MAY/JUNE — 2014

COLA'S

inSights

INTO *Plan of Required Improvement (PRI)*

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FROM THE CHAIR

Richard A. Wherry, M.D.
Chair, COLA Board of Director

Welcome to COLA's May/June issue of Insights!

This issue of InSights provides timely information on the Plan of Required Improvement (PRI) process for your laboratory. COLA Accredited laboratories have been provided the resources and information available to not only reduce the number of citations in their laboratory but in addition to focus on driving a culture of zero citations. This edition on PRI provides an Overview of PRI, what it means, what documentation is included in the packet received from COLA and how to interpret the information provided. The Overview article serves to explain the process of PRI and the necessary steps from Survey to Accreditation or Re-accreditation.

Within the sample PRI letter titled: "COLA Accredited Laboratory" you will find line by line examples and explanations of what each component of the letter includes along with a clear representation of what information COLA laboratories need to verify for accuracy and compliance.

Our Tips for Assistance in Compliance section imparts simple and easy to follow suggestions on the overall PRI process. From important deadlines, to educating laboratories as to how best to complete and return their paperwork this section and all of the other articles in this issue are a must read. COLA laboratories will learn key steps to suggestions on submitting documentation (how to label, remind labs of the timelines, etc.)

In this issue, we will also continue our salute to the Laboratory Excellence Award (LEA) laboratories. We hope that narratives of these laboratories that not only achieved zero citations, but also continuously strive for excellence in quality patient care will encourage and inspire all COLA laboratories to attain a culture of excellence in laboratory medicine.

InSights in the Plan of Required Improvement is a must read and we encourage you to share this issue with your laboratory and colleagues!

COLA

COLA INSIGHTS

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www.cola.org
www.LabUniversity.org
www.COLAcentral.com
www.criedu.org

Comments? Questions? Feedback?
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COLACares Scholarships given to nine lab science college students

COLA through its COLACares Scholarship program has bestowed scholarships to nine bright, enterprising students from the University of Maryland, Morgan State University and Community College of Baltimore County (CCBC). "This is a big part of our COLACares program and it shows our commitment to educating and engaging students in the world of laboratory medicine," stated COLA CEO Doug Beigel. The COLACares Scholarship Program, now in its 4th year has made a positive impact in the lives of motivated students who are excited about a career in the laboratory sciences.

Congratulations to the 2014 COLA Cares Scholarship Winners!

University of Maryland
Afang Tan, Karaleigh Leonard, Muhammed Saleem

Morgan State University
Prativa Kafle, Esperancia Azondekon

Community College of Baltimore County
Shelly Garland, Amanda Hagy, Jewel A. Richardson, Sadatra Everett

Thank you COLA Cares Scholarship Sponsors!

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- Continuing education to enhance competency and maintain state licensure
- CME credits for physicians to qualify as laboratory director for a moderate complexity laboratory, as outlined by CLIA
- Tools assisting in:
  - Meeting the requirements of CLIA, COLA, and other accrediting organizations
  - Improving laboratory processes and procedures
  - Preventing laboratory errors
  - Improving efficiency and promoting quality in laboratory operations

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Plan of Required Improvement (PRI) - Overview

As a COLA laboratory, part of the Accreditation process is the biennial survey of your organization. If there are any citations or recommendations noted by the surveyor, they will be reported to you in the Plan of Required Improvement (PRI). The PRI is a comprehensive document that includes:

1. A Cover Letter addressed to the Laboratory Director – This letter includes specific details regarding the PRI, important response deadlines as well as instructions as to how to respond to the PRI.

2. Laboratory Information – This is a listing of information in our database observed at the time of the survey. This information should be accurate and up-to-date. If it is not, please submit corrections either through COLAcentral™ (www.colacentral.com) or with your Agreement to the Plan of Required Improvement.

3. Plan of Required Improvement (PRI) – This report lists any citations, and includes specific instructions regarding the actions that must be taken to correct your citations. This customized plan is sorted as follows:

- Peer Review Comparison - This report has a statistical analysis showing your lab's performance compared to other laboratories with similar number of annual tests.
- Improvements needed within 30 days, documentation required; then
- Improvements to be completed in a timely manner, no documentation required.

Note: Repeat citations (citations that you also received during the prior COLA survey) are denoted with an asterisk (*).

4. Agreement to the PRI – This document states that you agree to correct and maintain corrections to all citations noted at the time of survey.

The PRI is received post-survey and allows ample time for laboratories to respond accordingly to maintain or improve their good standing with COLA. It is the responsibility of the Laboratory Director and staff to ensure that all parts of the PRI are addressed and that the response is returned to COLA within the specified timeframes.

"The laboratory director has 14 days to agree to the PRI or to appeal to COLA. The PRI asks the laboratory director to sign the agreement form and submit it to COLA, stipulating intent to correct all noncompliant criteria. The agreement and any required documents may be uploaded by using COLAcentral®." [1]

COLA's desire is for all of their accredited laboratories to achieve zero citations and be awarded the Laboratory Excellence Award (LEA) for Superior Performance. In each issue of InSights, COLA highlights an LEA laboratory as an example that a zero citation laboratory is not only possible but is being attained by several laboratories each year. The first step in achieving LEA status is complying with the PRI. With each survey cycle and day to day services provided, COLA accredited laboratories have the opportunity to improve their status and continuously improve patient care.

RESOURCES:

1. COLA Accreditation Manual (revised July 2014) p. 28

Example of PRI Letter

Explaination of terms and concepts

The following pages provides an example of a complete PRI letter. This example is provided to show laboratories what to expect in PRI communication from COLA if there are citations noted and corrective actions are necessary. All information in this example is fictitious. Any resemblance to real persons or laboratories, living /dead active/ inactive, is purely coincidental. For the purposes of this example generic titles of personnel, COLA ID# NNNN, and COLA Headquarters address were used to create a fictitious laboratory.

Important things to note will be highlighted and explained below.

