

a celebration of
EDUCATION
COLA Spring 2010 Symposium

April 21-24, 2010


**During Lab Week
Hilton Baltimore
Maryland**

Note: Topics and Schedule may change.



Jointly sponsored by the University of Wisconsin School
of Medicine and Public Health and COLA.



The Laboratory Director Education Qualification Track includes all General Sessions and the breakout sessions marked with the  icon.

Wednesday, April 21, 2010


3:00p - 8:30p
Participant Check-in

10:00a - 6:00p
Exhibit Set-up and Registration

6:30p - 8:30p
Industry Expo

Thursday, April 22, 2010

7:00a - 8:00a
Breakfast in Exhibit Ballroom

7:00a - 8:00a
Basics of Laboratory Medicine 
for Physicians
Verlin Janzen, MD, FAAFP

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:

At the end of the session, participants will be able to:

- Demonstrate a general understanding of what the CLIA regulations entail, and how they affect the POL
- Differentiate between CLIA and COLA

- Interpret 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

8:00a - 10:00a
Thursday AM General Session 

8:00a - 8:30a
Welcome: Opening Remarks, Logistics, CME Statement

8:30a - 9:00a
Celebrate Education
Tim Dumas, CLS & Verlin Janzen, MD, FAAFP

Let's celebrate laboratory education by getting focused and inspired to learn. This symposium has been planned to provide a great learning opportunity for all types of laboratory professionals. Take full advantage of the knowledge and experience of our presenters and open your mind to new ideas. Think about these points as you begin your days here:

- The importance of lab medicine to patient care
- Ask questions!
- How you will apply what you learn here
- How you will share what you learn with others
- Network! Expand your social and intellectual network to explore opportunities and learn from others
- Prepare to learn and use a great attitude to help get the most out of your attendance

Learning Objectives:

At the end of the session, participants will be able to:

- Devise strategies to get the most out of the session you attend

9:00a - 10:00a

20 Years and Counting - What's Next for CLIA?

Judith Yost, MA, MT(ASCP), Director, Division of Laboratory Services, Survey & Certification Group, Centers for Medicare and Medicaid Services

Ms. Yost will provide data, other pertinent information and examples to evoke an increased awareness of the challenges and successes of operating a national standardized laboratory oversight program. The CLIA program works to ensure accurate, reliable and timely testing, and is the largest, most complex and diverse oversight program at CMS. Gain a clear picture of how the CLIA program has evolved over time and ultimately demonstrated an added value to lab services' quality. Better visualize the improvements these efforts have accomplished and the opportunities they bring for the future as we focus on the areas of technology, personnel and quality standards for oversight for the past, present and future of lab medicine.

The presentation will also include a 2010 update on current and planned major projects, and on key issues of the CLIA program.

Learning Objectives:

At the end of the session, participants will be able to:

- Summarize how CLIA program has evolved over time
- Assess three changes to technology, personnel, and quality standards
- Outline CLIA program projects and issues
- Avoid PT referral situations in your lab
- Prepare for new QC policies and plan for their implementation

10:00a - 10:30a

Break in Exhibit Ballroom

10:30a - 12:00p

Breakout Session A (select one)

Ao1 Technology Workshop: Hematology Instruments

Facilitator: Terri Scott, CLS, MT(ASCP)

Looking for a new hematology instrument and don't know where to begin? If you want to evaluate and compare hematology instruments, you will benefit from this workshop. Fitting the instrument to the needs of the practice is the cornerstone of this workshop. You will gain experience with currently available hematology systems in a small group setting.

(Check for updates that will provide additional details, including which companies will be participating and the instruments that will be featured.)

Note: This session does not provide CME credit.

Learning Objectives:

At the end of the session, participants will be able to:

- Identify factors to consider when selecting a Hematology instrument
- Recognize the pitfalls encountered in the selection process
- Analyze the differences between systems and determine which system would be the most appropriate for a particular lab setting

Level: B, I

Intended Audience: IT, TC, LM, TP, ELD

Ao2 Introduction to Proficiency Testing  for Physicians

Verlin Janzen, MD, FAAFP

In this session, Dr. Janzen will focus on the basics of Proficiency Testing (PT). Physicians will learn how to select a PT provider, manage the PT process, and perform the laboratory director responsibilities relating to PT. *This session is designed for physician laboratory directors and for individuals without laboratory training. Individuals with laboratory training should attend Ao4.*

Learning Objectives:

At the end of the session, participants will be able to:

- Assess the value of proficiency testing (PT) as a valuable, practical, and quality enhancing exercise in any laboratory
- Participate in PT as required under CLIA '88 for all non-waived testing
- Summarize the CLIA requirements for the POL as it pertains to PT
- Evaluate and interpret PT results and reports; and, when problems occur, determine what actions should be taken to prevent an adverse effect on patient results

Level: B

Intended Audience: NLD

A03 Calibration Verification: Understanding its Impact on Quality Results

John D. Nagel, PhD, BCLD, FACB, Chief Scientific Officer, Maine Standards Co.

Hospital and independent clinical testing laboratories in the United States have been required to meet twice annual calibration verification testing requirements since 1988. In the 2003 Final Rule for the Clinical Laboratory Improvement Act of 1988 (CLIA '88), physician office laboratories (POL) were added to those laboratories required to perform and maintain documentation of calibration verification on a six month schedule, at a minimum. The Centers for Medicare and Medicaid (CMS) educated the POLs on this new requirement during the 2003 – 2005 timeframe during bi-annual inspections. In December 2007, CMS announced focused efforts that the POL facilities will be sanctioned if existing QC requirements are not met by use of a deficiency statement. We define and describe simple methods of meeting this regulatory requirement for the POL and its impact on the quality of results.

