

COLA'S

inSights

INTO *Proficiency Testing*

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NEW!





FROM THE CHAIR

It seems so wrong to think about “testing” of any kind during vacation season; however, we should never take a vacation from producing high quality laboratory test results. Proficiency Testing (PT) is a means of helping to ensure that your laboratory continually produces the highest quality, most accurate results possible.

In this issue of *Insights*, we hope to teach you about the PT process from several different perspectives: laboratory, PT provider, and COLA. This issue also includes lists of CMS-approved PT providers and CMS regulated analytes.

To further help you continually produce high quality laboratory test results, COLA is very excited to offer a new, innovative program: the *Continuous Quality Program (CQP)*. Through the *CQP*'s combination of education and consultation, we will help you educate and train your staff to look at testing from a “quality” perspective. The goal is to create an atmosphere where quality characteristics are so routine, they become second nature. More information can be found in the article on page 6.

Education is also at the forefront of our *Symposium for Clinical Laboratories*, which is detailed in a “pull-out” section at the end of this issue. In addition to high quality educational sessions, the *Symposium for Clinical Laboratories* is a great source for networking; comparing the latest laboratory instruments, test kits, and supplies; and for having fun! Won't you join us in Baltimore in October?

W. James Stackhouse, MD, MACP
Chair, COLA Board of Directors



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COLA INSIGHTS is published periodically by COLA, 9881 Broken Land Parkway, Suite 200, Columbia, MD 21046-1195.

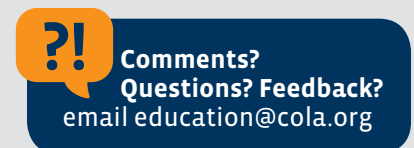
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Proficiency Testing: Overview

Proficiency Testing is similar to “unknowns” from high school chemistry lab.

Proficiency Testing, more commonly known as PT, is an external check used to monitor the quality of test results produced by the laboratory. It is a measure of the lab’s ability to analyze specimens of unknown values to obtain accurate results.

For regulated analytes (those analytes specifically listed in the CLIA regulations), the laboratory must be continuously enrolled in a PT program from the time patient testing is first performed. Failure to successfully participate in a PT program can lead to serious sanctions, such as an order to cease testing, loss of CLIA certification, and/or loss of Medicare & Medicaid reimbursements. (See p. 11 for a current list of regulated analytes.)

The Proficiency Testing process begins by choosing a PT provider from the list of CMS-approved providers. (See p. 10 for a current list of approved providers.) Depending on the analyte, the PT provider will deliver 2 – 5 specimens, known as challenges, 2 or 3 times per year. Providers will send five challenges for the regulated analytes at approximately equal intervals three times per year. Nonregulated analytes (those not listed in the CLIA regulations) are required to be challenged twice per year, either by PT or some other scientifically defensible means of comparison, such as split-sample analysis.

Laboratory Responsibilities

The most important aspect of PT is that the PT challenge specimens must be handled in the same manner as patient specimens. The primary purpose of PT is defeated if the challenges receive special treatment.

- The PT specimens should be incorporated into the routine patient workload.
- All testing personnel should perform PT at some point during the year. Do not delegate PT to only select personnel.
- PT challenges should not be repeated to report an average result. If patient specimens are not repeated, PT specimens should not be repeated.
- For each testing event, the Laboratory Director and the testing personnel (who actually performed testing for the PT event) sign a statement attesting that the PT challenges were handled in the same manner as patient specimens.

After testing is completed, submit results to the PT provider within the required time frame. The laboratory receives a grade of zero for the entire testing event if results are not submitted or if they are submitted after the cut-off date.

Other important PT rules¹ include:

- Do **NOT** discuss PT or PT results with any other laboratory (including satellite, affiliate, and reference laboratories) prior to the result submission date.
- Do **NOT** send PT specimens to another lab for testing. This also includes satellite, affiliate, and reference laboratories. If patient specimens would normally be referred for further testing, indicate this on the PT result form, but do NOT send the specimen.
- Do **NOT** perform testing on PT specimens received from another lab, but notify CMS that they were received.

Overview

Choose a PT provider from CMS-approved list

PT provider periodically sends unknown specimens

Handle PT specimens in the same manner as patient specimens

Report results to PT provider

PT provider checks results, compares them to results from similar laboratories, and prepares and sends graded report packets to labs

>> CONTINUED ON PAGE 4

PROFICIENCY TESTING: OVERVIEW

- Document everything involved in performing Proficiency Testing and keep this documentation for at least two years.

It is good laboratory practice to maintain the PT specimens under proper storage conditions until the graded report packet is received from the PT provider. This means that the specimens will be available for repeat testing if the PT performance review deems it necessary.

Review PT Performance

Laboratories should promptly review and evaluate the data in the graded report packet when it is received.

First, review the report for clerical, transcription, and/or omission errors.

- Ensure that the CLIA ID number is correct.
- Confirm that there is a score for all tests for which results were submitted.
- Verify that the PT provider used the actual submitted results when grading the event.
- Check to see that the correct test method codes were used, to ensure that results were compared to the correct peer group.

Next, review and evaluate the individual challenges.

