

## Symposium for Clinical Laboratories May 30 – June 2, 2018: Session Descriptions

The Symposium for Clinical Laboratories presents Keynote General Sessions of broad interest that all participants attend AND Breakout Sessions that you select based on your needs and interests.

### Breakout Session Topic Key

 Lab Director Qualification Track

 Clinical testing specialties

 Safety and Phlebotomy

 Personnel

 Business management and lab operations

 Quality management and quality improvement

 Regulations and CLIA compliance

*The session descriptions are also provided when you go to online registration.*

### Wednesday, May 30

8:15a – 4:00p **Liquid Chromatography/Mass Spectrometry Workshop** (separate registration)

Scientific, operational, compliance and regulatory experts share their knowledge and perspectives on LCMS technology. 6 PACE credits.

10:00a – 7:30p Symposium Check-in

### Thursday, May 31

7:00a - 8:30a Lab Director session

**Introduction to Laboratory Regulations and CLIA** 

**Verlin Janzen, MD, FAAFP**

**1.25 CME or PACE credits**

This session is designed for physicians, and will provide the novice laboratory director with an orientation to the medical laboratory. This is your starting point as you seek to qualify as a laboratory director of a moderate complexity lab. Dr. Janzen will discuss the language of the laboratory, acronyms, and terms used in office laboratories today. In addition, he will give an overview of the CLIA law and regulations that will allow the attendee to assimilate the subsequent session material into a coherent body of knowledge.

**Note: Breakfast will be served in the room to ensure that the session starts on time at 7am.**

#### Learning Objectives

- Demonstrate a general understanding of what the CLIA regulations entail, and how they affect the POL
- Differentiate between CLIA and COLA
- Understand some common laboratory lingo
- Plan for the upcoming courses in the lab director education qualification track, and summarize the importance of each topic in becoming a competent laboratory director

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8:45a- -10:00a Thursday Opening General Session 

### CMS CLIA Update 2018

Karen Dyer, MT(ASCP), DLM

1 CME or PACE credit

This session will provide an update on current CMS activities related to the CLIA Program. Specific topics will be included as CMS activities evolve between now and the meeting date.

#### Learning Objectives

- Outline current CMS activities that impact laboratories
- Summarize the overall CMS enrollment data for laboratories and the various certificate types in each category

### Thursday Breakout Session A 10:30a – 12:00p (select one)

A01	<p><b>Looking at Point-of-Care Testing through a New Value Lens</b> <b>Kim Futrell, BS, MT(ASCP)</b> <b>1.5 PACE credits</b></p> <p> The value-focused environment of today's healthcare is increasing demand for rapid, accurate, and integrated POCT. Improvements in patient outcomes, engagement, and satisfaction can be realized when laboratory results are made available in real-time at the patients' point-of-care; and the benefits of POCT are expanded with integration and laboratory oversight.</p> <p></p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>• Define the benefits, challenges, and factors increasing the demand for POCT</li><li>• Describe the value added by electronic integration of POCT and the importance of proper POCT management</li><li>• Appraise specific case study results involving cost savings and patient care improvements attributed to integrated POCT</li><li>• Apply an organization-wide concept to POCT costs and savings</li></ul>
A02	<p><b>Basics of Quality Control</b> <b>Verlin Janzen, MD, John Daly, MD, Karen Dyer, MT(ASCP), DLM</b> <b>1.5 CME or PACE credits</b></p> <p> A physician's office laboratory, even if it is only doing waived testing, must perform routine quality control (QC). Every clinical laboratory must have technical personnel who understand how to establish and implement an ongoing QC program to monitor the accuracy of the assay once it is in clinical use. The speakers will introduce QC to the novice laboratory director in this session designed for physicians and other non-laboratory trained attendees. Together we will thoroughly delve into practical QC - what to do, how to do it, how to record it, and most importantly the "minimums" that a laboratory director must do. <i>Introductory level for physician laboratory directors and for individuals without laboratory training.</i></p> <p></p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>• Differentiate between internal &amp; external quality control and the roles and importance of each in monitoring lab quality</li><li>• Illustrate the steps in the QC process</li><li>• Assist in the development of a laboratory QC policy and program</li><li>• Evaluate QC results to determine how the test system is performing, and when problems occur, determine what actions should be taken to prevent an adverse effect on patient results</li></ul>

