Symposium for Clinical Laboratories April 3 – 6, 2019: Session Descriptions

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

Breakout Session Topic Key

- Lab Director Qualification Track
- Clinical testing specialties
- Safety and Phlebotomy
- Personnel
- Business management and lab operations
- Quality management and quality improvement
- Regulations and CLIA compliance

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

Wednesday, April 3

8:15a – 4:00p **Liquid Chromatography/Mass Spectrometry Workshop** (separate registration)
Scientific, operational, and compliance experts share their knowledge, perspectives and useful resources on LCMS technology in this intermediate/advanced Workshop. 6 PACE credits.

10:00a – 7:30p Symposium Check-in

Thursday, April 4

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

Introduction to Laboratory Medicine and CLIA Regulations
Verlin Janzen, MD, FAAFP
1.5 CME or PACE credits
This session is designed for physicians, and will provide the novice laboratory director with an orientation to the medical laboratory. This is your starting point as you seek to qualify as a laboratory director of a moderate complexity lab. Dr. Janzen will discuss the language of the laboratory, acronyms, and terms used in office laboratories today. In addition, he will give an overview of the CLIA law and regulations that will allow the attendee to assimilate the subsequent session material into a coherent body of knowledge.
Note: Breakfast will be served in the room to ensure that the session starts on time at 7am.

Learning Objectives

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

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8:45a- -10:00a Thursday Opening General Session
CMS CLIA Update 2019
Karen Dyer, MT(ASCP), DLM
1 CME or PACE credit
This session will provide an update on current CMS activities related to the CLIA Program. Specific topics will be included as CMS activities evolve between now and the meeting date.

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

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

A01 **Most Frequent CLIA Citations and How to Avoid Them**
Megan Schmidt
1.5 PACE credits
One of the most important jobs of laboratory leadership is to ensure compliance with CLIA. Many presentations on avoiding CLIA inspection deficiencies focus on Staff Qualifications, but the most commonly deficiencies, as cited by CMS, are currently related to proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting, as well as the written policies and procedures for the analytic systems. This presentation will include an in-depth analysis of these and other common laboratory citations with a focus on tools to keep your lab compliant.

Learning Objectives
- Summarize frequent CLIA citations
- Formulate strategies to correct non-compliances and avoid citations
- Utilize tools for maintaining compliance

A02 **Basics of Quality Control**
Verlin Janzen, MD, John Daly, MD, Raelene Perfetto, MBA, MT(ASCP)
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. *Introductory level for physician laboratory directors and for individuals without laboratory training.*

Learning Objectives
- Differentiate between internal & external quality control and the roles and importance of each in monitoring lab quality
- Illustrate the steps in the QC process
- 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

Introduction to LC-MS
Amy Patton, MS, NREMT
1.5 PACE credits

This session is designed for novice LC-MS users and will explore the fundamentals of LC-MS theory while comparing it to other separation and detection techniques (i.e., GC-MS, time-of-flight, etc.). All aspects of the equipment will be discussed and the roles that the components play in everyday use of the system. This will allow for a discussion into the practical aspects of LC-MS usage and tips/tricks for creating a robust method. Time will be allotted for a review of common maintenance and troubleshooting techniques. Finally, a brief overview of LC-MS validation studies will be examined to give new laboratorians a taste of what is required for putting new instrumentation into use.

Highlights include:

- Overview of chromatography
- Overview mass spectrometry
- Types of mass spectrometry platforms
- Daily LC-MS use (from start-up to shut-down)
- What makes a good method?
- Maintenance and troubleshooting
- I have a new instrument…now what?

A04

Calibration Verification and Verification of Performance Specifications
Kathy Nucifora, MPH, MT(ASCP) and Kim Irwin, MT(ASCP)
1.5 PACE credits

This session will explain in detail the requirements for calibration verification and for verifying the performance specifications of a new test system, including how to perform both processes and how to evaluate performance and interpret your results. Sample worksheets will be provided.
This session will not address validations for LC-MS. That topic will be addressed in the LC-MS Workshop on 4/3 and Symposium session A03 on 4/4.

