

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.

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.

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

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

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

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

REGISTRATION FEES & DEADLINES					
Conference Registration	Early Bird received by June 14	Advance Price received June 15–July 27	Onsite Price received after July 27		
AACC Member	\$595	\$735	\$735		
Non-Member*	\$875	\$1,015	\$1,115		
AACC Trainee Member	\$185	\$200	\$200		
Trainee/Student Non-Member**	\$223	\$238	\$238		
AACC Emeritus Member	\$185	\$200	\$200		
Daily Registration (Sunday Only—includes entrance to plenary session, special session and Opening Mixer)	\$0	\$0	\$0		
Daily Registration (Monday–Thursday)	\$470	\$540	\$540		
Guest/Spouse	\$185	\$200	\$200		
AACC University Full-Day Course					
Member	\$289	\$299	\$299		
Non-Member	\$319	\$339	\$349		
AACC University Half-Day Course (Morning or After	noon)				
Member	\$149	\$189	\$199		
Non-Member	\$199	\$229	\$239		
Brown Bag Sessions					
Member	\$25	\$25	\$25		
Non-Member	\$25	\$25	\$25		

^{*}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.

REGISTRATION TYPES & EVENTS						
Registration Type		Full Conference	Guest/ Spouse	Daily	Expo Only	No Registration
EVENTS		 AACC Member Non-Member Trainee/Student Member Emeritus Member 	Limit 1 per full conference registrant	Admission/tickets for day registered only	Expo only, Exhibit Hall	
Plenary Sessions 10000 Series		√	√	√	X	X
Scientific Sessions 30000 Series		√	✓	√	X	X
Meet the Experts 60000 Series		√	\checkmark	√	X	X
AACC University 190000 Series	TICKET	\$	S	\$	S	S
Brown Bag Sessions 40000 Series morning 50000 Series afternoon	TICKET	\$	S	\$	\$	S
Special Events	TICKET	\$	\$	\$	\$	\$
AACC Opening Mixer & Division Networking Event Sunday, July 29		√	√	√	X	X
Clinical Lab Expo Exhibit Hall, July 31–Aug 2		√	✓	✓	✓	X
Poster Sessions Abstracts		√	√	√	X	X
Industry Workshops		√	√	√	√	X
OEM Lectures		✓	✓	✓	✓	X





May NOT purchase ticket X May NOT attend

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.

ENDOCRINOLOGY	SESSION N	UMBER DAY
Refining Measurement of Hemoglobin A1c (HbA1c): Do W	e Know What It Means? 32130	Monday
Clinical Assay Issues: What Endocrinologists Will Ask You	33107	Tuesday
Current Challenges of PTH Testing and Approaches to Dev Measurement Procedure	veloping a Reference 43107/5320	77 Tuesday
A Team Approach to Reducing Diagnostic Error: Optimizin Suspected Primary Aldosteronism	g Care for Patients with 34102	Wednesday
Endocrine Disrupting Chemicals in Children and Environm Opportunities for the Clinical Laboratory	ental Health—Emerging 34212	Wednesday
Measuring Low Estrone and Estradiol Levels in the Clinical	Lab: Why, When and How? 44102/5420	02 Wednesday
Oxytocin Testing: Status and Clinical Applications	44103/5420	O3 Wednesday
Toward Improving Parathyroid Hormone Measurements an Kidney Disease–Mineral and Bone Disorder (CKD-MBD)	d Management of the Chronic 35106	Thursday
GENOMICS/GENETICS	SESSION N	UMBER DAY
		UMBER DAY Sunday
GENOMICS/GENETICS Practical Next-Generation Sequencing: A Toolkit for Labor	atorians 193006	
GENOMICS/GENETICS Practical Next-Generation Sequencing: A Toolkit for Labor.	atorians 193006 Generation Sequencing 32103	Sunday
GENOMICS/GENETICS Practical Next-Generation Sequencing: A Toolkit for Labor Quality Control and Quality Assurance in the Era of Next-Control and Quality Assurance in the Era of Next-	Tentorians 193006 Seneration Sequencing 32103 Second 32415	Sunday
GENOMICS/GENETICS Practical Next-Generation Sequencing: A Toolkit for Labor. Quality Control and Quality Assurance in the Era of Next-Centering Clinical Applications of Circulating DNA Analysis	atorians 193006 Generation Sequencing 32103 S 32415 recision Medicine 32222	Sunday Monday Monday
GENOMICS/GENETICS Practical Next-Generation Sequencing: A Toolkit for Labor. Quality Control and Quality Assurance in the Era of Next-C Emerging Clinical Applications of Circulating DNA Analysis TDM and Pharmacogenomics: Complementary Tools for P Real-Time Next-Generation Sequencing for Infectious Dise	193006 Generation Sequencing 32103 S 32415 Trecision Medicine 32222	Sunday Monday Monday Monday