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A03	<p><b>Top 10 Common Citations</b> <b>Eileen McConnell, MT(ASCP)</b> <b>1.5 PACE credits</b></p> <p>Many laboratories struggle to comply with certain criteria and they are cited for deficiencies at inspection time. Areas of frequent noncompliance are about calibration, quality control, personnel, quality assessment and proficiency testing. COLA criteria are derived from the CLIA regulations, so the compliance concepts discussed are applicable and relevant to any non-waived lab, not just COLA labs. What is the surveyor looking for when evaluating your lab for compliance with these criteria? This session will focus on strategies to help you comply. Actions you can take to correct non-compliances with these criteria and maintain continuous compliance will be discussed. Questions about other criteria will also be fielded as time allows.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Anticipate surveyor expectations regarding these criteria</li><li>• Assess your lab's level of compliance with these criteria</li><li>• Apply strategies to correct non-compliances and maintain continuous compliance</li></ul>
A04	<p><b>IQCP and Microbiology</b> <b>Kathy Nucifora, MPH, MT(ASCP) &amp; Irwin Rothenberg, MBA, MS, MLS(ASCP)</b> <b>1.5 PACE credits</b></p> <p>Microbiology testing, including molecular infectious disease testing and direct antigen testing performed using non-waived instruments or devices that have internal control processes, are good candidates for IQCP. In addition, microbiology testing performed using media, identification systems, and susceptibility test systems can benefit from IQCP. The application of IQCP to Microbiology is no different than for all other laboratory specialties: IQCP is required when following manufacturer's instructions that incorporate the use of reduced QC. Without an IQCP, default CLIA QC requirements are applicable. The IQCP option, requiring the assessment of risk through all three phases of testing, rather than just the analytic phase, provides greater awareness of the entire microbiology testing process, broadens the scope of competency assessments, and improves orientation and training.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>• Summarize the principles of IQCP and its' application to general laboratory testing</li><li>• Outline distinctive QC requirements for Microbiology</li><li>• Apply requirements for IQCP that are specific to Microbiology</li><li>• Walk through a sample Microbiology IQCP</li></ul>
A05	<p><b>Introduction to Coagulation Testing in the Laboratory</b> <b>Kathleen Finnegan, MS, MT(ASCP)SH</b> <b>1.5 PACE credits</b></p> <p>Coagulation studies are performed in the laboratory when the clotting process is imbalanced. This imbalance can cause excessive bleeding or an unwanted thrombus or clot formation. The laboratory plays a major role in the evaluation of coagulation disorders.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Discuss the three major components of the mechanism of coagulation</li><li>• Describe the importance of specimen integrity for the performance of coagulation testing</li><li>• Differentiate the characteristics and application of routine coagulation testing</li></ul>

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A06	<p><b>Good Testing Practices for CLIA Certificate of Waiver and Certificate of Provider-Performed Microscopy Procedure Sites</b> <b>Heather Stang, MS, MT</b> <b>1.5 PACE credits</b></p> <p>Laboratory testing is a critical part of health care, and ultimately, the public's health. Facilities in the United States that perform laboratory testing on human specimens for health assessment/monitoring or disease diagnosis, prevention, or treatment are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Under the CLIA regulations, facilities performing only waived tests are not subject to routine regulatory oversight or personnel requirements, but are only required to obtain a Certificate of Waiver, pay biennial certificate fees, and follow manufacturers' test instructions. Under a CLIA Certificate of Provider-Performed Microscopy Procedures, laboratories must meet all applicable CLIA moderate complexity testing requirements, but are not subject to routine biennial inspections. To assure the quality of laboratory testing in these sites, CDC has been successful in developing and providing educational materials in an effort to protect and promote patient safety in the nation and beyond. In addition, by providing the material free-of-charge, all individuals and laboratory testing sites can access the information regardless of socioeconomic status. This session will include a presentation and discussion on good testing practices for waived and provider-performed microscopy testing. A waived testing scenario will be presented allowing the audience to participate in answering questions on good testing practices.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Obtain a general overview of the CLIA program</li><li>• Identify applicable CLIA regulations for testing under a CLIA Certificate of Waiver or CLIA Certificate of Provider-Performed Microscopy Procedures</li><li>• Identify good point-of-care practices for the three phases of waived testing</li><li>• Identify educational resources to assist with regulatory compliance</li></ul>
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### Thursday Breakout Session B 1:30p – 3:00p (select one)

B11	<p><b>Technology Workshop: Chemistry Instruments</b> <b>1.5 PACE credits</b></p> <p>In this workshop you will have the opportunity to assess general chemistry and immunoassay analyzers that may be suitable for your practice. The instrumentation shown will be appropriate for a small to moderate patient volume of testing. The handouts include guidelines for instrument selection. Small groups will have time with each instrument.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>• Identify factors to consider when selecting a chemistry instrument for the laboratory</li><li>• Recognize the pitfalls encountered in the selection process</li><li>• Analyze the differences between systems and determine which would be the most appropriate for a particular lab setting</li></ul>
B12	<p><b>Basics of Proficiency Testing</b> <b>Verlin Janzen, MD, John Daly, MD, Karen Dyer, MT(ASCP) DLM</b> <b>1.5 CME or PACE credits</b></p> <p>This session will focus on the basics of Proficiency Testing (PT). Physicians will learn how to select a PT provider, manage the PT process, and perform the laboratory director responsibilities relating to PT. <i>Introductory level for physician laboratory directors and for individuals without laboratory training.</i></p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>• Assess the value of proficiency testing (PT) as a valuable, practical, and quality enhancing exercise in any laboratory</li><li>• Participate in PT as required under CLIA '88 for all non-waived testing</li><li>• Summarize the CLIA requirements for the POL as it pertains to PT</li><li>• Evaluate PT results and interpret reports; when problems occur, determine what actions to take to prevent an adverse effect on patient results</li></ul>