Note: This session does not provide CME credit.

Learning Objectives:

At the end of the session, participants will be able to:

- Understand the current regulation: The evolution of calibration verification/linearity and the **positive** impact this practice has on overall quality of the patient reportable result
- Perform calibration verification/linearity: Keeping it simple and manageable for the lab
- Review, interpret, and document calibration verification/linearity: Understanding important parameters and explanation of results during laboratory inspections

Level: I

Intended Audience: TC, TP, IT

A04 Getting the Most Out of Your Proficiency Testing Results

Richard Gates, MLT(ASCP) & Leon Headley, MLS, CT(ASCP)

This breakout session provides insight into how to review and evaluate your proficiency testing (PT) results so that you may identify problems and resolve PT failures when they occur. We will discuss how to interpret your scores, recognize problems, and implement effective corrective actions to resolve PT problems. The importance of PT as a way to demonstrate quality and help to ensure accurate patient testing will be discussed. The session will relate the review of PT performance to the COLA criteria and provide helpful suggestions for laboratories to achieve and maintain compliance with COLA and CLIA.

Learning Objectives:

At the end of the session, participants will be able to:

- Interpret PT scores received from proficiency testing provider

- Recognize and investigate unsatisfactory and unsuccessful PT performance
- Determine and implement steps to take for corrective action
- Document corrective actions taken
- Retain all PT documentation for the required timeframe

Level: B, I

Intended Audience: COLA, ELD, TC, TP

Ao5 *Negotiating with Insurance Companies: Get Paid for In-house Lab Tests!*

Tim Dumas, CLS

This session is for anyone who has ever said “they won’t pay for us to do labs in house!” The ability to get fast results for certain critical tests is good medical practice that enhances patient care. Some offices don’t do in-house labs because they think it will cost too much. There is profit in lab tests and this session will help you find it.

Learning Objectives:

At the end of the session, participants will be able to:

- Decide if your lab and your patients can benefit by performing tests in-house
- Determine what’s legal and what’s not
- Practice the correct way to ask for reimbursement
- Apply principles to keep your lab costs down
- Work with insurance companies so they can earn a living, too

Level: B, I

Intended Audience: ELD, TC, LM, TP

Ao6 *Protime/INR Testing: Does the Method Matter?*

Toni Clinton, PhD (BCLD), MT(ASCP)

Technology has now made it possible for physicians and even patients to monitor their prothrombin time and/or INR results from the physician office, or a patient’s home. What are the disadvantages/ advantages of this practice? Are the results the same as those determined in a more standard clinical laboratory setting? What does it mean if the results vary? Real-life examples of troubleshooting and corrective action plans will be provided.

Learning Objectives:

At the end of the session, participants will be able to:

- Outline the basics of routine coagulation and testing
- Evaluate the limitations of point of care coagulation testing
- Compare and contrast the specimen types for point of care coagulation testing
- Apply the fundamentals of good laboratory practice as it relates to point of care and traditional test methods

Level: B, I

Intended Audience: ELD, TC, TP

Ao7 *I’m a Lab Consultant, Now What? 10 Business Basics to Get You Started*

Barry Craig, MLT, Laboratory Consulting, LLC

Do you have extensive experience in the lab and comprehensive knowledge of all the various regulations? Do you have what it takes to be your own boss? Laboratory consulting is a great vehicle to bring you independence and financial security, if you get started on the right track. This session will teach you the basics of starting your own consulting business and what it takes to succeed. You will learn about different business models, business taxes and deductions, insurance, and more. You will also learn economical ways to advertise your business and gain new clients.

Seven out of every ten new businesses fail in the first year, primarily due to poor planning. This session will help you to avoid the pitfalls that sink most businesses and help you to look like a Fortune 500 company, even on a small budget.

Note: This session does not provide CME credit.

Learning Objectives:

At the end of the session, participants will be able to:

- Determine if they have the mindset to be in business for themselves and to work independently
- Differentiate and understand three business models, the LLC, the Corporation, and the “S” Corporation
- Understand the basics of business taxation and allowable deductions
- Develop a plan for advertising and promoting their business
- Devise a payment structure and understand options for payment and basic bookkeeping
- Understand the development of contracts, the pros and cons of taking on employees, and the different approaches regarding where to consult

Level: B, I

Intended Audience: TC, LM

12:00p - 1:00p

Lunch

1:00p - 2:00p

Exhibits (and dessert!) in Exhibit Ballroom

2:00p - 3:30p

Breakout Session B (select one)

**B11 Technology Workshop:
Chemistry Instruments**

Facilitator: Pam Gottsponer, MT(ASCP)

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.

(Check for updates that will provide additional details, including which companies will be participating, and the instruments that will be featured.)

Note: This session does not provide CME credit.