- Use the Standard Deviation (SD) and Standard Deviation Index (SDI) to help determine if the test system is showing instability or imprecision.
- Pay attention to challenges where consensus is not obtained (automatic scores of 100%). “Self-grade” by comparing submitted results to the provider’s expected results as well as results obtained by other laboratories.
- Compare current results to past results to detect trends and/or method bias.

If all results are acceptable, document the review, and maintain all documentation for the required time period which, in most cases, is a minimum of two years. The retention period is determined by Federal, State, local, and institutional requirements. Ensure that you meet the longest retention times.

If any results are unacceptable, determine the cause; implement and evaluate corrective actions; and document everything and maintain documentation for the required time period.

Evaluate PT Performance

Looking at the scope of the problem can help determine its root cause. A problem with the PT specimen itself is indicated if more than one analyte from the same specimen is involved. Improper handling (such as improper reconstitution, or pipetting or dilution errors) and evaporation of the aliquot used for testing are possible causes.

Instrument or test system problems are indicated if more than one analyte or specimen on the same instrument or test system is involved, or if only analytes in a certain range are affected (which indicates a linearity or calibration issue). If the test system or instrument is the cause, patient results should also be evaluated.

If more than one instrument or test system is affected, look for factors that are common to all systems involved. The most obvious commonality is testing personnel. Confirm that all personnel are still competent to perform testing, and provide retraining and/or continuing education when necessary. Don’t overlook other common factors, such as unforeseen effects of new policies; modified kit, reagent, or specimen storage facilities; and/or unusual environmental factors (power outage, extreme temperature changes, electronic interference, etc.). Patient results should also be evaluated in this circumstance.

Finally, look at the overall grade for the PT event. Each testing event has three possible outcomes: satisfactory performance, unsatisfactory performance, or unsuccessful performance.

- *Satisfactory performance* is attaining the minimum score for an analyte, test, subspecialty, or specialty for a single testing event. For most specialties, the minimum score is 80%; however, exceptions do exist. For example, in Immunohematology, a score of 100% is required when performing ABO & Rh typing and/or compatibility testing.
- *Unsatisfactory performance* is defined as failure to attain the minimum score for an analyte, test, subspecialty, or specialty for a single testing event.
- Repeated *unsatisfactory performance* becomes *unsuccessful performance*, which is failure to attain a satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two-out-of-three consecutive testing events. Unsuccessful performance can lead to CMS sanctions including an order to cease testing or limitation, suspension, or revocation of CLIA certification.

>> CONTINUED ON PAGE 5

PROFICIENCY TESTING: OVERVIEW

To resolve unsuccessful performance, laboratories must:

- Investigate the root cause of the unsuccessful performance.
- Implement and evaluate corrective actions.
- Notify accrediting agencies or CMS of actions taken.

Laboratories that have been required to cease testing due to poor PT performance will also have to successfully complete two consecutive PT events, which can be either scheduled or off-cycle events, before patient testing can be reinstated.

All actions taken during the Proficiency Testing process have to be documented. This includes **all records** – from initial receipt in the laboratory; through PT specimen processing and handling, actual test performance, and result submission; to reviewing and evaluating graded reports, investigating problem root causes, and implementing and evaluating corrective actions.

All correspondence with PT providers, including details of any phone calls, should also be maintained. All documentation must be readily available for at least two years. (As stated above, the retention period may be longer in some areas.)

Quality patient care is a goal of all clinical laboratories. Producing accurate, reliable laboratory test results helps ensure quality patient care. PT is a means to monitor the quality of laboratory test results. Therefore, consistent, successful performance of Proficiency Testing is a goal every laboratory should strive to attain. ■

NOTE:

¹This is not an all-inclusive list. For more information, refer to subpart H of the CLIA regulations. http://www.cdc.gov/clia/regs/subpart_h.aspx

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Continuous Quality Program

COLA is a physician-directed organization whose purpose is to promote excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation.

Since “excellence in laboratory medicine and patient care” translates to quality patient care, quality has always been the heart of COLA’s mission. Through the COLA accreditation program, your laboratory’s quality has been evaluated through biennial surveys, which provide a snapshot of how your laboratory complies with federal and state regulations at the time of the survey. However, COLA knows that you want to provide excellent laboratory medicine and patient care at all times; that you want to create a culture of quality within your laboratory; and that you want to integrate quality policies and procedures into your daily routine. COLA’s new *Continuous Quality Program* can help you do this.

Through the launch of several new initiatives, COLA can help you grow beyond mere compliance and develop a culture of quality that permeates your laboratory on a daily basis. Through COLA’s *Continuous Quality Program* and our robust offerings of online courses, educational products, symposia, and live webinars, we can help you obtain the following positive outcomes:

- Heightened laboratory performance resulting in more accurate results;
- More reliable test results resulting in greater convenience for patients;
- More reliable test results resulting in greater efficiencies for providers;
- Laboratorians who avoid the disruptions and increased costs which occur with citations;
- Increased savings and greater efficiencies, since accurate testing decreases redundant expenditures associated with flawed test results.

Our Continuous Quality Advisors will work with your laboratory to help you obtain these outcomes and demonstrate a commitment to quality. One way they do this is by helping your laboratory personnel become familiar with and utilize the practical, informative, and educational resources available on www.COLACentral.com and www.LabUniversity.org.