Learning Objectives

- Define performance specifications
- Summarize the CLIA requirements regarding performance specifications and the purpose of the requirements
- Determine when verification or establishment is required and the applicable performance specifications that need to verified or established
- Utilize appropriate samples and procedures for performing the study
- Use appropriate methods for interpreting and determining the acceptability of the study
- Summarize calibration and calibration verification and compare the difference between them
- Define reportable range and recognize some other names for it
- Determine when calibration verification is required
- Identify acceptable materials for calibration verification
- Outline the steps to perform calibration verification
- Take appropriate action when calibration verification is not successful

A05

Value of Point of Care Blood Gas Testing, Acid-Base Balance and the Practical Applications of the Acid-Base Chart
Ellis Jacobs, PhD, DABCC, FACB
1.5 PACE credits

This presentation reviews the value of blood gas testing and the practical application of the acid-base chart as an indicator to distinguish between metabolic vs respiratory disturbances. The session identifies the terminology, causes, and symptoms of acid-base imbalance, and analyzes the acid base chart and its application in interpreting the acid-base status. There will be an in-depth look at the ability of blood gas testing to determine the

cause of reduced oxygen transport and release to tissues. Factors affecting oxygen uptake, transport, and release will be discussed. Reasons for reduced oxygen carrying capacity, different methods for oxygen saturation assessment and the pitfalls associated with some of these methods, and the value of measured vs calculated saturation using co-oximetry will be presented. This presentation will review the sources of error in blood gas/electrolyte testing and discuss how Point of Care testing (POCT) helps mitigate them. The outcome of the National Academy of Clinical Biochemistry evidence-based review of the scientific literature relating to blood gas/electrolyte POCT will be presented.

Learning Objectives

- Discuss the practical applications of the acid-base balance and how to distinguish between metabolic vs respiratory disturbances.
- Review the importance of base excess for in-depth analysis of metabolic versus respiratory imbalance
- Analyze the acid base chart and its application in interpreting the acid-base status
- Illustrate the use of blood gas testing to determine the cause of reduced oxygen transport and release to tissues
- Identify different methods for oxygen saturation assessment and the pitfalls associated with some of these methods
- List the sources of error in blood gas/electrolyte testing
- Describe how POCT reduces errors in blood gas/electrolyte testing
- Describe the evidence for the value of blood gas/electrolyte POCT

A06

Overview of Coagulation: From Basics to Bizarre, a Case Study Approach
Donna Castellone, MS, MASCP, MT (ASCP) SH
1.5 PACE credits

This session will begin with an overview of coagulation processes that occur in primary and secondary hemostasis. This will provide a basis of knowledge for participants. The impact of pre-analytical variables on coagulation outcomes will be discussed. An overview of routine coagulation testing, factor assays and lupus testing will also covered. Participants will be able to apply this knowledge and will be encouraged to actively participate in solving real life case studies that will range from basic to bizarre situations.

Learning Objectives

- Describe the principles of primary and secondary hemostasis
- Identify proper testing to aid in the diagnosis in bleeding or clotting disorders
- Perform best coagulation practices that can help to maximize outcomes and minimize costs
- Enhance problem solving skills by participating in interesting case studies

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

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B12

Basics of Proficiency Testing
Verlin Janzen, MD, John Daly, MD, Raelene Perfetto, MBA, MT(ASCP)
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. *Introductory level 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

B13

"Top 10" Common Citations
Irwin Rothenberg, MBA, MS, MLS(ASCP) and Kim Irwin, MT(ASCP)
1.5 PACE credits

The ten most frequently cited criteria are broadly categorized as relating to personnel management and competency, the fulfillment of laboratory director and technical supervisor responsibilities, and the proper performance of proficiency testing protocols. However, deficiencies in these areas affect all other aspects of laboratory quality performance, from quality control to customer service; from test utilization to employee safety.

