of these challenges, this session will provide essential scientific background, current practice guidelines and practical opportunities for resolution.
**MORNING**

10:30am–12:00pm  
**Sequence Gazing: Somatic Variant Calling and Interpretation for Next-Generation Sequencing**  
*Developed in cooperation with College of American Pathologists*

Attend this clinical next-generation sequencing (NGS) testing course to learn more about the emerging NGS component of precision medicine. These tests generate large amounts of genetic data that must undergo bioinformatic analysis to extract clinically useful results. While “sequence gazing” initially appears to be a daunting and technical task, the basic principles are approachable for all laboratorians. In this session, faculty will review the basic principles of sequencing and present the steps required to identify variants in clinical data [1]. Additionally, faculty will present the use of public databases and medical literature to determine the significance of these variants for patient care, with a focus on somatic variants [2]. Case studies will be used to reinforce concepts such as reporting of incidental variants and variants of uncertain significance [3–5]. Interactive audience response questions will allow participants to test their understanding in real time.

10:30am–12:00pm  
**ICP-MS: Essentials and Interactive Case Studies on Elemental Testing in Clinical Laboratories**

ICP-MS has great potential to provide sensitive, accurate and high-throughput measurement of trace elements in biological specimens. This scientific session will be presented by two laboratory directors who will review the principles behind ICP-MS, discuss method development and validation, and present its clinical application in trace element testing using clinical case studies.

10:30am–12:00pm  
**Toward Improving Parathyroid Hormone Measurements and Management of the Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD)**  
*Developed in cooperation with IFCC Scientific Division PTH Working Group*

This session will examine the importance and current state of parathyroid hormone (PTH) measurement, including pre-analytical and analytical challenges. Standardization efforts and advances in PTH reliable measurement will be discussed.

10:30am–12:00pm  
**Mastering Laboratory Data with Open-Source Computational Resources**  
*BASIC 35104*

This session will introduce available open-source computational resources that can be tailored for laboratory data processing. Real-world examples will illustrate the advantages and impacts of those tools in routine laboratory practice. The concepts of machine learning and its opportunities in the laboratory medicine field will be discussed, and basic data processing and visualization approaches will be explained.

10:30am–12:00pm  
**Harnessing the Power of Evidence-Based Medicine to Maximize Laboratory Cost Savings and Effective Test Utilization**  
*BASIC 35108*

Clinically irrelevant testing may contribute to negative patient outcomes (expensive subsequent tests/invasive procedures, initiation of therapeutics, increased hospital stay, iatrogenic anemia, and morbidity/mortality). The clinical laboratorian can play a major role in test utilization by leading a multi-disciplinary team focused on developing and implementing customized, evidence-based medicine test guidelines and interpretative comments for test results.

10:30am–12:00pm  
**Jumping the Pediatric Reference Interval Hurdles**  
*Developed in cooperation with Pediatric and Maternal-Fetal Division*

Ideal methods for establishing reference intervals are generally not feasible for pediatric populations, forcing labs to turn to alternative approaches. This session will review CLSI guidelines for generating reference intervals and discuss real-world applications to pediatrics.

10:30am–12:00pm  
**Traumatic Brain Injury Biomarkers: Ready for Prime Time**  
*INTERMEDIATE 35110*

Strategic biomarker selection for rapid and accurate traumatic brain injury (TBI) rule-out/rule-in will be discussed. Interpretation of the first FDA-cleared TBI test, coined the Brain Trauma Indicator, will be presented. Biomarker applications for aiding in clinical evaluation of symptomatic patients and appropriate utilization along with head CT will be discussed.
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