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B13	<p><b>Tales from the Field: Why you need a Technical Consultant</b> <b>Cathy Bohrer, MT(ASCP) &amp; Carol Vaughn, MT(ASCP)</b> <b>1.5 PACE credits</b></p> <p>Starting a lab sounds so easy. Buy an instrument, press “go,” and make a lot of money performing your own in-house lab tests. Right? Physician Office Laboratories, Urgent Care Clinics, and Freestanding Emergency Departments are a different world than the hospital laboratory environment. In this session we will discuss some of our experiences that have helped us better meet the needs of the moderately complex laboratories we set up and maintain. We will discuss the failed inspections we have come in to clean up, and how they could have been easily prevented if the laboratory had a qualified technical consultant from the beginning. We will share some real life stories and how experienced technical consultants can make your laboratory one that consistently produces quality results.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Summarize the benefits an experienced qualified technical consultant can bring to your lab</li><li>• Outline steps your lab can take to prevent a failing inspection and consistently produce quality results</li></ul>
B14	<p><b>OSHA Training</b> <b>Kelly Ogle, BS, MS, CMPM®, CHOP®</b> <b>1.5 PACE credits</b></p> <p>This session on OSHA will update you on everything you need to know about OSHA compliance so you can feel safe on the job. We will cover your employee rights and responsibilities, bloodborne pathogens, hazardous chemicals, fire and electrical safety, MRI and Lasers, ergonomics and workplace violence. There will be information on how to document your site-specific information. We will discuss bloodborne pathogens at length and will delve into the hazard communication standard. The speaker will show you the new Safety Data Sheet format and will introduce the new labeling requirements, highlighting the pictograms. Also we will be talking about how to conduct a walk-through audit of your office or lab.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>• Understand your rights under OSHA, as well as how to protect yourself from hazards you may encounter during your workday</li><li>• Discuss Bloodborne Pathogens, electrical and fire safety, ergonomics, workplace violence, MRI and laser safety, and hazard communications</li><li>• Learn the new labeling and SDS requirements under the new Hazard Communication Standard</li><li>• Recognize and interpret the newly required pictograms and understand how to read the new safety data sheets</li><li>• Realize the importance of a safe environment and what is recommended to review during a self-audit of your office</li></ul>
B15	<p><b>Competency Assessment</b> <b>Kathy Nucifora, MPH, MT(ASCP) &amp; Anne Ritter, MT(ASCP)</b> <b>1.5 PACE credits</b></p> <p>The quality of laboratory testing rests upon the knowledge, experience and skills of the laboratory staff. This involves not only carrying out technical procedures correctly, but the ability to recognize problems and know when to question the results. Quality work also means understanding quality control, calibration, maintenance, specimen handling, labeling, and storage and documentation. Often, the traditional "Performance Evaluations", especially in smaller laboratories, focuses on employee behavior, non-laboratory skills, attendance, and office relationships. While traditional performance evaluations serve a useful purpose, they are not sufficient to evaluate the technical skills of laboratory staff. Both CLIA and COLA require more detailed personnel assessments, known as Competency Assessments. Simple check lists alone are not sufficient - Competency Assessments must include 6 methods specified in the CLIA regulations. This workshop will provide the information you need to develop and implement competency assessments that meet regulatory requirements and ensure the quality of your staff.</p>

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### Learning Objectives

- Differentiate between Competency Assessment and the traditional Performance Evaluation
- Outline the six CLIA-required components of Competency Assessment
- Apply methods described to conduct and document appropriate Competency Assessments
- Comply with COLA criteria that address Competency Assessments

B16

### **Use of LCMS in the Pain Management Toxicology Laboratory**

**Garry Milman, PhD & Lauren Roppel, MSFS**

#### **1.5 PACE credits**

Part 1 of this introductory presentation on LCMS utilization in clinical toxicology laboratory will walk you through the specifics of analytical lab work. You will learn principles of liquid chromatography - mass spectrometry, definitions, strategies of lab workflow, as well as methodology of different sample preparations for LCMS analysis. Presentation covers pre-analytical and post-analytical aspects of drug testing.

Part 2 will go over what and when to validate, method development and optimization, how to create a validation plan, required parameters for validation and re-validation, documentation, and efficiency of validating. All concepts based off the Scientific Working Group for Forensic Toxicology (SWGTOX) "Standard Practices for Method Validation in Forensic Toxicology" and the U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research "Guidance for Industry Bioanalytical Method Validation" and are applicable to LC-MS/MS for clinical toxicology use.