Learning Objectives:

At the end of the session, participants will be able to:

- Identify factors to consider when selecting a Chemistry instrument for the laboratory
- Recognize the pitfalls encountered in the selection process
- Analyze the differences between systems and determine which system would be the most appropriate for a particular lab setting

Level: B, I

Intended Audience: IT, ELD, TC, TP, LM

B12 Personnel and Procedures for CLIA 
Compliance

Ann Bachman, CLC(AMT), MT(ASCP)

This session is a basic overview of some of the important aspects of the CLIA requirements. This session is designed to show the physician lab director how to meet the personnel requirements of a moderate complexity lab, and how to implement policies and procedures related to CLIA compliance. Development of a lab procedure manual will be discussed. Participants will learn about the education and experience requirements necessary for personnel to hold the CLIA-required positions in the lab, and will review example policies and procedures that relate to physician office laboratory (POL) operations. There will be an emphasis on clarification of terms and concepts associated with achieving CLIA compliance in a typical moderate complexity POL. This session will NOT focus on the specifics of QC, PT, verification of performance

specifications, or quality assessment, as these topics are extensive and will be covered in separate LD sessions or breakout sessions (see A02, C22, D32, E42).

Learning Objectives:

At the end of the session, participants will be able to:

- Apply the CLIA '88 requirements applicable to moderate complexity laboratories
- Obtain the appropriate CLIA certificate for the level of testing performed
- Evaluate and apply the personnel requirements for the level of testing performed
- Implement policies and procedures to achieve CLIA compliance
- Develop a laboratory procedure manual

Level: B

Intended Audience: NLD, LM, TP, PBT

B13 Understanding the Cost of Quality

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ) CQM/OE

Everyone in the laboratory should understand the underlying principles of the cost of quality and be aware of the positive and negative cost impacts of laboratory quality projects, accreditation inspections, and nonconformances. This program overviews four types of quality costs, with relevant laboratory examples. Participants will receive suggestions for how to track the costs of quality in their laboratories and identify and prioritize opportunities for improvements.

Learning Objectives:

At the end of the session, participants will be able to:

- Analyze each of the 4 types of quality costs with relevant laboratory examples
- Assess the economic case for a laboratory quality management system

- Develop one or more mechanisms to identify and track laboratory failure costs

Level: B, I

Intended Audience: QMS, ELD, TC, TP, LM

**B14 Personnel Scenarios:
Complying With the COLA PER Criteria**

Zerela Henry, BS, MLT(ASCP) & Pam Gottsponer, MT(ASCP)

This breakout session is designed to help ensure that your lab is compliant with the COLA personnel criteria (PER 1-6), with a focus on the criteria for personnel competency evaluation and personnel responsibilities. This session will provide real-life scenarios to address issues commonly found in labs of any size. It will also discuss ways to achieve compliance and to prevent or correct specific personnel issues related to the most frequently cited personnel criteria.

Note: This session refers to COLA accreditation criteria, but it presents personnel management concepts and principles that are applicable to all laboratories.

Learning Objectives:

At the end of the session, participants will be able to:

- Summarize frequently non-compliant COLA personnel criteria
- Illustrate non-compliant scenarios
- Formulate and implement appropriate corrective actions to achieve compliance

Level: B, I

Intended Audience: COLA, ELD, TC, TP, LM

B15 Finding the Fix to Common Laboratory Coding Errors

Shannon Smith, CRTT, CPC-I, CEMC, CMSCS, CPMA

This informative session will review common laboratory coding errors. Ms. Smith provides a comprehensive look at laboratory coding and how you can maximize the bottom line of your practice through your lab. You will review coding updates, as well as taking a comprehensive look at laboratory coding.

Learning Objectives:

At the end of the session, participants will be able to:

- Interpret the national coverage determination policies for laboratory services
- Summarize and compare the common laboratory codes utilized
- Implement strategies for enhancing laboratory revenue

Level: B, I

Intended Audience: TC, LM, TP

B16 Popular Tests: Fad, Fallacy, or For Real
Verlin Janzen, MD, FAAFP

In this session, Dr. Janzen will discuss several tests that have been in the medical news and popular press using a case study approach. Concepts of predictive value, number needed to treat (NNT), and likelihood ratios will be introduced and used in case discussion. This session is designed for laboratorians, nurses, and other non-physician medical personnel.

Learning Objectives:

At the end of the session, participants will be able to:

- Evaluate the pros, cons, and limitations of several popular tests
- Summarize the statistical terms and processes used to evaluate test performance in the clinical setting

- Apply these principles to test menu selection in the laboratory

Level: B, I

Intended Audience: TC, LM, TP

B17 The Technical Consultant – “Technically Speaking”

Lynn Glass, BS, MT(ASCP), Technical Support Specialist, MedSol, Inc.

The phrase, “Change in healthcare delivery is the only constant,” would seem to apply to the regulations clinical laboratories must adhere to, as they are continually being revised or re-interpreted through federal, state, and accreditation organizations and governing bodies. Assistance from a technical consultant should provide guidance and support to the clinical laboratory staff and empower them to take ownership of their laboratory operations and overall quality assessment of the testing process. This discussion will provide participants with information on technical consultant requirements and responsibilities, on-site and remote consulting options, and actual case studies demonstrating how the technical consultant and laboratory staff work together to correct deficiencies and provide the highest quality testing.

Note: This session does not provide CME credit.

