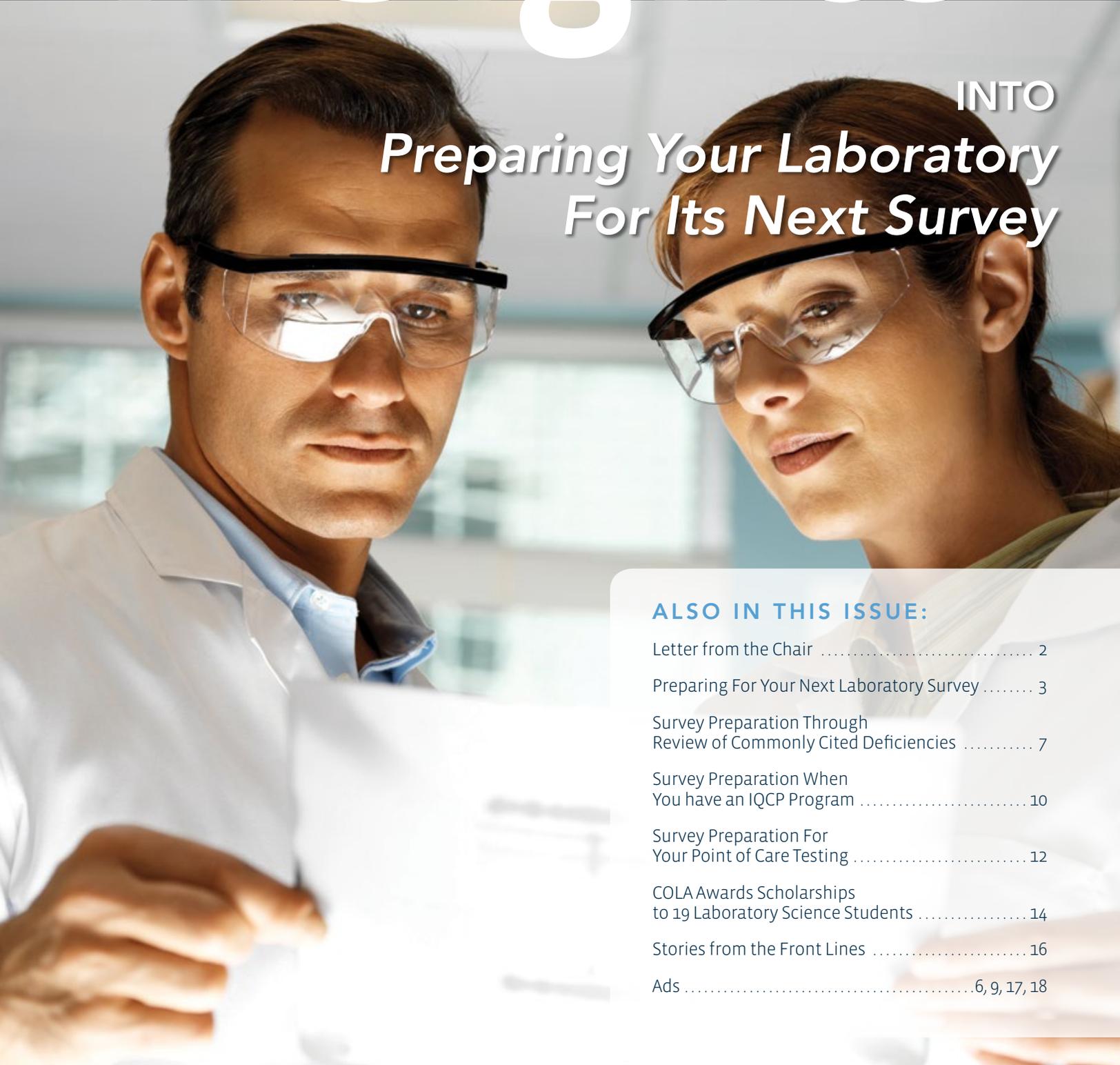


# inSights



INTO  
*Preparing Your Laboratory  
For Its Next Survey*

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## FROM THE CHAIR



Bradley J. Fedderly, MD, FAAFP,  
Chair, COLA Board of Directors

This issue of Insights discusses how to prepare for your next laboratory survey. When the time nears for your next survey, are you confident that all will go well? Do you have processes, policies and procedures in place that enable you and your staff to approach this event with confidence? Or do you have to scramble at the last minute to get everything in place, experiencing anxiety, and putting in extra hours to ensure that all the i's are dotted, t's crossed, documents signed, and records complete?

This need not be the case. If, instead of being viewed as a "final exam" for continued accreditation, surveys could be viewed as positive and valuable tools for improving the quality of patient care provided, then preparation can be viewed, as both a great learning opportunity, as well as validation of the laboratory's efforts toward compliance and quality work.

Our introductory article begins with a short history and explanation of the survey requirement, and the need to validate compliance with CLIA quality standards. This is followed by an overview of basic policies and procedures that must be in place, and actively followed, to meet compliance standards. These form the basis for a quality laboratory operation. This is followed by listing what you need to do the day before the survey so that everything is in place when the surveyor arrives on site. This facilitates a more efficient survey process, and reduces time spent attempting to find items for review at the last minute. The value of performing a Self-Assessment as part of the survey preparation process is discussed as well, and doing so is encouraged. Finally, post-survey, the benefits of sharing the survey results with your staff are enumerated.