COVER LETTER

LABORATORY INFORMATION

Ensure the correct contact information is listed for the laboratory including the Laboratory Name, Laboratory Director Name, other applicable Point of Contact listed for COLA (Laboratory Manager, Technical Consultant, etc.), Laboratory Address, and COLA ID#.

DATE OF LETTER

Note the date the letter was sent to the laboratory. This will be important in that the timed response period begins from that date. The accreditation process cannot continue until the necessary actions have been taken. "When we receive your signed agreement and acceptable documentation that is requested by the PRI, we can complete the accreditation process."[1]

IMPORTANT DUE DATES

These dates are crucial in ensuring compliance with COLA Accreditation criteria. There are two (2) dates listed. The first date ("Actions you must take by 05/30/14") is when the Laboratory Director must sign and return the "Agreement to the Plan of Required Improvement" to COLA. The second date ("Actions you must take by 06/15/14") is when the laboratory must submit the specified documentation demonstrating corrections for these citations. This is the documented Corrective Actions Plan for the PRI.

It is important the COLA ID number is printed on each page. It may be completed by simply adding the COLA ID number to the Header or Footer of the document that is created. This information can also be handwritten or stamped on each page, but it MUST be included to ensure proper processing for all pages of information received.

PLAN OF REQUIRED IMPROVEMENT INSTRUCTIONS

These are specific instructions for the surveyed laboratory regarding the number of citations identified, if there are any repeated citations from the last survey cycle and the total number of documentary citations. Many laboratories face challenges in not only the implementation of their accreditation criteria but also in the documentation of said criteria. The Laboratory Director should periodically review all documentation for accuracy and implementation throughout all aspects of laboratory operations.

REQUIRED IMPROVEMENTS

Address these necessary improvements as soon as possible. Although no documentation is required to be submitted, COLA reserves the right to verify compliance at any time.

REPEAT CITATIONS

"For laboratories that have been surveyed previously by COLA, we have denoted the citations that were observed during the previous survey that were not resolved at the time of the most recent survey. You had agreed to correct these problems prior to this survey when you submitted your Agreement to the Plan of Required Improvement. Please correct these citations as soon as possible. **Blatant disregard for correcting citations is grounds for denial of accreditation. COLA reserves the right to verify compliance at any time."**

CONTACT INFORMATION FOR COLA

COLA is always available to provide education, technical advice and support to their accredited laboratories. There are several ways to contact COLA.

"If you have any questions regarding this stage of COLA's accreditation process, either review the information regarding your laboratory on COLAcentral™ (www.colacentral.com) or contact COLA at (800) 981-9883."[2]

PLAN OF REQUIRED IMPROVEMENT

PEER REVIEWED COMPARISION

This section identifies citations for the laboratory and compares its findings within the specified peer group. This is done to ensure that laboratories are being surveyed on a comparable scale with similar laboratories. The total number of similar laboratories is provided and a quantitative value is provided for each variable category.

LABORATORY INFORMATION

This is the information on file with COLA regarding the laboratory. All of this information must be verified for accuracy. "At the time of survey, the following information was recorded. Please verify that this information is correct and update any changes/additions/ deletions to COLA via COLAcentral™ (www.colacentral.com). All information must be completed to receive a COLA accreditation certificate." [3]

"Personnel in the Laboratory" is of particular importance because it shows who is currently employed in the laboratory, what position they hold, if they are testing personnel and if they have access to COLA Central. The Laboratory Directory should always have access to COLA Central. This example Laboratory Director currently does not have access to COLA Central and this should be corrected immediately so that they can receive timely information regarding COLA Accreditation.

TESTS PERFORMED & INSTRUMENTS USED IN THE LABORATORY

This section of the PRI shows the Test Menu for the laboratory. All of this information must be verified for accuracy.

"COLA strives to accurately represent your test menu. Please be aware that we make every effort to match your test system to approved test systems listed in the FDA database. When an exact match is not possible, we will choose the test system which most accurately matches your test system. Any errors in the list of tests performed should be submitted to COLA with your Agreement to the Plan of Required Improvement." [4]

AGREEMENT TO THE PLAN OF REQUIRED IMPROVEMENT

The Laboratory Director must review, sign and return this document to COLA within fourteen (14) days of the date of the letter.

GROUPED CITATIONS AND ACTIONS REQUIRED

Each section provides detailed information of non-compliance and provides the suggested actions to resolve them. COLA provides the specific information required to address each citation from the laboratory survey. The information provided in the PRI letter is provided in chart form and the criteria is taken directly from the accreditation manual and includes:

- Question Number #
- Category
- Policy/criterion
- Non-Compliance Applies to Action Required
- Send to COLA

The Plan for Required Improvement (PRI) Letter is a tool that when used properly will ensure that the laboratory is in compliance with COLA Accreditation Criteria and also with Good Laboratory Practices. This letter is unique to every COLA accredited laboratory and has all the necessary information needed to provide survey results and corrective actions. All COLA labs should be aware of how to read and act upon the information provided in the PRI letter to ensure compliance with COLA Accreditation.

RESOURCES:

1. Sample PRI Letter, COLA June 2014, p.1
2. COLA Example PRI Letter p.7
3. COLA Example PRI Letter p.7
4. COLA Example PRI Letter p.8

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COLA Accredtited Laboratory
Attn: **Laboratory Director**, MD
Attn: **Laboratory Manager**
9881 Broken Land Parkway
Columbia, MD 21406

COLA ID: NNNN
05/16/14

Dear **Laboratory Director**, MD:

Your laboratory was recently surveyed by COLA on 5/15/2014 by COLA surveyor **We're pleased to assist you in maintaining quality lab practices.**

In order to help you comply with COLA's accreditation requirements, we are providing a Plan of Required Improvement (PRI). A series of reports have been included to review the laboratory's citations at different levels and indicates the actions you will need to take to correct citations. This customized plan shows each required improvement prioritized for your convenience. In fact, you may have already begun to implement some of these improvements as the result of the summary conference conducted by the COLA surveyor.