Learning Objectives:

At the end of this session, participants will be able to:

- Outline the educational and experience requirements to become a technical consultant
- Summarize the responsibilities of the technical consultant
- Illustrate how a technical consultant may empower staff to take ownership of the overall operation and quality assessment of the laboratory setting, while providing guidance in the process
- Compare how consulting services may be provided on-site or remotely

- Analyze QA reviews of actual citations given to POLs and assess steps in the corrective action plan

Level: B, I

Intended Audience: TC, LM, TP

3:30p - 4:00p

Coffee/beverage break

4:00 - 5:30p

Breakout Session C (select one)

C21 Quality Assessment for the LIS

Steward Macis, Antek Healthcare

This presentation will touch on the necessary steps required to create an effective Quality Assessment process for your LIS. QA of your LIS is necessary in order to comply with COLA criteria QA17, and is a beneficial activity for all laboratories with an LIS. Topics covered will include the pre-analytical, analytical, and post-analytical processes associated with data entry, LIS calculations, the storage and recovery of data, along with necessary maintenance of hardware and software components. This presentation is designed to be an outline to an effective LIS QA plan for integration to the overall laboratory QA program.

Note: This session does not provide CME credit.

Learning Objectives:

At the end of this session, participants will be able to:

- Design an effective quality assessment process for the laboratory information system
- Comply with COLA Criteria QA17
- Integrate the LIS QA plan into the overall QA program for the lab

Level: B, I

Intended Audience: IT, TC, LM, TP

C22 Top 10 Pre-analytic Errors 

Dennis Ernst, MT(ASCP)

This presentation discusses 10+ of the most common reasons specimens fail to yield accurate test results. Included among them are IV contamination, hemoconcentration, underfilling tubes, failure to mix, faulty centrifugation, delays in processing, and more.

Learning Objectives:

At the end of the session, participants will be able to:

- Analyze the most common specimen collection errors that threaten accurate results
- Associate errors in specimen collection with their impact on patient care
- Assess their specimen collection techniques to minimize pre-analytical errors that alter test results

Level: B, I

Intended Audience: NLD, ELD, TC, LM, TP, PBT

C23 Introduction to Quality System Concepts

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ) CQM/OE

There's always too much to do in too little time. This program overviews systematic process-based approaches for organizing the laboratory's many regulated management and technical activities. A process-based approach has been shown to be both more efficient and more effective in meeting regulatory and accreditation requirements.

A quality system encompasses method quality control and quality assurance measurements. It integrates both management and technical activities into easily understood work processes and procedures. This program presents a model for a quality system that fits any size, scope, or speciality of laboratory.

Learning Objectives:

At the end of the session, participants will be able to:

- Differentiate between quality control, quality assurance, and quality systems
- Illustrate the 12 essentials of a quality system (the 12 QSEs)
- Apply the two-part model for a laboratory quality management system

Level: B, I

Intended Audience: QMS, ELD, TC, LM, TP

C24 COLA Users Group: Accreditation Update
Zerela Henry, BS, MLT(ASCP)

While all accreditation programs for compliance with CLIA begin with the core requirements in the Federal regulations, COLA's approach has been shown to improve laboratory performance. COLA differentiates their program by a strong emphasis on educating the lab director and staff on practical ways to achieve a high quality laboratory operation. At this User's Group session, participants will have the opportunity to ask questions about implementing COLA criteria that will result in good laboratory practices.

Note: This session is repeated on Saturday morning as a general session. If you will be attending the symposium on Saturday, please select a different C breakout session. This session is intended for COLA participants that cannot attend this session on Saturday.

Learning Objectives:

At the end of the session, participants will be able to:

- Outline the phases of the COLA Survey Process
- Perform key responsibilities of the laboratory in the accreditation process
- Implement a plan to assure compliance with COLA Criteria

- Predict the impact an educated staff can have on the patient's outcome
- Summarize how COLA uses customer feedback to improve educational products and services

Level: B, I

Intended Audience: COLA, ELD, TC, LM, TP

C25 Basic Principles of Financial Compliance
Shannon Smith, CRTT, CPC-I, CEMC, CMSCS, CPMA

This session will teach the basic principles of the Anti-Kickback Statutes, Stark II rules, and the Civil False Claims Act. You will also learn how to identify potential areas of vulnerability within your practice, and how to manage your lab and practice in a financially compliant manner.

Learning Objectives:

At the end of the session, participants will be able to:

- Locate and interpret Stark II rules
- Manage potential areas of vulnerability within your practice
- Interpret the basic principles of the Anti-Kickback Statutes

Level: B, I

Intended Audience: ELD, TC, LM, TP

C26 Glucose Testing: Point of Care versus Traditional Methods
Toni Clinton, PhD (BCLD), MT(ASCP)

Glucose testing is routinely used in a physician office setting to provide rapid glucose results. The values are used to not only help determine patient compliance, but also in some cases to provide rapid results and interpretations of glucose tolerance tests.

This presentation will discuss the most common methods of glucose measurement, including sample types, standardization, and

its impact on patient care. Advantages and disadvantages of each method and sample type will be presented. Good laboratory practices for both point of care and traditional test methods will be discussed.