There are three subsequent discussions related to the survey process designed to assist you in customizing how you prepare. The first is a review of the deficiencies most frequently cited by CLIA surveyors during 2015, this is based on the results of over 17,000 laboratories surveyed; over 11,000 of which were POLs. Many of these were related to Personnel issues, as well as the Analytical and Post-analytical phases of testing.

The second article discusses how to prepare for your survey if you have implemented an Individualized Quality Control Plan (IQCP) as your equivalent quality control alternative to CLIA QC requirements for some or all of your non-waived testing. Special emphasis is on the need for comprehensive Quality Assessment to ensure the program continues to provide quality safeguards.

The last entry is focused on how to prepare for your survey when Point of Care (POC) testing is part of your laboratory operation. There are unique considerations and concerns when performing remote testing that must be properly addressed to meet quality patient care standards, including the monitoring, training and competency assessment of off-site, non-laboratory personnel, testing locations and instrumentation not under the immediate supervision of the laboratory staff, and ensuring that all proper policies and procedures are carried out. These present unique challenges for your survey preparation.

*Bradley J. Fedderly, MD*

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# Preparing For Your Next Laboratory Survey

## Introduction

The Clinical Laboratory Improvement Amendments, passed by Congress in 1988, (known as CLIA '88) mandated that all test sites performing non-waived testing must undergo a survey every two years. These surveys are designed to evaluate compliance with the quality standards set for all testing performed, and to ensure the accuracy, reliability and timeliness of patient test results. All laboratories issued a CLIA certificate of Compliance or Certificate of Accreditation must comply with the applicable survey requirements. Laboratories will either be surveyed by CMS/CLIA (generally by state CLIA surveyors) or by an accrediting organization, such as COLA, which has been granted deeming authority by CMS. All surveys focus on essentially the same areas, regardless of the regulatory agency.

Laboratory surveys are biennial events, usually scheduled within 18-24 months after the previous survey. Initial surveys for new laboratories are usually scheduled for 9-11 months from the effective date of the initial CLIA certificate.

Whether or not the survey dates are announced in advance, it would be prudent for laboratories to be organized for a survey during this time frame. It is important to be aware of how notification is provided, whether on-line, email, postal mail, telephone or fax, and to make sure that the notifications go to the proper individuals.<sup>1</sup> Additional surveys including complaint investigations, interim and follow up mandates are generally unannounced.

Most laboratory managers and supervisors feel the stress of preparing for their impending survey, even if they have worked to maintain a culture of continuous quality improvement. Stress-reduction can be achieved by ensuring that all steps have been taken to meet compliance requirements, to have advanced survey preparation, and to involve the staff in this process, as discussed below.

## Basic Compliance Requirements<sup>2</sup>

By following these general guidelines, your laboratory will be well prepared for a survey, whether announced or unannounced:

- Be familiar with the regulatory requirements for your laboratory as determined by your accreditation agency, such as COLA, as well as those of your state. These are based on the type of CLIA certificate you have; the complexity of your test menu; the specialties

represented; the test systems utilized, and whether outside reference work is performed by your laboratory.

- Ensure that all positions in the laboratory are filled by qualified personnel; have complete documentation of education, experience, training, and of regular competency assessments that follow the new CLIA guidelines; all job descriptions must be current.
- Establish and maintain written policy, process, and procedure manuals. These must include procedures for all phases of testing performed by the laboratory; and define quality control by the frequency, type and number used. Reference ranges, normal values and panic values must be defined. All manuals must include the Laboratory Director's review and approval for all procedures, including newly added and discontinued.
- Be enrolled and participate in a proficiency testing program appropriate for your test menu and specialties.
- Instrument calibration, maintenance, and quality control are performed as required.
- Instrument performance specifications have been verified (for FDA approved methods) or established (for modified FDA approved procedures or Lab Developed Tests) by laboratory personnel.
- Verify the security of your Laboratory Information System (LIS); as well as the accuracy of data entered, transferred and stored.
- Report forms must contain all elements required by regulations.
- Incorporate quality assessments into the daily routine of the laboratory. This includes assessing the quality through all phases of the testing process; taking corrective actions when needed; and following up to ensure that these have been effective.
- If utilizing IQCP (Individualized Quality Control Plan) as an alternative to CLIA quality control requirements for any testing, make sure that your QC plans have been periodically assessed and validated, and any updates made are reviewed and approved.
- Ensure that all required documentation is maintained in accordance with CLIA requirements and any state-specific requirements.

>> CONTINUED ON PAGE 4

### Preparing for Your Survey Day<sup>3</sup>

The surveyor will need to see documentation of all laboratory functions described below, including patient charts when requested, for the past two-years, or from the date of the last survey. These records should be collected *prior to the survey date* and readily available. The list below is not all-inclusive, but represents the basic items required. Depending on individual circumstances, the surveyor may request additional records.