Included as part of this report are:

- Laboratory Information – This is a listing of stored information in our database observed at the time of the survey. This information should be accurate and up-to-date. If it is not, please submit corrections either through COLAcentral™ (www.colacentral.com) or with your Agreement to the Plan of Required Improvement.
- Peer Review Comparison - This report has a statistical analysis showing your lab's performance compared to other laboratories with a similar number of annual tests.
- Plan of Required Improvement (PRI) - This report has specific instructions regarding the actions that must be taken to correct your citations. This customized plan is sorted as follows:
  - Improvements needed within 30 days, documentation required; then
  - Improvements to be completed in a timely manner, no documentation required.

  Note: Repeat citations (citations that you also received during the prior COLA survey) are denoted with an asterisk (*).
- Agreement to the PRI – This document states that you agree to correct and maintain corrections to all citations noted at the time of survey.

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After you have carefully reviewed the Plan of Required Improvement, sign the enclosed Agreement to the Plan of Required Improvement and return it to COLA. For some of the citations, COLA may require you to submit documentation of your corrective action. The PRI indicates which citations require documentation and what this documentation should include. It is important that we receive this documentation by the due date printed on the PRI. **When we receive your signed agreement and acceptable documentation that is requested by the PRI, we can complete the accreditation process.**

ATTENTION – Please note the following important due dates:

Actions you must take by **05/30/14**

- Review the entire PRI.
- Have the Laboratory Director sign and date the **Agreement to the Plan of Required Improvement**. Please either upload the signed agreement to COLAcentral™ (www.colacentral.com) or fax the agreement to (410) 381-8611.
- Develop an action plan for implementing all improvements in a timely manner.

Actions you must take by **06/15/14**

- Take action to correct the citations that require documentation (if any).
- Submit the specified documentation demonstrating your corrections for these citations to COLA by uploading to COLAcentral™, faxing, or mailing to COLA.
- **Be sure that your COLA ID is printed on each page.**

Thank you for choosing COLA as your accrediting organization. We look forward to a long and productive working relationship with you and your laboratory personnel. The next biennial survey of your laboratory will occur in approximately 18-24 months. If you have any questions or need additional explanation, please contact COLA at (800) 981-9883.

Sincerely,

Kathy Nucifora, MPH, MT(ASCP)
Accreditation Division Manager

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Plan of Required Improvement Instructions

Attached is the Plan of Required Improvement (PRI) based on the on-site survey of your laboratory on **5/15/2014** by COLA surveyor. Each improvement specifies the appropriate question number from the *COLA Laboratory Accreditation Manual*.

As a result of the survey, your laboratory received:

- Total number of citations issued: 10
- Total number of citations that are repeated from previous survey [denoted with an asterisk (*)]: 1
- Total number of documentary citations: 4

In addition, COLA has referenced relevant COLA educational materials that can be found on our website (www.colacentral.com) to further assist you in implementing your improvements. Please be aware that the educational products define what COLA considers to be sound laboratory practice and may promote standards that are higher than those meeting minimal requirements for accreditation.

Please follow the steps outlined below to complete the PRI.

Completing the Plan of Required Improvement

1. **Review the listing of information we have on your laboratory.**
   COLA strives to accurately represent your test menu. Please be aware that we make every effort to match your test system to approved test systems listed in the FDA database. When an exact match is not possible, we will choose the test system which most accurately matches your test system. Any errors in the list of tests performed should be submitted to COLA with your Agreement to the Plan of Required Improvement.
2. **Carefully read the Plan of Required Improvement.**
   Please sign, date and return the Agreement to the Plan of Required of Improvement by **05/30/14.**
3. **Implement the improvements included in the PRI.**

   Documentary citations:

   Address any documentary citations first.

   All citations that require documentation must have supporting documentation submitted to COLA by **06/15/14.** Ensure that all pages are labeled with your COLA ID, NNNN
   You may submit your documentation to COLA by:

   1. Uploading to COLAcentral™:
      a. Log on to www.colacentral.com
      b. Under the "Management/Compliance" tab, choose "Document Repository"
      c. Click the "COLA Documents" tab
      d. Click "Browse" to locate your document
      e. Click "Upload" or

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   2. Faxing to 410-381-8611 or
   3. Mailing to COLA.

   Required improvements (no documentation required)

   Address these necessary improvements as soon as possible. Although no documentation is required to be submitted, COLA reserves the right to verify compliance at any time.

   Repeat citations

   For laboratories that have been surveyed previously by COLA, we have denoted the citations that were observed during the previous survey that were not resolved at the time of the most recent survey. You had agreed to correct these problems prior to this survey when you submitted your Agreement to the Plan of Required Improvement. Please correct these citations as soon as possible. **Blatant disregard for correcting citations is grounds for denial of accreditation. COLA reserves the right to verify compliance at any time.**

If you have any questions regarding this stage of COLA's accreditation process, either review the information regarding your laboratory on COLAcentral™ (www.colacentral.com) or contact COLA at (800) 981-9883.

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Plan of Required Improvement for COLA Accredited Laboratory

COLA ID: NNNN **Survey Date: 5/15/2014 Surveyor:** COLA Surveyor

Peer Review Comparison					
Your peer group is laboratories with annual test volumes of 75,001-100,000	**Total Number of Laboratories in your Peer Group 404**				
		Laboratories in your peer group receiving the following scores:			
Survey Area	**Your Score %**	**>90%**	**89-80%**	**79-70%**	**Less than 70%**
Organization (ORG)	100	353	41	7	3
Facility (FAC)	100	398	6	0	0
Personnel (PER)	100	256	48	23	21
Proficiency Testing (PT)	82	322	66	10	6
Lab Information System (LIS)	100	264	5	0	2
Preanalytic (PRE)	100	395	9	0	0
Procedure Manual (APM)	100	391	11	0	1
Maintenance (MA)	94	351	44	6	2
Verification of Performance (VER)	57	367	12	3	22
Calibration (CA)	89	250	108	34	9
Quality Control (QC)	100	337	38	7	3
Specialty Specific Criteria	91	367	23	3	3
Postanalytic (PST)	100	395	8	0	0
Quality Assurance (QA)	100	373	17	5	4
Transfusion Services (TS)	N/A	44	1	0	0
Overall	96	388	10	0	0

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Your laboratory is compared against other laboratories with a similar number of annual tests. The **total number of laboratories** in your peer group is noted in the top right box. The columns list the number of labs in each percentile group.

