Symposium for Clinical Laboratories May 27- 30, 2020: 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
- Quality Control

You can also see the description of each session when you go to online registration.

You can see Speaker Information at: *http://labuniversity.org/symposium/#events-schedule*

Wednesday, May 27

1:00p – 5:00p **Beyond Service: The Business Side of Operating a Laboratory** (separate registration)
3.5 PACE credits. See http://labuniversity.org/symposium/#Workshop for details and agenda

10:00a – 7:30p Symposium Attendee Check-in

Thursday, May 28

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 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 Thursday Opening General Session
CMS CLIA Update 2020
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 **Leveraging a Teamwork Approach to Improve Your POCT Program**
Kim Futrell, MT(ASCP)
1.5 PACE credits
Point-of-care testing (POCT) is expected to continue to gain favor as our healthcare system progresses toward a value-based model. Yet, the overall diversity found in POCT makes its implementation and oversight complex. One of the greatest challenges is training and management of disparate groups of healthcare workers as end-users. Approaching POCT oversight with a multidisciplinary team work approach can improve both the quality of the POCT program and the relationships between departments. Taking into perspective the viewpoints of end users and carefully assessing workflow where POCT is introduced can set the stage for a successful POCT program that is an integral part of improving patient outcomes.
Learning Objectives

- Relate recent changes in healthcare to continued growth of POCT
- Describe opportunities for the laboratory to collaborate with other departments for quality POCT
- Contrast differences in perspective between nursing and laboratory departments as it pertains to POCT
- Recommend ways to improve the laboratory/end user relationship in POCT

A02 **Basics of Quality Control**
Verlin Janzen, MD
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. We 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 **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

A04 **Who Knew? Where we were, Where we are & Where are we going!**

Donna Castellone, MS, MASCP, MT (ASCP)SH

1.5 PACE credits

Healthcare has grown in leaps and bounds and so has our profession. Over the years, the progress in technology and methods has transformed how we function in the laboratory. Where we started out and where we are now is hard to imagine. Not only has the physical laboratory changed but the amount of regulations, training and compliance issues have evolved into a complicated realm of processes in addition to performing laboratory testing. There have been many behind the scenes events that have shaped laboratory medicine and will continue to impact how and why we test. This session will look at the past, present and future of laboratory medicine. So whether you are a baby boomer or a millennial, there will be something for all to remember or learn!

Learning Objectives:

- Identify regulations in the laboratory, how they began and where we are today
- Understand the impact of quality outcomes
- Understand how physicians order tests and are reimbursed
- Evaluate what you can do to enhance your career in this environment

A05 **HIPAA and ID Theft for Medical Offices and Laboratories**

Kelly Ogle, BS, MS, CMPM®, CHOP®

1.5 PACE credits

This session is ninety minutes packed with information on HIPAA, patient confidentiality, information security, and identity theft prevention. We take a patient from the very first contact with the practice/laboratory all the way through the billing process, pointing out privacy and security risks along the way. We even discuss contingency plans and breach notification. Also, we will be reviewing the importance of electronic security methods and how to assess your vulnerabilities.

Medical Identity theft is a concern for every medical facility. This can be from prescription use to false treatment claims. This seminar includes valuable hints for protecting identity as well as a response when the unthinkable happens.

Learning Objectives:

- Identify privacy and security risks in your laboratory
- Discover ways to prevent these risks
- Recognize your responsibility to recognize and respond to a security breach
- Discuss documentation and what it means to be HIPAA compliant
- Summarize importance of protecting identity for everyone
- Outline what to do if someone steals your identity or that of someone you know

A06 **Medical and Legal Aspects in Phlebotomy**
Kathleen Finnegan, MS, MT(ASCP)SH
1.5 PACE credits
Health care workers who collect blood must exhibit professionalism and be trained properly in all areas of phlebotomy. Phlebotomy is an invasive procedure. Healthcare workers that perform phlebotomy incorrectly can and will be held legally accountable for their skills. This presentation will review guidelines to avoid lawsuits, describe situations that may have legal ramifications and discuss the legal aspects associated with phlebotomy procedures
Learning Objectives:
- Define malpractice, negligence, and review how to avoid legal issues
- Discuss the standard of care and the guidelines to follow
- Describe the type of phlebotomy errors that may be a potential lawsuit