1. A copy of the current CLIA Certificate for the surveyor to review and retain.
2. Personnel files for all laboratory staff who are filling CLIA mandated positions (including Laboratory Director, Technical Supervisor/Consultant, and Clinical Consultant) as well as for all laboratory employees performing non-waived testing. Files must include proof of education according to CLIA '88 requirements: Acceptable Documentation:
  - High School diploma,
  - GED (General Education Diploma),
  - Transcripts (must have date of graduation),
  - College degrees (AS, BS, MS, and PhD),
  - Foreign Equivalency evaluations for non US schools
  - MD/DO Licenses.
  - Laboratory professionals must have either copies or transcripts of their highest degrees (AS, BS, MS, PhD) available. **Note:** ASCP and other professional society membership cards or certificates cannot be accepted as proof of qualification in place of academic diplomas.
  - Nurses: A bachelor's degree in Nursing meets the education requirement for a bachelor's degree in a biological science for high complexity testing personnel. An associate's degree in Nursing meets the requirement for an associate's degree in a biological science for moderate complexity testing personnel.
  - Medical Assistants must have at least their high school diplomas (or higher degrees, if earned) available to perform moderate complexity testing.
  - Those employees with only foreign educational documents must have them evaluated for equivalency to a US high school diploma, or college degree by an officially recognized education evaluation organization.
- In those states that license laboratory personnel, a copy of a current state license can be accepted. It is advisable to have copies of the corresponding educational degree as well.
3. Competency assessments including all CLIA required methods of evaluation. New employees must be evaluated at six months and also one year after their hire; other employees must be evaluated yearly.
4. Training documents for all new employees or some proof of their previous experience, such as resumes and prior instrument training.
5. Current job descriptions for all employees.
6. Policy & Procedure Manual(s) including all Instrument Operator's Manuals.
7. Current package inserts for all kit tests and reagents (including all waived methods).
8. Package inserts for all controls and calibration materials used during the survey period.
9. Proficiency testing (PT) records including instrument tapes, test report forms, attestation statements, graded results, and corrective actions taken for all unsatisfactory scores.
10. Instrument/equipment/pipette calibration, maintenance, and function check records for current and discontinued instruments used during the survey period.
11. Temperature and humidity records.
12. All quality control (QC) records, graphical representations, charts, and any other documentary logs involved.
13. IQCP studies, if EQC has been utilized as an alternative Quality Control option prior to 2016; or if new tests have been added for alternative quality control options.
14. Test requisitions and report forms used for all laboratory testing. The surveyor may ask to review several patient charts.
15. Incident Management Plan and any reports.
16. Quality Assessment (QA) Plan and documentation of implementation and follow up - QA reviews.

### **As part of the survey process, laboratories may be required to:<sup>4</sup>**

- Test samples, including proficiency testing, or perform procedures.
- Permit interviews of all personnel concerning the laboratory's compliance.
- Permit personnel to be observed performing all phases of the testing process.
- Permit access to all areas encompassed under certification, including, but not limited to:
  - a) Specimen procurement and processing areas
  - b) Storage facilities for specimen reagents, supplies, records, and reports
  - c) Testing and reporting areas
- Permit observation of transfusion services, where applicable.

### **Self-Assessments<sup>5</sup>**

Should the laboratory perform a pre-survey self-assessment?

This can be a very useful tool to help the laboratory prepare for the survey process, allowing the lab to identify areas of weakness in processes, identify ways to improve overall operational efficiencies, and then make the improvements needed.

Laboratories that complete the Self-Assessment (offered by many Accrediting organizations, including COLA) and put a lot of effort into the process have done better, as a whole, on their on-site surveys. These laboratories generally have greater awareness of the requirements and will have had the opportunity to come into compliance before the on-site survey takes place.

This educational activity is designed to guide the laboratory management and staff toward the goal of improved laboratory performance. It is recommended that the laboratory repeat the Self-Assessment in each two-year cycle to assure continual compliance, quality performance, and readiness for subsequent on-site surveys.

### **Share the Results with Your Staff**

Once the survey has been completed and an exit conference or interview has occurred with the surveyor all findings should be shared with the laboratory personnel. Sharing the

information in a timely fashion will allow your laboratory the opportunity to begin addressing deficiencies immediately, and by incorporating laboratory personnel in this process, this will set the course for preparing for the next survey.

### **Conclusion**

Preparing for a laboratory inspection brings anxiety and stress above and beyond those of a normal work day, but being prepared and doing well on your laboratory inspection requires a team effort. By including staff in the preparation for upcoming inspections, several goals can be realized:

1. Educating the staff to all the regulatory requirements of your surveying agency.
2. Shared responsibility for the outcome of the survey; shared credit for a successful outcome, and shared problem solving when deficiencies are found.
3. Shared knowledge leads to strengthened understanding and sense of ownership of the laboratory's culture of quality.

The survey process, above all else, should be considered as an opportunity for continued process improvement through leadership and team effort.