### Learning Objectives:

- Outline the principles of liquid chromatography and mass spectrometry
- Summarize strategies for lab workflow and methodology of different sample preparations
- Create a validation plan that meets requirements
- Apply concepts from published guidance documents for clinical toxicology use

B17

### **Near Patient Testing – Why care?**

**Tammy Zinsmeister & Sana Grant**

#### **1.5 PACE credits**

Reimbursement trends are making it increasingly challenging for clinicians to provide lab testing to patients right in their practice. Working together to build broad awareness about the importance and value of near patient testing (NPT) to the health in a community is a central challenge in the coming years. In this session, the presenters will share COLA's research findings related to clinician expertise on the value of NPT in our healthcare delivery system. Also, participants will have the opportunity to engage in small table conversations to generate ideas for sharing the story and building a community of advocates to educate public and private decision-makers on why they should care about access to NPT.

### Learning Objectives:

- Summarize challenges clinicians face to providing lab testing in their practice
- Outline findings on the value of near patient testing
- Build a community of advocates for access to NPT

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Thursday Breakout Session C 3:30p – 5:00p (select one)

C21 	<p><b>Technology Workshop: Laboratory Information Systems</b> <b>1.5 PACE credits</b></p> <p>Use this opportunity to compare and evaluate multiple working laboratory information systems (LIS). The groups will be small so all your questions and concerns may be addressed. The information will be valuable whether you are already using an LIS or are evaluating one for your laboratory.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>• Understand the multiple functions for computers in the lab (i.e. instrument data acquisition, billing, appointment management, tracking of referred specimens, laboratory record keeping)</li><li>• Identify which types of features are desired in a computer system and how to ask questions</li><li>• Analyze the differences between the systems and determine which LIS would be the most appropriate for a particular lab setting</li></ul>
C22   	<p><b>Pre &amp; Post-analytic Issues, Introduction to QA (3:30-5:30p)</b> <b>John Daly, MD</b> <b>2 CME or PACE credits</b></p> <p>Most laboratory errors occur during the pre- and post-analytic phases. Learn about common errors and how to correct and prevent them. Quality Assessment (QA) monitors all phases of the testing process to ensure quality results and ongoing continuous improvement of lab operations. In this introductory level session, learn how this process has evolved and how to perform effective QA in your lab that is both meaningful and meets the requirements.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>• Evaluate which testing phase is most prone to laboratory error</li><li>• Outline areas where laboratory errors most commonly occur</li><li>• Formulate corrective actions and preventive measures to avoid these errors</li><li>• Outline the role of informatics in the clinical laboratory and apply steps in informatics utilization to avoid laboratory errors</li><li>• Define Quality Assessment</li><li>• Summarize the role, structure and components of acceptable Quality Assessment Plans</li><li>• Outline how to develop a “culture of quality” in your laboratory</li></ul>
C23  	<p><b>Molecular Genetic Laboratory Testing</b> <b>Gianella Garcia Hughes, PhD</b> <b>1.5 PACE credits</b></p> <p>Molecular based technologies have been expanding in the diagnostic environment. Most of these technologies are based on the Polymerase Chain Reaction (PCR for short), of either DNA or RNA, which are the nucleic acids inside cells. These technologies are highly sensitive to contamination by amplified nucleic acids from previous runs. Therefore, it is very important to observe proper guidelines and correct layouts when working in molecular genetic laboratories. In addition, it is essential to be informed about all the different tests, equipment, methods, materials, quality control standards, and proficiency testing available before choosing the best option for your laboratory’s or practice’s interests.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Compare different molecular genetic laboratory layout options</li><li>• Select equipment that ensures good laboratory practices</li><li>• Outline test procedures</li><li>• Plan for Quality control and contamination control</li><li>• Summarize expectations for Method validation and Proficiency testing</li></ul>

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C24	<p><b>Effective Quality Assessment</b> <b>Angelia Dooley, MT, BS &amp; Irwin Rothenberg, MBA, MS, MT(ASCP)</b> <b>1.5 PACE credits</b></p> <p>Quality Assessment (QA) is a pro-active, continuous process of systemic reviews that monitor all phases of laboratory testing; ensuring that all standards of performance are met; and that any deficiencies noted are addressed immediately. An effective QA plan is able to identify problems to avoid potentially negative impacts on your patients. Follow-up audits are performed to ensure that the corrective actions taken were effective. The “Quality Assessment Plan” details this process as well as defining roles and responsibilities. QA is a key component in creating a culture of quality for your laboratory.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Define Quality Assessment and differentiate from Quality Control</li><li>• Summarize the objectives, components, and structure of Quality Assessment plans</li><li>• Implement your QA plan by performing QA reviews</li><li>• Apply the longer-term goal of creating a culture of quality</li></ul>
C25	<p><b>Phlebotomy Hot Topics</b> <b>Kathleen Finnegan, MS, MT(ASCP)SH</b> <b>1.5 PACE credits</b></p> <p>Proper blood collection ensures better patient care by reducing errors. Blood specimens obtained from patients have an important role for prognosis, diagnosis and patient management. This talk will address issues relating to phlebotomy practice. We will review the new CLSI standards and explore ways to reduce specimen rejection.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Discuss the updated CLSI guidelines for quality blood collection</li><li>• Determine how to increase the quality of blood collection and reduce specimen rejection</li><li>• Discuss complications of blood collection</li></ul>
C26	<p><b>Hemoglobin A1c – How Sweet it Is!</b> <b>Nicole Colby, MLS(ASCP)<sup>cm</sup>, SBB<sup>cm</sup>, SC<sup>cm</sup></b> <b>1.5 PACE credits</b></p> <p>This presentation will cover how Hemoglobin A1c is created in the body, different testing methodologies, and various patient factors and conditions that influence Hemoglobin A1c testing and results, including hemoglobinopathies.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Summarize the advantages and disadvantages between different test methods for Hemoglobin A1c.</li><li>• Describe the impact of various patient conditions on Hemoglobin A1c values.</li><li>• Outline other options for diagnosing and monitoring diabetes in patients whose Hemoglobin A1c values may be inaccurate.</li></ul>