MAS	S SPECTROMETRY	SESSION NUMBER	DAY
TICKET	The Secrets to Success: Implementing Robust LC-MS/MS Methods in the Clinical Laboratory	193007	Sunday
	Quantitative Protein Mass Spectrometry: A Step-by-Step Guide to Designing Your First Assay	32106	Monday
TICKET	Quantitative Analysis of Low-Abundance Protein Targets by Immuno-Affinity Enrichment and Multiple Reaction Monitoring	42109/52209	Monday
TICKET	Next-Generation Clinical Mass Spectrometry Here and Now	42110/52210	Monday
	Liquid Chromatography Method Development to Enable High-Quality LC-MS assays	33217	Tuesday
TICKET	A Beginner's Guide to Developing Clinical Mass Spectrometry Assays	43114/53214	Tuesday
	Mass Spectrometry Applications for Monoclonal Antibody Therapeutics: Which Road to Travel	34103	Wednesday
TICKET	Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) Analysis of Testosterone and Estradiol in Serum	44123/54223	Wednesday
	ICP-MS: Essentials and Interactive Case Studies on Elemental Testing in Clinical Laboratories	35105	Thursday

PEDI	ATRIC/MATERNAL-FETAL	SESSION NUMBER	DAY
	Update on Thyroid Disease in Pregnancy	32102	Monday
TICKET	Update on Gestational Diabetes Mellitus: Current National and International Diagnostic Criteria	42122/52222	Monday
TICKET	Inborn Errors of Metabolism: From Newborn Screening to Diagnosis	43125/53225	Tuesday
	New Approaches for Drug Screening in Pediatrics	34106	Wednesday
	Accurate Measurement of Thyroid Hormones in Disease and Pregnancy	34107	Wednesday
	Endocrine Disrupting Chemicals in Children and Environmental Health—Emerging Opportunities for the Clinical Laboratory	34212	Wednesday
	Jumping the Pediatric Reference Interval Hurdles	35109	Thursday

N	T-OF-CARE TESTING	SESSION NUMBER	DAY
ı	Rise and Shine! The Essential Elements of a Point-of-Care Testing Boot Camp—Part 1	191003	Sunday
	Afternoon Reveille! Continuing the Essential Elements of a Point-of-Care Testing Boot Camp—Part Two	192009	Sunday
	Blood Gas Testing: Basics and Beyond	192012	Sunday
	Challenges of Implementing Rapid HIV Testing into an HIV Testing Algorithm	32104	Monday
	Enhancing Patient Care Using POCT: Tackling Current and Future Challenges	32418	Monday
	Guidance for Evaluating the Hypoxemic Patient in the Critical Care Setting	33122	Tuesday
	Emergency Department Workflows: Data-Driven Approaches to Common Questions	43106/53206	Tuesday
	There's No Place Like Home: Exploring Hospital at Home Care Strategies	43108/53208	Tuesday
	Innovations in Body Fluid Testing	34216	Wednesday
C	ISION MEDICINE & ONCOLOGY	SESSION NUMBER	DAY
	Implementing a High(er) Sensitivity Cardiac Troponin Assay: Lessons Learned from One Institution about Analytical Validation and Clinical Protocol Development	32101	Monday
	Implementation of a Multidisciplinary Cancer Precision Medicine Program: An Institutional Experience	32416	Monday
	TDM and Pharmacogenomics: Complementary Tools for Precision Medicine	32222	Monday
	Lipoprotein-Related Precision Medicine—Implications in Risk Stratification and Emerging Therapies of Coronary Heart Disease and Aortic Valve Disease	32226	Monday
	Gaps in Knowledge and Controversies Surrounding Thyroglobulin Measurement and Interpretation	33103	Tuesday

33221

Tuesday

Opportunities for Clinical Chemists in Precision Oncology Multi-Omic Clinical Trials

Interpretation

OX	ICOLOGY/TDM	SESSION NUMBER	DAY
	President's Invited Session: A View from the Trenches of the Opioid Epidemic: How Do We Win the War?	32109	Monday
	Real-Time Toxicology Testing and Case Discussion for Drugs of Abuse	32411	Monday
	The Burden of Proof: Understanding Impacts of Laboratory Testing and Technology	32227	Monday
CKET	Therapeutic Drug Monitoring of Anticoagulant Agents by Coagulation Laboratory Tests	42107/52207	Monday
	Urine Drug Testing: Debates over Best Practices to Assess Compliance and Manage the Opioid Crisis	33102	Tuesday
CKET	How People Try to Beat Drug Testing and Defend Positive Results	43102/53202	Tuesday
CKET	Implementing or Extending Toxicology Laboratory Services—What and How?	44105/54205	Wednesday
CKET	What Is My Patient Using? Facilitating the Accurate Interpretation of Urine Drug Screen Results	44113/54213	Wednesday
TIL	IZATION & LAB MANAGEMENT	SESSION NUMBER	DAY
CKET	Trust, but Verify: Getting the Most Out of Verification Protocols for FDA-Approved Methods	191002	Sunday
	The Role of the Clinical Laboratory in Transplantation	32412	Monday
	Contributing Factors to Diagnostic Errors in the Clinical Laboratory Identified by Laboratorians: What Can We Fix Right Now?	32414	Monday
	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	32220	Monday
	Speed Dating: Navigating Pain Points in the Clinical Laboratory	33110	Tuesday
	Navigating through Go-Live "Hiccups" with Instrumentation, Automation and Informatics: An Application Showcase	33218	Tuesday

34104

34219

35108

Wednesday

Wednesday

Thursday

Informatics: An Application Showcase

and Effective Test Utilization

Are Your Lab Tests Viable under PAMA Medicare Reimbursements?