Learning Objectives:

At the end of the session, participants will be able to:

- Summarize the roles of the clinical laboratory and the physician office in glucose measurement and monitoring
- Compare and contrast the most common methods for glucose measurement
- Compare the differences between specimen types for glucose measurement
- Apply the fundamentals of good laboratory practice as it relates to point of care and traditional test methods
- Illustrate the limitations and advantages of each sample type used for glucose measurement

Level: B, I

Intended Audience: ELD, TC, LM, TP

6:00p - 8:00p

Reception for participants, faculty, and exhibitors

Friday, April 23, 2010

7:00a - 8:00a

Breakfast in Exhibit Ballroom

7:00a - 8:00a

QA of PT: Proficiency Testing Problem Resolution 

Verlin Janzen, MD, FAAFP & Kathy Nucifora, MPH, MT(ASCP)

In this session, Dr. Janzen and Ms. Nucifora 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 illustrate how to identify problems, how to determine the root cause, how to formulate a solution, and then how to follow up later to see if the solution worked. *This session is designed for physician laboratory directors and for individuals without laboratory training. Individuals with laboratory training should attend Ao4 instead (Thursday at 10:30am).*

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

Learning Objectives:

At the end of the session, participants will be able to:

- 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

8:00a - 9:30a

Friday AM General Session 

8:00a - 8:15a

Opening Remarks

8:15a - 9:30a

How CLSI Documents Help Your Laboratory Ensure CLIA Compliance

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ) CQM/OE

Laboratory directors are responsible for ensuring compliance with all CLIA requirements and this is a huge task. The requirements specify what the laboratory must do, but provide no recommendations for how to comply. Wouldn't it be helpful if there was an easier way to meet requirements than having your laboratory staff figure this out themselves? The easier way is to use consensus-derived approved standards and guidelines published by the Clinical and Laboratory Standards Institute (www.CLSI.org). CLSI volunteers from laboratory disciplines, industry, and government partner to develop and update useful

guidelines for how laboratories can meet specific CLIA requirements such as those for procedures manuals, document control, equipment management, test method verification, quality control, and proficiency testing, as well as standards for technical issues such as blood sample collection and hematology testing. This program overviews the important benefits of using CLSI products and services in your laboratory.

Learning Objectives:

At the end of the session, participants will be able to:

- Differentiate between a standard and a guideline
- Create a “Top 10 List” of CLSI documents essential to a successful POL
- Evaluate several types of CLSI resources available to your laboratory
- Use CLSI resources to meet CLIA requirements

9:30a - 10:30a

Exhibits in Exhibit Ballroom

10:30a - 12:00p

Breakout Session D (select one)

D31 Technology Workshop:

Laboratory Information Systems

Facilitator: Rebecca Kenner, MT(ASCP) DLM

This workshop provides an opportunity to compare and evaluate multiple working laboratory information systems (LIS). The groups will be small so all your questions and concerns may be addressed. The information will be valuable whether you are already using an LIS or are evaluating one for your laboratory.

(Check for updates that will provide additional details, including which companies and systems will be participating.)

Note: This session does not provide CME credit.

Learning Objectives:

At the end of the session, participants will be able to:

- 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

Level: B, I

Intended Audience: IT, TC, LM, TP

D32 Introduction to Quality Control for Physicians 

Verlin Janzen, MD, FAAFP

A physician’s office laboratory, even if it is only doing waived testing, must perform routine quality control (QC). Every clinical laboratory must have technical personnel who understand how to establish and implement an ongoing QC program to monitor the accuracy of the assay once it is in clinical use. Dr. Janzen will introduce QC to the novice laboratory director in this session designed for physicians and other non-laboratory trained attendees. Together you’ll 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. *This session is designed for physician laboratory directors and for individuals without laboratory training. Individuals with laboratory training should attend E44.*

Learning Objectives:

At the end of the session, participants will be able to:

- 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

Level: B

Intended Audience: NLD

D33 Write it Right:

Better Laboratory Documents

Lucia M. Berte, MA, MT(ASCP)SBB, DLM;
CQA(ASQ) CQM/OE

Procedures are meant to be instructions to the staff on how to do their assigned tasks. However, conventional laboratory “SOPs” do not reflect the way work really happens in the laboratory and thus, these documents are often ignored or written only to please the inspectors. Most laboratory SOPs are too long and hard to follow. Learn how to make good documents that serve your staff—not vice-versa!

Learning Objectives:

At the end of the session, participants will be able to:

- Develop and use four different types of documents
- Differentiate between “process” and “procedure”
- Utilize resource information to help your laboratory develop better documents

Level: I

Intended Audience: QMS, ELD, TC, LM, TP

**D34 Incident Management:
Meeting COLA Criteria QA20**

Irwin Rothenberg, MBA, MS, MT(ASCP) &
Leigh Ann Smith, MLS(ASCP)

This session will discuss Incident Management (IM) and explain the differences between IM, quality assessment, and occurrence management. Development and implementation of an incident management plan that complies with COLA criteria QA 20.1 and 20.2 will be discussed, and example case studies will demonstrate key points, including root cause analysis. The session will discuss other relevant COLA QA criteria and provide tips to support compliance and prevent repeat citation for QA 20.

Note: This session refers to COLA accreditation criteria, but it presents incident management and quality assessment concepts that are applicable to all laboratories.

Learning Objectives:

At the end of the session, participants will be able to:

- Distinguish between Quality Assessment (QA) and Incident Management (IM) Programs
- Demonstrate how to implement QA and IM as an integral part of Laboratory Quality Management
- Apply investigative skills to identify potential causes and resolutions of incidents

Level: B, I

Intended Audience: COLA, ELD, TC, LM, TP

D35 Laboratory Training That Won't Put Your Staff to Sleep

Terry Jo Gile, MT(ASCP) MA Ed.

