CRI® Symposium for Clinical Laboratories
Aligning Education and Excellence in Laboratory Medicine

OCTOBER 7-10, 2015 • Tropicana Las Vegas • LAS VEGAS, NV

“As usual, a well-organized and informative symposium that always delivers and exceeds expectations!”
- Ronnie Morales, Woodbury, NY, October 2014

ANNOUNCING
IQCP WORKSHOP EVENT:
OCTOBER 7, 2015
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 Key

Lab Director Qualification Track

- Business aspects of lab operations
- Clinical testing specialties
- Quality management and quality improvement
- Safety and Phlebotomy
- Regulations and CLIA compliance
- The latest in QC practices

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

**Wednesday, Oct. 7, 2015**  
IQCP Workshop 8:30a – 4:00p (separate registration)

**Wednesday, Oct. 7, 2015**  
Symposium Check-in 10:00a – 8:00p

**Thursday, Oct. 8, 2015**

7:00a - 8:15a Lab Director session  
*Basics of Laboratory Medicine for Physicians*  
Verlin Janzen, MD, FAAFP  
Family Physician and Laboratory Director, Hutchinson Clinic, Hutchinson KS  
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

8:45a-10:00a Opening General Session  
*CLIA Update 2015*  
Karen W.Dyer MT(ASCP) DLM  
Director (Acting), Division of Laboratory Services, Centers for Medicare & Medicaid Services  
1 CME or PACE credit

This session will provide an update on current CMS activities. The status of recently published regulations for Proficiency testing referral in addition to a status update on the planned changes to the PT regulations for laboratories and PT programs will be discussed. An update
on the status of the implementation of Individualized Quality Control Plans will be presented.

Learning Objectives
- Outline regulatory requirements for PT referral
- Summarize the status of the PT rule in progress
- Outline plans for IQCP implementation as the end of the Education and Transition period is reached.
- Summarize the overall CMS enrollment data for laboratories and the various certificate types in each category

### Thursday Breakout Session A (select one)

<table>
<thead>
<tr>
<th>A01</th>
<th>Future Outlook for Laboratory Point-of-Care Testing</th>
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<tbody>
<tr>
<td></td>
<td>Kim Futrell, MT(ASCP), Products Marketing Manager, Orchard Software</td>
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<td>1.5 PACE credits</td>
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<td>With emerging technological innovations in healthcare, including smartphone apps, biosensors, lab-on-a-chip, and wearable devices—all of which offer a closer connection to the patient—Point-of-Care (POC) technologies are quickly becoming part of the transformation of the healthcare landscape. The driving concept in support of Point-of-Care testing (POCT) is to bring testing closer to the patient and results conveniently and quickly to the provider to expedite diagnosis and thereby treatment. Empowering providers to make decisions at the patient’s side has the potential to significantly impact healthcare delivery and to help address the challenges of health disparities. Yet POCT, along with its benefits, brings quite a few challenges, particularly from the perspective of the laboratory trying to oversee and manage remote testing; and testing typically performed by non-laboratory personnel. Additionally, as the volume of POCT increases, so does the importance of having the results electronically incorporated into the EHR or data warehouse in order to include the results in analytics necessary for risk stratification and population health management. Development, implementation, and connectivity of portable diagnostic and monitoring devices for POCT can be part of a successful shift from curative medicine, to predictive, personalized, and preemptive medicine and laboratory leaders can be a part of making this successful.</td>
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<td>Learning Objectives</td>
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<td>- Explain the current factors and healthcare changes that are shaping the laboratory POCT market.</td>
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<td>- Identify how POCT will change with the restructuring of the healthcare delivery system.</td>
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<td>- Outline the benefits and challenges laboratories face in the oversight and management of POCT.</td>
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<td>- Evaluate POCT connectivity needs and concerns, including the importance of including POCT in healthcare analytics.</td>
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<table>
<thead>
<tr>
<th>A02</th>
<th>Introduction to Quality Control</th>
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<td>Verlin Janzen, MD &amp; John Daly, MD</td>
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<td>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. Dr. Janzen and Dr. Daly 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.</td>
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<td>Learning Objectives</td>
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<tr>
<td></td>
<td>- Differentiate between internal &amp; external quality control and the roles and importance of each in monitoring lab quality</td>
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<td>- Illustrate the steps in the QC process</td>
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</table>
- Assist in the development of a laboratory QC policy and program
- 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