This session will provide you with a discussion of each citation, beginning with identifying the specific citation and how it relates to the broader laboratory operation; defining compliance; providing non-compliant scenarios, and the appropriate steps to take to address these deficiencies in an effective and sustainable manner.

Learning Objectives

- Identify, and summarize the ten most frequently cited COLA Criteria
- Define compliance for each criteria
- Illustrate non-compliant scenarios
- Formulate the implementation of appropriate corrective actions to achieve compliance.

B14

OSHA Training- Keeping Your Lab Safe
Milly Keeler, BSMT (ASCP), CLC (AMT), CCCP®
1.5 PACE credits

When was the last time you ***really*** looked at your OSHA safety manual? Does it cover what you need for compliance? Are your policies/procedures really being followed by everyone? Do staff understand their rights and responsibilities as defined by OSHA?
In this session we will discuss blood borne pathogens, hazardous chemicals, workplace violence, emergency action plans, fire and electrical safety. We will discuss the three core elements of an effective safety program; Management Leadership, Worker Participation, Find and Fix Hazards. Leave with effective ways to make your lab a safer workplace. Remember, safety starts with You!

Learning Objectives

- Understand your rights and responsibilities under OSHA
- Discuss Bloodborne Pathogens, electrical and fire safety, ergonomics, workplace violence, and chemical hazards; how to protect yourself from these and other hazards you encounter during your workday
- Review the UN Global Harmonizing Standard (GHS) for chemical labeling and how to read Safety Data Sheets (SDSs)
- Discuss the three core elements of effective safety and health programs
    - Management Leadership

	○ Worker Participation ○ Find and Fix Hazards • Realize the importance of a safe environment and what is recommended to review during a self-audit of your laboratory
B15	**Competency Assessment: How, Who, What, When and WHY** **Donna Castellone, MS, MASCP, MT (ASCP) SH** **1.5 PACE credits** Competency assessment continues to be a complicated process. The goal of this workshop is to provide participants with information that can help minimize the complexity and time invested to complete this directive. The difference between training and competency will be discussed as well as who can perform these tasks. All elements of competency will be reviewed. Being able to integrate competency assessment into routine work can eliminate some of the tedious processes. Case studies will be used to encourage audience participation in solving common problems that occur during competency assessment. Learning Objectives • Define Competency • Explain difference between training and competency • List the elements required for competency assessment • Discuss who can perform competency assessments
B16	**Hematology M+Ms: Morphology and Mystery (Case Studies)** **Karen A. Brown, MS, MLS(ASCP)^{CM}** **1.5 PACE credits** Hematology instrumentation has advanced to now routinely include at least a five-part differential and, in some laboratories, automated cell image analysis. Yet, a manual examination of the blood smear is still an essential procedure that provides valuable diagnostic information. This session will use case studies to define important morphologic variations and physiologic processes in selected disease conditions. Learning Objectives • Morphologically differentiate abnormal variations in RBCs, WBCs, and platelets • Explain underlying physiological processes for abnormal RBC, WBC, and platelet morphology • Describe the morphologic basis for distinguishing benign from malignant WBC disorders • Correlate abnormal cellular morphologic variations with selected case studies
B17	**Family Medicine- Current Trends in POCT** **Jane Smith, MS, MT(ASCP)SI, DLM** **1.5 PACE credits** Point-of-care tests (POCTs) are increasingly used in family medicine to facilitate screening, diagnosis, monitoring, treatment, and referral decisions for a variety of conditions. A study identified 34 POCTs that would be beneficial to add to family medicine and reported 30 conditions for which they considered POCTs would be useful for diagnosis, monitoring, and treatment decisions. An overview of current POCT testing will be summarized based on what physicians found useful for their family medical practice. Learning Objectives • List the top 10 POCTs that clinicians considered to be most beneficial to add to their family medicine practice • Describe the types of conditions for which the top 10 POCTs would be useful • Evaluate available waived POCTs for running the top 10 POCTs for family medicine practice • Recommend future POCTs family practice clinicians would find most beneficial to add their family medicine practice