Do your required inservices lack luster? Does your "under 40" crowd spend time texting during your presentations? When you give it do they get it? Training by Gaming is the answer and this program will show you how. Using a Jeopardy style format of Q&A complete with music, sound effects, and photos; participants will discover a fun way to test employees' knowledge in any area of laboratory practice. Participants in this program will observe a computer based education tool designed specifically for the physician office laboratory (POL). You will have the opportunity to experience firsthand how the gaming program works, and compete with other teams in an entertaining, informative, and fun format.

Note: This session does not provide CME credit.

Learning Objectives:

At the end of the session, participants will be able to:

- Describe the components of effective training
- Explain the importance of timing and location for training
- Describe different methods used for different age groups
- Describe the proper use of various training methods for the POL

Level: B

Intended Audience: TC, LM, TP, PBT

D36 LEAN for the Physician Office Laboratory

Toni Clinton, PhD (BCLD), MT(ASCP)

LEAN is the buzzword now in the clinical laboratory industry. How do the principles of LEAN apply to the physician office laboratory? This session will present the basic concepts of LEAN. A case study approach will then be used to demonstrate how LEAN can be used to optimize even the smallest volume physician office laboratory.

Learning Objectives:

At the end of the session, participants will be able to:

- Summarize the fundamental concepts of LEAN
- Compare and contrast the implementation of LEAN in several clinical laboratory settings
- Develop a workflow plan that will meet the learner's individual laboratory setting

Level: B, I

Intended Audience: QMS, ELD, TC, LM, TP

D37 Lab Management:

Transitioning from Bench Tech to Lab Manager

Alyn Hansen, MT(ASCP), H & L Clinical Consulting

In the hospital environment there is always someone else with laboratory experience to bounce questions off. Moving to the physician office lab where you are the one and only expert can be daunting. Being technically competent and a whiz at fixing the analyzers only begins to describe your expected skills. Here we will talk about laboratory management skills that the office manager will expect you to know. You are expected to wear a lot of hats as a POL manager, and here you will find some answers, tips, checklists, and more to help. We will discuss everything from personnel to quality control to proficiency testing to the regulations that touch every aspect of lab management, and talk about where to find some of the answers. The lab's existence depends on revenue – here you will also find some billing primers to give you a start.

Note: This session does not provide CME credit.

Learning Objectives:

At the end of the session, participants will be able to:

- Describe the expected skills of a physician office laboratory manager
- Apply basic principles of laboratory management in a POL
- Find and use resources to effectively manage a POL
- Summarize personnel requirements
- Outline QC and PT requirements
- Select a test menu
- Develop a budget based on known expenses and future needs

Level: B, I

Intended Audience: TC, LM, TP

12:00p - 1:00p

Lunch

1:00p - 2:30p

Breakout Session E (select one)

E41 Immunizing Your Lab From a Phlebotomy-Related Lawsuit

Dennis Ernst, MT(ASCP)

When improperly performed, venipunctures can injure patients and lead to complications including nerve damage, hemorrhage, injuries from fainting, and errors from patient misidentification. This presentation outlines policies, procedures and practices based on CLSI standards that phlebotomists and their managers can implement to minimize their risk of patient injury and litigation. Case studies from the files of an expert witness in phlebotomy lawsuits will be used to illustrate key concepts.


Learning Objectives:

At the end of the session, participants will be able to:

- Identify the most common injuries that poor phlebotomy technique inflicts upon patients
- Associate errors in technique, judgment, and supervision with phlebotomy-related injuries
- Evaluate their own vulnerability, or the vulnerability of their employees and facility, to phlebotomy-related lawsuits

Level: B, I

Participant: ELD, TC, LM, TP, PBT

E42 Quality System Approach to Quality Assessment 

Kathryn Connolly, CQA(ASQ), MT(ASCP) & Zerela Henry, BS, MLT(ASCP)

Confused about Incident Management? Want to know how it fits with Quality Assessment and Quality Management Systems? During this breakout, you will learn about Quality Assessment (QA) and Incident Management (IM). Real-life case studies enhance the learning experience. Tips and guides for identifying, studying, and resolving incidents are shared allowing participants to develop practical applications for use in their laboratories.

Learning Objectives:

At the end of the session, participants will be able to:

- Select areas to assess in your Quality Assessment plan
- Evaluate how Incident Management can be applied in the laboratory
- Demonstrate how Quality Assessment, Incident Management, and Quality Systems are related

Level: B, I

Intended Audience: NLD, ELD, TC, QMS, LM, TP, PBT

E43 HIPAA and FACTA

Ann Bachman, CLC(AMT), MT(ASCP)

HIPAA Privacy and Security Laws apply to laboratories but laboratory risks may be overlooked by the parent organization. Learn how to evaluate and minimize your risks and what corrective actions must be implemented if there is a breach.

Laboratories may also be subject to FACTA “Red Flag” rules. This session includes an introduction to this important piece of legislation as well as a model program, ready for customization to meet your needs.

Learning Objectives:

At the end of the session, participants will be able to:

- Illustrate how HIPAA regulations apply to the laboratory
- Evaluate your risks
- Implement required corrective actions following the discovery of a breach
- Summarize FACTA “Red Flag” rules and develop a compliance program for your lab

Level: B, I

Intended Audience: ELD, LM, TC, TP

E44 Quality Control Basics: COLA QC Criteria

Louise Jackman, MT(ASCP) & Rebecca Kenner, MT(ASCP) DLM

The purpose of this session is to provide participants with information on the performance, evaluation and interpretation of quality control using the COLA Criteria. We will be concentrating on Quality Control criteria that are the most frequently cited as non-compliant. The presentation today will focus on external quality control for waived testing, non-waived quantitative and general qualitative quality control testing. It will not cover the specifics of specialty and sub-specialty quality control.