### A03 Nonconforming Events: Unearthing Buried Treasure
Luci Berte, MA, MT(ASCP)SBB,DLM; CQA(ASQ)CMQ/OE
Quality Management Systems Educator, American Society for Quality (ASQ) Certified Quality Auditor and Quality Manager

1.5 PACE credits

A problem that goes unreported to those who can fix it is a problem that remains buried and is highly likely to recur. Laboratory problems are known as “nonconforming events” because the problem is due to a need or requirement that went unfulfilled. This program describes how your laboratory can implement a nonconforming event management program, analyze the wealth of information that problems represent, and remove the root cause(s).

**Learning Objectives**
- Outline the elements of a nonconforming event management program
- Distinguish between remedial, corrective, and preventive actions
- Use resource information to help your laboratory develop better documents

### A04 Best Practices for Phlebotomy
Kathleen Finnegan, MS MT(ASCP)SH
Clinical Associate Professor and Program Director of the Phlebotomy Training Program, Dept. of Clinical Laboratory Sciences, Stony Brook University, New York

1.5 PACE credits

Proper phlebotomy technique ensures patient safety and better patient care by reducing pre-analytical errors. The quality of blood specimens obtained from patients has an important role for prognosis, diagnosis, treatment and patient management. The laboratory staff must recognize the importance of good phlebotomy technique for overall quality of laboratory results.

**Learning Objectives:**
- Describe best practices in phlebotomy techniques and procedures.
- Discuss the guidelines for good phlebotomy practice.
- Discuss phlebotomy procedures to increase the overall quality of specimen collections

### A05 What Does IQCP Mean for Your Lab?
Kathy Nucifora, MPH, MT(ASCP)
Accreditation Division Director, COLA, Columbia, MD

1.5 PACE credits

CMS is publishing guidance for a new, more meaningful alternate QC option that will replace EQC. The new option is called Individualized Quality Control Plan (IQCP), and it embraces the concept of Risk Assessment to determine the “right” QC for your laboratory. Begin this transition with the information you will need to develop your QC plans.

**Learning Objectives**
- Follow the evolution of IQCP from conception to implementation.
- Apply Risk Assessment tools in determining the “right QC” for your laboratory.
- Walk through a sample Risk Assessment.
A06 **Professional and Medical Ethics**
Edward J. Peterson, Jr., MBA, MT(ASCP)
Director of Laboratories, Barnes-Jewish Hospital, St. Louis, MO
1.5 PACE credits

Healthcare professionals are defined by a standard of conduct deep-rooted in commitment, confidentiality, and relationships. As professionals we recognize a personal accountability and a moral obligation to all customers served—clients, employees, employers, physicians, organizations, and the public. This session will provide an overview of professional and medical ethics and its impact on the healthcare profession and the healthcare system.

**Learning Objectives**
- Define medical ethics
- Identify the five ethical principles
- Discuss the difference between the deontological and the teleological ethical theories
- Analyze and choose the most appropriate approach to an ethical situation

Thursday Breakout Session B (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 system would be the most appropriate for a particular lab setting

B12 **Introduction to Proficiency Testing**
Verlin Janzen, MD & John Daly, MD
1.5 CME or PACE credits

In this session, Dr. Janzen and Dr. Daly 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 and interpret PT results and reports; and, when problems occur, determine what actions should be taken to prevent an adverse effect on patient results
### Flowcharts: How to Make Them and Reap the Benefits