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

B11 **Technology Workshop: Chemistry Instruments**
1.5 PACE credits
In this workshop you will have the opportunity to assess general chemistry and immunoassay analyzers that may be suitable for your practice. The instrumentation shown will be appropriate for a small to moderate patient volume of testing. The handouts include guidelines for instrument selection. Small groups will have time with each instrument.
Learning Objectives
- Identify factors to consider when selecting a chemistry instrument for the laboratory
- Recognize the pitfalls encountered in the selection process
- Analyze the differences between systems and determine which would be the most appropriate for a particular lab setting

B12 **Basics of Proficiency Testing**
Verlin Janzen, MD
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 **OSHA and Bloodborne Pathogens Training**
Kelly Ogle, BS, MS, CMPM®, CHOP®
1.5 PACE credits
This session on OSHA will update you on everything you need to know about OSHA compliance so you can feel safe on the job. We will cover your employee rights and responsibilities, bloodborne pathogens, hazardous chemicals, fire and electrical safety, MRI and Lasers, ergonomics and

	workplace violence. There will be information on how to document your site-specific information. We will discuss bloodborne pathogens at length along with lab safety and responsibilities. The speaker will delve into the hazard communication standard to show you the new Safety Data Sheet format and will introduce the new labeling requirements with pictograms. Also, we will be talking about how to conduct a walk-through audit of your office or lab. 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 and how it relates to the lab setting. • Identify problems in electrical and fire safety, ergonomics, workplace violence, MRI and laser safety • Learn hazard communications and the new labeling and SDS requirements under the new Standard • Recognize and interpret the newly required pictograms and understand how to read the new safety data sheets • Realize the importance of a safe environment and what is recommended to review during a self-audit of your office
B14	**How to Conduct an Audit and Root-Cause Analysis: We Are Still Learning** **Donna Castellone, MS, MASCP, MT (ASCP)SH** **1.5 PACE credits** Conducting purposeful audits is an important task and can uncover a break in the testing process. Audits should also be conducted on laboratories' quality-management systems, to ensure that processes are in place. Implementing a 'quick-hit' audit can be vital in documenting the most common laboratory deficiencies. Such audits don't have to be lengthy, only performed with a purpose. While this process can be time-consuming and challenging endeavor it can end up being moving targets that result in more questions than answers. The next step is to uncover the "why" of any issues. Rerunning a specimen is not a root-cause analysis, although it may provide some answers. Uncovering all possible venues in the testing process may uncover gaps that may be the source of an error in testing. Conducting a systematic analysis can help to uncover the root cause of a problem. Using templates throughout the laboratory to ensure standard operating procedures is vital, and will help guide all departments towards compliance when performing audits and root cause analysis. Best practices will be covered, and tips for minimizing the time invested in performing these tasks while maximizing results. Learning Objectives • Describe how to conduct systematic root-cause analysis • Identify the advantages of conducting purposeful audits • Enhance problem solving skills by utilizing case studies
B15	**Good Laboratory Practices for Genetic Testing Specimen Collection** **Kathleen Finnegan, MS, MT(ASCP)SH** **1.5 PACE credits** Phlebotomy plays a key role in patient care. Genetic testing can provide information about a person's genes and chromosomes. This type of molecular testing has become expansive for the screening, detection, diagnosis and monitoring of inborn errors of metabolism or inherited metabolic disorders. The proper collection of a blood specimen for genetic testing is a critical step for accurate results Learning Objectives: • Discuss the importance of proper blood collection for genetic testing • Explore genetic testing and its uses • Summarize the different types of genetic testing and what these tests can identify

B16 **The Opioid Crisis and the Laboratory**
Irwin Rothenberg, MBA, MS, MT(ASCP)
1.5 PACE credits

Laboratory technology rises to the challenge of the opioid addiction crisis. Huge numbers of deaths attributed to prescription and illicitly manufactured opioids are occurring in the United States. Recent data has shown that greater than 40% of patients receiving opioid therapy may develop "opioid use disorder." An essential tool toward determining the potential for opioid abuse by patients is drug testing. This testing is done to determine if a patient is taking opioids or other pain medications as prescribed, or to determine if a patient is abusing other substances; these tests also monitor continued drug therapy, and adjustments to dosage as needed.