Your score is the percentage of COLA criteria found to be in compliance during your on-site survey when compared to the number of criteria that are applicable to your laboratory. If you do not perform testing in a given specialty area, those criteria are not included in the calculation of your score. The **Overall Score** is based on the total number of criteria applicable to your laboratory.

Your **Peer Group** is based on the size of your laboratory and is determined by the number of tests performed annually. The peer group size ranges are:

- 0-2000
- 2,001-10,000 w/ 0-3 specialties
- 2,001-10,000 w/ 4 specialties
- 10,001-25,000 w/ 0-3 specialties
- 10,001-25,000 w/ 4 specialties
- 25,001-50,000
- 50,001-75,000
- 75,001-100,000
- 100,001-500,000
- 500,001-1,000,000
- Greater than 1,000,000

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Laboratory Information
(as of 5/15/2014)

At the time of survey, the following information was recorded. Please verify that this information is correct and update any changes/additions/deletions to COLA via COLAcentral™ (www.colacentral.com). All information must be completed to receive a COLA accreditation certificate.

COLA ID Number	NNNN
CLIA ID Number	AAAAAAAAAA
Laboratory Director	Laboratory Director, MD
Address	Attn:Laboratory Manager
Telephone	123-456-7890
Fax	123-456-7891
COLA Surveyor	COLA Surveyor
Survey Date	5/15/2014
Number of Physicians	4
Specialties	**Hematology:** Routine Hematology, Routine Hematology
Enrollment Expires	1/21/2015
Name on COLA Accreditation Certificate	COLA Accredited Laboratory

Proficiency Testing Program

Provider Name	Account Number
XYZ PT PROVIDER	000000

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Personnel in the Laboratory

Name	Position	COLACentral Access	Email Address
Director, Laboratory	Laboratory Director	No	ld@COLALab.com
Personnel, Technical	Laboratory Personnel	Yes	tp@COLALab.com
Assistant, Medical	Laboratory Personnel	No	
Manager, Laboratory	Laboratory Manager	Yes	lm@COLALab.com
Assistant, Medical	Laboratory Personnel	No	

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Tests Performed & Instruments Used in the Laboratory

COLA strives to accurately represent your test menu. Please be aware that we make every effort to match your test system to approved test systems listed in the FDA database. When an exact match is not possible, we will choose the test system which most accurately matches your test system. Any errors in the list of tests performed should be submitted to COLA with your Agreement to the Plan of Required Improvement.

Instrument	Complexity	Analyte	Regulated?
Specialty: Hematology / Routine Hematology			
ABBOTT CELL-DYN 1800	Moderate	Hematocrit	Yes
ABBOTT CELL-DYN 1800	Moderate	Hemoglobin	Yes
ABBOTT CELL-DYN 1800	Moderate	Platelet Count	Yes
ABBOTT CELL-DYN 1800	Moderate	Red Blood Cell Count (Erythrocyte Count) (RBC)	Yes
ABBOTT CELL-DYN 1800	Moderate	White Blood Cell Count (Leukocyte Count) (WBC)	Yes
ABBOTT CELL-DYN 1800	Moderate	White Blood Cell Differential (WBC Diff)	Yes
Specialty: Hematology / Coagulation			
Coag-Sense Prothrombin Time (PT/INR) Monitoring System	Waived	Prothrombin Time (PT)	Yes
Specialty: Chemistry / Urinalysis			
Siemens MULTISTIX 10 SG Reagent Strips	Waived	Urine Qualitative Dipstick Bilirubin	No
Siemens MULTISTIX 10 SG Reagent Strips	Waived	Urine Qualitative Dipstick Blood	No
Siemens MULTISTIX 10 SG Reagent Strips	Waived	Urine Qualitative Dipstick Glucose	No
Siemens MULTISTIX 10 SG Reagent Strips	Waived	Urine Qualitative Dipstick Ketone	No
Siemens MULTISTIX 10 SG Reagent Strips	Waived	Urine Qualitative Dipstick Leukocytes	No
Siemens MULTISTIX 10 SG Reagent Strips	Waived	Urine Qualitative Dipstick Nitrite	No
Siemens MULTISTIX 10 SG Reagent Strips	Waived	Urine Qualitative Dipstick pH	No
Siemens MULTISTIX 10 SG Reagent Strips	Waived	Urine Qualitative Dipstick Protein	No
Siemens MULTISTIX 10 SG Reagent Strips	Waived	Urine Qualitative Dipstick Specific Gravity	No
Siemens MULTISTIX 10 SG Reagent Strips	Waived	Urine Qualitative Dipstick Urobilinogen	No

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AGREEMENT TO THE PLAN OF REQUIRED IMPROVEMENT

As Laboratory Director of, COLA Accredited Laboratory COLA ID NNNN I agree to implement the Plan of Required Improvement (PRI) prescribed by COLA and dated 05/16/14, within the time limits set forth in the PRI.

Date **Laboratory Director Signature**

IMPORTANT: RETURN THIS FORM TO COLA BY 05/30/14.