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

C21

Technology Workshop: Laboratory Information Systems
1.5 PACE credits

Use this opportunity to compare and evaluate multiple working laboratory information systems (LIS). The groups will be small to allow for questions and discussion. The information will be valuable whether you are already using an LIS or are evaluating what is available and best suited 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

C22

Pre & Post-analytic Issues, Introduction to QA (3:30-5:30p)
John Daly, MD
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

Tips & Tools from a Consultant for Laboratory Compliance
Dan Leighton, MS, MT(ASCP), HCLD(ABB), CLB & Kim Irwin, MT(ASCP)
1.5 PACE credits

Experienced Laboratory Consultant and COLA examiner will provide an overview of the inspection process and discuss common citations. Solutions in the form of downloadable software will be demonstrated and provided as measures for how these citations can be avoided or resolved. Participants will be introduced to ‘fill-in-the-blanks’ PDF™ Templates that may be downloaded and used directly from laboratory desktop computers. Once downloaded, these tools do not require program experience or an internet connection.
Bringing a laptop or Ipad to use during this session is encouraged.

Learning Objectives

- Discuss components of the Laboratory Inspection process
- Understand the Deficiency Remedial Process
- Become aware of common Pitfalls that result in Citations
- Download and use PDF tools to meet compliance documentation requirements

C24

Procedure Manuals
Eileen McConnell, MT(ASCP)
1.5 PACE credits

Procedure manuals form the foundation of a quality laboratory They not only provide directions for test performance, but define and organize the entire spectrum of laboratory function. These documents provide direction for all phases of testing from the pre-analytical phase, such as specimen acquisition and handling; though the analytical and post-analytical phases that include test data management and documentation requirements. Procedure manuals also provide guidance for incident management, quality assessment, staff training and many other operational policies. This session will discuss the information that should always be included, from both practical need as well as regulatory requirement viewpoints. The digitalization of information is not only changing the format for procedure manuals, but enhancing access, and providing the ability to immediately update, review and amend its contents. Procedure manuals are more important, more accessible, more comprehensive, and more useful than ever before.

Learning Objectives

- Summarize the importance of procedure manuals for quality laboratory patient care
- Outline the requirements of CLIA and/or your Accrediting Organization when creating or updating your procedure manual
- Discuss the importance of the organizational policy component of your procedure manuals
- Understand how technology is changing how we access, update, and document changes to procedure manuals

C25

Technical Consultant Responsibilities
Kathy Nucifora, MPH, 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 position responsibilities and interaction with other staff in the lab and facility will be addressed.

Learning Objectives

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

C26

Phlebotomy Ps and Qs: Problems and Quandaries in Specimen Collection
Karen A. Brown, MS, MLS(ASCP)^{CM}
1.5 PACE credits

Phlebotomists routinely encounter dangerous conditions, problem patients, and other issues during blood collection. This session will suggest techniques that can help you avoid or safely manage these difficulties. Areas to be discussed include:

- risks associated with venous blood collection, such as improper vein selection and needlestick exposure
- unusual patient situations that impact phlebotomy practice, including the cancer and bariatric patient
- communication barriers and methods to improve patient interactions, like developing good listening skills and effective communication approaches with the elderly

Designed for phlebotomists and phlebotomy students who have comprehension of the basics of the venipuncture technique, this session will enhance your skills, build your knowledge base, and help you deliver the highest quality in patient care.