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

Harnessing the Power of Evidence-Based Medicine to Maximize Laboratory Cost Savings

SUNDAY

JULY 29



PLENARY & EDUCATION SESSIONS



PLENARY

5:00pm-6:30pm

BASIC

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.



SUNDAY JULY 29



Registration fees apply for each course.

MORNING HALF DAY

8:30am-11:30am

BASIC 191001

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

BASIC 191002

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.

8:30am-11:30am

BASIC 191003

Rise and Shine! The Essential Elements of a Point-of-Care Testing Boot Camp—Part 1

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 morning session will focus on important elements of operator training techniques and device connectivity using interactive techniques and audience response. (See Part 2 for focus areas in the afternoon session.) All sessions will include the importance of building clinical partnerships for successful POCT program delivery.

8:30am-11:30am

INTERMEDIATE 191004

Protein Electrophoresis Interpretation and Reporting Workshop—Part 1

Protein Electrophoresis has been available for over 40 years, and as a widespread technique, there are differences in the methodologies, applications and uses, interpretation, and reporting. This course plans on covering four main areas of this staple testing in the clinical laboratory: testing, troubleshooting, case interpretation and reporting.

8:30am-11:30am

INTERMEDIATE

191005

Seriously? You're Giving Me Heartburn! Utilizing QSEs to Organize Your Quality Management Program

Jean Ball, MBA, MT(HHS), MLT(ASCP), of the College of American Pathologists, and Pamela Melcher, MT(ASCP), of Carolinas HealthCare System, have collaborated on several CAP inspections. Implementing some regulatory requirements not only can be problematic for healthcare institutions and systems, but also can give one a downright bad case of heartburn! Helping laboratories marry up the requirements with real-life strategies for compliance could elevate the practice of laboratory medicine and, ultimately, patient care.

Jean will present the regulatory requirements that have proven to be problematic to laboratories. Pam will follow with proven strategies for compliance. The audience will be given scenarios to work through and encouraged to share their own strategies and challenges.

AFTERNOON HALF DAY

12:30pm-3:30pm

BASIC 192009

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 I 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

INTERMEDIATE 192010

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.

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SUNDAY JULY 29

AACC UNIVERSITY TICKET

Registration fees apply for each course.

AFTERNOON HALF DAY

12:30pm-3:30pm

INTERMEDIATE

92011

Protein Electrophoresis Interpretation and Reporting Workshop—Part 2

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.

12:30pm-3:30pm

BASIC 192012

Blood Gas Testing: Basics and Beyond

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.

12:30pm-3:30pm

INTERMEDIATE

192013

ANA IFA: A Workshop for Laboratory Leaders

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

3:30pm-4:30pm

11002

Investigating Startups in the Medical Testing Space: Lessons Learned

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

8:30am-11:30am and 12:30pm-3:30pm

BASIC 193006

Practical Next-Generation Sequencing: A Toolkit for Laboratorians

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.

8:30am-11:30am and 12:30pm-3:30pm

BASIC 193007

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

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, postimplementation monitoring and troubleshooting.

8:30am-11:30am and 12:30pm-3:30pm

BASIC 193008

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

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.

MONDAY

JULY 30



PLENARY & EDUCATION SESSIONS



PLENARY

8:45am-10:15am

BASI0

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.

BROWN BAG SESSIONS II

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

BASIC

SPEAKER: Chuck Barber, JADAK, Syracuse, NY

42110 or 52210 **Spectrometry Here and Now** SPEAKER: Steven Wong, PhD, DABCC (TC), FAACC,

SPEAKER: Saswati Das, MBBS, MD, Quest Diagnostics,

SPEAKER: Renee Ned-Sykes, MMSc, PhD, Centers for

Wake Forest University School of Medicine, Winston-Salem, NC

Implementation in a Clinical Laboratory

CDC Exploration of Opportunities and

Laboratory Workforce Development

Disease Control and Prevention, Atlanta, GA

Going beyond LDL Cholesterol: Clinical

SPEAKER: Valentinas Gruzdys, PhD, University of

SPEAKER: Ron Schifman, MD, Southern Arizona VA

Indications and Methodologies for

Rule-Based Strategies for Improving

Laboratory Utilization Management

Advanced Lipid Testing

Utah, Salt Lake City, UT

and EQA

Challenges in Supporting Clinical

Next-Generation Clinical Mass

Risk Management: Practical

Gurgaon, Haryana, India

The Pyramid and the Policies—Safety Controls in the Lab

INTERMEDIATE

42101 or 52201

42102 or 52202

SPEAKER/MODERATOR: Dan Scungio, BS, MT(ASCP), SLS, CQA (ASQ), Sentara Healthcare, Hampton, VA

ANA Testing: The Renaissance of Indirect Immunofluorescence Assay (IFA)

INTERMEDIATE

42103 or 52203

SPEAKER: Vincent Ricchiuti, PhD, Laboratory Corporation of America Holdings, Dublin, OH

INTERMEDIATE

Practical Applications of Biological Variation Data from Clinical Diagnostic Tests