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Grouped Citations and Actions Required

NNNN : COLA Accredited Laboratory

***Repeat citations (citations from the previous survey that were unresolved at the time of the current survey) are denoted with an asterisk (*).**

Question Number #	Category	Policy/criterion	Non-Compliance Applies to:	Action Required	Send to Cola
PT 15 *	General	PT 15 Does your PT record keeping include: A copy of the attestation form signed by the director and the testing personnel?	The PT records do not include signed attestation forms for the second and third PT events of 2012 and the first PT event of 2013.	Sign the attestation form and retain a copy of the form. The laboratory director and the persons performing the tests must sign the attestation form.	Please submit documentation to COLA that lab testing staff and the lab director and or designee have received instruction in the procedure to sign and to retain signed attestation forms as part of the lab's PT record keeping.
VER 1	General	VER 1 Prior to patient testing, have each of the following performance specifications been verified and documented for each non-waived test or method: Accuracy?	The lab director did not document his review and acceptance of the accuracy studies performed on the two Abbott Cell Dyn 1800s installed December 2013 prior to patient testing. **Targets:** ABBOTT CELL-DYN 1800	To verify accuracy, test specimens with a known value and verify you can obtain the same value or a value very close to the known value. It is the laboratory director's responsibility to establish the requirements for this procedure, including determination of an acceptable range of variance around the known value for each test. Establish a procedure to verify accuracy of all non-waived tests prior to initiating patient testing. Include: · The number and type of specimens to be tested. Commercially available calibrators, controls, proficiency samples, or previously verified patient samples are allowed. · The number of times each sample will be tested. · The allowable variation from the known value. Document the date of testing, initials of the person performing testing, identity of the specimens tested, known value of each specimen, results obtained for each specimen, and a determination of acceptability. Have the laboratory director review and signify approval of the results by signing and dating the documentation.	Please submit to COLA a statement signed by the lab director that he is aware all instrument performance verifications must be reviewed and determined to be acceptable by the lab director, prior to patient testing.
VER 3	General	VER 3 Prior to patient testing, have each of the following performance specifications been verified and documented for each non-waived test or method: Reportable patient	The lab director did not document his review and acceptance of the reportable range studies performed on the two Abbott Cell Dyn 1800s installed December 2013 prior to patient testing.	To verify reportable range, test specimens of known value that are representative of the highest and lowest values of the manufacturer's reportable range for the test. Verify you can obtain the same range and, if not, establish a narrower reportable range that will be used for your laboratory. Patient	Please submit to COLA a statement, signed by the lab director, that he is aware all instrument performance verifications must be reviewed

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		range?	**Targets:** ABBOTT CELL-DYN 1800	results which exceed the reportable range (either high or low) must be reported as greater than or less than the maximum or minimum specimen value obtained by your laboratory, unless another procedure has been developed to dilute and retest specimens that exceed the maximum range. It is the laboratory director's responsibility to establish the requirements for this procedure, including determination of an acceptable range of variance around the known value for each test and how to report results that fall outside of the verified reportable range. Establish a procedure to verify reportable range of all non-waived tests prior to initiating patient testing. Include: · The number and type of specimens to be tested. Commercially available calibrators, controls, proficiency samples, or previously verified patient samples are allowed. · The number of times each specimen will be tested. · The allowable variation from the known value. · How test results that fall outside of the reportable range will be reported. Document the date of testing, initials of the person performing testing, identity of the specimens tested, known value of each specimen, results obtained for each specimen, a determination of reportable range, and how test results that fall outside of the reportable range will be reported. Have the laboratory director review and signify approval of the results by signing and dating the documentation. Maintain this documentation for as long as the laboratory performs the test by this method and for two additional years once the method has been discontinued.	and determined to be acceptable by the lab director, prior to patient testing.
CA 2	General	CA 2 Is calibration verification performed according to the manufacturer's instructions including: The number, type and concentration of materials to be used, Use of materials at low, medium and high values within the reportable range, as determined by the laboratory, Acceptable limits for calibration verification,once every six months or more often if required by laboratory procedures?	Calibration verification was performed June 2012 and January 2013 for all required tests on the Clinical Data Envoy 500 Chemistry Analyzer. This analyzer was taken out of service April 30, 2013. **Targets:** Clinical Data, Envoy 500 Chemistry Analyzer	Establish a schedule to perform calibration verification at least once every six months.Perform calibration verification following the manufacturer's instructions, or those defined by the laboratory during verification of performance specifications.Use specimens with confirmed values at the low, mid-point, and high end of the laboratory's reportable range. Compare results obtained to your criteria for acceptability. Document the materials used, expected values, results obtained, whether performance is acceptable, and who performed calibration verification.Train all staff in proper calibration verification procedures.	Please submit documentation to COLA that lab testing staff have received training in the performance requirements for calibration verification.
LDR 2	General	LDR 2 Does the Laboratory Director meet the Procedural Responsibilities of the position?	The lab director did not document his review and acceptance for the accuracy, precision and reportable range studies performed on two Abbott Cell Dyn 1800s	The Laboratory Director is responsible for the overall operation and administration of the laboratory. To meet the Procedural Responsibilities, as defined by CLIA: Ensure that test systems provide quality lab services for all phases of testing; select	