**Luci Berte**, MA, MT(ASCP)SBB,DLM; CQA(ASQ)CMQ/OE  
Quality Management Systems Educator, American Society for Quality (ASQ) Certified Quality Auditor and Quality Manager  
1.5 PACE credits

All work is a series of processes, with laboratories of all sizes, scopes, and specialties having preanalytic, analytic and postanalytic processes. Flow charts provide an easy means to visualize your laboratory's work processes and greatly simplify procedure writing, staff training and competence assessment and corrective actions to nonconformances. This program demonstrates how to document laboratory work processes as simple one-page flow charts rather than the multi-page verbal descriptions commonly called “SOPs.” Participants will learn about different flow chart display methods and will be provided with examples of common basic laboratory flow charts.

**Learning Objectives**
- List and describe 6 basic flow chart symbols.
- Explain how to create a basic process flow chart.
- Identify the procedures the process activities represent.

### STD's – Diagnosis, Screening and Surveillance

**Margaret Blaetz**, M, MLT(ASCP)  
Laboratory Manager, Regional Women's Lab, Marlton, NJ  
1.5 PACE credits

Sexually transmitted infections (STIs) remain an important focus area for public health. There have been a number of key advances in diagnostic procedures, in particular, with respect to nucleic acid amplification and rapid point-of-care tests. The purpose of this session is to provide a basic understanding of the principles of laboratory tests in the context of screening and diagnostic approaches as components of STI control.

**Learning Objectives:**
- Summarize key advances in diagnostic procedures for STIs
- Outline the principles of laboratory test used for screening and diagnosis

### Competency Assessment

**Kathy Nucifora**, MPH, MT(ASCP)  
Accreditation Division Director, COLA, Columbia, MD  
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

<table>
<thead>
<tr>
<th>B16</th>
<th>OSHA Training</th>
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<tbody>
<tr>
<td>Ann Bachman, CLC(AMT), MT(ASCP)</td>
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<tr>
<td>Director, Compliance Department, DoctorsManagement, LLC, Knoxville, Tennessee</td>
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This session on OSHA will update you on everything you need to know about OSHA compliance to improve your safety and health on the job. We will cover your OSHA rights, bloodborne pathogens, hazardous chemicals, fire and electrical safety, MRI and Lasers, ergonomics and workplace violence. The only thing missing will be 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.

**Learning Objectives**
- 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.
- Learn OSHA’s newest record keeping requirements
- Recognize and interpret the newly required pictograms and understand how to read the new safety data sheets.
- Outline what OSHA is doing to improve safety and health for healthcare workers.

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**Thursday Breakout Session C** (select one)

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<thead>
<tr>
<th>C21</th>
<th>Technology Workshop: Laboratory Information Systems</th>
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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

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<thead>
<tr>
<th>C22</th>
<th>Quality Assessment in the Clinical Laboratory</th>
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<tbody>
<tr>
<td>John Daly, MD, FCAP</td>
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<tr>
<td>Chief Medical Officer, COLA</td>
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Quality Assessment (QA) monitors all phases of the testing process to ensure quality results and ongoing continuous improvement of lab operations. 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
- 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

<table>
<thead>
<tr>
<th>C23</th>
<th>Navigating Drugs of Abuse Testing: Personnel and Reimbursement</th>
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<tr>
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<td>Ann Bachman, CLC(AMT), MT(ASCP)</td>
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This session will cover the different types of drugs of abuse (DOA) testing and the CLIA/COLA requirements for each, with a focus on personnel qualifications. New CPT codes and Medicare's G codes will be reviewed, with the appropriate use of each. We will discuss the current controversies with drug testing and other regulations that come into play.