An effective drug screening program involves a two-step process: the initial screen, usually utilizing urine as the preferred specimen (immunoassay) tests; and then the confirmatory Mass Spectrometry (MS) testing. These laboratory procedures are the methods most commonly utilized to test for drugs. Using a combination of both allows a high level of sensitivity and specificity, ensuring an extremely low chance for false positives or false negatives.

Our discussion is centered on the reality that the opioid epidemic shows no sign of abating soon, and laboratory professionals continue to play a key role in providing vital data for discovering new opioid analogues, and tracking their distribution and use. By supplying healthcare teams with essential information identifying drug use, and monitoring opioid treatment, laboratories help ensure that patients are offered prompt and effective care and given the support needed to avoid future problems. When this information is lacking, the result is a continued escalation in the opioid epidemic.

B17 **Inspection Readiness: Keeping Your Point of Care Testing Ready for CLIA, COLA, CAP, and TJC!**
Jeanne Mumford, MT(ASCP)
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, College of American Pathology, The Joint Commission, 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 variety of health care settings. 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 your Quality Management Plan
- Address challenges of inspection readiness
- Develop and implement corrective action plans
- Implement strategies to stay Inspection Ready

Thursday Breakout Session C 3:30p – 5:00p, except where noted (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) **Verlin Janzen, 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	**Coding and Billing for the Physician-based Laboratory** (3:30-5:30) **Shannon O. DeConda, CPC, CEMC, CEMA, CPMA, CRTT** **2.0 PACE credits** During this session we will review coding concerns for lab based services, and will include a review of CPT, ICD-10, and modifier usage. We will then turn our attention to potential bundling edits and medical policies that can impact revenues for the physician based lab. Be prepared to cover an array of issues in the fast paced session that will be a great review for the seasoned professional and great training for the newbie to coding/billing. Learning Objectives • Review CPT, ICD-10, and modifier usage, and deal with lab coding concerns • Outline bundling edits and medical policies that can impact lab revenue
C24	**Supervisory Survival Guide: Consensus Approaches to Universal Problems** **Fred Rodriguez, Jr., MD** **1.5 PACE credits** Engage in a dynamic, interactive educational experience focused on discussion of actual supervisory "challenges." A "reversed classroom" format will draw from the participants personal experiences to discuss "universal" supervisory problems. Practical, reality based approaches for dealing with universal supervisory challenges will be explored. Time will be allotted to each of the following supervisory topics, using an event from a participant's personal experience as the basis for discussion • Evaluation and Feedback (including performance issues versus discipline issues) • Incentives, Motivation, Mentoring, Coaching, and Team Building • Conflict Resolution (including achieving and maintaining quality in the midst of chaos) • Dealing With Administration (including budgets, personnel, and purchasing) The discussion for each topic will try to address a consensual approach for dealing with the actual supervisory "challenge" followed by an open comment/question/answer period and summation statements. Learning Objectives • Improve patient care outcomes through enhanced management of laboratory human resources by reviewing the following management techniques: ○ Team building, mentoring, and motivation

	○ Conducting employee performance evaluation ○ Resolving employee conflict • Dealing with administration regarding resource needs • Foster post-meeting networking between practicing supervisors and managers
C25	**Effective Quality Assessment** **Irwin Rothenberg, MBA, MS, MT(ASCP) and Steve Richards, MT(ASCP), MHA** **1.5 PACE credits** Quality Assessment (QA) is a pro-active, continuous process of systemic reviews that monitor all phases of laboratory testing; ensuring that all standards of performance are met; and that any deficiencies noted are addressed immediately. An effective QA plan is able to identify problems to avoid potentially negative impacts on your patients. Follow-up audits are performed to ensure that the corrective actions taken were effective. The "Quality Assessment Plan" details this process as well as defining roles and responsibilities. QA is a key component in creating a culture of quality for your laboratory. Learning Objectives • Define Quality Assessment and differentiate from Quality Control • Summarize the objectives, components, and structure of Quality Assessment plans • Implement your QA plan by performing QA reviews • Comply with COLA criteria that address Quality Assessment • Apply the longer–term goal of creating a culture of quality
C26	**Current Topics and Future Trends in Proficiency Testing** **Kathy Nucifora, MPH, MT(ASCP)** **1.5 PACE credits** This session will address current topics in Proficiency Testing, such as how to handle PT samples when components of a test are distributed among multiple laboratories, and inform attendees about the proposed regulatory changes to Proficiency Testing requirements, including the latest information available on the timeline for publication and implementation. Attendees will get information necessary to prepare for upcoming changes, and understand the impetus for these long-awaited revisions to the CLIA regulations regarding PT.