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#### RESOURCES:

1. Rothenberg, I. Preparing For Your Next Inspection June 2016. AAFP PT POL Insight.
2. Preparing For an Initial laboratory Survey. Oregon Health Authority. <http://public.health.oregon.gov/LaboratoryServices/ClinicalLaboratoryRegulation/Documents/init.pdf>
3. COLA Survey Scheduling Letter – Documents Necessary for the COLA Survey.
4. CLIA Inspections: Information for your Lab on CLIA Inspections. <http://www.aafp.org/practice-management/regulatory/clia/inspections.html>
5. COLA Laboratory Accreditation Manual. May 2016. COLA Accreditation: How It Works, What To Do. Step 2. Completing the Self-Assessment. P. 21

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# Survey Preparation Through Review of Commonly Cited Deficiencies

## Introduction

Preparation for an upcoming survey almost always starts with a review of the results of the previous survey. Labs should conduct a review of all the deficiencies that were cited, all corrections made, and any additional observations noted during the post survey summation conference. These previous citations are always on the radar for review during upcoming surveys. It is important to ensure that all corrections made have been maintained, or updated, as needed. It is also a good idea to keep abreast of recent regulatory or technological changes affecting laboratories, and whether these might create new issues for compliance.

Besides ensuring that all previous deficiencies cited are now in compliance, an awareness of the most frequently cited laboratory deficiencies by federal, state and private regulatory agencies over the past year can also provide additional guidance for quality checking your laboratory operation. Remember, the surveyor is not just looking for regulatory non-compliance, but is actually assessing the quality of your results, practices, and problem resolution processes.

Each agency has their own list of deficiencies most often cited during the past year, and all have close, but non-identical alignment as to the specific items and their frequency. This list is based on the results of CLIA surveys of 17,372 laboratories, of which 11,156 were physician office laboratories (POLs)<sup>1</sup>.

The most frequently cited deficiencies are concentrated in a few key areas of the laboratory organization and operation: namely the analytic and post-analytic phases of testing, as well as personnel issues. Interestingly, all of these are inter-related through defined Laboratory Director Responsibilities. The importance of laboratory directors fulfilling their responsibilities cannot be overstated; when these are not properly carried out, when oversight is not properly provided, deficiencies may occur in all areas of the laboratory operation: Personnel, Proficiency Testing, Calibration and Verification, Quality Control, Quality Assessments, Maintenance, and General Organization, (issues with documentation and the correct execution of Policies and Procedures). Following are the most frequently cited deficiencies during 2015:

## Analytic Systems:

“The laboratory must define criteria for those conditions that are essential for the proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with manufacturer’s instructions, if provided. These conditions must be documented and monitored.”

- “The procedure manual must include the requirements for specimen acceptability, microscopic examination, step-by-step performance of the procedure, preparation of materials for testing, etc.”
- “The Laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in non-waived analytical systems.”
- “The performance of the test systems must follow manufacturer’s instructions, and in a manner that provides test results within the laboratory’s stated performance specifications for each test system.”
- “The laboratory must perform and document calibration verification procedures following the manufacturer’s calibration verification instructions using the criteria verified or established by the laboratory at least once every six months, or whenever certain instances occur.”
- “Reagents, solutions, culture media, control materials calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or of substandard quality.”

## Personnel:

- “The laboratory must have a director who meets the qualification requirements for the complexity level of the laboratory, and provide overall management and direction in accordance with regulations.”

These include<sup>2</sup>:

## General Responsibilities

- ✓ *Verify that all of the following responsibilities are properly performed if delegated*
- ✓ *Must be accessible to the laboratory to provide on-site, telephone, or electronic consultation as needed*

**>> CONTINUED ON PAGE 8**

## **SURVEY PREPARATION THROUGH REVIEW OF COMMONLY CITED DEFICIENCIES**

- ✓ *May direct no more than five labs*
- ✓ *Ensure that the physical plant and environmental conditions are appropriate for the testing performed and provide a safe environment from physical, chemical, and biological hazards*

### **Procedural Responsibilities**

- ✓ *Ensure testing systems provide quality laboratory services for pre-analytic, analytic, and post-analytic phases of testing*
- ✓ *Ensure test methods selected have the capability of providing quality results*
- ✓ *Ensure verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method*
- ✓ *Ensure that reports of test results include pertinent information required for interpretation*
- ✓ *Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions*
- ✓ *Ensure that an approved procedure manual is available to all personnel*
- ✓ *Ensure that laboratory personnel are performing the test methods as required for accurate and reliable results*

### **Personnel Responsibilities**

*Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results*

- ✓ *Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results*
- ✓ *Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to verify that they maintain competency to:
 
  - *Process specimens*
  - *Perform test procedures*
  - *Report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills**
- ✓ *Have a written list of responsibilities of each individual in the laboratory that specifies the level of activity each is authorized to perform; whether supervision is required for specimen processing, test performance, or results reporting;*

*and whether consultant or director review is required prior to reporting patient test results*

- ✓ *Ensure that a general supervisor provides on-site supervision of high complexity test performance by certain testing personnel*

### **Proficiency Testing (PT) Responsibilities**

- ✓ *Ensure that the laboratory is enrolled in an approved proficiency testing (PT) program*
- ✓ *Ensure that PT samples are tested in the same manner as patient samples*
- ✓ *Ensure that PT results are returned on time to the PT program*
- ✓ *Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT results are found to be unsatisfactory*
- ✓ *Ensure that PT samples are performed according to COLA and CLIA regulations prohibiting referral of specimens and communication of results*

