Symposium for Clinical Laboratories April 5-8, 2017: Session Descriptions

The Symposium for Clinical Laboratories includes 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

● Business management and lab operations

○ Clinical testing specialties

● Quality management and quality improvement

● Safety and Phlebotomy

● Regulations and CLIA compliance

● Personnel

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

Wednesday, April 5

8:15a – 4:00p Liquid Chromatography/Mass Spectrometry Workshop (separate registration)
Regulatory, scientific, operational and compliance experts share their knowledge and perspectives on LCMS technology. 6 PACE credits.

10:00a – 7:30p Symposium Check-in

5:00p – 6:00p The New COLAcentral
Sarah Lorenz
1 PACE credit
COLA labs- We’ve redesigned COLAcentral with you in mind. The enhanced COLAcentral web portal is here. You spoke and we listened. You wanted a faster and easier-to-navigate portal to help run your lab more efficiently. We’ve streamlined COLAcentral and created a more responsive interface with faster load times, improved communication channels and instant access to the tools you use most.

COLAcentral is an online, secure, web portal that manages compliance activities for COLA laboratories, consultants and integrated health systems. Receive alerts, update your lab profile, view survey results, and prepare for upcoming surveys all in one central location. Whether you manage one laboratory or hundreds, COLAcentral will reduce the paperwork and headaches involved in laboratory compliance administration allowing you to focus on what matters most whether that be educating a new person in the laboratory, performing instrument calibration or taking care of a patient. Administration should always be convenient, real-time and hassle free and with COLAcentral it is!

Thursday, April 6

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.
Symposium for Clinical Laboratories April 5-8, 2017: Session Descriptions

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

8:45a - 10:00a Thursday Opening General Session
CMS CLIA Update 2017
Karen Dyer, MT(ASCP) DLM
1 CME or PACE credit
This session will provide an update on current CMS activities, including an update on Precision medicine and lab developed test issues with CLIA modernization. The status of planned changes to the PT regulations for laboratories and PT programs will be discussed.

Learning Objectives
- Outline regulatory requirements for PT referral
- Summarize the status of the PT rule in progress
- Describe the presidential initiative “Precision Medicine”
- Outline issues related to lab developed tests
- 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 Molecular and Genetic Testing: How to Position your Laboratory for New Technology
Megan Schmidt
1.5 PACE credits
- Molecular testing is transitioning from research to clinical laboratories. With this change, clinical laboratories are faced with new requirements and challenges to standardize, document and follow test procedures. Laboratories must also demonstrate end to end sample traceability and comply with CLIA and other accreditation organizations. This presentation will provide a basic background for clinical molecular testing, key examples of some of the challenges facing laboratories and the support provided by laboratory information systems with the management of data.

Learning Objectives
- Define molecular testing and its transition into the clinical laboratory.
- Describe key examples of some of the challenges encountered in the clinical laboratory.
- Recognize the functionality that Laboratory Information Systems provide to support molecular testing

A02 Basics of Quality Control
Verlin Janzen, MD, John Daly, MD, Karen Dyer, MT(ASCP) DLM
1.5 CME or PACE credits
- 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.

Learning Objectives
<table>
<thead>
<tr>
<th>Symposium for Clinical Laboratories April 5-8, 2017: Session Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Differentiate between internal &amp; external quality control and the roles and importance of each in monitoring lab quality</td>
</tr>
<tr>
<td>• Illustrate the steps in the QC process</td>
</tr>
<tr>
<td>• Assist in the development of a laboratory QC policy and program</td>
</tr>
<tr>
<td>• 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</td>
</tr>
</tbody>
</table>

### A03 Phlebotomy and Needle Safety
Kathleen Finnegan, MS, MT(ASCP)SH
1.5 PACE credits

- Needle sticks are always a concern of the phlebotomist. It is important to know how to avoid a needle stick and what to do if one does occur, including the treatment options.