Learning Objectives
- Outline CLIA/COLA personnel requirements for high complexity testing for drugs of abuse
- Define test methodologies used in drug testing
- Summarize and use new coding guidelines
- Recognize other laws that impact drug testing
- Discuss current issues surrounding DOA testing

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<tr>
<th>C24</th>
<th>Reference Range Verification</th>
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<tr>
<td></td>
<td>Margaret Blaetz, MCM, MLT(ASCP)</td>
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<td>Laboratory Manager, Regional Women’s Lab, Marlton, NJ</td>
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Verification of reference ranges for tests and analyzers is important in your laboratory. When you examine test results from different populations, you quickly discover that what is "normal" for one group is not necessarily normal for another group. Consideration of all relevant variables must be made to determine which is best for your analytes and your environment.

During this presentation, we will consider the following:
- Current laboratory ranges
- Manufacturer's ranges
- Published reference ranges
- Locally established reference ranges

Learning Objectives:
- Summarize relevant variables that effect reference ranges
- Outline why verified reference ranges are necessary and beneficial
- Consider and use available information to develop appropriate reference ranges for your patient population

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<tr>
<th>C25</th>
<th>Pediatric and Geriatric Phlebotomy</th>
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<tr>
<td></td>
<td>Kathleen Finnegan, MS MT(ASCP)SHCM</td>
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<td>Clinical Associate Professor and Program Director of the Phlebotomy Training Program, Dept. of Clinical Laboratory Sciences, Stony Brook University, New York</td>
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Collecting blood from a pediatric or geriatric patient is challenging and require expertise and knowledge. The health care worker needs to be familiar with various techniques and develop competence in relating psychologically with children and the elderly.

Phlebotomists encounter many different groups of patients where some require different technical skills and effective communication for each age specific group. Collecting blood from a geriatric patient can be challenging and requires expertise, understanding and knowledge of the geriatric population. Physical and emotional factors relating to the aging process can cause difficulty with blood collection. The health care worker needs to be familiar with various techniques to ensure specimen integrity and develop competence in relating psychologically with the elderly patient.

Learning Objectives
• Describe fears and concerns for the pediatric patient
• Identify punctures sites for the pediatric patient
• Define the physical and emotional changes associated with the aging process
• Discuss the proper technique to use on a pediatric or geriatric patient

How the Diagnostic Industry is Helping Laboratories Survive Today’s Challenges
Terri Wolek, MBA, MT(ASCP)
Sr. Sales Product Manager, Bio-Rad Laboratories, Inc.
1.5 PACE credits

With today's ever changing news about changing regulations, short staffing, technology advances and budgetary issues, it is no wonder the laboratory is struggling. Laboratory staff now need to keep on top of all these changes and still improve the quality of their patient results with faster turnaround times. This session will expose some of the new trends in laboratory testing, discuss innovative approaches some diagnostic companies are offering to assist with today's challenges. Learn how you, the laboratory professional, can be integral to your doctors and the rest of laboratory community by becoming a resource for overcoming these challenges.

Learning Objectives
• Discuss the impact that new reimbursement rates have at a time of shrinking laboratory budgets.
• Gather information on how LEAN processes and other quality initiatives can improve your laboratory's quality metrics and other laboratory goals.
• Review the new trends in laboratory testing and automation
• Learn how to become a valuable resource for your doctors, fellow laboratories and sharing your expertise and knowledge for becoming the best laboratory possible

Friday Oct. 9, 2015
7:00a - 8:30a Lab Director session
Responsibilities of the Lab Director: Regulatory
Verlin Janzen, MD, FAAFP
Family Physician and Laboratory Director, Hutchinson Clinic, Hutchinson KS
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. Note: Breakfast will be served in the room to ensure the session starts on time at 7am.
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 Morning General Session
HIV and Hepatitis C: What’s New in 2015
Donna E. Sweet, MD, AAHIVS, MACP
Professor of Internal Medicine, University of Kansas School of Medicine-Wichita
Certified HIV specialist by the American Academy of HIV Medicine
Principal Investigator and Director of the Kansas AIDS Education and Training Center
1.0 CME or PACE credit

Dr. Sweet will discuss the current trends and epidemiology of HIV and HCV disease, covering the latest approach to the treatment of HIV and Hepatitis C with a focus on the newest drugs available. She will discuss the unique aspects of caring for a patient with HIV and Hepatitis C co-infection from her experience in caring for both of these populations for the past 30 years.