	Learning Objectives • Discuss advantages, disadvantages, and challenges associated with the collection of blood specimens from various anatomic sites and in special patient conditions • Identify precautionary measures and actions that promote safe use of phlebotomy equipment • List barriers to effectively communicating with patients
C27	**Molecular Diagnostics and POCT** **Ellis Jacobs, PhD, DABCC, FACB** **1.5 PACE credits** With advancing technology, molecular diagnostics are moving into the realm of Point of Care Testing (POCT). Rapid molecular diagnostic testing is increasingly becoming important for disease identification, treatment and prevention. However, traditionally, molecular tests have been limited to specialty laboratories primarily because the technologies employed require sample purification and sophisticated instruments, are labor and time intensive, expensive, and require highly operators. With the advent of molecular POCT, with sensitivity, specificity and predictive values in the 97-99.9% range, utilizing both polymerase chain reaction (PCR) and isothermal nucleic acid methodologies, this is changing. Learn the various molecular technologies and systems currently available and discuss how they could be implemented effectively at the point of care. Learning Objectives • Understand the unique aspect of nucleic acid testing in POCT • List the various molecular technologies employed in POCT • Describe the characteristics of the various molecular POCT systems on the market

Friday, April 5

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

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 CLIA-regulated laboratory director qualifications and responsibilities, 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

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

West Nile, Zika, Ebola Update
Elissa Passiment, Ed.M., MT(ASCP)
1.25 CME or PACE credits
The challenges presented by Ebola, Zika and West Nile include current prevalence (especially for the vector-borne diseases), timely environment detection and laboratory testing and reporting. How the patients and their samples are handled as well as efficiencies of laboratory tests will be described. The latest guidance for each disease from the CDC will be discussed.

Learning Objectives
- Describe some of the issues in providing laboratory services for Ebola, Zika and West Nile
- Discuss the changing prevalence of these diseases
- Evaluate the data and which CDC guidelines apply to your laboratory

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

D31

Reducing Human Errors in Point of Care Testing through Performance Improvement and Measuring Quality Indicators
Jeanne Mumford, MT(ASCP)
1.5 PACE credits
Whether you have an established or new and growing Point of Care program, making meaningful quality improvements can be achieved through the use of a quality dashboard and indicators. In this presentation, you'll learn how to choose a quality indicator (QI) and measure it over time in order to establish annual targets. Through the use of multidisciplinary team meetings in your hospital or physician's office, you'll learn how to improve patient safety and even help your teams meet national patient safety goals and be inspection ready. You'll see how to build a quality dashboard, go through the process of setting targets and discuss corrective actions that will help you to meet them. If you are looking for help for your POCT program to be more inspection ready, be highly efficient and safer for your patients, then this presentation is for you.

Learning Objectives
- Learn how to select indicators
- Learn how to manage expectations for reducing human errors and improving patient safety through quality indicators
- Describe how to gather baseline data and determine your target goals for your indicators

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

SmartLabTools™ Quality Control System – A Simplified Approach to Meeting Basic QC Requirements

Dan Leighton, MS, MT(ASCP), HCLD(ABB), CLB

1.5 PACE credits

A QC Workshop using Interactive PDF forms created to allow for immediate statistical assessment of Quality Control data. Participants will be shown how to download provided templates, customize QC parameters and enter QC results to demonstrate the interactive interpretation. Attendees will be provided FREE QC software to take back to their labs. Bringing a laptop or iPad to use during this session is encouraged.

SmartLabTools™ Quality Control System provides a simplified practical approach to the immediate assessment of quality control data through the use of a collection of PDF™ templates programmed with statistical calculations necessary to assist the operator in determining if a quality control result is acceptable. This provides the foundation for the justification of reporting patient results. The interactive QC software may be applied as the primary, or as a secondary QC measure; for detection of Biases, and alert to potential Shifts, or Trends that could immediately or eventually affect the accuracy or reliability of patient test results

Participants will learn how to:

- create a technically effective and cost effective Daily Quality Control Program using PDF Templates programmed for the immediate Statistical Assessment of Quality Control data
- download and setup QC templates, calculate QC Statistics, customize QC parameters, enter QC results for interpretation, and document corrective actions
- interpret the Statistical Parameters calculated to permit the laboratory to assess continued accuracy and precision of test methods
- confidently setup, and teach others the QC program using the provided PDF Templates, QC procedures, and Training Materials