Friday, May 29

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. **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 **Friday AM General Session**

Putting Patient Safety First--the Role of Laboratory Professionals in Laboratory Medicine
Catherine Otto, PhD, MBA, MLS(ASCP)^{CM}
1.25 CME or PACE credits
Laboratory test information plays a vital role in medical decisions that directly impacts patient health outcomes. Laboratory testing services are provided in diverse settings, from waived testing physician office laboratories (POLs), pharmacies, home care, insurance screenings, wellness fairs to large physician office laboratories, independent laboratories, hospitals and healthcare systems. Regardless the laboratory testing setting, patients expect and deserve to receive care that is safe, effective, efficient, timely, patient-centered and equitable. It is time for us to step up, speak out and take action to put "Patient Safety First in Laboratory Medicine."
Learning Objectives
- Define patient safety as it relates to laboratory medicine using the six quality aims
- List one method to improve patient safety for each of the six quality aims
- Describe the role of the 5 healthcare professional competencies for improving patient safety

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

D31 **Pre-analytical Variables in Coagulation Testing- A case based approach**
Donna Castellone, MS, MASCP, MT (ASCP) SH
1.5 PACE credits
Minimizing errors in any laboratory is always a concern. Pre-analytical errors in coagulation can further impact patient results. Being able to understand what impacts results and how to implement measures to control them is an important quality metric. This session will look at common problems and not so common problems that laboratories encounter and how their coagulation results can be impacted. A review of basic coagulation concepts will help participants understand what they should expect from coagulation testing and patient outcomes. Real life case studies will be presented to enhance problem solving skills.
Learning Objectives
- Identify common pre-analytical errors in the coagulation laboratory
- Describe measures that can be implemented to minimize errors in the laboratory
- Enhance problem solving skills

D32 **Personnel- Required Positions and Competency**
Verlin Janzen, 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 **Urinalysis: Never Leave This Test for Last!**

Maria Brock, MT(ASCP)SH, ART

1.5 PACE credits

Attend this session and get an overview on how to properly perform routine urinalysis: physical assessment, chemical analysis (dipsticks), and microscopic identification of formed elements. This is a practical program that will provide you with the necessary technical skills for high quality routine urinalysis.

Learning Objectives

- Identify the proper techniques for urine chemical analysis
- Identify common microscopic elements in urine sediment
- Correlate urine chemistry results, physical characteristics, and microscopic elements with disease states

D34 **"Top 10" Common Citations**

Nicole Colby, MLS(ASCP)^{cm}, SBBcm, SC^{cm}

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

D35 **Meaningful Competency Assessment**

Irwin Rothenberg, MBA, MS, MT(ASCP) & Steve Richards, MT(ASCP), MHA

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 evaluations serve a useful purpose, they are not sufficient to evaluate the technical skills of laboratory staff. Both CLIA and COLA require more detailed personnel assessments, known as Competency Assessments. Simple check lists alone are not sufficient - Competency Assessments must include 6 methods specified in the CLIA regulations. This workshop will provide the information you need to develop and implement competency assessments that meet regulatory requirements and ensure the quality of your staff.

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

D36 **Using Risk Management Tools**
Jan Frerichs, MT(ASCP)
1.5 PACE credits

Risk management is the process of looking at what can go wrong and what can be done to prevent errors from happening. Laboratory testing today is done in places other than a traditional laboratory and by many different kinds of personnel which presents challenges for laboratory managers. This session will review risk management tools and principles and how they can be utilized by the laboratory to improve cost effectiveness of laboratory operations and improve patient safety. During the session we will also be identifying risk management tools that can be utilized when bringing new instruments and procedures into the laboratory. A review of statistics used in performance verification will be presented. The session will also include problem-solving exercises.