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			installed December 2013 prior to patient testing.	appropriate test methods, ensure verification of performance characteristics of tests performed; provide consultation to labs clients; assure that an approved procedure manual is readily available to staff; and ensure that lab personnel are performing tests as required for accurate and reliable results.	
LDR 4	General	LDR 4 Does the Laboratory Director meet the Proficiency Testing Responsibilities of the position?	Attestation forms signed by the testing staff and the lab director, or designee, were missing for the second and third PT events of 2012 and for the first PT event of 2013. Documentation that the graded PT results were reviewed by the lab director, or designee, and testing staff were missing for second PT event of 2012 and the third PT event of 2013.	The Laboratory Director is responsible for the overall operation and administration of the laboratory.To meet the Proficiency Testing Responsibilities, as defined by CLIA: enroll in an approved PT program; ensure that PT samples are tested in the same manner as patient samples; ensure compliance with regulations that prohibit referral or communication of PT; submit PT results on time; review PT results and assure that corrective action is identified and implemented when PT results are unsatisfactory.	
PT 5	General	PT 5 Do you follow the same procedures for testing PT samples as you do for patient samples?	Participation in proficiency testing has not been rotated among all lab staff who perform testing. All attestation forms seen during this survey were signed by the same individual.	· Process and test each PT specimen as if it were a patient sample, using the testing procedures established and conducted in your laboratory. · Do not repeat PT samples, unless you would routinely repeat a patient sample with similar results. · Do not send PT samples to another laboratory for testing. · Ensure all personnel that routinely perform patient testing take turns performing the PT. Monitor personnel as they perform PT and/or review test records to ensure PT samples are handled in the same manner as patient samples.	
PT 16	General	PT 16 Does your PT record keeping include: An indication of the review of the graded PT results by the director as well as the supervisory and testing personnel?	The PT records do not contain a documented review of the graded PT results for the second event of 2012 and the third event of 2013.	Retain the documented reviews by the laboratory director, supervisory personnel, and testing personnel of the graded reports from the PT provider.	
MA 26	General	MA 26 Are maintenance logs kept that contain: The datesperformed and who performed it?	The maintenance logs for the Hematology Analyzers do not identify the staff member who performed each maintenance procedure.	Establish maintenance logs that permit staff to fill in their initials and the date they performed specific maintenance procedures and function checks.Use log sheets provided by the manufacturer, if available, or create your own. Use these logs to verify equipment is properly maintained.Keep maintenance logs for a minimum of two years.	
VER 2	General	VER 2 Prior to patient testing, have each of the following performance specifications been verified and documented for each non-	The lab director did not document his review and acceptance of the precision studies performed on the two Abbott Cell	To verify precision, test specimens with a known value repeatedly on different days and with different operators to verify you can consistently obtain the same value or a value very close to the	
		waived test or method: Precision?	Dyn 1800s installed December 2013 prior to patient testing. **Targets:** ABBOTT CELL-DYN 1800	known value. It is the laboratory director's responsibility to establish the requirements for this procedure, including determination of an acceptable range of variance around the known value for each test. Establish a procedure to verify precision of all non-waived tests prior to initiating patient testing. Include: · The number and type of specimens to be tested. Commercially available calibrators, controls, proficiency samples, or previously verified patient samples are allowed. · The number of times each sample will be tested. · The allowable variation from the known value. Document the date of testing, initials of the person performing testing, identity of the specimens tested, known value of each specimen, results obtained for each specimen, and a determination of acceptability. Have the laboratory director review and signify approval of the results by signing and dating the documentation. Maintain this documentation for as long as the laboratory performs the test by this method and for two additional years once the method has been discontinued.	

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Patient Centered Laboratory Excellence (PCLE)

COLA is proud to introduce the Patient Centered Laboratory Excellence program (PCLE). This groundbreaking program is specially designed to assist laboratories in participating in the Patient-Centered Medical Home & ACO Models of care and to be recognized for their efforts.

Through the PCLE program, COLA is taking laboratory quality beyond the confines of CLIA 88 by expanding its accreditation services to include waived testing labs.

The PCLE Program helps waived and non-waived laboratories:

- Achieve a continuous quality culture in the lab
- Integrate best practices into the PCMH/ACO model
- Make better informed, needs appropriate resource decisions
- Gain recognition from payer incentive programs

COLA's PCLE program is scalable to fit the needs of all laboratories, no matter the annual test volume, number of specialties performed or certificate type. PCLE brings laboratories multiple benefits:

- Provides a continuous quality framework designed to support the lab's involvement in the PCMH/ACO care models
- Positions laboratories to participate in PCMH/ACO quality incentives
- Criterion is scalable and meaningful to practice operations
- A PCLEexcelerator scoring mechanism enables labs to evaluate their readiness to participate in the PCMH/ACO model
- Focuses on communication, regulatory requirements, test selection, analytics and other key elements that are necessary for PCMH/ACO success

Enrollment in COLA's PCLE program is the first step in your laboratories successful participation in a PCMH/ACO program and receiving a "Gold Seal of Approval" in laboratory excellence as a PCLE Laboratory. **PCLE recognition will set your laboratory apart and could lead to gaining recognition from payer incentive programs.**

It's time for your lab to participate in the PCMH program that has been designed for laboratories by COLA, the experts in laboratory medicine. **Let COLA's PCLE program help your laboratory find success in many ways in the Patient Centered Medical Home model.**

COLA

To learn more about PCLE call COLA at 800-981-9883 or visit:
www.cola.org/patient-centered-laboratory-excellence-pcle/

Point of Care technologies that include internal or electronic quality checks, such as the iSTAT, were the impetus for the regulatory allowance of equivalent quality control practices by CMS in 2004. The first allowable equivalent quality control practice, EQC, is being phased out and replaced by a new equivalent quality control option based upon risk assessment, Individualized Quality Control Plans (IQCP). Labs using an EQC protocol for technologies such as the iSTAT, must either revert to the regulatory requirement of running two levels of external controls each day of patient testing, or implement IQCP prior to January 1, 2016.

IQCP makes sense and here is an option for you!
Introducing the IQCP Program that can assist you in developing and implementing IQCP

The IQCP program has numerous benefits, enabling you to:

- Perform a meaningful risk assessment
- Customize the QC plan for each test in its unique environment
- Optimize your current QC/QA processes
- Provide equivalent quality testing to meet the CLIA QC regulations
- Ensure continuous quality patient care

As a COLA member you will receive a 15% discount on the IQCP Implementation Package

ORDER YOUR IQCP IMPLEMENTATION PACKAGE
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Tips in Compliance

Plan of Required Improvement (PRI)

From the first COLA Laboratory to a newly surveyed site, all laboratories must be in compliance with COLA Accreditation Criteria. COLA takes into consideration the effort needed to stay in compliance for every type of laboratory. From a Physician Office Laboratory to a Reference Laboratory each Surveyor is tasked with assessing the laboratory and if necessary, providing a Plan of Required Improvement.