Following this workshop, participants will be able to:

- Set up and use the Daily QC Statistical Assessment Template (SLT_105)
- Establish QC Limits for SLT_105 Template (-2SD, +2SD)
- Enter Data quickly on the Template using TAB Key
- Describe Statistical Tools used in QC data interpretation for “QC O.K.” or “QC Out”
- Set up Flagging sensitivity for alerting to potential Shifts or Trends, *(requires manual review of flagged(*) results)*
- Understand QC Terms: Mean, SD, CV%, Bias, SDI(Z-score)
- Document Corrective Actions on the Daily QC Template
- Define the QC Requirements of the Assay
- Evaluate Published Mean and QC Limits for each level of Control
- Use Tools to Calculate Labs own Mean and QC Limits for each level of Control
- Use Tools to Calculate preliminary QC Limits using Historical CV (%CVh)
- Use Tools to Calculate Allowable Error Limits for the assay
- Understand Basic Westgard Rules for QC Acceptance
- Use of QC Limits Conversion Calculator Tool
- Download and Customize QC Review Forms
- Understand benefits of Cloud Storage and Sharing of Files with TC in a Web Folder
- Understand QC Compliance Responsibilities
- Follow SLT website links to external QC Learning Resources

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D34

Quality Assessment: QA, QC, QM OH My!
Donna Castellone, MS, MASCP, MT (ASCP) SH
1.5 PACE credits
This session will provide participants with an overview of a quality management system and the processes that should be in place. It will provide a basis for developing and maintaining a quality system. The principles of quality assurance and meaningful quality control will be discussed. Performing root cause analysis and audits will be reviewed. Case studies will be presented in which participants will have the opportunity to solve common laboratory quality problems.

Learning Objectives
- Describe the roles of quality assurance, quality management and quality controls in the laboratory
- Identify processes within the laboratory that can benefit from root cause analysis and corrective action plans
- Perform and conduct purposeful QC, and audits
- Demonstrate the cost effectiveness of implementing quality processes

D35

Tickborne Diseases on the Rise: Laboratory Testing and Diagnosis
Nicole Colby, MLS(ASCP)^{cm}, SBB^{cm}, SC^{cm}
1.5 PACE credits
The incidence of tickborne infections in the United States have risen significantly over the past decade. Proper utilization of laboratory testing is important for correct diagnosis of the infections and treatment of the patient. This session will review signs and symptoms of the most common tickborne diseases, what tests are available for a small to medium-sized laboratory to test in-house, as well as information to help make sense of the variety of test options that can be ordered at reference laboratories.

Learning Objectives
- Describe proper utilization of laboratory testing for correct diagnosis
- Summarize signs and symptoms of common tickborne diseases
- Compare and select appropriate test methods for your laboratory

D36

Acute & Chronic Kidney Disease: Challenges & Issues
Elissa Passiment, Ed.M., MT(ASCP)
1.5 PACE credits
This presentation will review acute kidney injury (AKI), chronic kidney disease (CKD), the current staging of renal disease, and the challenges to recognizing each type. There will be a discussion of the various diagnostic equations in use and possible new ones, how they are being used and the controversy surrounding the interpretation of the results.

Learning Objectives
- Define acute kidney injury and chronic kidney disease
- Discuss the challenges to diagnosing both types of kidney disease
- Evaluate the efficacy of the tests and calculations for kidney disease

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

E41

Building a Strong Lab Team
Milly Keeler, BSMT (ASCP), CLC (AMT), CCCP®
1.5 PACE credits

With 10,000 baby boomers leaving the workforce every single day, it is likely that your lab is feeling the impact of worker shortages. What are you doing to ensure your laboratory is adequately staffed, competent and ready for the challenges that lie ahead? In this session we will discuss ways to effectively recruit new lab talent as well as manage and motivate current employees. We will discuss job descriptions, on-boarding, team building, conflict resolution as well as other important tools that contribute to building a strong lab team with a culture of caring and excellence.