Learning Objectives
- Summarize the current trends and epidemiology of HIV and HCV disease.
- Outline current approaches to the treatment of HIV and Hepatitis C
- Describe the unique aspects of caring for a patient with HIV/Hep C co-infection

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

<table>
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<tr>
<th>D31</th>
<th>Basics of How to Set Up Mass Spectrometry</th>
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<tr>
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<td>Geza S. Bodor, MD, DABCC</td>
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<td>Professor of Pathology, University of Colorado, Denver and Section Chief, Chemistry and Toxicology at VA ECHCS</td>
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This presentation is intended for those laboratory directors, managers or supervisors that are considering bringing LCMSMS into an existing clinical laboratory. We will discuss what you need to know before you commit to adding this technology, and explore what’s involved with setting up the technology in the clinical lab. (Method development, validation, writing SOPs, setting up PT are also necessary, but outside of the scope of this presentation.)

Learning Objectives
- Outline space and facility requirements including electrical, gas, ventilation, and necessary reagents and accessories
- Consideration of regulatory requirements, procedures, and documentation
- Plan for necessary training and personnel

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<thead>
<tr>
<th>D32</th>
<th>Pre and Post-analytical Issues</th>
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<tr>
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<td>John Daly, MD, FCAP</td>
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<td>Chief Medical Officer, COLA</td>
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Most laboratory errors occur during the pre- and post-analytic phases. Learn about common errors and how to correct and prevent them.

**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

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**Effective Training: The Path to Competence**
Luci Berte, MA, MT(ASCP)SBB,DLM; CQA(ASQ)CMQ/OE  
Quality Management Systems Educator, American Society for Quality (ASQ) Certified Quality Auditor and Quality Manager  
1.5 PACE credits

New employees need training in the processes and procedures of their respective jobs, and all employees need training for new or changed processes and procedures. Effective training programs are essential for staff to achieve the expected level of competence. In this program, participants will learn how to use laboratory process and procedure documents to develop training in preanalytic, analytic, and postanalytic laboratory processes.

**Learning Objectives**
- Explain the link between work processes and procedures and a training event
- Describe eight forms useful in a training program
- Prepare a training event packet

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**Preanalytical Variables in Phlebotomy**
Kathleen Finnegan, MS MT(ASCP)SH
Clinical Associate Professor and Program Director of the Phlebotomy Training Program, Dept. of Clinical Laboratory Sciences, Stony Brook University, New York  
1.5 PACE credits

Pre analytical variables play a key role in the quality of specimens that are obtained for laboratory testing. The quality of blood specimens has an important role for prognosis, diagnosis, treatment and the monitoring of patient’s care. Hospital staff must recognize the importance of good phlebotomy technique and the affect of pre-analytical variables on the quality of the specimen.

**Learning Objectives:**
- List pre-analytical variables involved with phlebotomy practice.
- Describe pre-analytical variables and their affect on laboratory testing.
- Discuss phlebotomy procedures to increase the overall quality of specimen collections
- Discuss proper tube selection, handling and collection.
- Describe laboratory criteria for specimen rejection.
- Discuss the revised CLSI standards for venipuncture A3-H6 2007
Quality Assurance Plans for Point of Care Testing in a Hospital Setting

Jeanne Mumford, MT(ASCP)
Pathology Supervisor for POCT, Johns Hopkins Hospital, Baltimore, MD
1.5 PACE credits

Quality assurance is important in labs of all sizes and types. This session will focus on QA for moderately complex and waived point of care tests in hospital settings, but the concepts are also applicable to other lab settings. This session will summarize how to monitor the performance of the point of care tests by using annual correlations, proficiency testing, calibration validation studies, QC logs and annual competency training for testing personnel. A well-rounded QA program also includes semiannual internal lab inspections to keep you inspection ready for any regulatory agency.