A recent statistical analysis of over 3000 COLA surveys conducted in 2011 showed that two of the top ten citations involved Proficiency Testing (PT) issues. PT issues could be due to problems in your test systems that can affect the quality of your laboratory results and consequently diminish the quality of your patient care.

Proficiency Testing issues could be due to problems in your test systems that can affect the quality of your laboratory results and consequently diminish the quality of your patient care.

Other common citations were found in the areas of Quality Control, personnel training and competency, and instrument calibration and maintenance. A problem in any one of these areas could lead to questions about the accuracy of laboratory test results. This lack of confidence leads to an increase in repeat testing, which utilizes additional reagents and supplies and wastes time that could be spent on other tasks. The *Continuous Quality Program* incorporates targeted educational resources to address specific issues such as these, and to facilitate improving and maintaining quality throughout your laboratory.

With the right policies and procedures in place, and properly trained and competent staff to carry them out, you can have an efficient laboratory that produces high quality, accurate test results leading to excellence in patient care. We here at COLA want to work with you through our *Continuous Quality Program* to ensure that this happens consistently in your laboratory. ■

Proficiency Testing: Provider Responsibilities

CLIA requirements also apply to PT providers.

Once approved by the Centers for Medicare and Medicaid Services (CMS), Proficiency Testing (PT) providers are obligated to perform specific responsibilities, which include:¹

- providing technical assistance to laboratories;
- providing quality PT challenge specimens that mimic patient specimens during testing;
- scientifically determining correct/expected results for each challenge;
- notifying labs of shipping schedules;
- evaluating and scoring testing results;
- providing event and summary reports; and
- resolving technical, administrative, and scientific problems.

When providers receive lab-submitted results, the results are compared to results submitted by other laboratories, checked to determine if correct/expected results are obtained, and graded so the laboratory can determine whether satisfactory or unsatisfactory performance was achieved. PT providers will also calculate statistical data (i.e., mean, standard deviation, standard deviation index, and coefficient of variance) and include them in the report packet for the laboratory to use in evaluating PT performance.

NOTE:

¹List is NOT all inclusive – for a complete listing of PT provider responsibilities, refer to Clinical Laboratory Improvement Amendments, subpart I, section 493.901; last accessed July 2012; http://www.cdc.gov/clia/regs/subpart_i.aspx#493.901

The group used for comparison depends on the specific analyte, the test methodology, and the number of labs testing the analyte.

- The *peer group* is the most ideal since it consists of all laboratories using the same method and instrument to test for the specific analyte. Since there must be a minimum number of labs for the group to be statistically valid, it is not always possible to be compared to a peer group.
- If that minimum number is not met, the PT provider will use a *method group* to compare results. The method group consists of labs using the same method (i.e., photometry, impedance, ELISA, etc.) but not necessarily the same instrument.
- If there are not enough laboratories using the same method to constitute a statistically valid group, the next group used for comparison is the *all methods group*, which, as the name implies, contains all methods of testing for the specific analyte.

PT providers are required to share information on laboratory performance with accrediting agencies and CMS, so laboratory PT performance can be monitored by these agencies. Accredited laboratories must tell their PT providers which accrediting organization (AO) will monitor the PT results and give permission for the PT provider to share their results with their AO. ■

Proficiency Testing: COLA Processes

COLA works hand-in-hand with Proficiency Testing providers to monitor laboratory PT performance and then works hand-in-hand with laboratory personnel to resolve PT problems and improve laboratory quality.

As required by the Centers for Medicare and Medicaid Services (CMS), COLA monitors laboratory Proficiency Testing (PT) performance of regulated analytes.¹ The monitoring process begins in the Fall when COLA contacts each Proficiency Testing (PT) provider to obtain a list of their offerings and their shipping calendar for the upcoming year. COLA uses this information to develop a schedule that defines the time periods when results from the three required events for the year should be available from each provider. The schedule is used throughout the year to monitor the data submitted by the PT providers.

When the PT data is obtained, it is analyzed to determine each laboratory's PT performance. This analysis results in two possible scenarios:

- No PT performance problems are identified.

The laboratory has obtained passing scores for each analyte, test, subspecialty, or specialty. No further action is required until the next PT event when the process is repeated.

- PT performance problems are identified.

The laboratory has received at least one failing score. Previous PT event scores are checked to determine a pattern of performance, which determines the next actions to be taken.

Unsatisfactory performance is failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a single event. (At a minimum, the last three PT events are reviewed to ensure that there is only the single failure and that no other failure pattern exists.) The laboratory is required to take and document corrective action to address the cause of the unsatisfactory performance. Properly addressing the root cause of the problem will prevent the problem from recurring, which will prevent unsatisfactory PT performance from becoming unsuccessful PT performance (failure to attain a satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two-out-of-three consecutive testing events). The PT documentation must be retained in the laboratory for the appropriate retention period² and must be available for review by the COLA surveyor.

COLA understands that laboratory personnel may need help when investigating the root cause of PT failures, developing corrective actions to address them, and/or developing plans to prevent them from occurring in the first place, so we offer several different resources as assistance. These resources include online courses & webinars, downloadable LabGuides and, our latest resource, the new *Continuous Quality Program*. (See p. 6 for more information on the *Continuous Quality Program*.) Several classes at our next Symposium for Clinical Laboratories also focus on Proficiency Testing. For additional information, see the special Symposium section beginning on p. 13.