Learning Objectives

- Review essential components of job descriptions for laboratory personnel
- Learn how to effectively recruit high performing staff as well as motivate current employees
- Develop ways to perform effective training/onboarding and meaningful competency assessment
- Discuss ways to provide mentoring and ongoing support to create a high performing laboratory team

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.

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

Point of Care Connectivity: Untangling the Web
Leandra Soto, MT (ASCP)^{cm}
1.5 PACE credits

Understanding that Point of Care connectivity is crucial for the current needs of bedside testing, expanding the Point of Care Coordinator basic knowledge of IT concepts, definitions and Facilities' requirements are all fundamental to a successful program.

In this presentation, I will discuss what are the elements needed for an instrument connection and will give you tips on how to obtain them. I will also share with you how to communicate with IT and teach you how to understand their needs. When evaluating and purchasing new POCT instruments, you will want to keep these requirements in mind. Troubleshooting methods can include 1) verifying instrument connections and configurations for both wireless and hardwire applications; 2) working with POCT vendors on interface issues; and lastly 3) working with your local IT specialists at your facility.

Learning Objectives

	• Understand basic IT terms and definitions for successfully setting up Point of Care instruments • Compare connectivity models including wired and wireless connections • Resolve connection issues including errors involving the instruments, middleware and/or facilities' network problems
E44	**Future Trends: The Clinical Laboratory as Information Central for Patient Care** **Irwin Rothenberg, MBA, MS, MLS(ASCP)** **1.5 PACE credits** The growth of laboratory medicine has now taken patient testing beyond the physical confines of the laboratory to off-site locations nearer to the patient, anywhere in the world. This has resulted in the exponential growth of test data generated and transmitted back to central laboratories for interpretation and dissemination. Additional growth is anticipated in the future with the continued development of remote/electronic /wearable technology for lifelong monitoring of patients with chronic conditions or even the genetic propensity to develop certain illnesses. Laboratories will have the responsibility to properly organize, store, interpret and transmit this data, whether to the ordering physician or the patients themselves. The laboratory profession will have to evolve to accommodate these new responsibilities, serving not only the medical community, but the public. Learning Objectives • Summarize how laboratory medicine is evolving in response to advances in both clinical and digital technology, enabling the advent of personalized medicine and improved value-based healthcare • Outline how laboratory organization and function are already changing to meet these new expectations, demands and responsibilities • Discuss steps to take now to prepare your laboratory for these trends to continue
E45	**Laboratory and Point-of-Care Options for Sexually-Transmitted Disease Testing** **Nicole Colby,** MLS(ASCP)^{cm}, SBB^{cm}, SC^{cm} **1.5 PACE credits** Explore options for laboratory and point-of-care testing for various sexually transmitted diseases, including Chlamydia, Gonorrhea, HIV/Aids, Syphilis, and Trichomoniasis. We will cover signs and symptoms of each condition, how to properly collect specimens, information about different methods (point-of-care, molecular, etc.), and how to properly report the results. Learning Objectives • Summarize testing options for STDs • Outline signs and symptoms of various STDs • Describe proper specimen collection • Report STD results properly
E46	**IQCP: An Alternative Quality Control Option** **Terri Wolek, MBA, MT(ASCP) & Angelia Dooley, MT, BS** **1.5 PACE credits** Come to this session to learn about IQCP as an alternative QC option that many labs have implemented with positive outcomes. We will discuss IQCP as a pathway to quality patient testing. You will gain a better understanding of QC practices, how to address QA failures and the impact that will make on your IQCP. Also learn what type of QC plan and documentation the inspectors are looking for when implementing IQCP. Learning Objectives • Describe the alternative QC option IQCP • Discuss how IQCP leads to quality patient testing • Address QA failures and their impact • Create compliant QC documentation