Learning Objectives

- Identify risk management tools and resources that can be used to perform a risk assessment (RA)
- Evaluate hazards to determine risk level
- Identify steps to mitigate risk and monitor on-going effectiveness of risk mitigation
- Describe statistics used in new instrument/method performance verification
- Develop a validation/verification plan for bringing new test systems into the laboratory

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

E41 **Preparing for and Surviving Disasters**
Fred Rodriguez, Jr., MD
1.5 PACE credits

Laboratories and institutions are vulnerable to natural and manmade disasters. Developing policies and procedures, and conducting active "drills" in advance of actual disaster events, can mitigate some of the adverse impact of an unanticipated disaster event. In this session, using dynamic and interactive educational techniques, faculty and participants draw from their own experiences to analyze and discuss various types of disasters (e.g. natural, infrastructure failures, terrorist, etc.) to explore how to develop and execute disaster plans to appropriately respond to and survive different types of events.

Learning Objectives

- Describe and analyze various types of disasters (e.g. natural, infrastructure failures, terrorist, etc.) they have experienced
- Discuss the development and execution of disaster plans that appropriately address the response to and survival of different types of events
- Establish a network with peers to develop future support prior to and in response to disaster events

E42	**Quality Assessment of Proficiency Testing** **Verlin Janzen, MD** **1.5 CME or PACE credits** In this session, Dr. Janzen 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	**Hematology: Interesting Yet Challenging Case Studies** **Maria Brock, MT(ASCP)SH, ART** **1.5 PACE credits** Examine various aspects of hematology by reviewing a series of case presentations. These case studies will be used to explain significant findings for a variety of hematologic disorders, including: anemias, leukemias, myeloproliferative disorders Learning Objectives • Recognize morphologic changes and the identification of normal and abnormal cells • Correlate clinical data with hematologic disease states • Describe appropriate laboratory testing to identify and differentiate hematological disorders
E44	**QC Back to Basics** **Jan Frerichs, MT(ASCP)** **1.5 PACE credits** In today's clinical laboratory a majority of patient testing is done on platforms that perform discrete testing. QC results are no longer associated with a batch of patient samples, but only reflect what is happening on the instrument at a point in time. Laboratories are also using instruments in different ways with many types of staff. The growth of decentralized testing has also created QC challenges for the laboratory. In the laboratory today the quality focus has shifted from the instrument to the patient. Accrediting agencies are requiring clinical labs to control the entire testing process: pre-analytical, analytic and post-analytical. This presentation will review the basic statistical tools used to interpret quality control results, Interlab QC (INLQC) reports, and proficiency testing results. Tools to develop a cost effective quality control program that addresses sources of error throughout the entire analytic process will be discussed. Learning Objectives • Describe statistical tools used in the interpretation of daily laboratory QC, Interlab QC reports, and proficiency testing • Identify the pre-analytical, analytical and post-analytical parts of the testing process • Review CLIA regulations for QC • Identify common QC problems • Select QC rules and establish limits

E45

Creating and Sustaining a Leading Laboratory
Diana Kremitske, MHA, MS, MT(ASCP) and Barbara Caldwell, MS, MASCP, MLS(ASCP)^{CM}SH^{CM}
1.5 PACE credits

This educational session focuses on the elements of a leading laboratory. It emphasizes how laboratory leaders invest in their employees, enhancing their technical as well as leadership skills to drive peak performance. Through training efforts, staff are kept up-to-date on the required skills necessary to meet institution expectations, address changing industry trends, and to use new technologies within the laboratory. This session will emphasize the importance of open communications from laboratory leaders in efforts to foster trust-based professional relationships throughout. It will include a focus on the laboratory leader's commitment to raising the laboratory's visibility and value while playing a pivotal role in the lives of patients and the community. A case-based presentation will discuss how Geisinger Medical Center addresses these elements of a leading laboratory to drive superior performance from all levels of laboratory employees.