Documentation of corrective action taken must be sent to COLA for review when a pattern of unsuccessful performance is seen. The original documentation must be retained in the laboratory for the appropriate retention period and must be available for review by the COLA surveyor. Copies of the documentation can be mailed, faxed, or emailed to COLA, or uploaded to the document repository on www.COLACentral.com so it can be reviewed to resolve the unsuccessful performance event.

The following patterns indicate unsuccessful performance:

- FF (last two events)
- FPF (last three events)

where "F" is a failing score and "P" is a passing score.

The laboratory must cease testing the analyte, test, subspecialty, or specialty when a pattern of repeated unsuccessful performance occurs:

- FFF (last three events)
- FFPF (last four events)
- FPFF (last four events)
- FPFPF (last five events)

>> CONTINUED ON PAGE 9

PROFICIENCY TESTING: COLA PROCESSES

To reinstate testing, the laboratory must pass two consecutive PT events.³ These events can be two routine events, two off-schedule events, or one routine and one off-schedule event. The PT provider will send results to COLA automatically, but this may not happen until several weeks after the laboratory receives a copy of the graded results. To allow the laboratory to reinstate testing as soon as possible, COLA encourages the laboratory to send us a copy of their results, after they have been reviewed and evaluated.

The goal of Proficiency Testing is help ensure accurate laboratory testing which, in turn, leads to quality patient care. COLA helps achieve this goal by monitoring PT performance and working with COLA laboratories to address PT failures. ■

NOTES:

¹Proficiency Testing (and/or other means used to verify test accuracy) for unregulated analytes is monitored through the PT review process during each laboratory's biennial survey.

²In most cases, documentation must be retained for at least two years. The required retention period is the longest period mandated by Federal, State, local, and/or institutional regulations.

³Unless the laboratory's first PT event is a failing score, the patterns listed in this article always follow two consecutive passing events.



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RESOURCE:

Centers for Medicare and Medicaid Services, CLIA Approved Proficiency Testing Programs - 2012; last accessed July 2012; <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ptlist.pdf>

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IgG
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IgE
Infectious Mononucleosis
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CHEMISTRY

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Amylase Aspartate Aminotransferase
(AST or SGOT)
Bilirubin, total
Blood Gases:
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Cholesterol, HDL
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RESOURCE:

Centers for Medicare and Medicaid Services, CLIA Brochure #8, last accessed July 2012
<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIABrochure8.pdf>

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Schedule at-a-Glance

Note: topics and schedule may change.

Lab Director Qualification Sessions that offer CME credit through the University of Wisconsin School of Medicine and Public Health are indicated with .

Wednesday, October 10, 2012

10:00a - 8:30p Participant Check-in

Thursday, October 11, 2012

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

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

8:00a – 10:00a AM General Session

8:00a – 8:30a Opening Remarks and Overview


8:30a – 9:00a *Current Concerns & Potential Improvements*
John T. Daly, MD

9:00a – 10:00a *CLIA Hot Topics: Personnel Competency and IQCP*
Judy Yost, MA, MT(ASCP)

10:00a – 10:30a Exhibits and Break in Exhibit Ballroom

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

A01 *Effective Training*
Barry Craig, MLT

A02 *Introduction to Proficiency Testing* 
Verlin Janzen, MD, FAAFP & John Daly, MD

A03 *Manuals & Records for Labs Without an LIS*
Elizabeth Staubs, MT(ASCP)SH

A04 *Getting the Most Out of Your Proficiency Testing*
Rick Gates, MLT(ASCP) & Leon Headley, MLS, CT(ASCP)

A05 *Phlebotomy CSI (Challenging Sticks Investigation)*
Lisa O. Ballance, BSMT(ASCP), CLC(AMT)

A06 *The Right Stuff: Getting the Right Equipment for Your Lab*
Tim Dumas, CLS

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*

B12 *Personnel & Procedures for CLIA Compliance* 
Ann Bachman, CLC(AMT), MT(ASCP)

B13 *Becoming a Quality Control Expert*
Terri Wolek, MT(ASCP)

B14 *Complying With the COLA Personnel Criteria*
Pam Gottsponer, MT(ASCP) & Irwin Rothenberg, MBA, MS, MT(ASCP)

B15 *Best Practices for Waived Testing*
Elizabeth Staubs, MT(ASCP)SH & Barry Craig, MLT

B16 *Prenanalytical Benchmarks and Process Improvement*
Lisa O. Ballance, BSMT(ASCP), CLC(AMT) & Dennis Ernst, MT(ASCP)

B17 *How Can CLSI Documents Benefit Your Lab?*
Luann Ochs, MS

3:30p – 4:00p Exhibits and Coffee Break in Exhibit Ballroom

4:00p – 5:30p Breakout Session C (select one)

C21 *The Impact on Laboratories by the Ever-changing Arena of Healthcare – How HITECH EMR/EHR Stimulus, ICD-10, LOINC, ACOs, Molecular Testing and Integrated Diagnostics May Affect Your Lab*
Curt Johnson