### **Quality Control Responsibilities**

- ✓ *Ensure that quality control and quality assessment programs are established and maintained to identify failures in quality as they occur*
- ✓ *Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system*
- ✓ *Ensure that remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. Patient test results are reported only when the system is functioning properly*

### **Competency Assessment**

- *"The laboratory must establish and follow written policies and procedures to assess employee competency."*

These include<sup>3</sup> :

- ✓ *Direct observation of routine patient test performance;*
- ✓ *Monitoring the recording and reporting of test results;*
- ✓ *Review of intermediate test results or worksheets;*
- ✓ *Direct observation of instrument maintenance;*
- ✓ *Blind sample testing (such as Proficiency Testing); and*
- ✓ *Assessment of problem solving skills.*

*Evaluations should occur semi-annually for the first year and annually thereafter for all testing personnel, supervisors and technical consultants.*

## Post-Analytic Systems

“The test report must indicate the following: for positive patient identification, either the patient’s name and identification number, or a unique patient identifier and a patient identification number, the name and address of the laboratory location where the test was performed, and other requirements as specified.”

## Conclusion

It is important to remember as you prepare for your survey, that during the survey process, “emphasis is placed on the laboratory’s quality systems as well as the structures and processes throughout the entire testing process that contribute to quality test results. The surveyor selects a cross-section of information from all aspects of the laboratory’s operation for review to assess the laboratory’s ability to produce quality results. The surveyor reviews the cross-section of information to verify that *“the laboratory has established and implemented appropriate ongoing mechanisms for monitoring its practices and identifying and resolving problems effectively.”*”<sup>4</sup>

## RESOURCES:

1. CLIA UPDATE – January 2016. Division of Laboratory Services. Centers for Medicare and Medicaid Services Top 10 DEFICIENCIES in the Nation – CMS Surveys. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAtopten.pdf>
2. COLA Laboratory Accreditation Manual. May 2016.
3. CLIA Brochure #10 - What Do I Need to Do to Assess Personnel Competency? [http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA\\_CompBrochure\\_508.pdf](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf)
4. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Principles-of-Documentation-for-the-Statement-of-Deficiencies-CMS-2567.pdf>

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# Survey Preparation When You have an IQCP Program

## Introduction

The Individualized Quality Control Plan (IQCP) became the official alternative to CLIA quality control requirements for non-waived testing on January 1, 2016, replacing the Equivalent Quality Control (EQC) option. IQCP is based on risk management through customized quality control plans developed for each analyte chosen. These individualized quality control plans are the result of risk assessments performed on all factors related to the testing process, through all phases of the testing process.

Each IQCP includes The Risk Assessment (which includes Risk Identification and Risk Evaluation); the Quality Control Plan, and periodic Quality Assessments.<sup>1</sup>

**Risk Assessment** is the process of identifying and evaluating the potential failures and errors that could occur during the pre-analytical, analytical, and post-analytical phases of testing. This includes determining the frequency and seriousness of these potential failures and errors, and whether present processes are in place to detect and mitigate these. This information, used to identify and evaluate potential risks (i.e. errors with the potential to cause harm) is derived from studying the following components of the testing process: Specimens, Test System, Reagents, Laboratory Environment, and Testing Personnel.

**The Quality Control Plan** is based upon the analysis and review of the laboratory's data, and any additional actions needed to mitigate new risk potentials found. QC plans must include the number, type, and frequency of QC, as well as criteria for acceptance. Its effectiveness must be monitored, investigating errors and adjusting the plan when/if necessary. The CLIA regulatory requirements for quality control that are being replaced by the IQCP should be included with the documentation as well.

**Periodic Quality Assessments of the IQCPs** must be performed at regular intervals; and when quality failures occur. The Risk Assessment and QC Plan should be re-evaluated when necessary.

The Laboratory Director is responsible for deciding whether the laboratory will utilize IQCP for some or all of its tests and for ensuring that the quality control plan (QCP) developed effectively meets the IQCP requirements. The laboratory director may assign, in writing, specific duties for developing the IQCP to qualified laboratory personnel but is still responsible overall for the entire testing process.

The Laboratory Director must review and approve the IQCP before it is put into use.

## Survey Preparation

The process for developing Individualized Quality Control Plans requires extensive use of resource material, and analyses of the resultant data to identify risk potential, and then to evaluate mitigation strategies. Subsequent quality assessments also require studies to ascertain the effectiveness of the quality control plans. All this work must be documented, and records kept for as long as the QC plans developed are in use.