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C27

### **Getting Things Done with COLAcentral, Now and in the Future**

**Chris Paris and Kathy Nucifora, MPH, MT(ASCP)**

#### **1.5 PACE credits**

This session for COLA labs will hold small group, interactive sessions to provide instruction on some of the practical uses of COLAcentral, our customer portal. These sessions will focus on real-world issues that crop up in laboratories with regards to COLA laboratory accreditation and the use of COLAcentral. We will discuss where we are headed with COLAcentral, report any new findings or initiatives, and invite your input.

#### Learning Objectives:

- Explore practical uses of COLAcentral that you may not have been aware of
- Discuss ways COLAcentral can assist with lab accreditation issues
- Summarize future enhancements and initiatives related to COLAcentral

## Friday, June 1

7:00a - 8:30a Lab Director session

### **Personnel- Laboratory Director Responsibilities (Regulatory)**

**Verlin Janzen, MD**

#### **1.5 CME or PACE credits**

If you are a new laboratory director or want to learn more about the responsibilities and duties of directing a laboratory, this session will provide insight into the position. In this session, Dr. Janzen covers the basics of laboratory regulation, personnel issues, and general administrative duties relating to the laboratory director functions.

#### Learning Objectives

- Summarize the CLIA qualification requirements to be a laboratory director of a moderate complexity and/or high complexity physician office laboratory
- Perform the responsibilities (according to CLIA) of the laboratory director
- Evaluate which responsibilities may be delegated to other laboratory personnel

8:45a - 10:00a **Friday AM General Session** 

### **HIV & Hepatitis C**

**Donna Sweet, MD, AAHIVS, MACP**

#### **1.25 CME or PACE credits**

In this session, Dr. Sweet will cover the latest approach to treatment of HIV and HCV disease with a focus on the newest drugs available. She will also cover treatment of patients who are co-infected with HIV and Hepatitis C from her experience in caring for both of these populations for over 30 years. Dr. Sweet cares for approximately 1300 HIV infected patients with approximately 100 of those being co-infected with hepatitis C.

#### Learning Objectives

- Discuss the current trends and epidemiology of HIV and HCV disease
- Explain the current approaches to the treatment of HIV and Hepatitis C
- Recognize the needs of a patient who is co-infected with HIV/Hepatitis C

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Friday Breakout Session D 10:30a – 12:00p (select one)

D31 	<p><b>Practical Hematology: The Anemias</b> <b>Maria Brock, MT(ASCP)SH, ART</b> <b>1.5 PACE credits</b></p> <p>If you need a practical information -filled overview of the anemias, then this workshop is for you! Hematologists or generalists, who perform routine CBC's and microscopic examination of peripheral blood are expected to detect important diagnostic findings to assist the physician in providing the best patient care. But have you had enough exposure to the difficult scenarios and case histories needed to gain a solid comfort level with this critical task? Attend this workshop to hear a discussion of the different types of anemias and learn how to handle the diverse cases encountered in the laboratory.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Identify normal and abnormal RBC morphology</li><li>• Correlate morphological findings with various disease states</li><li>• Manage adverse and difficult hematology cases</li></ul>
D32   	<p><b>Personnel- Required Positions and Competency</b> <b>John Daly, MD</b> <b>1.5 CME or PACE credits</b></p> <p>The CLIA regulations specify personnel positions for moderate and high complexity laboratories that must be filled by qualified individuals that meet their defined responsibilities. Personnel must be properly trained and their competency must be regularly evaluated using defined methods. This session will discuss the personnel requirements and steps for compliance.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>• Identify and summarize CLIA personnel requirements for each position</li><li>• Illustrate instances of non-compliance</li><li>• Implement appropriate corrective actions to achieve compliance</li><li>• Discuss rationale for competency</li><li>• Outline six CMS requirements for Competency Assessment</li></ul>
D33  	<p><b>Inspection Readiness</b> <b>Eileen McConnell, MT(ASCP)</b> <b>1.5 PACE credits</b></p> <p>Preparing for a laboratory survey often means increased anxiety and stress above that of the normal workday routine. Yet laboratories performing quality work are always prepared for an inspection, announced or unannounced, and generally do well. There is no secret to this achievement, but understanding the strategic role and benefits of periodic surveys is just as important as knowing how to prepare for these events. This session not only provides you with information on how to prepare and maintain inspection readiness, but discusses why understanding the inspection's purpose can help achieve the required support of your entire staff.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>• Manage the survey process as part of the continuum of providing quality laboratory services rather than as a separate event</li><li>• Maintain a laboratory operation that will always be prepared for an inspection</li><li>• Outline the typical survey framework and review of laboratory records and processes</li></ul>