#### Learning Objectives:
- Define occupational exposures
- Discuss what are considered occupational exposures
- Discuss the risk of infection after an occupational exposure
- Define circumstances, locations and personnel that are involved with accidental needle sticks
- Discuss how we can prevent accidental needle sticks

### A04 What You Don’t Know Can Hurt You! Establishing a Billing and Coding Compliance Plan for Your Laboratory
Milly Keeler, BSMT (ASCP), CLC (AMT), CCCP®
1.5 PACE credits

- The medical field is the most highly regulated industry. Is YOUR Laboratory in compliance with all the billing and coding rules and regulations that affect you? What you don't know CAN hurt you! In this session you will learn about 5 of the major regulatory policies that you must be aware of: False Claims Act, Anti-Kickback Statute, Physician Self-Referral Statue, Exclusion Authorities, and Civil Monetary Penalties Law. How do you avoid violating any of these laws to steer clear of fines/penalties and sanctions? How do you ensure staff compliance? In this session we will review the seven essential components of a billing and coding compliance plan as defined by the OIG (Office Inspector General) and provide you with resources to develop your own site specific Laboratory Compliance Plan.

#### Learning Objectives
- Gain awareness that the medical field is the most highly regulated industry (& why it is so).
- Name the five major policies that affect every Laboratory (False Claims Act, Anti-Kickback Statute, Physician Self-Referral Statue, Exclusion Authorities, Civil Monetary Penalties Law)
- Recite some of the fines/sanctions put on those that failed to meet the requirements.
- Name resources available to assist your Laboratory with compliance
- Describe how to develop an Laboratory Compliance plan

### A05 Technical Consultant Responsibilities
Eileen McConnell, MT(ASCP)
1.5 PACE credits

- The ability of a laboratory to provide quality services cannot be achieved without the direct involvement of dedicated Technical Management. In a moderate complexity lab, this is the Technical Consultant (TC) and in a high complexity lab this is one or more Technical Supervisors (TS). These positions are required by CLIA and are important roles for the regulatory and operational success of the laboratory. This presentation will review the qualifications required for the role of a TC/TS. The responsibilities of the position and interaction with other staff in the laboratory and facility will also be addressed.
Symposium for Clinical Laboratories April 5-8, 2017: Session Descriptions

Learning Objectives:
- Summarize the qualifications and responsibilities of each position
- List examples of how these responsibilities are carried out
- Describe the relationship of the technical consultant/supervisor to other positions in the laboratory

A06 HIPAA and Identity Theft for Medical Offices and Laboratories
Kelly Ogle, BSDH, MIOP, CMPM®, CHOP®
1.5 PACE credits
- Ninety minutes packed with information on HIPAA, patient confidentiality, information security, and identity theft prevention. We take a patient from the very first contact with the practice/laboratory all the way through the billing process, pointing out privacy and security risks along the way. We even discuss contingency plans and breach notification. Also, we will be reviewing the importance of electronic security methods and how to assess your vulnerabilities.
- Identity theft is a concern for every business, workplace, and individual. This seminar includes valuable hints for protecting identity as well as a response when the unthinkable happens.
Learning Objectives:
- Identify privacy and security risks in your laboratory
- Discover ways to prevent these risks
- Recognize your responsibility to recognize and respond to a security breach
- Discuss documentation and what it means to be HIPAA compliant
- Summarize importance of protecting identity for everyone
- Outline what to do if someone steals your identity or that of someone you know

Thursday Breakout Session B 1:30p – 3:00p (select one)

B11 Technology Workshop: Chemistry Instruments
1.5 PACE credits
- 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.
Learning Objectives
- Identify factors to consider when selecting a chemistry instrument for the laboratory
- Recognize the pitfalls encountered in the selection process
- Analyze the differences between systems and determine which would be the most appropriate for a particular lab setting