C22 *QA of PT: Proficiency Testing Problem Resolution* 
Verlin Janzen, MD, FAAFP & John T. Daly, MD

C23 *Calibration Verification & Performance Specifications*
Judy Dixon, MS, BSMT(ASCP)

C24 *Incident Management*
Irwin Rothenberg, MBA, MS, MT(ASCP) & Leigh Ann Smith, MLS(ASCP)

C25 *Venipunctures: Managing the Risk*
Dennis Ernst, MT(ASCP)

C26 *I'm a Lab Consultant, Now What? 10 Business Basics to Get You Started*
Barry Craig, MLT

6:00p – 8:00p Reception for participants, faculty, and exhibitors

Friday, October 12, 2012

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

8:00a – 9:30a AM General Session 

8:15a – 9:30a *HIV Diagnosis and Treatment: The Importance of Laboratory Medicine*
Donna Sweet, MD, MACP

9:30a – 10:30a Exhibits and Break in Exhibit Ballroom

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

D31 *Technology Workshop: Laboratory Information Systems*

D32 *Introduction to Quality Control* 
Verlin Janzen, MD, FAAFP & John T. Daly, MD

D33 *HIPAA, Ethics & Confidentiality*
Tim Dumas, CLS & Barry Craig, MLT

D34 *Complying with the COLA QC Criteria*
Pam Gottsponer, MT(ASCP) & Judy Dixon, MS, BSMT(ASCP)

D35 *OSHA Training: Bloodborne Pathogens*
Elizabeth Staubs, MT(ASCP)SH


D36 *Billing & Coding Basics*
Shannon O. DeConda, CPC, CPC-I, CPMA, CMSCS, CEMC, CRTT

D37 *Let's Talk About QC Practices!*
Terri Wolek, MT(ASCP)

12:00p – 1:00p Lunch

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

E41 *EP23: Laboratory Quality Control Based on Risk Management*
Luann Ochs, MS

E42 *Pre-analytic Top 10* 
Dennis Ernst, MT(ASCP)

E43 *Popular Tests- Fad, Fallacy or For Real?*
Verlin Janzen, MD, FAAFP

E44 *COLA Users Group: Accreditation Update*
Irwin Rothenberg, MBA, MS, MT(ASCP) and Rachael Kelly

E45 *LEAN Six Sigma for the Lab*
Joanne Broccolino, BS, MT(ASCP)

E46 *Are You Ready for a Billing/Coding Audit?*
Shannon DeConda, CPC, CPC-I, CPMA, CMSCS, CEMC, CRTT

2:30p – 3:30p Ice Cream Social and Exhibits in the Exhibit Ballroom

3:30p – 5:30p PM General Session

3:30p – 4:30p *Right Diagnosis, Right Lab Test, Right on Time* 
Michael Laposata, MD, PhD & James Meisel, MD, FACP

4:30p – 5:30p *Jumping the Generation Gap*
Tim Dumas, CLS

4:30p – 6:00p Concurrent LD session: *Preparing for Inspection* 
Ann Bachman, CLC(AMT), MT(ASCP)

5:30p or 6:00p Adjourn

Saturday, October 13, 2012

7:00a – 7:15a Breakfast in General Session Ballroom

7:00a – 1:30p AM & PM General Session

7:15a – 8:15a *Lab Director Responsibilities: Regulatory*
Verlin Janzen, MD, FAAFP

8:15a – 9:15a *COLA Users Group: Accreditation Update*
Irwin Rothenberg, MS, MBA, MT(ASCP)

9:30a – 10:45a *Perspectives on Being a Laboratory Director – Financial Considerations*
Tim Dumas, CLS

10:45a – 11:45a *Negotiating with Insurance Companies*
Tim Dumas, CLS

11:45a – 12:00p Lunch

12:00p – 1:00p *Lab Director Responsibilities: Practical Application*
Verlin Janzen, MD, FAAFP

1:00p – 1:30p *Can We Speak Frankly About Being a Lab Director in 2012?*
Verlin Janzen, MD, FAAFP

1:30p Conclusion and Adjourn – Travel Safely



COLA Symposium for Clinical Laboratories

Growing Strong for You!

COLA's Symposium for Clinical Laboratories has not only maintained its prominent standing in the laboratory medicine field, it has continued to improve and grow stronger – even in the recent times of economic uncertainty.

That is due to the exceptional, rewarding, educational experience you are sure to have when you attend the Symposium. It does not matter if you are a first-time or repeat attendee, or a novice or seasoned laboratory professional, as shown by comments from past attendees.

“Thank You! This is my first COLA experience. I feel you’ve provided many tools for me to utilize in the future at my laboratory.”

“I have attended many conferences hosted by ASCP, AMT, ASCLS, CLMA, and COLA in the past 18 years. COLA Symposia by far are the most organized, efficiently executed, and useful. Even the attendees seem to be more engaged and cared about learning the material.”

Our Symposium staff work diligently to schedule timely, relevant, informational sessions presented by enthusiastic, dynamic speakers. While the Lab Director Program¹ is the heart of the Symposium, laboratory personnel from phlebotomists to lab assistants to laboratory scientists to managers are sure to be intrigued by the compelling, interactive sessions presented by our knowledgeable, well-respected faculty, who are passionate about the field of laboratory medicine.