42104 or 52204

SPEAKER: Paul Johnson, PhD, MBA, MT(ASCP), Upstate Medical University, Syracuse, NY

Developed in cooperation with Clinical Translational Science Division

Critical Test Results Boot Camp

BASIC

SPEAKER: Qian Sun, MD, PhD, National Institutes of Health, Bethesda, MD

42105 or 52205

Therapeutic Drug Monitoring of **Anticoagulant Agents by Coagulation Laboratory Tests**

INTERMEDIATE 42107 or 52207

SPEAKER: Yifei Yang, PhD, University of Chicago, Chicago, IL

Integrating Moving Average of Normals

Healthcare System, Tucson, AZ

INTERMEDIATE

BASIC

BASIC

BASIC

42111 or 52211

42112 or 52212

INTERMEDIATE

42113 or 52213

INTERMEDIATE

42114 or 52214

42115 or 52215

SPEAKER/MODERATOR: Tony Badrick, PhD, FAACC, RCPA QAP, Sydney, Australia

What Does the Physician Need from the Laboratory?

INTERMEDIATE

42108 or 52208

SPEAKER: Eugenio Zabaleta, PhD, OhioHealth Mansfield Hospital, Mansfield, OH

Building Strong Communications between Laboratory and IT Staff

BASIC 42116 or 52216

SPEAKER: Abbey Vangeloff, MS, Yahara Software, Madison, WI

Quantitative Analysis of Low-Abundance Protein Targets by Immuno-Affinity Enrichment and Multiple Reaction Monitoring

42109 or 52209

SPEAKER: Wenfang Wu, PhD, Berg LLC, Framingham, MA

The CDC Lipids Standardization Programs—Ensuring the Quality of Cardiovascular Disease Biomarker Measurements

INTERMEDIATE

42117 or 52217

SPEAKER: Uliana Danilenko, PhD, Centers for Disease Control and Prevention, Atlanta, GA

BROWN BAG SESSIONS II

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

Laboratory Assessment of Anemia

BASIC

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

42118 or 52218

42121 or 52221

Discrepancies in Electrolyte Measurements between Direct and Indirect Ion-Selective **Electrodes**

BASIC

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

INTERMEDIATE

42122 or 52222

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**

INTERMEDIATE 42123 or 52223

SPEAKER: Bernard Cook, PhD, DABCC, FAACC, Henry Ford Hospital, Detroit, MI

The Challenges of Distinguishing In Vivo from In Vitro Hemolysis

BASIC

SPEAKER: Merih Tesfazghi, PhD, Washington University School of Medicine, St. Louis, MO

42124 or 52224

The CDC Hormone Standardization (HoSt) Program—Improving Clinical Measurements of Testosterone and

INTERMEDIATE

42125 or 52225

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**

INTERMEDIATE 42126 or 52226

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)

BASIC

42127 or 52227

SPEAKER: Carolyn Burdette, National Institute of Standards and Technology, Gaithersburg, MD

Strategies to Improve Rapid Diagnosis of Ethylene Glycol Poisoning in the **Emergency Department**

BASIC

42128 or 52228

SPEAKER: Sheng-Ying Lo, Geisinger Medical Laboratories, Danville, PA

Emerging Challenges in Protein Electrophoresis Interpretation

BASIC

42129 or 52229

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

INTERMEDIATE

42130 or 52230

SPEAKER/MODERATOR: Amanda Harrington, PhD, Loyola University Medical Center, Maywood, IL

Viral Hepatitis: Advances and Current Challenges

INTERMEDIATE

42131 or 52231

SPEAKER: Patricia Slev, PhD, DABCC, University of Utah/ARUP, Salt Lake City

Ionized or Albumin-Adjusted Calcium?

BASIC

MODERATOR/SPEAKER: Tahir Pillay, MD, PhD, University of Pretoria, Pretoria, Gauteng, South Africa

42132 or 52232

Ethnic Variation: A Challenge for Different Common Laboratory Parameters

BASIC

42133 or 52233

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?

BASIC 42134 or 52234

SPEAKER: Barnali Das, MD, DNB, PGDHHM, Corresponding Member, IFCC C-RIDL, Kokilaben Dhirubhai Ambani Hospital, Mumbai, Maharashtra, India



MEET THE EXPERT

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.

BASIC 62102

MONDAY JULY 30

SCIENTIFIC SESSIONS

MORNING

10:30am-12:00pm

INTERMEDIATE

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.

10:30am-12:00pm

INTERMEDIATE

32102

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.

10:30am-12:00pm

INTERMEDIATE

32103

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.

SCIENTIFIC SESSIONS

MORNING

10:30am-12:00pm

BASIC 32104

Challenges of Implementing Rapid HIV Testing into an HIV Testing Algorithm

New generations of HIV point of 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

BASIC 32105

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

BASIC 32106

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

INTERMEDIATE

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

INTERMEDIATE

32108

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

INTERMEDIATE

32109

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 analgesics. 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

INTERMEDIATE

3211

Invited Oral Abstracts: Global Health

Session description forthcoming.
Check www.aacc.org/2018am for more details.

10:30am-12:00pm

INTERMEDIATE

32130

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.

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

BASIC 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-postanalytical 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 AACCsponsored 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

Implementation of a Multidisciplinary Cancer Precision Medicine Program: An Institutional Experience

Developed in cooperation with Molecular Pathology

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.