When a laboratory receives a Plan of Required Improvement, it will include the following components: [1]

- Due dates for submission of the agreement and any documentation required.
- A summary showing the total citations, number of repeat citations, and number of citations requiring documentation.
- A Peer Review Comparison showing your laboratory's performance compared to that of other COLA labs having the same annual test volume.
- A listing of the personnel and test systems at the time of the on-site survey.
- A Grouped Citations and Actions Required table. This table lists each citation, and identifies any repeat citation with an asterisk. It includes the reason the surveyor cited the criterion, a list of actions to be taken to address each citation, and if required, a description of the documentation that needs to be submitted to COLA as evidence of correction.

IMPORTANT THINGS TO REMEMBER[2]

If a laboratory is found to be noncompliant with one or more of COLA's criteria for laboratory performance:

- **10 days** after the on-site survey, the laboratory will receive a report of the results in a Plan of Required Improvement (PRI)
- When receiving the PRI, the following **deadlines** must be kept in mind...

  • Signed agreement form to correct all noncompliance must be received by COLA no later than the date indicated in the PRI (**14 days**)

  • Survey documentation, as requested by COLA, must be received by COLA no later than the date indicated in the PRI (**30 days**)

  • Under special consideration, laboratories that require additional documentation may be permitted to submit final documentation no later than the date indicated in your PRI (**60 days**).

Please keep in mind that COLA may have other Requirements that may apply until noncompliance is corrected. Those are highlighted in the Accreditation Manual.[3]

Appeals to Plan of Required Improvement [4]

A laboratory director may appeal a PRI if he or she feels that the laboratory already complies with the criteria cited as noncompliant at the time of survey. The laboratory director should provide invoices, copies of laboratory records, and other documentation supporting the appeal. COLA reviews this information, along with other pertinent material provided by the surveyor. If COLA agrees with the laboratory director, then the PRI, or the specific criteria cited, will be reversed. If COLA still believes the laboratory is not in compliance, then the laboratory is notified that it must still fulfill the PRI as issued.

Taking Corrective Action

Completing the Plan of Required Improvement (PRI)[5]

If the survey results indicate the laboratory is not in compliance with all of the COLA criteria, the laboratory will receive a Plan of Required Improvement (PRI). The PRI contains detailed instructions concerning necessary improvements, documentation required from the laboratory to prove completion of the plan, and whether the laboratory is subject to probation or resurvey.

The Laboratory Responsibilities During the PRI Process

Develop a corrective action plan for each noncompliance.

In each instance where COLA identifies a noncompliance that requires corrective action, the laboratory is expected to take charge and correct the noncompliance following the schedule and guidelines provided by COLA.

Provide COLA with Documentation Showing Proof of Corrective Action.

The laboratory may also be required to provide COLA with timely documentation that demonstrates proof of corrective action – closely following the actions indicated in the Plan of Required Improvement.

Provide Any Needed Training.

The laboratory's corrective action plan should factor in any employee training needs to support your required improvements.

Additional Informatiton.

If the laboratory director agrees to correct noncompliance in a timely manner, the laboratory is approved for accreditation upon providing the signed agreement and any documentation requested. If the noncompliance is of a more serious nature, the laboratory is required to correct them in a more expedient manner and to send COLA additional information documenting actions it has taken to correct the problems. The laboratory may be placed on probation for a specified time period during which additional mentoring by COLA staff may occur. If major noncompliance is found, COLA reserves the right to impose other requirements, such as a resurvey or completion of relevant educational courses at the laboratory's expense. While COLA makes every attempt to contact laboratories, those that fail to respond to COLA correspondence may be denied accreditation.

COLA's goal for all laboratories to have zero citations is attainable. By COLA accredited laboratories taking the necessary time to review the Plan of Required Improvement Letter well in advance of their surveys to ensure that any existing citations have been satisfied, and also to ensure that any potential citations are addressed well in advance, zero citations or at least reducing the number of citations is certainly achievable.

RESOURCES:

1. COLA Accreditation Manual (revised July 2014) p.28
2. COLA Accreditation Manual (revised July 2014) p.29
3. COLA Accreditation Manual (revised July 2014) p.29
4. COLA Accreditation Manual (revised July 2014) p.31
5. COLA Accreditation Manual (revised July 2014) p.28

ANNOUNCING THE CRI® IQCP WORKSHOP SERIES

"Individualized Quality Control for your Laboratory"

Mark your Calendars for Scheduled Dates and Locations

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or call (800) 981-9883

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inSights SPOTLIGHT:
LABORATORY EXCELLENCE AWARD

COLA continues to feature a laboratory that has shown excellence not only in their compliance with accreditation standards, but also overall high quality patient care. COLA Accredited laboratories that meet the Laboratory Excellence Award (LEA) have had zero citations on their survey; no unsuccessful Proficiency Testing (PT) for any regulated analyte/subspecialty/specialty for the last two years and had no substantiated complaints for the past two years.

NOVANT HEALTH ONCOLOGY SPECIALISTS

Winston Salem, NC

Laboratory Director:
Susan Hines, MD

Laboratory Managers:
Laura Burdick, MT (HEW)
Janet Hardy, MT (ASCP)

About the Lab:

Novant Health Oncology Specialists laboratory in Winston Salem serves patients from over 10 counties across the state of North Carolina. It is one of the Novant Health's Medical physician clinics serving the Novant Health Derek L. Davis Cancer Center. In addition to the main location in Winston-Salem at Novant Health Forsyth Medical Center, five other satellite clinics provide care across the state. Dr. Susan Hines, MD serves as the lab director for all Novant Health Oncology Specialists locations.