Learning Objectives
- Develop a QA program for the testing performed
- Monitor the performance of point of care tests
- Utilize various tools to monitor and assess quality

IQCP Education and Transition Period: Tools for Success

1.5 PACE credits

In the years since the final CLIA regulations were published, defined parameters for laboratories performing external quality control (QC) have been widely debated. As a result, the Individualized Quality Control Program (IQCP) has emerged. With the newly published CMS IQCP Guidelines and the education and transition period underway, now is the time to prepare! To assist laboratories during the education and transition, CRI has developed a new IQCP educational program. This session will review the tools available to educate your staff and implement IQCP in your laboratory. Included will be an overview of resources/tools available to implement IQCP, answering the question: “How can IQCP be implemented within my laboratory, while ensuring regulatory compliance?” Discussed will be a comprehensive educational program that is customizable, easy to use, and provides the building blocks necessary to develop an IQCP unique to your laboratory.

Learning Objectives
- Prepare to implement IQCP
- Select from available resources and tools to educate your staff
- Use available resources and tools to implement IQCP in your lab

Implementing HL7 Systems Interfaces In Theory and Practice

Joe Kaplan
Director, Systems Integration Group, Schuyler House
1.5 PACE credits

Meaningful use of information technology in healthcare involves storing patient health information as discrete elements in electronic data systems (EMR, HIS, LIS, etc.). As more practices adopt these systems the problem of exchanging data between them becomes central. An interface between an LIS and another system is a highly customized affair that depends on many details of a particular lab's practice. Since many system interface experts have little or no experience in a lab these projects proceed most easily when the laboratory takes a leadership role in the implementation process. The laboratory's involvement in these projects is so crucial that the actions of a savvy laboratorian can make literally
months of difference in the time it takes to go live on with an HL7 interface to an HIS or EMR. But the typical laboratory technologist has not had any training or preparation for this type of activity. This presentation will introduce the laboratorian to basic concepts in the systems interface project and provide an overview of the most common implementations. The discussion will conclude with an in depth look at some specific challenges that can cause these projects to run in to trouble.

Learning Objectives
- Take a leadership role in the implementation of an HL7 System Interface
- Recognize the most common use cases for an HL7 System Interface
- Identify the personnel involved in an HL7 System Interface Project
- Identify the phases of an HL7 System Interface Project
- Identify the lab’s role in completing the HL7 System Interface Project
- Utilize some of the relevant terminology in an HL7 System Interface Project
- Recognize some specific problems and challenges that may arise over the course of an implementation project

E42  **Quality Assessment of Proficiency Testing**  
Verlin Janzen, MD & John Daly, MD  
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  **Management of Laboratory Operations**  
Edward J. Peterson, Jr., MBA, MT(ASCP)  
Director of Laboratories, Barnes-Jewish Hospital, St. Louis, MO  
1.5 PACE credits

Laboratory management is the integration and coordination of organizational resources that include people, equipment, procedures, and supplies to provide quality laboratory services as efficiently, both financially and operationally, and effectively as possible. Success requires a vast array of skills founded on sound principles of management science. This session will discuss the basic skills and concepts necessary to manage a laboratory through organizational systems, people and financial stewardship.