SCIENTIFIC SESSIONS

MID-DAY

12:30pm-2:00pm

ADVANCED

32417

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

BASIC 32418

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

INTERMEDIATE

32431

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-4:00pm

INTERMEDIATE

32210

Invited Oral Abstracts: Clinical Applications

Session description forthcoming. Check www.aacc.org/2018am for more details. 2:30pm-5:00pm

BASIC 32220

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

INTERMEDIATE

3222

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

INTERMEDIATE

3222

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

BASIC 32223

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.

SCIENTIFIC SESSIONS

AFTERNOON

2:30pm-5:00pm

INTERMEDIATE

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

INTERMEDIATE

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

INTERMEDIATE

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.

2:30pm-5:00pm

INTERMEDIATE

The Burden of Proof: Understanding Impacts of Laboratory Testing and **Technology**

This session will compare numerous aspects of clinical and forensic testing. Topics include similarities and differences between clinical and forensic toxicology laboratories, rigors and expertise behind scientific support in forensic matters, the use of NGS in forensic DNA cases, and numerous examples of forensic and clinical science where the scientific process has failed to support accepted and applied principles.

2:30pm-5:00pm

INTERMEDIATE

Validation of Laboratory-Developed Tests: Will You Be Ready?

Developed in cooperation with Mass Spectrometry and Separation Sciences Division, TDM and Toxicology Division

This session will help clinical laboratories understand the history, development and perspectives of validation for laboratory-developed tests. We will present risk-based models for the validations and real-life examples based on New York State reviews of the LDTs to provide insights into the proper validation process for LDTs.

LATE AFTERNOON SPECIAL SESSION

4:30pm-6:00pm

BASIC 32229

AACC Disruptive Technology Award Session

AACC's Disruptive Technology Award recognizes innovative testing solutions that improve patient care through diagnostic performance or access to highquality 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.

TUESDAY

JULY 31



PLENARY & EDUCATION SESSIONS



PLENARY

8:45am-10:15am

13001

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 II

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

OSHA Safety Programs You Need to Know

INTERMEDIATE

SPEAKER/MODERATOR: Dan Scungio, BS, MT(ASCP), SLS, CQA (ASQ), Sentara Healthcare, Hampton, VA

43101 or 53201

How People Try to Beat Drug Testing and **Defend Positive Results**

BASIC

43102 or 53202

SPEAKER: Amitava Dasgupta, PhD, DABCC, NRCC, University of Texas at Houston Medical School, Houston, ΤX

Integrating Preanalytical Quality Indicators for Laboratory Testing Efficiency

INTERMEDIATE

43103 or 53203

SPEAKER: Aparna Ahuja, BD Diagnostics, Franklin Lakes, NJ

The Quest for Quality through **Competency Assessment**

INTERMEDIATE

43104 or 53204

SPEAKER/MODERATOR: Elia Mears, MS, MT(ASCP)SM, Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL

How to Select and Utilize an Appropriate **Method for Testosterone Testing**

INTERMEDIATE 43105 or 53205

SPEAKER: Yusheng Zhu, PhD, DABCC, FAACC. Pennsylvania State University Hershey Medical Center, Hershey, PA

Emergency Department Workflows: Data-Driven Approaches to Common Questions

BASIC

43106 or 53206

SPEAKER: Christine Snozek, PhD, DABCC, FAACC, Mayo Clinic, Scottsdale, AZ

Current Challenges of PTH Testing and Approaches to Developing a Reference Measurement Procedure

INTERMEDIATE

43107 or 53207

SPEAKER: Candice Ulmer, Centers for Disease Control and Prevention, Atlanta, GA

There's No Place Like Home: Exploring

BASIC

43108 or 53208 Hospital at Home Care Strategies

SPEAKER: Michelle Parker, PhD, University of Toronto, Toronto, ON, Canada

HIV Diagnostics: Past, Present and Future

INTERMEDIATE 43109 or 53209

SPEAKER: Vincent Ricchiuti, PhD, Laboratory Corporation of America Holdings, Dublin, OH

Developed in cooperation with Clinical Translational Science Division

Pharmacogenomics in Laboratory Medicine: Moving to an Era of Precision Medicine

INTERMEDIATE

43110 or 53210

SPEAKER: Mahesheema Ali, PhD, Baylor College of Medicine/Texas Children's Hospital, Houston, TX

Method Validations: Plan Development and Data Evaluation

BASIC 43111 or 53211

SPEAKER: Stephanie Inman, Atrium Health, Rock Hill,

Overview and Recent Recommendations for Bone Turnover Markers

BASIC 43112 or 53212

SPEAKER: Jennifer Powers, PhD, ABCC, Core Lab for Clinical Studies, St. Louis, MO

Emerging Trends in Autoimmune and Paraneoplastic Encephalopathy Testing

BASIC

43113 or 53213

SPEAKER: Christopher Farnsworth, Washington University in St. Louis, Maplewood, MO

A Beginner's Guide to Developing Clinical **Mass Spectrometry Assays**

BASIC

43114 or 53214

SPEAKER: Pratistha Ranjitkar, PhD, DABCC, Medical College of Wisconsin, Milwaukee, WI