B12 Basics of Proficiency Testing
Verlin Janzen, MD, John Daly, MD, Karen Dyer, MT(ASCP) DLM
1.5 CME or PACE credits
- 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. This session is designed for physician laboratory directors and for individuals without laboratory training.
Learning Objectives
- Assess the value of proficiency testing (PT) as a valuable, practical, and quality enhancing exercise in any laboratory
- Participate in PT as required under CLIA ‘88 for all non-waived testing
- Summarize the CLIA requirements for the POL as it pertains to PT
- Evaluate PT results and interpret reports; when problems occur, determine what actions to take to prevent an adverse effect on patient results
<table>
<thead>
<tr>
<th>Session</th>
<th>Title</th>
<th>Speaker</th>
<th>Description</th>
<th>Learning Objectives</th>
</tr>
</thead>
</table>
| B13     | Creating a Strong Lab Team: Everything from Job Descriptions, Behavior Based Interviewing, Training, Competency Evaluation to Mentoring; How to Build a Culture of Caring and Excellence | Milly Keeler, BSMT (ASCP), CLC (AMT), CCCP® | Personnel are the single most decisive factor in the success of your laboratory. It doesn't matter how good the equipment is if you don't have qualified, trained employees to appropriately use it. With continued financial pressure and demand of having to do "more with less," recruiting (or keeping) the most valuable individuals for your laboratory is crucial. How do you find the "right" employee for the job? How do you ensure adequate training to ensure their success? How do you maintain competency and encourage professional growth? In this session you will be introduced to practical ways to find, train and build a laboratory staff that is caring and committed to excellence in laboratory testing. | - Review essential components of effective job descriptions for laboratory personnel  
- Describe qualifications (education & training) required as well as attributes of high performing lab employees  
- Discuss how behavioral interviewing can assist with successful interviewing and hiring  
- Learn how to perform effective, meaningful training and competency assessment  
- Identify ways to build a strong mentoring team to support lab staff |
| B14     | OSHA Training | Kelly Ogle, BSDH, MIOP, CMPM®, CHOP® | 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. | - Understand your rights under OSHA, as well as how to protect yourself from hazards you may encounter during your workday  
- Discuss Bloodborne Pathogens, electrical and fire safety, ergonomics, workplace violence, MRI and laser safety, and hazard communications  
- Learn the new labeling and SDS requirements under the new Hazard Communication Standard  
- Recognize and interpret the newly required pictograms and understand how to read the new safety data sheets  
- Realize the importance of a safe environment and what is recommended to review during a self-audit of your office |
| B15     | Future and Value of Laboratory Professionals | Elissa Passiment, Ed.M., MT(ASCP) | Laboratory professionals contribute to the science of medicine and enable everyone on the health care team to provide quality care. With the advent of genetic/molecular tests and test methods, our services will help individuals avoid or prepare for conditions. Concerns about diagnostic and medical errors focus the need for our invaluable information and challenges our roles for years to come. We will examine medicine’s needs for our services and how they can be best utilized to optimize patient care and safety. | - Describe how our services are utilized  
- Analyze our current practices and the new services we need to provide in light of diagnostic error discussions  
- Evaluate initiatives our colleagues and the CDC are exploring to improve patient care and safety |
Symposium for Clinical Laboratories April 5-8, 2017: Session Descriptions

B16  Toxicology Testing….Is it a Good Fit for Your Laboratory?
Leigh Ann Smith, MLS(ASCP) CLS & Rebecca Kenner, BS, DLM, MT(ASCP)
1.5 PACE credits

Are you considering expanding your lab services into toxicology testing? With the epidemic of overdoses from Opioid abuse and the recommendation by the CDC to screen and monitor patients prescribed opioid pain medication, Urine drug testing is being implemented across the country. Urine drug testing is being utilized by not only pain management and substance abuse clinics but by physician office laboratories to meet the monitoring standards. This presentation will briefly point out the need for drug testing. It will describe how the facilities use urine drug testing to meet best practice standards. The difference between POCT, immunoassay screening and LCMS/MS testing will be discussed. And finally, this presentation will explain the implementation process focusing on the compliance standards from personnel to validation.