***All resources used, analyses performed and documentation of studies performed should be available for surveyor review.***

An example of records that may be utilized when performing the Risk Assessment<sup>3</sup>

- Records for all types of QC in use for the test, including external control results and graphs, electronic, procedural/built-in
- Package inserts and/or operators manuals for the test system/device
- Package inserts for all reagents, including controls and calibrators
- Previous EQC qualifying study for the test, if performed
- Records of calibration, maintenance, function checks and service records for the instrument
- Relevant literature about the test
- Proficiency testing records
- Applicable regulatory or accreditation criteria requirements
- Environmental monitoring records
- Personnel qualification, training and competency records
- Information about how the test is used in your lab (screening, diagnosis, treatment decisions)
- Problem logs, complaints or incidents
- Any comparisons of results with another method
- Policies for repeat testing & result review before reporting
- Relevant Quality Assessment reviews and activities

**Once risks for errors are identified, there are analytic tools for assessing severity, frequency, and impact on the testing process, including**

- Process Map
- Fishbone Diagrams
- Risk Assessment Matrix Tables.

These tools should also be available for surveyor review.

## **The Quality Control Plan<sup>4</sup>**

Your QC Plan must include the number, type and frequency of testing, and criteria for acceptable result(s) of the quality

control(s). Your data must support the rationale for the number, type and frequency of testing. The QC Plan may also describe the use of electronic controls, procedural controls, training and competency assessment and all other QC activities.

- The QC plan that is developed as part of IQCP must:
- Include the name of your lab, the test name and the effective date of the plan
- Include the Regulatory requirement being replaced
- List the types of control materials that are available and will be utilized (electronic, internal (procedural), external), the number of controls to run, and when to run them
- Describe the proper handling, storage and use of external (liquid) control materials
- Describe how control results will be reviewed to determine if they are acceptable
- Describe what to do if they are not acceptable
- Include procedures for documenting Quality Control results and corrective actions
- Describe any other activities that will be used to control risk and ensure accurate and reliable results

Many of these items are familiar as components of a “traditional” written Quality Control program that documents Quality Control policies and procedures, and these items remain necessary and important. For an IQCP, you will also be incorporating the final item in the list, the additional activities derived from the outcome of your Risk Assessment that will create the most effective QC plan for the test when performed in your lab. In addition to your determination of the appropriate number, type and frequency for running controls, this includes all of the various activities that you already have, or will now put in place to reduce the risk of errors and ensure accurate and reliable results for the test.

### The Quality Assessment Plan<sup>5</sup>

In order to review the QC Plan for effectiveness, the following resources may be utilized:

- QC data sheets review;
- Delta check logs
- PT records (scores, testing failures, trends)
- Complaint reports
- Patient results review
- Specimen recollection logs
- Specimen rejection or quantity not sufficient logs
- Panic value call logs
- Turnaround time reports
- Temperature logs
- Records of preventive measures, corrective actions, & follow-up
- Personnel competency records

- Maintenance logs
- Training logs
- FDA alerts

These resources enable your Quality Assessment to:

- ✓ Make sure that your QCP is working as expected
- ✓ Monitor errors and QC failures
- ✓ Identify errors and failures so you can take the appropriate corrective action
- ✓ Investigate the cause of the error and reassess your risk assessment, if indicated
- ✓ Evaluate whether any changes need to be made in the QCP

These activities should be documented and available to your surveyor. Any corrective actions taken should likewise be fully documented.

### Conclusion

The surveyor will review all records of your IQCP process, including what resources were used, how your data was analyzed, how your risk assessment was translated to your individualized quality control plan, and whether and how often you performed Quality Assessments, and if any changes were made to your QC Plans.

Don't forget that documentation of your Laboratory Director's involvement is required as well:

- Authorizing the use of IQCP in the laboratory
- Delegating steps in the IQCP process
- Approval of all plans developed before implementation

Finally, have available personnel records indicating training on the IQCP process and plans developed.

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### RESOURCES:

1. IQCP Brochure 13, What Is An IQCP? November 2014. Section1: What Is Risk Assessment (RA)? <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf>
2. Ibid.
3. Individualized Quality Control Plan (IQCP) Implementation Guide. Risk Management: The Core Concept of IQCP Introduction to Risk Management. Pp. 19-20. . COLA Resources, Inc. 2013
4. Individualized Quality Control Plan (IQCP) Implementation Guide. Risk Management: The Core Concept of IQCP Introduction to Risk Management. Pp. 44-45 COLA Resources, Inc. 2013
5. Individualized Quality Control Plan (IQCP): Developing an IQCP: A Step-By-Step Guide. CDC/CMS. Pp.45. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf>

# Survey Preparation For Your Point of Care Testing

## Introduction

One of the fastest areas of growth is point-of-care testing (POCT), estimated to be increasing at 10-12% annually, compared to a 6-7% annual increase in other clinical lab testing. Although home-based POCT is also increasing, 70% of POCT takes place in hospitals, doctors' offices and other –provider –locations, and this growth is predicted to continue. The compelling concept behind POCT is that lab testing can take place conveniently, closer to the patient, increasing the speed of results and the likelihood of a faster diagnosis in support of more immediate clinical management decisions. Used appropriately, POCT can be a key component in –meeting the goals of simultaneously improving patient outcomes and reducing healthcare costs.<sup>1</sup>

These advantages are further enhanced by continuous technological innovation, improving the quality, convenience, connectivity, speed, and range of applications.