NOTE:

¹ The Lab Director Program has been approved by the Centers for Medicare and Medicaid Services (CMS) as a means for physicians to obtain the required 20 CME credits in laboratory medicine to qualify as directors of laboratories performing moderate complexity testing. The LD Program is offered at the Symposium for Clinical Laboratories and as online courses offered through COLA's LabUniversity at www.LabUniversity.org.

“I talked to several people about a hematology issue I was having and did not get a logical response. I ran this issue by her and she hit the root of the problem spot on! Thanks so much!”

– comment about Terese Wolek, MT(ASCP), faculty

“Very knowledgeable and able to communicate well with entry-level LDs” “Superb presenter”

– comments about Verlin Janzen, MD, faculty

Attending the COLA Symposium for Clinical Laboratories will also afford the opportunity to visit our outstanding Exhibit Hall, where leading manufacturers will be exhibiting the most up to date laboratory products! Our exhibitors understand your laboratory needs, relish your enthusiasm, and help you learn about the latest technologies so you can meet your needs and benefit your lab.

Our Symposium staff research every detail to make your stay with us an exceptional one. For this conference, they have selected the Hilton Baltimore, recipient of the 2012 TripAdvisor Certificate of Excellence Award, which is an honor awarded to establishments that achieve outstanding traveler reviews on TripAdvisor, the world's largest travel site.

Won't you grow stronger with us? Join us in Baltimore in October 2012 by registering for the COLA Symposium for Clinical Laboratories. (Click on the link for more Symposium information, including the full schedule and session descriptions.) ■

Baltimore

COLA's Symposium for Clinical Laboratories | October 10-13, 2012

Speakers of Note



To provide you with the best possible learning experience, COLA strives to provide outstanding, enthusiastic Symposium speakers who are well-known and well-respected in the field of laboratory medicine. We'd like to take a few moments to introduce a few of these dynamic individuals.

JAMES MEISEL, MD, FACP

Dr. Meisel has an extensive background in many different aspects of medicine and laboratory medicine.



- **Education:** Dr. Meisel is an Associate Professor of Medicine at Boston University School of Medicine in Boston, MA. He serves as a general internal medicine doctor practicing at Boston University Medical Center, where he works as both an academic hospitalist and a clerkship director for students on their internal medicine rotations. Before joining the BU faculty in 2008, he served as an inpatient clinician educator, resident clinic preceptor, and primary care physician at Massachusetts General Hospital in Boston.
- **Faculty Development:** Over the last decade, Dr. Meisel participated in faculty development programs at the Harvard Schools of Medicine, Business and Graduate Education, National Library of Medicine Medical Informatics, McMaster University How to Teach Evidence Based Clinical Practice, and the University of Massachusetts Medical School Teachers of Tomorrow program.
- **Government Relations:** While at Massachusetts General, Dr. Meisel served on the Clinical Laboratory Advisory Committee, and since 2008, has been an active member of the Clinical Laboratory Integration into Healthcare Collaborative (CLIHCC®) workgroup at the CDC.

Dr. Meisel received his bachelor's degree in Economics at Brandeis University prior to earning his doctorate at the State University of New York at Buffalo School of Biomedical Sciences. He completed his internship and residency in internal medicine at New England Deaconess Hospital and Harvard Medical School, both in Boston.

MICHAEL LAPOSATA, MD, PHD

Dr. Laposata also has noted expertise in many varied aspects of medicine and laboratory medicine.



- **Research:** His research program, with more than 150 peer reviewed publications, has focused on fatty acids and their metabolites. His research group is focused on the study of fatty acid alterations in cystic fibrosis.
- **Clinical:** Dr. Laposata's clinical expertise is in the field of blood coagulation, with a special emphasis in the diagnosis of hypercoagulable states.
- **Extraordinary Clinical Achievement:** Dr. Laposata implemented a system whereby the clinical laboratory data in coagulation and other areas of laboratory medicine are systematically interpreted, resulting in the generation of a patient-specific, narrative paragraph by a physician with expertise in the area. This service is essentially identical to the service provided by physicians in radiology and anatomic pathology, except that it incorporates clinical laboratory test results. In 2005, Dr. Laposata was recognized for this innovation by the CDC's Institute of Quality in Laboratory Medicine.
- **Education Awards:** Dr. Laposata is the recipient of 14 major teaching prizes from Harvard, the Massachusetts General Hospital, and the University of Pennsylvania School of Medicine.

Among others, these awards include:

- The 1989 Lindback award (a teaching prize with competition across the entire University of Pennsylvania system);
- The 1998 A. Clifford Barger mentorship award from Harvard Medical School;

[» CONTINUED ON PAGE 16](#)

SPEAKERS OF NOTE

- Election to the Harvard Academy of Scholars in 2002 and to the Vanderbilt University School of Medicine Academy for Excellence in Teaching in 2009; and
- What he considers his highest award – achieved by vote of the graduating class – for teaching in years 1 and 2 at Harvard Medical School in 1999, 2000, and 2005.

Dr. Laposata is the Edward and Nancy Fody Professor of Pathology and Medicine at Vanderbilt University School of Medicine. He is also the pathologist-in-chief at Vanderbilt University Hospital and the director of clinical laboratories.