Learning Objectives
- Describe toxicology testing
- Summarize important needs for drug screening
- Outline how the lab fits into best practices in pain management and substance abuse monitoring
- Describe how the testing is done using immunoassay testing and LCMS/MS confirmation testing
- Focus on compliance when implementing toxicology services

B17  The New COLA central (1:30-2:30p)
Sarah Lorenz
1 PACE credit

COLA labs- We’ve redesigned COLA central with you in mind. The enhanced COLA central web portal is here. You spoke and we listened. You wanted a faster and easier-to-navigate portal to help run your lab more efficiently. We’ve streamlined COLA central and created a more responsive interface with faster load times, improved communication channels and instant access to the tools you use most.

COLA central is an online, secure, web portal that manages compliance activities for COLA laboratories, consultants and integrated health systems. Receive alerts, update your lab profile, view survey results, and prepare for upcoming surveys all in one central location. Whether you manage one laboratory or hundreds, COLA central will reduce the paperwork and headaches involved in laboratory compliance administration allowing you to focus on what matters most whether that be educating a new person in the laboratory, performing instrument calibration or taking care of a patient. Administration should always be convenient, real-time and hassle free and with COLA central it is!

Limited seating! This session is also offered on Wednesday 4/5 at 5:00p and at 3:30p Thursday (C27)

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

C21  Technology Workshop: Laboratory Information Systems
1.5 PACE credits

This breakout provides an 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.

Learning Objectives
- Understand the multiple functions for computers in the lab (i.e. instrument data acquisition, billing, appointment management, tracking of referred specimens, laboratory record keeping)
- Identify which types of features are desired in a computer system and how to ask questions
- Analyze the differences between the systems and determine which LIS would be the most appropriate for a particular lab setting
**Symposium for Clinical Laboratories April 5-8, 2017: Session Descriptions**

<table>
<thead>
<tr>
<th>Session</th>
<th>Title</th>
<th>Presenter(s)</th>
<th>Credits</th>
<th>Description</th>
</tr>
</thead>
</table>
| C22     | Pre & Post-analytic Issues, Introduction to QA (3:30-5:30p) | | 2 CME or PACE credits | 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. Learning Objectives:  
  - Evaluate which testing phase is most prone to laboratory error  
  - Outline areas where laboratory errors most commonly occur  
  - Formulate corrective actions and preventive measures to avoid these errors  
  - Outline the role of informatics in the clinical laboratory and apply steps in informatics utilization to avoid laboratory errors  
  - Define Quality Assessment  
  - Summarize the role, structure and components of acceptable Quality Assessment Plans  
  - Outline how to develop a “culture of quality” in your laboratory |
| C23     | Hemolysis and Pre-analytical Variables | Kathleen Finnegan, MS, MT(ASCP)SH | 1.5 PACE credits | Hemolysis results when red blood cells are damaged or destroyed releasing hemoglobin. Hemolyzed specimens can result from patient conditions but most often result from procedural errors in specimen collection and handling. Numerous factors are associated with pre-analytical errors. These errors can compromise specimen integrity and impact patient care. Learning Objectives:  
  - Recognize the cause of hemolysis.  
  - Discuss how to prevent hemolysis  
  - Determine how to reduce pre-analytical variables and specimen rejection |
| C24     | Quality Assessment | Kathy Nucifora, MPH, MT(ASCP) & Irwin Rothenberg, MBA, MS, MT(ASCP) | 1.5 PACE credits | 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. Learning Objectives:  
  - Define Quality Assessment and differentiate from Quality Control  
  - Summarize the objectives, components, and structure of Quality Assessment plans  
  - Implement your QA plan by performing QA reviews  
  - Apply the longer–term goal of creating a culture of quality |
### Symposium for Clinical Laboratories April 5-8, 2017: Session Descriptions