Hundreds of tests once considered too complex for POCT are now routinely performed outside the laboratory. Sensor technologies enable the rapid analysis of blood samples for many critical care assays, including<sup>2</sup>

- Blood gases/electrolytes
- Cardiac markers
- Cholesterol/lipids
- Coagulation monitoring (INR; ACT, Heparin; Hemostasis Assessment)
- Drugs of abuse testing (DOA)
- Fecal occult blood
- Glucose monitoring; Hemoglobin A1C
- Hematology
- Infectious diseases (such as Influenza and Rapid Strep)
- Pregnancy and fertility
- Tumor/cancer markers
- Urinalysis testing
- Other Chemistries (Magnesium, Lactate, Micro-albumin, Creatinine)
- D-dimer for thromboembolism

## Managing Your POCT

### The Importance of a POCT Coordinator and Management Team

Management of POCT can be challenging. Testing may include multiple sites, many different POCT devices/kits, and dozens of operators that have to be managed in order to assure quality. Larger facilities with numerous devices and

locations often employ dedicated point-of-care coordinators (POCC) to ensure proper usage of POCT equipment.

Interdisciplinary POCT management teams that include the laboratory, physicians, and nurses, are considered as the most effective way to ensure that the quality of work performed is maintained, and could include all or some of the following responsibilities.<sup>3</sup>

- Determining the test menu
- Selecting methodologies
- Establishing policies and procedures
- Confirming proper training and competency assessment
- Overseeing regulatory compliance (QC, QA, PT, Calibrations, Maintenance, etc.)
- Recordkeeping and documentation is maintained
- Documenting corrective action where necessary
- Providing advisory assistance to the end users of POC technologies

In fact, encouraging face-to-face communication among the principals goes a long way toward improving effort and performance in meeting regulatory requirements. It is more effective for lab leaders to explain the stringent accreditation requirements in-person to build rapport around a common goal.

## Challenges of POCT

### Ensuring Compliance

Since the single biggest challenge of a laboratory's POCT is maintaining quality, the potential for errors often raises concern about the reliability of test results. In contrast to the core lab, where errors occur most frequently in the pre- and post-analytic phases, POCT errors occur primarily in the analytic phase of testing<sup>4</sup>.

This can be related to a lack of understanding or training of non-laboratory staff who are typically involved in POCT, or as a result of test limitations and misuse of POCT in extreme environmental conditions. While the laboratory offers a structured, controlled testing environment, testing conditions for POCT can vary tremendously. Additionally, the connectivity needed to get POCT results into the EHR fast enough to effect a change in patient care is challenging.

One way to ensure compliance is to conduct regular inspections at POCT sites. Facilitating inspections serves a dual purpose: face-to-face communication and an on-site

review of compliance. In addition, for sites that have deficiencies during these annual inspections, reports can be sent to the department leadership requiring mandatory corrective-action plans. The utilization of training and competency records, environment of care, safety, reagent storage and labeling, documentation of results, and correct/ current procedures has proven highly beneficial.<sup>5</sup>

### Non-laboratory Testing Personnel

Clinical personnel with minimal laboratory knowledge, such as nurses or medical assistants, often perform the majority of POCT. They are often unfamiliar with routine laboratory procedures regarding the importance of proper patient preparation, sample collection, calibration, instrument maintenance, and quality control. A related concern is that POCT equipment will not be used and maintained properly, or will not include appropriate quality control and quality assessment procedures.

Initial training is required prior to POCT device operation, followed by documented competency assessments at specific intervals, regardless of the complexity of the instrumentation in use.

It is important to note, however, that waived POCT automatically becomes high complexity if it is used for testing other than strictly according to the manufacturer's directions. The high complexity designation impacts personnel requirements, as well as the need for Proficiency Testing.

### **Survey Day**

Preparation for the survey is the same as for the testing performed in core laboratory, but it is important to have a POCT coordinator assigned to accompany the surveyor to all sites, prepared to answer questions specific to how testing is monitored from that location, the qualifications of the on-site testing personnel, the logistics of specimen handling (and splitting with the core laboratory, if needed), as well as reagent storage and data handling. Complete records should be present on site, or electronically available. Personnel training and ongoing competency assessment records for non-laboratory testing staff should be complete, even if all the testing performed is waived. Policy and procedure manuals must be accessible from all testing sites.

### **Conclusion**

POCT should be considered as part of the continuum of the clinical laboratory's contribution to patient care and it is a fundamental responsibility of the laboratory director and administrative staff, regarded with the same expectations of quality throughout the total testing process. POCT can be a critical factor in providing improved laboratory services.