Learning Objectives

- Explore how leading laboratories demonstrate a focus on strategic partnerships for quality outcomes within their organizations
- Recognize the importance of creating laboratory visibility and communicating the impact of the laboratory team on patient care
- Identify approaches to integrate the laboratory team with other members of the health care team to achieve quality outcomes.
- Consider the importance of "trusted leadership" to the success of the laboratory and the actions that leaders must take to gain their team's trust
- Identify and determine training and professional development required to prepare members of the laboratory team to respond to changes within their laboratory, which will allow them to stay competitive in a technologically advancing market
- Review a case study example of a leading laboratory in action

E46

Toxicology: A Toxi-*logical* Review of Drugs of Abuse Testing
Nicole Colby, MLS(ASCP)^{cm}, SBBcm, SC^{cm}
1.5 PACE credits

The number of laboratories performing Drugs of Abuse testing has increased over the years due to the number of patients abusing illicit and prescription drugs and the Opioid Crisis. Proper performance and reporting of the testing is crucial to enable the ordering caregiver to provide proper care to the patient. This session will provide a general overview of manual and automated screening methods, as well as LC/MS/MS confirmation methods; and common citations that are identified during COLA surveys of laboratories performing manual or automated screening methods.

Learning Objectives

- Understand the differences between manual screening, automated screening, and confirmation methods for drugs of abuse testing
- Recognize FDA approved versus non-FDA approved screening methods
- Understand the purpose and proper performance of urine validity testing
- Identify and correct commonly seen citations seen in laboratories performing manual and automated screening methods

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

3:30p – 4:30p **Strategies for Advancing Biosafety in Clinical Laboratories**
Ren Salerno, PhD
1.0 CME or PACE credits

Ensuring that laboratory personnel can safely perform testing with all types of patient specimens is critically important for laboratory directors, managers,

supervisors, and testing personnel. There are biosafety risks associated with specimens tested for infectious agents and specimens that could potentially harbor pathogens. Dr. Reynolds Salerno, Director of the Division of Laboratory Systems (DLS), Centers for Disease Control and Prevention (CDC), will discuss the importance of ensuring biosafety for the environment as well as for personnel who work in all types of clinical laboratories and point-of-care testing sites. He will provide information on assessment tools for identifying and mitigating biosafety risks, and evaluating mitigation measures. He will also describe applicable safety regulations and biosafety guidelines and standards. Last, he will review DLS' training resources related to laboratory biosafety, including those that offer free continuing education credits, and other DLS biosafety initiatives.

Learning Objectives

- Describe biosafety risks associated with specimens that could potentially harbor pathogens
- Raise awareness of existing safety regulations and biosafety guidelines and standards
- Understand how to apply bio-risk management systems and methods to address clinical laboratory biosafety
- Explore available training resources

4:30p – 5:15p **Glucose Meters and Regulatory Compliance: Important Factors for Effective Use of POCT**
William Clarke, PhD, MBA, DABCC
.75 PACE credits

This session will discuss important considerations for use of glucose meters, both analytically and in terms of regulatory compliance. Additionally, the impact of current regulatory guidelines and the FDA guidance on POC glucose implementation will be discussed.

Learning Objectives

- List factors that can influence glucose meter performance
- Discuss important factors for regulatory compliance
- Describe the impact of the FDA guidance for glucose meters on workflow and operations in healthcare facilities

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**
Verlin Janzen, 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 Lab Operational Processes**
Verlin Janzen, 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, May 30 *The focus is on Lab Directors, but all are welcome to attend*

7:00a – 11:45a **General Sessions:**

7:00a – 7:45a **New Developments in the Lab**
Verlin Janzen, 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 – 8:30a **Toxicology**
Nicole Colby, MLS(ASCP)^{cm}, SBB^{cm}, SC^{cm}
.75 CME or PACE credits
Overview of toxicology testing and discussion of common issues.

8:30a – 9:00a **Besides CLIA- What Else? OSHA, Hazmat, Facilities**
Verlin Janzen, 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

Symposium for Clinical Laboratories May 27- 30, 2020: Session Descriptions

9:00a – 10:15a **Responsibilities of the Lab Director 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, he 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

10:15a – 10:30a **Waived Testing**
Verlin Janzen, MD
.25 CME or PACE credits
Overview of common citations for waived testing and how to avoid them.

10:30a – 11:30a **Inspections – Preparing for a Successful and Educational Experience**
Verlin Janzen, 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

11:30a - 11:45a **"Graduation Ceremony"** Summary and Conclusion
Dr. Janzen will summarize the learnings of the day and provide practical insight into the role of laboratory director to conclude the laboratory director curriculum.

11:45a **Adjourn**