Note: This session refers to COLA accreditation criteria, but it presents quality control concepts and principles that are applicable to all laboratories.

Learning Objectives:

At the end of the session, participants will be able to:

- Apply COLA requirements for Quality Control
- Interpret quality control and Levey Jennings graphs
- Identify and investigate quality control failures
- Implement corrective actions for quality control failures
- Review case studies of quality control

Level: B, I

Intended Audience: COLA, ELD, LM, TC, TP

E45 What’s New in Lab Safety for 2010-Ask the Safety Lady

Terry Jo Gile, MT(ASCP) MA Ed.

Are you complacent about your safety program? Has your safety officer lost his/her enthusiasm for the job? Is a CAP or Joint Commission inspection looming on the horizon? Then it is time to jumpstart your safety initiatives and stop paying lip service to your safety activities. This program will cover:

- Ergonomic improvements that must justify their return on investment (ROI)
- The new Global Harmonizing System (GHS) and how it will impact your Chemical Hygiene Plan
- The impact of the new CLSI document on laboratory waste management
- How to bounce back from an OSHA inspection
- Computer-based competency testing that will reenergize your staff

Terry Jo Gile, the Safety Lady®, will be here to share her expertise and preview some breakthrough safety strategies that are more than just lip service and will put you ahead of the learning curve. As always, Terry Jo will

entertain as well as inform and allow ample time for you to “Ask the Safety Lady” about any issues you are facing at your facility.

Learning Objectives:

At the end of the session, participants will be able to:

- Analyze the GHS and how it will impact chemical hygiene
- Illustrate ergonomic improvements that will enhance lab safety
- Interpret the impact of the new CLSI document on waste management issues
- Utilize the latest in training technology for competency testing

Level: B, I

Intended Audience: ELD, TC, LM, TP, PBT

E46 Microbiology Basics for the POL

Paula Mister, MS, MT(ASCP)SM, Educational Coordinator for Clinical Microbiology, Johns Hopkins Hospital

This session will discuss proper specimen collection and basic microbiological techniques for physician office laboratories in a hands-on and interactive format. There will be demonstrations of specimen collection devices, plates, test devices, and other useful examples from the clinical microbiology laboratory.

The presentation will begin with proper specimen collection for 3 common types of specimens obtained in physician office laboratories: urine, throat and genital. Then, basic microbiological techniques for recovery and ID of pathogens from these body sources will be discussed, including proper streaking of plates, necessary QC, proper incubation for plates or tests, correct storage of reagents, urine colony counts, classic laboratory microbiologic ID of pathogens with illustrations and demo plates, and the use of rapid devices for ID of pathogens from these sources.

Learning Objectives:

At the end of the session, participants will be able to:

- Demonstrate proper specimen collection for 3 common specimen types
- Summarize proper storage of reagents, and proper storage of specimens when testing is delayed
- Illustrate basic microbiology techniques suitable for the POL
- Outline necessary quality control procedures
- Compare classic laboratory microbiologic ID of pathogens with the use of rapid devices

Level: B

Intended Audience: ELD, TC, LM, TP

2:30p - 3:30p

Ice Cream Social and Exhibits in the Exhibit Ballroom

3:30p - 5:45p

Friday PM General Session 

3:30p - 4:45p

The Present and Future of Waived Testing

Cyril M. Hetsko, MD, FACP

Waived testing will be discussed and evaluated as this form of laboratory testing becomes more commonly used. A brief history and the current status of waived laboratory testing will be presented, including some of the objective observations which have been made during onsite survey evaluations in recent years. Best Practices for Waived Testing will be reviewed and the future of waived testing will be considered.

Learning Objectives:

At the end of the session, participants will be able to:

- Outline the CLIA requirements for waived testing

- Evaluate areas of concern regarding waived testing
- Implement best practices for waived testing to ensure reliable results
- Plan for possible future changes regarding the regulation of waived testing

4:45P - 5:45P

Resiliency Rx: The Benefit of Humor to Relieve Stress

Tim Dumas, CLS

Resiliency: ability to adjust easily to change, flexibility, spirit.

Can attitude impact your health? Is there a magic formula to a stress free life? How can we reduce stress and increase resiliency? We choose the attitude we have in life. We may not be able to control the events, but we can be in charge of our physical, mental and emotional responses.

Note: This session does not provide CME credit. Those in the LD qualification track must attend Preparing for the Inspection instead, which runs concurrently.

Using established principles and measurable tools we will:

- Discover the use of humor, empathy, and purpose to develop understanding, tolerance, and a positive attitude
- Explore attitude and how it affects the bottom line
- Evaluate and understand your personal mission and how it relates to your company's mission
- Provide perspective – improve productivity and creativity through humor

We will gain valuable tools and learn while exploring:

- **Attitude** – how it affects your bottom line and how to control it

- **Play** – how humor can function in the work place
- **The “Make Their Day” philosophy**
- **Being present** – empathy and communication at its fullest potential

OR

4:45P - 6:00P

Concurrent Lab Director Session  Preparing for the Inspection

Ann Bachman, CLC(AMT), MT(ASCP)

Laboratory surveys can be a stressful occurrence. This session will help you understand what the surveyors evaluate and what you need to do to prepare for their arrival. Handouts will include an Inspection Preparation Checklist.