<table>
<thead>
<tr>
<th>Session Code</th>
<th>Session Title</th>
<th>Presenter(s)</th>
<th>PACE Credits</th>
<th>Description</th>
</tr>
</thead>
</table>
| C25          | Communication Biohazard                           | Chérie Petersen             | 1.5          | We’re all infinitely aware that the laboratory’s contribution to patient care is enormous; however, are we equally aware that our communication skills often jeopardize our relationship to the patient care team? Laboratory professionals are experts in their field, no doubt, but at times the delivery, or packaging, of their expertise can sabotage the actual value. This session engages participants with an energetic, focused, interactive, and humorous approach, which uncovers and explores some of the communication biohazard that can be pervasive within any laboratory. Attendees will have the opportunity to identify some of the communication pitfalls that occur all too frequently while developing appropriate communication strategies to align their communication delivery methods with the value of their expertise. Learning Objectives  
- Deliver more effective communication that better represents individual experience and expertise  
- Uncover improved approaches for delivering routine and redundant information to common customer groups  
- Recognize the impact that poor communication has on the laboratory |
| C26          | Inspection Readiness                              | Eileen McConnell, MT(ASCP)  | 1.5          | 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. Learning Objectives  
- Manage the survey process as part of the continuum of providing quality laboratory services rather than as a separate event  
- Maintain a laboratory operation that will always be prepared for an inspection.  
- Outline the typical survey framework and review of laboratory records and processes  
**This session is also offered on Friday as E45** |
| C27          | The New COLAcentral                               | Sarah Lorenz                | 1            | COLA labs- We’ve redesigned COLAcentral with you in mind. The enhanced COLAcentral web portal is here. You spoke and we listened. You wanted a faster and easier-to-navigate portal to help run your lab more efficiently. We’ve streamlined COLAcentral and created a more responsive interface with faster load times, improved communication channels and instant access to the tools you use most. COLAcentral is an online, secure, web portal that manages compliance activities for COLA laboratories, consultants and integrated health systems. Receive alerts, update your lab profile, view survey results, and prepare for upcoming surveys all in one central location. Whether you manage one laboratory or hundreds, COLAcentral will reduce the paperwork and headaches involved in laboratory compliance administration allowing you to focus on what matters most whether that be educating a new person in the laboratory, performing instrument calibration or taking care of a patient. Administration should always be convenient, real-time and hassle free and with COLAcentral it is!  
**Limited seating! This session is also offered on Wednesday 4/5 at 5:00p and Thursday at 1:30p (B17)** |
Symposium for Clinical Laboratories April 5-8, 2017: Session Descriptions

Friday, April 7

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
Lessons from Ebola and Zika  
Elissa Passiment, Ed.M., MT(ASCP)  
1.25 CME or PACE credits
The challenges presented by Ebola were not remarkably different that those laboratorians have faced before – with HIV and Hepatitis. However, the reactions of the media and the public affected how the patients and their samples were handled as well as how we thought of our laboratory safety procedures. This session will describe the lessons learned by the CDC and others and present the most recent guidance from that agency and how this prepared us for Zika.
Learning Objectives
- Describe some of the issues that arose while providing laboratory services during the Ebola outbreak and the preparations for Zika
- Discuss what to consider when determining the personnel safety risks within the laboratory
- Evaluate the lessons learned and which CDC guidelines apply to your laboratory

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

D31 Life Cycle of A New Point of Care Test Request  
Leandra Soto, MLS(ASCP)\textsuperscript{cm}, Serafina Brea, MLS(ASCP)\textsuperscript{cm} and Jeanne Mumford, MT(ASCP)  
1.5 PACE credits
In this session you will learn how to manage new test requests in your point of care program. You'll learn from experiences and from shared techniques on how to analyze the request and its possible impact to your existing program. You'll also learn how to overcome challenges of interfacing point of care devices and how to manage your point of care program locally and in a large health care system.
Learning Objectives:
- Identify key components in developing a formal approval structure for new test requests
- Recognize and overcome common IT issues when interfacing point of care devices
- Learn how to integrate new tests into your point of care program
### D32 Personnel- Required Positions and Competency

**John Daly, MD**  
1.5 CME or PACE credits  

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.  