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D34 	<b>Financial Perspectives of Running a Laboratory</b> <b>Tim Dumas, MLT</b> <b>1.5 PACE credits</b> The laboratory is a business, and in order to offer your patients the advantages of timely results you must consider the financial aspects of setting up and operating an in-office lab.  Learning Objectives <ul style="list-style-type: none"><li>• Formulate ways to maximize laboratory revenue</li><li>• Compare laboratory income to expenses</li><li>• Calculate cost per test</li><li>• Select a practical laboratory test menu that is right for your patient population</li><li>• Choose the right analyzer(s) for your needs</li><li>• Determine personnel needs</li><li>• Monitor lab revenue</li></ul>
D35 	<b>Calibration Verification and Verification of Performance Specifications</b> <b>Anne Ritter, MT(ASCP) &amp; Angelia Dooley, MT, BS</b> <b>1.5 PACE credits</b> This session will explain in detail the requirements for calibration verification and for verifying the performance specifications of a new test system, including how to perform both processes and how to evaluate performance and interpret your results. Sample worksheets will be provided.  Learning Objectives <ul style="list-style-type: none"><li>• Define performance specifications</li><li>• Summarize the CLIA requirements regarding performance specifications and the purpose of the requirements</li><li>• Determine when verification or establishment is required and the applicable performance specifications that need to be verified or established</li><li>• Utilize appropriate samples and procedures for performing the study</li><li>• Use appropriate methods for interpreting and determining the acceptability of the study</li><li>• Summarize calibration and calibration verification and compare the difference between them</li><li>• Define reportable range and recognize some other names for it</li><li>• Determine when calibration verification is required</li><li>• Identify acceptable materials for calibration verification</li><li>• Outline the steps to perform calibration verification</li><li>• Take appropriate action when calibration verification is not successful</li></ul>
D36  	<b>Point of Care Testing: Expanding POCT in the POL and in a large Health Care System</b> <b>Jeanne Mumford, MT(ASCP)</b> <b>1.5 PACE credits</b> Managing Point of Care Testing in any setting has its challenges. In this session, I'll review the steps to determine if a particular POCT is the right fit for your program. Whether it is a new test kit or a new instrument, there are several factors to consider before allowing new tests to be performed at the point of care. We'll also discuss the strategies of standardizing across diverse clinics and/or a large health care system and discuss successes and failures of one such healthcare system. Finally, this session will teach key considerations for building multidisciplinary teams and approaches to meaningful communication amongst these teams.

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- Learning Objectives:
  - Identify the Right Point of Care Test for Your Setting
  - Learn how to keep your Quality Assurance Plan up to date
  - Identify key communication skills for successful multidisciplinary team meetings and partnerships

### Friday Breakout Session E 1:00p – 2:30p (select one)

E41	<p><b>The Power of We: Building Leaders through Teamwork</b> <b>Maria Brock, MT(ASCP)SH, ART</b> <b>1.5 PACE credits</b></p> <p>World Class leaders know that their employees are their greatest resource, therefore TEAM BUILDING strategies are essential. But which strategies are the best? In this dynamic course, you will learn several innovative, proven tools to engage your employees and supercharge their creativity. Active listening skills will help you discover important information and define specific needs and problems among your team. Feedback loops are a collaborative problem-solving process that will assist in generating diverse and specific solutions to challenges in your own lab. You will return to your workplace a more confident, innovative, creative leader, ready to build effective team.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>● Develop team building strategies that improve employee engagement</li><li>● Make use of proven active listening skills to improve your ability to gain helpful information</li><li>● Lead problem solving sessions using the feedback loop</li></ul>
E42	<p><b>Quality Assessment of Proficiency Testing</b> <b>Verlin Janzen, MD &amp; John Daly, MD</b> <b>1.5 CME or PACE credits</b></p> <p>In this session, Dr. Janzen and Dr. Daly will show the importance of evaluating your PT performance and following up on any problems or issues. The concept of quality assessment will be introduced, and ways to monitor your PT performance and identify and resolve problems will be discussed. Case study examples will be used to give the new Lab Director some hands-on experience in how to identify problems, how to determine the root cause, how to formulate a solution, and then how to follow up later to see if the solution worked.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"><li>● Apply quality assessment concepts to evaluate PT performance</li><li>● Monitor PT performance to identify problems</li><li>● Determine root cause of PT problems</li><li>● Formulate solutions to correct PT problems</li></ul>
E43	<p><b>Testing and Reporting Updates for Various Infectious Diseases</b> <b>Nicole Colby, MLS(ASCP)<sup>cm</sup>, SBB<sup>cm</sup>, SC<sup>cm</sup></b> <b>1.5 PACE credits</b></p> <p>This presentation will discuss updates on what tests are available, recommended reflex testing, and reporting updates for various infectious diseases including Hepatitis B, Hepatitis C, HIV, syphilis, and lyme disease.</p>