Learning Objectives:

At the end of the session, participants will be able to:

- Assess the purpose of laboratory surveys and how the surveys proceed
- Develop a plan to prepare for laboratory surveys
- Predict and manage survey pitfalls
- Implement corrective actions to correct identified deficiencies before the survey
- Design and apply a correction plan after a survey

5:45P or 6:00P

Adjourn**Saturday, April 24, 2010**

7:00a

Breakfast in General Session Ballroom

7:15a - 11:45a

Saturday AM General Session 

7:15a - 8:15a

Lab Director Responsibilities: Regulatory

Verlin Janzen, MD, FAAFP

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

Learning Objectives:

At the end of the session, participants will be able to:

- 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

8:15a - 9:15a

COLA Users Group: Accreditation Update

Zerela Henry, BS, MLT(ASCP)

While all accreditation programs for compliance with CLIA begin with the core requirements in the Federal regulations, COLA's approach has been shown to improve laboratory performance. COLA differentiates their program by a strong emphasis on educating the lab director and staff on practical ways to achieve a high quality laboratory operation. At this User's Group session, participants will have the opportunity to ask questions about implementing COLA criteria that will result in good laboratory practices.

Learning Objectives:

At the end of the session, participants will be able to:

- Outline the phases of the COLA Survey Process

- Perform key responsibilities of the laboratory in the accreditation process
- Implement a plan to assure compliance with COLA Criteria
- Predict the impact an educated staff can have on the patient's outcome
- Summarize how COLA uses customer feedback to improve educational products and services

9:30a - 10:30a

Can it Get Any Worse?**Resolving Laboratory Survey Outcomes**

Cyril M. Hetsko, MD, FACP & Pam Gottspomer, MT(ASCP)

Hear the scoop from COLA's Chief Medical Officer and one of COLA's experienced laboratory surveyors. During this session, Dr. Hetsko and Ms. Gottspomer share their findings on laboratory non-conformances, and describe how COLA worked with the laboratories to resolve these issues. They bring to light the most common problems encountered by laboratories, and discuss ways to achieve compliance with CLIA and COLA criteria.

Learning Objectives:

At the end of the session, participants will be able to:

- Examine five of the common deficiencies found during a laboratory survey
- Develop a plan to implement the activities necessary to comply with the criteria cited in common deficiencies
- Examine the consequences of PT sharing and other violations

10:30a - 11:45a

Perspectives on Being a Laboratory Director – Financial Considerations

Tim Dumas, CLS

The laboratory is a business, and in order to offer your patients the advantages of timely results you must consider the financial aspects of setting up and operating an in-office lab.

Learning Objectives:

At the end of the session, participants will be able to:

- Formulate ways to maximize laboratory revenue
- Compare laboratory income to expenses
- Select a laboratory test menu that helps you care for your patients
- Choose the right analyzer(s) for your needs
- Monitor lab revenue

11:45a - 12:00p

Lunch

12:00p - 1:30p

Saturday PM General Session 

12:00p - 1:00p

Lab Director Responsibilities: Practical Application

Verlin Janzen, MD, FAAFP

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.

Learning Objectives:

At the end of the session, participants will be able to:

- 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

1:00p - 1:30p

Can We Speak Frankly About Being a Laboratory Director?

Verlin Janzen, MD, FAAFP

In 20 hours, a qualified physician can meet the education qualifications to become a CLIA-accepted laboratory director. However, this conference is not the end of your learning. It's a beginning. The process starts anew for every participant – there are new concepts, ideas, and regulations – all part of being a laboratory director in 2010 and beyond.

Learning Objectives:

At the end of the session, participants will be able to:

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

1:30p

Conclusion and Adjourn – Travel Safely

KEY FOR BREAKOUT SESSIONS:

Level: B = Basic I = Intermediate A = Advanced

Intended Audience:

NLD = Novice Laboratory Director
 ELD = Experienced Laboratory Director
 TC = Technical Consultant
 LM = Lab Manager
 QMS = Quality Management Systems
 TP = Testing Personnel
 IT = Instrument Technology
 PBT = Phlebotomist
 COLA = COLA Labs

Suggested breakout sessions, based on intended audience:

	NLD	ELD	TC	LM	QMS	TP	IT	PBT	COLA
A	A02	A01, A04, A05, A06,	A01, A03, A04, A05, A06, A07	A01, A05, A07		A01, A03, A04, A05, A06	A01, A03		A04
B	B12	B11, B13, B14	B11, B13, B14, B15, B16, B17	B11, B13, B14, B15, B16, B17	B13	B11, B12, B13, B14, B15, B16, B17	B11	B12	B14
C	C22	C22, C23, C24, C25, C26	C21, C22, C23, C24, C25, C26	C21, C22, C23, C24, C25, C26	C23	C21, C22, C23, C24, C25, C26	C21	C22	C24
D	D32	D32, D31, D33, D34, D36	D31, D33, D34, D35, D36, D37	D31, D33, D34, D35, D36, D37	D33, D36	D31, D33, D34, D35, D36, D37	D31	D35	D34
E	E42	E41, E42, E43, E44, E45, E46	E41, E42, E43, E44, E45, E46	E41, E42, E43, E44, E45, E46	E42	E41, E42, E43, E44, E45, E46		E41, E45	E44