Measurement of Steroid Hormones by Mass Spectrometry

INTERMEDIATE

43115 or 53215

SPEAKER: Lumi Duke, MS, Centers for Disease Control and Prevention, Atlanta, GA

Developed in cooperation with Endocrinology Division, Mass Spectrometry and Separation Sciences Division

Flow Cytometry for Beginners: Basic Principles and Applications in the Clinical Laboratory

BASIC

43116 or 53216

SPEAKER: Ashton Brock, PhD, University of Virginia, Charlottesville, VA

BROWN BAG SESSIONS II

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**

BASIC

43117 or 53217

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**

BASIC 43118 or 53218

SPEAKER: Claire Knezevic, PhD, Johns Hopkins Medical Institutes, Baltimore, MD

BASIC

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

43119 or 53219

Revving Up the Contact System: The Interface between Anaphylaxis, **Complement Activation and Thrombosis** **INTERMEDIATE**

43120 or 53220

SPEAKER/MODERATOR: Neil Harris, MBChB, MD, DABCC, FCAP, FAACC, University of Florida College of Medicine, Gainesville, FL

Topics in Coagulation—Clinical Case **Vignettes**

INTERMEDIATE

43121 or 53221

SPEAKER: Lindsay Bazydlo, PhD, DABCC, University of Virginia, Charlottesville, VA

Ferritin: Should We Use Reference Intervals or Medical Decision Thresholds? INTERMEDIATE 43122 or 53222

SPEAKER: Paul Yip, PhD, FCACB, DABCC, University Health Network, Toronto, ON, Canada

Heterophile Antibodies: An Interference You Can't Afford to Miss

INTERMEDIATE

43123 or 53223

SPEAKER: Anu Maharjan, PhD, University of Utah/ ARUP Laboratories, Salt Lake City, UT

Setting and Evaluating Quality Metrics

INTERMEDIATE

SPEAKER: Joshua Bornhorst, PhD, DABCC, Mayo Clinic, Rochester, MN

43124 or 53224

Developed in cooperation with Management Sciences and Patient Safety Division

Inborn Errors of Metabolism: From **Newborn Screening to Diagnosis**

BASIC 43125 or 53225

SPEAKER: Khushbu Patel, PhD, DABCC,

UT Southwestern, Dallas, TX

Minimum Retesting Intervals: Importance, Determination, Advantages, Challenges of **Enforcement**

INTERMEDIATE

43127 or 53227

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

INTERMEDIATE

43128 or 53228

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**

INTERMEDIATE 43129 or 53229

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

BASIC 43131 or 53231

SPEAKER: Saptarshi Mandal, AIIMS Jodhpur, Jodhpur, Rajasthan, India

Promoting the Clinical Laboratory to Patients, Students and the General Public 43132 or 53232

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

MEET THE EXPERT

HPV-Associated Cancers and the HPV Vaccine

BASIC 63101

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

MORNING

10:30am-12:00pm

INTERMEDIATE

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

BASIC 33103

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

INTERMEDIATE

33104

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.

SCIENTIFIC SESSIONS

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

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

Surviving the Regulatory and Accreditation Landscape: The "Must-Know" Secrets for

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 quidance 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

BASIC 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.

10:30am-12:00pm

INTERMEDIATE

Invited Oral Abstracts: Mass Spectrometry

Session description forthcoming. Check www.aacc.org/2018am for more details.

10:30am-12:00pm

BASIC 33110

Speed Dating: Navigating Pain Points in the **Clinical Laboratory**

This interactive session will provide a "speed-dating" format for discussing specific pain points related to technologies in the lab (POC, LDT, LIS and automation). Attendees will rotate between four tables every 20 minutes. While at each table, attendees will pair up and discuss two pre-defined scenarios, which will be followed by a high-level summary and further discussion.

10:30am-12:00pm

INTERMEDIATE

Real-Time Next-Generation Sequencing for Infectious Diseases: Challenges and **Opportunities**

There's a lot of excitement for real-time next-generation sequencing as the "next big thing" for clinical microbiology. This session will separate the hype from the hope for these technologies for clinical infectious diseases with a focus on metagenomics and viral/bacterial WGS.

10:30am-12:00pm

INTERMEDIATE

33122

Guidance for Evaluating the Hypoxemic Patient in the Critical Care Setting

Despite the frequency of measurement and the physiologic importance of oxygen, laboratorians are often not familiar with how PO2, %O2Hb, Hb and other measurements are used to calculate oxygen-related parameters—such as O2 content, O₂ delivery, A–a difference, PaO₂/FIO₂ ratio and oxygenation index—and how the clinician uses them to evaluate and monitor hypoxemia, pulmonary ventilation and perfusion in critically ill patients.

This session will be presented by a laboratory director and a practicing critical care physician to provide clinical, pathophysiological and practical information that will allow the participant to understand the important pre-analytical factors in these measurements, and how to calculate and interpret oxygen and oxygen-related parameters for diagnosing and managing patients in critical care settings.

SCIENTIFIC SESSIONS

AFTERNOON

2:30pm-4:00pm

INTERMEDIATE

33212

Invited Oral Abstracts: Molecular Diagnostics and Genomics

Session description forthcoming. Check www.aacc.org/2018am for more details.