Symposium for Clinical Laboratories April 3 – 6, 2019: Session Descriptions

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

3:30p – 4:30p **Introduction to Next Generation Sequencing Technologies**
Gianella Garcia Hughes, PhD
1.0 CME or PACE credits
Fourteen years ago next-generation sequencing (NGS) technologies appeared on the market. Since then, NGS has been quickly adapted into many translational research areas such as agrigenomics, forensic science, ancestry, nutrigenomics, and clinical diagnostics. In 2013, the Food and Drug Administration granted marketing authorization for the first high-throughput NG sequencer, Illumina's MiSeqDx, which allowed the development and use of a large number of genome-based tests. This has been a great start for the application of genomic knowledge in clinical practice and will profoundly change the diagnosis, prognosis, and treatment of many diseases.

Learning Objectives
- Describe NGS and its uses
- Outline research areas that have adopted NGS
- Summarize the use of NGS for the development of genome-based tests
- Outline applications for genomic knowledge in clinical practice

4:30p – 5:15p **Inspection Preparedness: More Than Just a State of Mind**
Nancy Stratton, CEO of COLA
.75 PACE credits
Visits by accrediting organizations can be scheduled or unscheduled. Preparing staff for these visits, which can occur at any time throughout the year, can decrease the usual anxiety. This presentation will focus on staff preparedness throughout the year. As an example, COLA's educational approach will be presented to illustrate how inspection preparation can be accomplished.

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

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

4:30p – 5:00p **Practical Utilization**
John Daly, MD
.5 CME or PACE credits
In this session there will be an overview of tools that can be used to effectively order laboratory tests and discussion of those tools you should be requesting be made available to optimize laboratory test ordering.

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

5:00 – 6:00p **What is? Overview of Operational Processes**
John Daly, MD
1 CME or PACE credit
This session focuses on other important topics for the laboratory director regarding lab operations and regulatory compliance, including instrument verification and validation, calibration and calibration verification, random and systemic errors, split sample testing and instrument maintenance.
Learning Objectives
- Discuss components of laboratory test validation and verification
- Differentiate between calibration and calibration verification
- Outline steps which may be taken in troubleshooting problems with an instrument or laboratory test
- Summarize important steps in instrument maintenance for quality laboratory practice

Saturday, April 6 *The focus is on Lab Directors, but all are welcome to attend*

7:00a – 11:30a **General Sessions:**

7:00a – 7:45a **New Developments in the Lab**
John Daly, MD
.75 CME or PACE credits
The focus will be a discussion of molecular testing available including laboratory developed tests, molecular microbiology tools, and discussion of pharmacogenomics.

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

7:45a – 8:15a **Toxicology**
Nicole Colby, MLS(ASCP)^{cm}, SBB^{cm}, SC^{cm}
.5 CME or PACE credits
Overview of toxicology testing and discussion of common issues.

8:15a – 8:45a **Besides CLIA- What Else? OSHA, Hazmat, Facilities**
John Daly, MD
.5 CME or PACE credits
This presentation will discuss the laboratory regulatory requirements including safety in the laboratory and those CLIA requirements for the laboratory facility.

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

8:45a – 10:00a **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

10:00a – 10:15a **Waived Testing**
John Daly, MD
.25 CME or PACE credits
Overview of common citations for waived testing and how to avoid them.

10:15a – 11:15a **Inspections – Preparing for a Successful and Educational Experience**
Verlin Janzen, MD, John Daly, MD and Nicole Colby, MLS(ASCP)^{cm}, SBB^{cm}, SC^{cm}
1 CME or PACE credit
This session will review the most frequent citations seen during laboratory CLIA inspections with tips on preventing them. Includes advice on maintaining continuous compliance every day in your laboratory.

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

11:15a - 11:30a **"Graduation Ceremony"** Summary and Conclusion
.25 CME or PACE credits
Dr. Janzen & Dr. Daly will summarize the learnings of the day and provide practical insight into the role of laboratory director to conclude the laboratory director curriculum.

11:30a **Adjourn**