## Symposium for Clinical Laboratories May 30 – June 2, 2018: Session Descriptions

	<p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Describe the differences between different tests available for the infectious diseases covered</li><li>• Utilize the reflex algorithms recommended by the CDC and other organizations used for diagnosing the covered infectious diseases</li></ul> <p>Interpret and report the results of testing for the infectious diseases</p>
E44	<p><b>Procedure Manuals</b> <b>Irwin Rothenberg, MBA, MS, MLS(ASCP)</b> <b>1.5 PACE credits</b></p> <p>Procedure manuals form the foundation of a quality laboratory. They not only provide directions for test performance, but define and codify the entire spectrum of laboratory function, providing direction for all phases of testing from the pre-analytical phase, such as specimen acquisition and handling; through the analytical and post-analytical phases, such as test data management and documentation requirements. Procedure manuals also include guidance for incident management, quality assessment, staff training and many other operational policies. This session will discuss the information that should always be included, from both practical need as well as regulatory requirement viewpoints. The digitalization of information is not only changing the format for procedure manuals, but enhancing access, and providing the ability to immediately update, review and amend its contents. Procedure manuals are more important than ever, more accessible than ever, more comprehensive than ever, and more useful than ever.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Summarize the importance of procedure manuals for quality laboratory patient care</li><li>• Outline the requirements of CLIA and/or your Accrediting Organization when creating or updating your procedure manual</li><li>• Discuss the importance of the organizational policy component of your procedure manuals</li><li>• Understand how technology is changing how we access, update, and document changes to procedure manuals</li></ul>
E45	<p><b>Coding and Billing for the Physician-Based Lab</b> <b>Shannon O. DeConda, CPC, CPC-I, CEMC, CMSCS, CPMA</b> <b>1.5 PACE credits</b></p> <p>During this session we will review coding concerns for lab based services, and will include a review of CPT, ICD-10, and modifier usage. We will then turn our attention to potential bundling edits and medical policies that can impact revenues for the physician based lab. Be prepared to cover an array of issues in the fast paced session that will be a great review for the seasoned professional and great training for the newbie to coding/billing.</p> <p>Learning Objectives:</p> <ul style="list-style-type: none"><li>• Review lab coding concerns, including CPT, ICD-10, and modifier usage</li><li>• Outline bundling edits and medical policies that can impact lab revenue</li></ul>
E46	<p><b>How to Get the Most Out of Proficiency Testing</b> <b>Nancy Anderson, MMSc, MT(ASCP)</b> <b>1.5 PACE credits</b></p> <p>Proficiency testing (PT) is an important tool for assuring the quality of clinical laboratory testing. It is used to monitor test performance and identify problems in the testing process and is required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It can also serve as a valuable educational resource and as a means of assessing the competency of testing personnel. This breakout session will provide participants with an overview of the CLIA PT requirements and will explore the potential use and value of PT beyond that of meeting regulatory requirements. Participants will be asked to share their suggestions and ideas for ways in which they have made the most of their PT experiences. They will also be invited to discuss challenges they have experienced with PT and explore solutions to the challenges.</p>

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### Learning Objectives

- List four regulatory requirements for each required PT analyte or test
- Describe the CLIA requirement for verifying test accuracy for analytes or tests that are not specifically listed in the regulations
- Identify steps that the laboratory should take when testing PT samples and submitting results
- Describe benefits of performing PT in addition to meeting regulatory requirements

### 3:30p – 5:15p Friday PM General Sessions:

#### 3:30p – 4:30p Meeting the Dynamic Challenges for Quality and Patient Safety

Sharon Ehrmeyer, PhD, MT(ASCP)

#### 1.0 CME or PACE credits

Once upon a time, we naively thought quality and patient safety were ensured just by getting the right QC and proficiency testing results. The Institute of Medicine shattered that illusion with its 1999 report on the huge number of deaths in hospitalized Americans caused by medical errors. Despite numerous “fixes” over time, medical error now ranks the third leading cause of death in the U.S.! Since 60% – 80% of diagnostic decisions are based on “laboratory” results (regardless of where generated), we are part of this problem. Certainly error reduction throughout the testing process is essential for quality results. But more is needed! This presentation will focus on current and future quality and patient safety challenges and solutions for “laboratory” testing.

#### Learning Objectives:

- Summarize current and future testing challenges
- Discuss and apply solutions/approaches to improve quality in the testing process and address patient safety concerns

#### 4:30p – 5:15p Jumping the Generation Gap

Tim Dumas, MLT

#### .75 PACE credits

Many offices today face the issue of older generations, notebook in hand, working side by side with the younger Generation X'ers and Millennials glued to a tiny screen.