2:30pm-5:00pm

BASIC 33213

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

INTERMEDIATE

Solving Laboratory Diagnostic Challenges with Technology, Automation and Innovation—Closing the "Brain-to-Brain"

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

INTERMEDIATE

33215

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

INTERMEDIATE

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

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

INTERMEDIATE

Liquid Chromatography Method Development to Enable High-Quality LC-MS

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.

SCIENTIFIC SESSIONS

AFTERNOON

2:30pm-5:00pm

BASIC 33218

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. Problembased learning will be used to provide recommendations and strategies for successful implementation of these systems.

2:30pm-5:00pm

INTERMEDIATE

33219

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]. Laboratorians 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

33221

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.

WEDNESDAY

AUGUST 1



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 II

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**

44101 or 54201

BASIC

SPEAKER: Vickie Trace, Mayo Clinic Florida, Jacksonville, FL

Measuring Low Estrone and Estradiol Levels in the Clinical Lab: Why, When and How?

BASIC

44102 or 54202

SPEAKER: Run Zhang Shi, PhD, Stanford Medical Center Clinical Laboratories, Palo Alto, CA

Oxytocin Testing: Status and Clinical **Applications**

INTERMEDIATE

44103 or 54203

SPEAKER: Damien Gruson, PhD, Cliniques Universitaires Saint Luc, Brussels, Belgium

CLIA Roles, Qualifications and

INTERMEDIATE

44104 or 54204 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?

BASIC 44105 or 54205

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

BASIC

44106 or 54206

SPEAKER: Joesph Wiencek, PhD, University of Virginia School of Medicine, Charlottesville, VA

Developed in cooperation with Society for Young Clinical Laboratorians

Getting Started with Machine Learning in the Laboratory

BASIC

44107 or 54207

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**

INTERMEDIATE

44108 or 54208

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

INTERMEDIATE

44111 or 54211

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

INTERMEDIATE

44112 or 54212

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**

BASIC 44113 or 54213

SPEAKER: Allison Chambliss, PhD, DABCC, FAACC, Keck Medicine of the University of Southern California, Los Angeles, CA

Controversies and Solutions in Body Fluid

INTERMEDIATE 44114 or 54214

SPEAKER: Darci Block, PhD, Mayo Clinic, Rochester, MN

Markers of Metabolic Bone Disease, Their **Prognostic Value and Novel Approaches**

BASIC 44115 or 54215

SPEAKER: Christopher Farnsworth, Washington University in St. Louis, Maplewood, MO

Planning for Downtime

INTERMEDIATE

SPEAKER: Yachana Kataria, PhD, Boston Children's Hospital, Boston, MA

44116 or 52216

BROWN BAG SESSIONS II

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

LOINC Adoption for Both Medical and Clinical Trials Laboratories

INTERMEDIATE 44117 or 54217

SPEAKER: Pamela Banning, MLS(ASCP)CM, PMP(PMI), 3M HIS, West Linn, OR

Clinical Relevance of Emergency **Laboratory Tests**

BASIC

44118 or 54218

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

The CDC Vitamin D Standardization-**Certification Program Improving the Clinical Measurement of Total** 25-Hydroxyvitamin D

INTERMEDIATE

44119 or 54219

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

INTERMEDIATE

44120 or 54220

SPEAKER: Jessica Colon-Franco, PhD, DABCC, Medical College of Wisconsin, Milwaukee, WI

BASIC

Pharmacogenomics and Opioid Addiction: Can SNPs Reveal Susceptibility?

44121 or 54221

SPEAKER: Grace Williams, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Prevalence of Biotin Use in the United

Lab Test Accuracy

States and Its Broad Impacts on Clinical

INTERMEDIATE

44122 or 54222

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

INTERMEDIATE

44123 or 54223

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

INTERMEDIATE

44124 or 54224

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**

BASIC 44125 or 54225

SPEAKER: Stefani Thomas, Johns Hopkins University, Baltimore, MD

Serum vs. Plasma: Which Specimen Should You Use?

BASIC

44126 or 54226

SPEAKER: Jeffrey Chance, PhD, BD Life Sciences— Preanalytical Systems, Franklin Lakes, NJ

Are You a Leader or Manager in the Clinical Laboratory?

BASIC

44127 or 54227

SPEAKER: Kenneth Hoekstra, PhD, FAACC, Quest Diagnostics, Sedro-Woolley, WA

Paraneoplastic Panel Utilization for Better **Patient Care and Test Effectiveness**

INTERMEDIATE 44128 or 54228

SPEAKER: Rongrong Huang, Houston Methodist Hospital, Houston, TX

How Blood Tests Are Affected by Transfusion or Apheresis

BASIC

44130 or 54230

SPEAKER: Saptarshi Mandal, AIIMS Jodhpur, Jodhpur, Rajasthan, India

Therapeutic Drug Monitoring: Immunoassays vs. LC-MS/MS

INTERMEDIATE

44131 or 54231

MODERATOR/SPEAKER: Kamisha Johnson-Davis, PhD, DABCC, FAACC, University of Utah/ARUP Laboratories, Salt Lake City, UT

MEET THE EXPERT

10:30am-11:30am

Nucleic Acid Detection Using CRISPR-Dx

BASIC 64101

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.