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### RESOURCES:

1. Futrell, K. POCT: POCT Supports New Demands. Changes in healthcare open door for point-of-care testing to improve outcomes. December 9, 2013. <http://www.iaclid.ir/DL/elm/poctsupportsnewdemands.pdf>
2. Futrell, K. Laboratory Point of Care Testing: A Future Outlook. POCT Progression and the Importance of Connectivity Orchard Software Whitepaper. June 2015. [http://www.orchardsoft.com/files/white\\_paper\\_lab\\_poc\\_testing.pdf](http://www.orchardsoft.com/files/white_paper_lab_poc_testing.pdf)
3. Ibid.
4. Ibid.
5. Eden, PR; Herring, CF; Davis, CM. Getting Ready for your Laboratory Inspection. Lab Management- The Inspection Ready Lab. MLO. July 2016. <http://www.mlo-online.com/getting-ready-for-your-laboratory-inspection>

# COLA AWARDS SCHOLARSHIPS TO COLACARES SCHOLARSHIPS TOTAL \$9,500

COLA, with the help of industry partners, has awarded 19 laboratory science students studying at East Coast colleges and universities with a \$500 scholarship, for a total of \$9,500. The *COLAcare Scholarship* awards stem from COLA's GiveBack365 initiative. GiveBack365 was designed to foster awareness of careers in the medical laboratory industry and to provide support to aspiring laboratorians.

## The 2016 winners are:

Anita Rachel Abraham	Virginia Commonwealth University
Ayomikun Adebayo	Morgan State University
Kesiena Apojetavwo	Dutchess Community College
Mercedes Brinn	Beaufort County Community College
Hana Chammack	University of Delaware
Rachel Childs	Virginia Commonwealth University
Quy-Hien Riley Dang	Virginia Commonwealth University
Savannah Drake	Virginia Commonwealth University
Yuka Forrest	Anne Arundel Community College
Seana Fraser	The George Washington University
Ariel Holder	Community College of Baltimore County
Morgan Hunsecker	PA College of Health Sciences
Deksisa Kejela	University of Maryland
Sasha Lombardo	Anne Arundel Community College
Monica Matamoros	Davidson County Community College
Kaitlin Pierce	Virginia Commonwealth University
Amanda Stamatelaky	Tidewater Community College
Erin Wambaugh	West Virginia University
Emily Zelger	York College of PA

COLA established the scholarship program in 2012 to attract more students to the laboratory profession and to create greater awareness of the importance of quality lab practices in the delivery of safe, effective health care.

“COLA and our program sponsors are proud to provide this financial support to these deserving students, each of whom met the scholarship’s exacting criteria demonstrating their

success in their respective institution’s Medical Laboratory Science or Technology programs,” said Douglas Beigel, CEO of COLA. “With a projected increase in the number of current laboratory job vacancies in the U.S., these scholarships will help the next generation pursue clinical laboratory science careers. Most important, it will enable them to make a difference in the lives of patients.”



## GB365

Sponsored by COLA

# 19 LABORATORY SCIENCE STUDENTS

The scholarships are being funded in part through the generosity of industry sponsorships from Carolina Liquid Chemistries and Medica Corporation and Merge.



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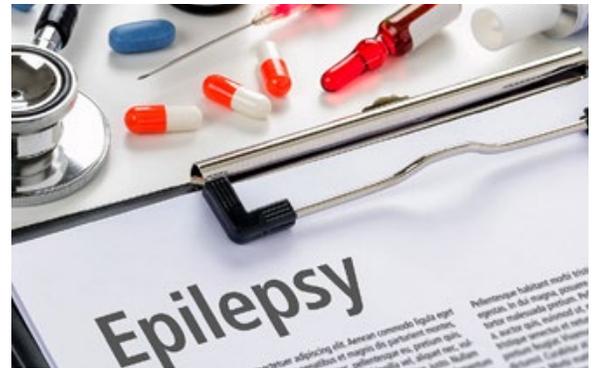


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## Stories from the Front Lines: WHAT IF...



Our daughter, Rachel, has Epilepsy. For proper seizure control, her medications need to be at the proper levels. This can pose significant challenges, especially if other system-taxing, chemotherapeutic agents are added into the mix for other medical conditions that arise.

Recently, she was on another medication, Accutane, for a dermatology condition. When she was tested for the Accutane levels an increase in her liver numbers was detected, which was a cause for concern and led to backing off the additional therapy.

At around the same time, she had her scheduled test to check the levels of her anti-epileptic/anti-convulsant medications, Topamax and Keppra, which have successfully controlled her Epilepsy since 2012. They both came back as "0," despite the fact that she regularly took these medications. (The normal readings when taking these drugs as prescribed should be in the range of 2.0 – 25.0 ug/ml and 5.0 to 63.0 ug/ml, respectively.) Obviously, the first thought was that her test results were in error, with these results being an anomaly. Indeed, later tests showed this to be the case.

However, what if her liver numbers as a result of taking the additional medication had been more pronounced? What if she had needed to back off

Keppra and Topomax for a time, in order to allow her liver to recover? It would have been best to actually have confidence in the numbers reported to be able to make the most educated decision.

If it was a problem of the samples being switched, was there someone else out there who was given the results of our daughter's blood sample? The ramifications are obvious, including delays in or incorrect treatment. The results could be disastrous. It makes you realize the importance of quality laboratory testing, and that regulations governing the practice of laboratory medicine are there for a reason.

**Visit [LabTestingMatters.org](http://LabTestingMatters.org) to read more Stories from the Front Line of the Lab and join us as we build a community to support quality laboratory medicine. If you are interested in sharing your story with the Lab Testing Matters Community you can contact [info@labtestingmatters.org](mailto:info@labtestingmatters.org).**

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