Both are effective employees, but they don't always see each other that way.

An efficient *team* must optimize good communication, build respect and encourage understanding. By using empathy and having fun with music, culture and technology, we will explore why we act the way we do and how that can build a strong and harmonious team.

#### The class will help you:

- Improve multi-generation team performance
- Define the workplace generations
- Identify and enhance work ethics and styles
- Reduce conflict and cultivate empathy through **generational** understanding
- Utilize the full impact of Verbal, Written, and Electronic communication

**NOTE: PACE credit only. Those in the LD qualification curriculum must attend *Practical Utilization* and *What is?* instead, which run concurrently**

## Symposium for Clinical Laboratories May 30 – June 2, 2018: Session Descriptions

4:30p – 6:00p **Concurrent Lab Director CME sessions:**

4:30p – 5:00p **Practical Utilization** 

**John Daly, MD**

**.5 CME or PACE credits**

In this session there will be an overview of tools that can be used to effectively order laboratory tests and discussion of those tools you should be requesting be made available to optimize laboratory test ordering.

Learning Objectives

- Determine where tests are most efficiently performed i.e. POS vs. Reference Laboratory
- Introduce practitioners to tools which are available to assist them in ordering the >4000 analytes available
- Emphasize the necessity of a robust IT laboratory system to incorporate the laboratory utilization tools
- Summarize the effect of improper laboratory test utilization

5:00 – 6:00p **What is? Overview of Operational Processes** 

**John Daly, MD**

**1 CME or PACE credit**

This session focuses on other important topics for the laboratory director regarding lab operations and regulatory compliance, including instrument verification and validation, calibration and calibration verification, random and systemic errors, split sample testing and instrument maintenance.

Learning Objectives

- Discuss components of laboratory test validation and verification
- Differentiate between calibration and calibration verification
- Outline steps which may be taken in troubleshooting problems with an instrument or laboratory test
- Summarize important steps in instrument maintenance for quality laboratory practice

**Saturday, June 2** *The focus is on Lab Directors, but all are welcome to attend*

7:00a – 11:30a **General Sessions:**

7:00a – 7:45a **New Developments in the Lab** 

**John Daly, MD**

**.75 CME or PACE credits**

The focus will be a discussion of molecular testing available including laboratory developed tests, molecular microbiology tools, and discussion of pharmacogenomics.

Learning Objectives:

- Explore new developments in drug therapy
- Consider advantages of personalized medicine
- Define Lab Developed Tests
- Recognize that changes to FDA-approved tests places them in high complexity category
- Describe complimentary roles of CMS and the FDA regarding the clinical laboratory
- Describe fundamentals of molecular technology
- Compare advantages of molecular microbiology over traditional technologies
- List examples of molecular microbiology products that can be used at point of care

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7:45a – 8:30a **Besides CLIA- What Else? OSHA, Hazmat, Facilities** 

**John Daly, MD**

**.75 CME or PACE credits**

This presentation will discuss the laboratory regulatory requirements including safety in the laboratory and those CLIA requirements for the laboratory facility.

Learning Objectives:

- Outline CLIA requirements for facilities
- Outline OSHA requirements general laboratory safety
- Summarize laboratory fire and electrical safety
- Raise awareness that accidents do happen and develop mind-set of reducing the opportunity for accidents

8:30a – 9:45a **Responsibilities of LD Part 2, Practical Aspects** 

**Verlin Janzen, MD**

**1.25 CME or PACE credits**

In Lab Director Responsibilities: Regulatory, Dr. Janzen provided an overview of the regulations and personnel a laboratory director needs in order to be successful. In this session, Dr. Janzen will summarize the laboratory director's responsibilities when it comes to the technical areas of the laboratory in quality control, proficiency testing, and quality assessment, and provide some practical insight and tips for the new Laboratory Director.

Learning Objectives

- Implement practical ways of meeting the CLIA requirements for the laboratory director
- Satisfy most CLIA laboratory director requirements with one-hour meetings every month and an additional annual meeting with your laboratory staff
- Plan for what needs to be accomplished in the first weeks of being named "laboratory director" of your POL

9:45a – 11:15a **Inspections – Preparing and Thriving** 

**Verlin Janzen, MD**

**1.5 CME or PACE credits**

This session will review the most frequent citations seen during laboratory CLIA inspections with tips on preventing them. Includes advice on maintaining continuous compliance every day in your laboratory.

Learning Objectives

- Summarize the most frequent inspection citations
- Utilize tips presented to prevent those citations
- Maintain continuous compliance every day

11:15a - 11:30a **"Graduation Ceremony"**  Summary and Conclusion

**.25 CME or PACE credits**

Dr. Janzen & Dr. Daly will summarize the learnings of the day and provide practical insight into the role of laboratory director to conclude the laboratory director curriculum.

11:30a **Adjourn**