**Learning Objectives**  
- Identify and summarize CLIA personnel requirements for each position  
- Illustrate instances of non-compliance  
- Implement appropriate corrective actions to achieve compliance  
- Discuss rationale for competency  
- Outline six CMS requirements for Competency Assessment

### D33 Competency Assessment

**Kathy Nucifora, MPH, MT(ASCP) & Irwin Rothenberg, MBA, MS, MT(ASCP)**  
1.5 PACE credits  

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 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.  

**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

### D34 Financial Perspectives of Running a Laboratory

**Tim Dumas, CLS**  
1.5 PACE credits  

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**  
- Formulate ways to maximize laboratory revenue  
- Compare laboratory income to expenses  
- Calculate cost per test  
- Select a practical laboratory test menu that is right for your patient population  
- Choose the right analyzer(s) for your needs  
- Determine personnel needs  
- Monitor lab revenue
### D35  
**Are You a Customer Service Have or Have Not?**  
Chérie Petersen  
1.5 PACE credits  

There is no doubt that customer service is a critical component of quality patient care. Having said that, many laboratorians think customer service skills only need to be applied in the presence of patients. The patient experience isn't just about what we do when we're with them (which for a laboratorian is rare), but also what we do as we interact with everyone associated with their care. So HOW do you provide great customer service?  

**WHAT** are the necessary skills and activities associated with providing great customer service (i.e., quality patient care)? And, do YOU have those skills? This session will provide an opportunity for self-assessment utilizing a customer service skills preferred profile and an interactive discussion regarding the dos and don’ts of outstanding customer service.  

**Learning Objectives**  
- Identify the positive financial impact that comes with implementing customer service excellence within the laboratory  
- Utilize a self-assessment tool to benchmark themselves against a customer service preferred profile while identifying the skills and activities where personal improvement would yield better customer service and quality patient care outcomes  
- Recognize what happens during customer service interactions that can cause poor outcomes and a negative experience for customers (i.e., colleagues, other healthcare providers, patients, and patients’ families)  
- Determine the skills and activities that promote outstanding customer service  

### D36  
**“Top 10” Common Citations**  
Eileen McConnell, MT(ASCP)  
1.5 PACE credits  

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.  

**Learning Objectives:**  
- Anticipate surveyor expectations regarding these criteria  
- Assess your lab’s level of compliance with these criteria  
- Apply strategies to correct non-compliances and maintain continuous compliance
### E41 Standardizing Point of Care Testing and Harmonizing Workflows Between Hospitals and Ambulatory Locations
Jeanne Mumford, MT(ASCP)

- **1.5 PACE credits**

No matter how large or small or how many hospitals or ambulatory sites you have in your health care system the steps to standardizing test systems and harmonizing workflows resonate throughout the health care industry. In this session, we'll talk about the details of integrating 3 community hospitals, 2 academic hospitals, 40 physician offices and at least 12 university clinics into one Point of Care program. You'll learn about challenges and successes when standardizing and harmonizing workflows, procedures and test devices.

#### Learning Objectives:
- Establish open communication and identify key players in standardization of point of care tests
- Discuss tools and strategies for multidisciplinary collaboration
- Identify POCT clinical considerations and managerial challenges

### E42 Quality Assessment of Proficiency Testing

- **1.5 CME or PACE credits**

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. *This session is designed for physician laboratory directors and for individuals without laboratory training.*

#### Learning Objectives:
- Apply quality assessment concepts to evaluate PT performance
- Monitor PT performance to identify problems
- Determine root cause of PT problems
- Formulate solutions to correct PT problems

### E43 CLIA QUALTY SYSTEM REGULATIONS - Verifying performance specifications, calibration, and calibration verification
Margaret Blaetz, CLC(AMT), CCCP(AAPOL)

- **1.5 PACE credits**

The CLIA Quality System Regulations require laboratories to check (verify) the manufacturer's performance specifications provided in the package insert--for accuracy, precision, reportable range, and reference ranges--for each test that the laboratory performs. The verification process helps to assure that the test, when used in your laboratory by your testing personnel for your patient population, is performing as the manufacturer intended.