Learning Objectives
- Define what is management and the four basic elements.
- Discuss the role of quality management in lab operations.
- Discuss how leadership is employed in effectively managing people in your organization
- Identify the steps necessary to make sound decisions and resolve problems encountered in managing.
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<th>E44</th>
<th>Internal Lab Inspections: Are You Inspection Ready?</th>
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| Jeanne Mumford, MT(ASCP)  
Pathology Supervisor for POCT, Johns Hopkins Hospital, Baltimore, MD |
| 1.5 PACE credits |

Self-conducted lab inspections are a great way to stay inspection ready. This session will go over the criteria and how they relate to the current CLIA, COLA, The Joint Commission, College of American Pathology regulations. We will explore some challenges that are faced by Point of Care Coordinators who work closely with nurses and other clinical care staff in a hospital or POL setting. There will also be a review of some of the corrective action plans that are expected when a site “fails” an inspection and how to follow up on those corrective action plans.

Learning Objectives
- Develop internal inspections as part of a QA program
- Address challenges that laboratorians face
- Develop and implement corrective action plans
- Implement strategies to stay Inspection Ready

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<th>E45</th>
<th>New Testing and the FDA – To regulate or not to regulate</th>
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| Margaret Blaetz, MCM, MLT(ASCP)  
Laboratory Manager, Regional Women's Lab, Marlton, NJ |
| 1.5 PACE credits |

The goal of a new test is to improve upon the accuracy, precision, sensitivity and/or specificity of an existing test. The development of all new tests is highly regulated.

- Commercial laboratory tests are those that are performed using commercially manufactured kits and equipment. Development and manufacturing is regulated by the FDA.
- Laboratory-developed tests (LDT’s) are developed, evaluated and validated within one particular laboratory. CMS and CLIA highly regulate these lab-developed assays.

The evolution of LDT technology, marketing and business models marks the need for increased regulatory oversight. The purpose of this session is to outline the FDA's phased-in enforcement of regulatory requirements for LDT’s which will impact new test development as well as new uses for FDA-Approved reagents and equipment. I will share my experience with introducing an LDT in my laboratory.

Learning Objectives:
- Summarize reasons why LDTs need increased oversight
- List items a lab needs to consider before utilizing an LDT
- Outline the FDA’s phased-in enforcement
- Predict how FDA enforcement will impact new test development

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<th>E46</th>
<th>Pharmacogenetic Testing for Gene Variation and its Clinical Utility</th>
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| Safedin Sajo Beqaj, PhD, HCLD, CC(ABB)  
Scientific/Technical Laboratory Director, Pathology Inc., Torrance, California  
Medical Laboratory Director and Clinical Consultant, Molecular Testing Labs, LLC, Vancouver, WA |
| 1.5 PACE credits |

Personalized medicine is often defined as “the right treatment for the right person at the right time. Pharmacogenetic testing (PGx) is part of the personalized medicine as it predicts the responses to medications based on genetic information. PGx combines patient genetic information and pharmacological information to help prevent serious adverse
drug reactions and guide the medication selection and dosing for patients. This session will provide an introduction to PGx and explore its diversity and direct impact to drug metabolism. Learn the technology used for PGx genetic testing with examples, and the existing guidelines and future of PGx testing.

Learning Objectives
- Describe Pharmacogenetics (PGx) and its direct impact to drug metabolism
- Outline the most common PGx testing in clinical diagnostics (genes and panels used for therapy management)
- Describe the technology used for PGx genetic testing
- Discuss clinical interpretation of PGx genetic variation, genotype/phenotype interpretation, and gene to drug interaction
- Summarize existing guidelines and the future of PGx testing

Friday Afternoon General Sessions

3:30p – 4:30p

Working With Your Physicians to Improve Lab Test Ordering
James Hernandez, MD, MS
Associate Professor of Laboratory Medicine and Pathology, Medical Director of Laboratories, Chair for Division of Lab Medicine, Mayo Clinic, Arizona
1.0 CME or PACE credit

Many laboratories are responding to the need to work with their clinicians to scrutinize and to optimize test utilization. This session will describe why it is difficult for clinicians to change their test ordering patterns and how laboratorians can guide them. The key role of the test utilization management committee will be described.