He received his MD and PhD from Johns Hopkins University School of Medicine and completed a postdoctoral research fellowship and residency in Laboratory Medicine (Clinical Pathology) at Washington University School of Medicine in St. Louis. His first faculty position was at the University of Pennsylvania School of Medicine in Philadelphia in 1985, where he was an Assistant Professor and director of the hospital's coagulation laboratory. In 1989, he became Director of Clinical Laboratories at the Massachusetts General Hospital and was appointed to the faculty in pathology at Harvard Medical School.

On Friday afternoon, October 12, Drs. Laposata and Meisel join forces to present:

Right Diagnosis, Right Laboratory Tests: Exploring the Challenges and Role of the Medical Technologist in 2012

This presentation will explain the challenges of appropriate test selection and correct results interpretation that all practicing clinicians face. The presenters will use an innovative “dueling doctors” format, featuring a laboratory director (Dr. Laposata) and an internist (Dr. Meisel), discussing the sometimes mutually exclusive challenges in achieving accurate and rapid diagnosis.

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

- Describe the sometimes mutually exclusive challenges faced by the laboratory director and the general internist in test selection and results interpretation;
- Explain how highly trained testing personnel may provide accurate test identification guidance to the clinician;
- Describe the potential benefits and challenges that each of the case studies presents in your clinical setting.

“The dueling docs were articulate, engaging, funny and knowledgeable. The audience was thrilled to have their role as CLSs/MLSs in medicine so well understood and appreciated. Dr. Meisel brought up problems he was having diagnosing patients and which lab test would be best in certain situations and Dr. Laposata explained the complexity of laboratory testing. Both men looked to the MLS and the DCLS (in the future) to answer their questions about testing.”

Comments about Michael Laposata, MD, PhD
and James L. Meisel, MD, FACP

Original posting: *Advance for Medical Laboratory Professionals*,
08/22/2011 [http://laboratorian.advanceweb.com/Multimedia/
Photo-Gallery/Conference-Wrap-AACCASCLS-2011.aspx](http://laboratorian.advanceweb.com/Multimedia/Photo-Gallery/Conference-Wrap-AACCASCLS-2011.aspx)

DONNA SWEET, MD, MACP

Dr. Sweet is best known for her medical treatment and research on AIDS. She has been recognized locally, nationally, and internationally for her work, which includes:

- Extensive work with the Health Resource Service Administration on Ryan White^a issues;
- Past national Co-Chair of the CDC HRSA AIDS Advisory Council (CHAC);
- Certified HIV specialist by the American Academy of HIV Medicine, of which she is the current Board Chair;
- Principal Investigator and Director of the Kansas AIDS Education and Training Center.

Additional Ryan White accomplishments of note include:

- She has administered Ryan White Part B funds at her clinic since these funds first became available for patients;
- Principal Investigator and Medical Director of the Ryan White Part C Early Intervention Program since 1993;
- Granted funds to begin a Ryan White Part D Family Services program to care for women, infants, children and youth who are infected and affected by HIV in 2009.



>> CONTINUED ON PAGE 17

SPEAKERS OF NOTE

In March 2000, the AMA identified Dr. Sweet as one of four “Heroes in Medicine” by awarding her with one of the first *Pride in the Profession* awards, for her leadership in confronting AIDS issues and her care for patients with the disease.

She lectures in her home state of Kansas as well as nationally and internationally to educate other health care providers about HIV and AIDS. She works closely with the Eurasian Medical Education Program of the American College of Physicians and has been educating physicians about HIV/AIDS internationally for more than 11 years.

In addition to her work with HIV/AIDS, Dr. Sweet is actively involved with the American College of Physicians and COLA and the American Medical Association. She is

- Past Chair of the American College of Physicians Foundation Board;
- Chair Emeritus of the American College of Physicians Board of Regents, where she served as Chair for the 2005-2006 term. At the conclusion of her term, she was named a Master of the ACP (MACP) for her service to medicine and to the American College of Physicians.
- A past ACP representative to the COLA Board of Directors;
- Member and past Chair of the COLA Board of Directors;
- ACP delegate to the AMA; and
- A member of the Council on Medical Service of the AMA.

Dr. Sweet began her medical career when she graduated from the University of Kansas School of Medicine and completed her residency training at the University of Kansas-Wichita and affiliated hospitals. She is board-certified in internal medicine and is a Professor of Internal Medicine at the University of Kansas School of Medicine-Wichita. She is also the Director of Internal Medicine Education at Via Christi Regional Medical Center-St. Francis in Wichita.

NOTE:

¹ In response to the AIDS crisis, the Kansas State Congress enacted the Ryan White CARE (Comprehensive AIDS Resources Emergency) Act in August 1990 to improve the availability of care for low-income, uninsured, and underinsured individuals and families affected by HIV and AIDS. Click here for more information: http://www.kdheks.gov/hiv/ryan_white_care.html

On Friday morning, October 12, Dr. Sweet will be presenting:

HIV Care: What’s New in Laboratory Medicine

HIV testing and care is rapidly changing. During this session, Dr. Sweet will provide the most recent updates on HIV infection and the importance of early HIV testing. She will discuss acute HIV infection and the new developments in HIV immunoassays as well as the recent FDA approval of in-home HIV testing.