The laboratory is responsible for performing calibration as directed by the manufacturer’s test system instructions, and when calibration verification of the test system (see below) does not produce acceptable results. The laboratory is also responsible for calibration verification to check calibration. Regulations describing how and when calibration verification is to be performed for non-waived (moderate and high complexity) tests will be reviewed.

#### Learning Objectives:
- Summarize accuracy, precision, reportable range and reference range
- Outline why verified reference ranges are necessary and beneficial
- Summarize calibration and calibration verification
- Outline corrective action when calibration verification fails
### E44  Negotiating With Insurance Companies

Tim Dumas, CLS  
1.5 PACE credits  
This session is for anyone who has ever said “they won’t pay for us to do labs in house!” The ability to get fast results for certain critical tests is good medical practice that enhances patient care. Some offices don’t do in-house labs because they think it will cost too much. There is profit in lab tests and this session will help you find it.  
**Learning Objectives**  
- Decide if your lab and your patients can benefit by performing tests in-house  
- Determine what’s legal and what’s not  
- Practice the correct way to ask for reimbursement  
- Apply principles to keep your lab costs down  
- Work with insurance companies so they can earn a living, too

### E45  Inspection Readiness

Eileen McConnell, MT(ASCP)  
1.5 PACE credits  
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.  
**Learning Objectives**  
- Manage the survey process as part of the continuum of providing quality laboratory services rather than as a separate event  
- Maintain a laboratory operation that will always be prepared for an inspection.  
- Outline the typical survey framework and review of laboratory records and processes  

This session is also offered on Thursday as C26

### E46  IQCP in 2017: How’s it Going?

Terri Wolek, MBA, MT(ASCP) & Angelia Dooley, MT, B.S.  
1.5 PACE Credits  
Come to this session to learn about the most common pitfalls from COLA surveyors related to IQCP. This session will improve your chances of passing your next inspection as it relates to QC practices, how to address other QA failures and the impact that will make on your IQCP. Also, learn what type of action and documentation the inspectors are looking for from your lab.  
**Learning Objectives:**  
- Avoid common pitfalls related to IQCP  
- Address IQCP QA failures  
- Predict the actions and documentation that inspectors want
Symposium for Clinical Laboratories April 5-8, 2017: Session Descriptions

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

3:30p – 4:15p Working Collaboratively with Your Nurses
James Hernandez, MD
.75 CME or PACE credits
Physicians, laboratorians and nurses can sometimes view the same situation quite differently. They may share similar perspectives, but have much different perceptions. This session suggests ways that we can all understand each other’s viewpoints better in order to work more collaboratively.
Learning Objectives:
• Describe Real Colors® and how it can be used to understand each other
• Review instructive case scenarios that illustrate how physicians, laboratorians and nurses may miscommunicate and how to improve communications regarding lab testing

4:15p – 5:15p Pharmacogenomics: Personalized Medicine in the Laboratory
Tiffany Roberts, PhD, DABCC, DABHI
1 PACE credit
Pharmacogenomics (PGx) is a clinical specialty concerned with how a patient’s genetic makeup affects his or her response to medications. Genetic factors can influence both drug efficacy (how well it works) and the likelihood of an adverse event (such as toxic effects). This presentation will provide a basic background for clinical PGx, key examples of the clinical benefits of PGx testing, the standard laboratory PGx instrumentation and workflow, as well as common questions and thoughts on the future of PGx testing.
Learning Objectives:
• Define PGx and explain its role in patient care.
• Describe key examples of PGx clinical utility.
• Recognize the laboratory instrumentation used for PGx and describe a basic workflow.
• Answer the three most common questions clinicians ask about PGx.
NOTE: PACE credit only. Those in the LD qualification curriculum must attend Practical Utilization and What is? instead, which run concurrently

4:15p – 6:00p Concurrent Lab Director CME sessions:

4:15p – 5:00p Practical Utilization
John Daly, MD, Verlin Janzen, MD & James Hernandez, MD
.75 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.

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, April 8**

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.

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.

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

11:30a **Adjourn**