WEDNESDAY | AUGUST 1

SCIENTIFIC SESSIONS

MORNING

10:30am-12:00pm

INTERMEDIATE 34101

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.

10:30am-12:00pm

INTERMEDIATE 34102

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.

SCIENTIFIC SESSIONS

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.

10:30am-12:00pm

INTERMEDIATE

Accurate Measurement of Thyroid Hormones in Disease and Pregnancy

Developed in cooperation with American Thyroid Association, Endocrine Society/PATH, Endocrinology

Correct diagnosis and consistent treatment of thyroid disorders depend on accurate and reliable thyroid hormone tests. However, discrepant measurement results have been reported due to wide variability in commercially available immunoassays for these tests. This session will explore the applications, shortfalls and future of thyroid hormone testing.

10:30am-12:00pm

INTERMEDIATE

Journal of Applied Laboratory Medicine's Hot Topics of 2018: From the Kidney to the **Heart: Analytical and Clinical Complexities** of the Cardio-Renal Systems

Proper utilization of cardiac and renal biomarkers is fundamental to a quality clinical laboratory. This includes maintaining up-to-date knowledge of the latest assays, such as high-sensitivity troponin and cystitis C, and awareness of the complex interplay between diseases, such as HIV and cardiac pathology. This session's focus will be the laboratorian-clinician interface for defining imminent aspects of cardiac and renal disease. High-sensitivity troponin confounders, quality management issues and innovations for current/future clinical applications of cardiac and renal biomarkers will be explored. In addition to presenting applied knowledge, the session will include ample Q&A time with the expert panel of speakers.

10:30am-12:00pm

INTERMEDIATE

34110

Invited Oral Abstracts: Emerging Biomarkers and Technologies

Session description forthcoming. Check www.aacc.org/2018am for more details.

SCIENTIFIC SESSIONS

MORNING

LATE BREAKING SESSION

10:30am-12:00pm

INTERMEDIATE

34120

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 tissuebased diagnoses for fibrillary glomerulonephritis and amyloidosis have recently evolved, based on proteomics approaches, to include non-invasive serumbased markers.

AFTERNOON

2:30pm-4:00pm

INTERMEDIATE

34215

Invited Oral Abstracts: Hot Topics in Lab Medicine

Session description forthcoming.
Check www.aacc.org/2018am for more details.

2:30pm-5:00pm

INTERMEDIATE

34211

Harmonization of Laboratory Systems and Reference Standards in Clinical Laboratories

This will be a combination of a traditional podium presentation and a 30-minute interactive discussion forum. Following the three main presentations (30 minutes each plus 10 minutes for questions), an interactive discussion forum will be held. Participants will be asked to share their views on the current challenges with laboratory harmonization and potential strategies to move toward harmonization of laboratory systems and reference intervals/test result interpretation.

2:30pm-5:00pm

INTERMEDIATE

34212

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

INTERMEDIATE

2/21

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

INTERMEDIATE

34214

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

INTERMEDIATE

34216

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

INTERMEDIATE

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 cellbased 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

ADVANCED

34218

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-cTnI, 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.

2:30pm-5:00pm

INTERMEDIATE

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.

4:00pm-5:00pm

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

This event will use the "Family Feud" game showstyle 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 CF credit.

THURSDAY

AUGUST 2



PLENARY & EDUCATION SESSIONS



PLENARY

8:45am-10:15am

BASIC

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.

THURSDAY | AUGUST 2

MEET THE EXPERT

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.

BASIC 65101

THURSDAY | AUGUST 2

SCIENTIFIC SESSIONS

MORNING

10:30am-12:00pm

INTERMEDIATE

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

INTERMEDIATE

35102

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

BASIC 35103

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.

THURSDAY | AUGUST 2

SCIENTIFIC SESSIONS

MORNING

10:30am-12:00pm

INTERMEDIATE

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

BASIC 35105

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

INTERMEDIATE

35106

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 preanalytical and analytical challenges. Standardization efforts and advances in PTH reliable measurement will be discussed. 10:30am-12:00pm

BASIC

35107

Mastering Laboratory Data with Open-**Source Computational Resources**

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

BASIC

35108

Harnessing the Power of Evidence-Based Medicine to Maximize Laboratory Cost Savings and Effective Test Utilization

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 multidisciplinary team focused on developing and implementing customized, evidence-based medicine test guidelines and interpretative comments for test results.

10:30am-12:00pm

BASIC 35109

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.

LATE BREAKING SESSION

10:30am-12:00pm

INTERMEDIATE

Traumatic Brain Injury Biomarkers: Ready for Prime Time

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.



SCIENTIFIC MEETING

& CLINICAL LAB EXPO

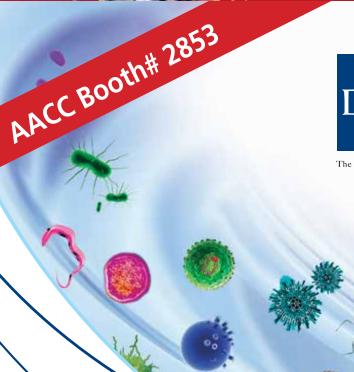
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