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

- Summarize the rationale behind the importance for early HIV testing;
- Utilize available methods to identify acute HIV infection;
- Outline and evaluate the upcoming new testing algorithm for HIV infection;
- Examine the importance of laboratory medicine in the care of HIV patients. ■

“I found this to be a very valuable presentation, serving to enlighten us on the current HIV situation (in this country and the world). Dr. Sweet presented personal and down to earth examples of community impact as well as an excellent description of the types and workflow of lab testing currently in use. She gave us an easy to grasp explanation of methods and appropriate use for populations in testing. This was the best general session in my opinion.”

“This was a great and interesting presentation. Dr. Sweet is an obvious expert who understands how to relay the most relevant information with respect to the current culture, technology, and healthcare.”

Comments about Donna Sweet, MD, MACP

Join us in Baltimore to learn more about Proficiency Testing.

Proficiency Testing Sessions

These sessions address various aspects of Proficiency Testing.

A02 – Intro to Proficiency Testing

Presented by: Verlin Janzen, MD, FAAFP & John T. Daly, MD

 (LD Track)

In this session, Dr. Janzen and Dr. Daly will focus on the basics of Proficiency Testing (PT). Physicians will learn how to select a PT provider, manage the PT process, and perform the laboratory director responsibilities relating to PT.

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

A04 – Getting the Most Out of Your Proficiency Testing

Presented by: Rick Gates, MLT(ASCP) & Leon Headley, MLS, CT(ASCP)

Presented by veteran COLA employees deeply knowledgeable in the Proficiency Testing (PT) process, this session provides insight into how to review and evaluate your PT results so that you may identify problems and resolve PT failures when they occur. You will learn how to interpret your scores, recognize problems, and implement effective corrective actions to resolve PT problems.

Using PT to demonstrate quality and help to ensure accurate patient testing will be also discussed. Additionally, the session will relate PT performance review to COLA criteria and provide helpful suggestions for laboratories to achieve and maintain compliance with COLA and CLIA.

C22 – QA of PT: Proficiency Testing Problem Resolution

Presented by: Verlin Janzen, MD, FAAFP & John T. Daly, MD

 (LD Track)

In this session, Dr. Janzen and Dr. Daly will show the importance of evaluating your PT performance and following up on any problems or issues. The concept of quality assessment will be introduced, and ways to monitor your PT performance and identify and resolve problems will be discussed.

Case study examples will be used to illustrate

- how to identify problems;
- how to determine the root cause;
- how to formulate a solution; and
- how to follow up to see if the solution worked.

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

Related Sessions

Even though these sessions do not focus solely on PT specifically, they provide important related information that will prove useful in your laboratory.

General Session – CLIA Hot Topics: Personnel Competency and IQCP

Presented by: Judy Yost, MA, MT(ASCP)

This session will provide an update on

- Current CMS activities regarding annual personnel competency assessment, with guidance and tips to improve its efficiency and effectiveness in your laboratory while remaining in compliance with CLIA.
- The status of the recently published proposed Patient Access rule and the timing of plans to publish a final rule.
- The status of the planned changes to the PT regulations for laboratories and PT programs (a joint CDC and CMS effort)
- CMS's new and exciting proposal for the new QC policy "IQCP," the "Right QC," and its guidance document (based on key CLSI EP-23 consensus document concepts). It will include CMS's plans for its implementation, transition from EQC, educational period, and the potential impact on nonwaived CMS certified and accredited laboratories.

Baltimore

COLA's Symposium for Clinical Laboratories | October 10-13, 2012

General Session – Current Concerns & Potential Improvements

Presented by: John T. Daly, MD

This session will explore two current areas of concern in laboratory medicine: waived testing and utilization of the technical consultant.

- Waived testing does not mean waived oversight! Waived testing is growing, but many waived labs have quality problems. There are many important considerations for good laboratory practices in pre-analytic, analytic, and post-analytic activities. The most common issues will be discussed during this session.
- The technical consultant (TC) position is one that is undervalued – until you hire a good one. Then you'll say, "What did I ever do without this person?!" During this session, Dr. Daly will compare the Lab Director responsibilities with those of the TC, highlighting the areas where the TC can be invaluable in establishing good laboratory practices. He will also show when the physician lab director should NOT also hold the position of TC.

B12 – Personnel & Procedures for CLIA Compliance

Presented by: 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 required CLIA-defined 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.



E44 – COLA Users Group: Accreditation Update

Presented by: Irwin Rothenberg, MBA, MS, MT(ASCP) & Rachael Kelly

All CLIA accreditation programs begin with the core requirement to be in compliance with the Federal regulations. COLA's approach emphasizes ready access to educational resources provided directly to laboratory staff and management, as the primary tool to achieve both regulatory compliance and a high quality laboratory operation responsive to its customer base.

At this Users Group session, participants will have the opportunity to review the COLA Accreditation process, consider COLA's utilization of customer feedback as drivers to technological changes, and be introduced to COLA's new *Continuous Quality Program (CQP)*.

Lab Director Session – Preparing for Inspection

Presented by: Ann Bachman, CLC(AMT), MT(ASCP)

To help alleviate some of the stress associated with laboratory surveys, 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.

General Session – Lab Director Responsibilities: Regulatory

Presented by: 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.

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