Learning Objectives:
- Describe why clinicians are often reluctant to change their test ordering patterns
- Outline the ingredients of a utilization management committee

4:30p – 5:30p

Empowerment as a Function of Leadership and Peak Performance
Diana Mass, MA, MT(ASCP)
Associated Laboratory Consultants, Valley Center, CA
Clinical Professor of Hematology and Director of the Clinical Laboratory Sciences Program (retired), Arizona State University
1.0 PACE credit

A major factor that influences a quality conscious environment is empowered leaders who have the ability to foster productive outcomes. Leaders must create an organizational culture of empowered people who have the freedom to exhibit self-direction in achieving their institutional mission and goals. In the work environment all staff members are leaders. Discussion will center on the elements and benefits of empowerment, influence strategies, and self-empowering tools which promote peak performance that can assure patient safety and thus quality patient outcomes.

Learning Objectives:
- Describe the value and function of empowerment which leads to a culture of pride and quality performance.
- Apply influence strategies that will promote patient safety and improve patient outcomes.
- Implement self-empowering tools which maintain leadership skills and peak performance.

Note: This session does not provide CME credit. Those in the LD qualification track must attend What is...? An Overview of Operational Processes instead, which runs concurrently.
Concurrent Lab Director session: **What is...? An Overview of Operational Processes**

John T. Daly, MD, FCAP  
Chief Medical Officer, COLA  
1.5 CME or PACE credits

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, Oct. 10, 2015**

*All attendees are welcome to stay for the Saturday Sessions. Saturday attendance is not limited to those in the Lab Director Qualification Track.*

**7:00a – 12:45p**

**General Sessions**

**7:15a – 8:15a**  
**CLIA Personnel & Competency Requirements**  
John Daly, MD, FCAP  
Chief Medical Officer, COLA  
1.0 CME or PACE credit

The CLIA regulations specify personnel positions 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 rational for competency
- Outline six CMS requirements for Competency Assessment

**8:15a – 8:45a**  
**CLIA Facilities Requirements for Clinical Laboratories**  
John Daly, MD, FCAP  
0.5 CME or PACE credits

Facilities requirements encompass suitable space and a safe environment for the performance of laboratory testing. This session will explore the requirements and the steps necessary for compliance.

**Learning Objectives**
- Outline OSHA requirements for facilities and general laboratory safety
- Summarize laboratory fire and electrical safety
- Raise awareness that accidents do happen
- Develop mind-set of reducing the opportunity for accidents
- Implement a plan of action should an accident occur

8:45a – 10:00a

Responsibilities of the Lab Director Part 2: Practical Aspects
Verlin Janzen, MD, FAAFP
Family Physician and Laboratory Director, Hutchinson Clinic, Hutchinson KS
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

10:00 – 10:30a

Instrument and Kit Selection
Verlin Janzen, MD
0.5 CME or PACE credits

The laboratory director has an important role in test method and kit selection. Learn where to find sources of useful information for the test method selection process, and learn how to differentiate characteristics of laboratory test methods and kits to evaluate their suitability for your laboratory.

Learning Objectives
- Outline the role of the laboratory director in test method and kit selection
- Evaluate differentiating characteristics of laboratory test methods/kits that are important when Laboratory Directors assist in the selection process
- Identify sources of useful information for the test/method selection process

10:45a – 12:30p

Surviving Your Inspection and Beyond
Verlin Janzen, MD
1.75 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
In 20 hours, a qualified physician can meet the education qualifications to become a CLIA-accepted laboratory director. However, this conference is not the end of your learning. It's a beginning. The process starts anew for every participant - there are new concepts, ideas, and regulations - all part of being a laboratory director in 2015 and beyond.

Learning Objectives

- Evaluate the current issues affecting laboratory directors and managers
- Develop a plan of action to perform the responsibilities of the laboratory director, laboratory manager, or laboratory testing professional
- Summarize the topics presented in the workshops, breakouts, and general sessions at the Symposium