The Winston-Salem location received the COLA Lab Excellence award last year for the first time. With 14 oncologists on staff, the lab provides critical testing that enables patients to receive chemotherapy with a hope for healing. The dedicated staff in Winston-Salem collects blood from 150 patients every day with 361,964 tests done per year at the Winston-Salem location. Their test menu includes Chemistry, Hematology, Thyroid, PSA, Ferritin, Vitamin B12, PT / INR, and Urinalysis as well as assistance with bone marrow collection.

This recognition for lab excellence meant so much to all of the lab staff. It was a goal that the lab had always dreamed of receiving because it represented their passion for providing truly remarkable patient care and service to the community. With over 86 years of combined experience, Laura Burdick and Janet Hardy not only oversee the quality control and daily operations of this busy lab, but they also work on the bench and supervise the phlebotomy staff and satellite operations. Over the years, each COLA inspection provided education and insight that continuously improved their procedures and quality of testing. The dedication and perseverance paid off and not only did they receive the COLA Lab Excellence Award, but they were also recognized with the ACE award for Lab Excellence in the Novant Health Physician Group.

CONGRATUALTIONS TO THE STAFF AT NOVANT HEALTH ONCOLOGY SPECIALISTS! KEEP UP THE GREAT WORK!!

NEWS RELEASE

COLA RESOURCES, INC. TO SHOWCASE IQCP TOOL AT AACC EXPO

CRI to Demonstrate Customizable IQCP E-Optimizer™ at Clinical Lab Conference

Columbia, MD, July 8, 2014 – The educational subsidiary of COLA, COLA Resources Inc.® (CRI) showcased an innovative, intuitive software program to help laboratories implement emerging quality control guidelines at a press conference at the American Association for Clinical Chemistry (AACC) Annual Meeting and Clinical Laboratory Expo, Tuesday, July 29 at 9:00 a.m. at McCormick Place, Chicago, IL. The press conference was accessible via teleconference. CRI also conducted live demonstrations of the software tool throughout the Expo at Booth #1054.

The new tool, called the **CRI IQCP E-Optimizer™** is designed to help laboratories implement the Centers for Medicare & Medicaid Services' (CMS) new Individualized Quality Control Plan (IQCP) guidelines, scheduled to go into effect January 1, 2016. The E-Optimizer helps labs biopsy their current QC methods; receive customized recommendations on how to align their QC programs with IQCP guidelines; and develop and implement their own individualized test system QC. The program, which can be customized for any test system in a laboratory, including waived, moderate or high complexity tests, allows labs to meet the following key objectives:

- Perform a meaningful Risk Assessment
- Create an economically and clinically beneficial QC Plan customized by test method, utilization, environmental factors, and personnel competency
- Optimize current QC/QA processes
- Adhere to federal, state and accrediting organization requirements
- Ensure continuous quality patient care, with optimal clinical outcomes
- Identify new initiatives and ongoing measures to improve the quality of patient care

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www.criedu.org

"IQCP is a critically important development in quality control in the laboratory, providing a framework for customizing a plan for each laboratory's unique test systems and environment," said Rose Mary Casados, President of CRI. "Because IQCP takes a more comprehensive approach to quality control, CRI developed these educational tools to clearly explain the steps labs need to take to both understand and implement it, which we will showcase at this important lab conference."

Casados said CRI also offers a workbook format tool, the **CRI Implementation Guide**, to guide labs through the implementation of IQCP. The guide also assists laboratorians in developing a Risk Assessment Plan, by using such tools as Process Mapping, Fishbone, and a Risk Identification Table.

She added that AACC Members and Expo attendees are eligible for a $50 discount on purchases of the E-Optimizer, workbook, or an Implementation Package which includes both tools. They should use the Coupon Code "IQCPAACC." The offer is valid until August 31, 2014. For more information, visit http://www.criedu.org/iqcp-implementation-tools/.

About COLA Resources, Inc. (CRI)

CRI is a leader in online continuing education for physicians, laboratory personnel and allied health professionals. CRI offers continuing education through online courses, informational products in both electronic and hard copy form, webinars on cutting-edge technology and regulatory issues, and CRI on-site Symposia for Clinical Laboratories, providing live educational sessions and interactive workshops with leading industry organizations. For more information, visit its website at www.criedu.org or call 1-800-981-9883.

Important Information For You and Your Laboratory Director

EDUCATION STARTS NOW...
PREPARE AS IQCP REPLACES EQC
Register today for this one-day interactive educational workshop on Individualized Quality Control Plan (IQCP).

CRI®'s IQCP Workshop Series comes to Orlando's Buena Vista Palace Hotel & Spa

Prepare to implement the new Centers for Medicare & Medicaid Services (CMS) IQCP Interpretive Quality Control Guidelines.

Date: Wednesday, October 15, 2014
Time: 8:30am – 4:00pm
Location: Buena Vista Palace Hotel & Spa
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Topics include:
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- Developing an Individualized Quality Control Plan

Registration: Symposium Attendees — $249 | Non-Symposium Attendees — $199
Continental breakfast & lunch will be provided.

To register, visit **www.criedu.org** or **www.labuniversity.org** or **call CRI® at 1-800-981-9883.**

COLA Insights Goes Public

Insights is reaching MORE Laboratory Professionals.

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Since it's launch COLA Insights magazine has provided criteria highlights, technical bulletins, and timely topics that address the needs of everyday laboratory personnel. This invaluable resource could only be accessed through COLA's membership portal. Now COLA will re-launch Insights with open access to the public through COLA.org.

In honor of Insights Magazine now being offered to COLA labs and ALL laboratory professionals for the first time online – COLA wants to give advertising vendors two enticing offers*:

1. Take 25% off any size ad in both our September/October and November/December 2014 issues.

2. Get one month free for a digital ad (180 x 150) on the popular COLA AdNetwork which delivers over 75,000 impressions monthly over seven COLA websites.

**This offer is valid for any vendor that does not have an existing contract during September-December 2014.*

Don't wait. These special advertising opportunities are available for a limited time. Contact Jahmai Sharp-Moore at jsharp-moore@cola.org or call 1.800.981.9883 ext. 3735.