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COLA'S

# inSights

INTO

## *IQCP — COLA Criteria & Implementation*

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# FROM THE CHAIR



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

In this issue of Insights, we discuss how COLA laboratories will be affected by the adoption of IQCP as their policy option in place of standard CLIA-required quality control procedures for non-waived testing. In April, 2014 COLA was the first accreditation organization to recognize IQCP as the QC option to replace EQC. As of January 1, 2016, EQC will not be accepted as a QC option.

To ensure proper performance compliance by our laboratories if IQCP is implemented, COLA has developed new IQCP criteria: QC 31.1 – 31.13; these replace EQC criteria: QC 24.1 – QC 24.4.

We begin with an overview of how and why IQCP was developed; the component steps for the development of an IQCP for any test in any laboratory; the need for continuous monitoring to ensure that the effectiveness of the IQCP is maintained; a summary of the new COLA IQCP criteria; and finally, which present quality control criteria are replaced when IQCP is utilized for any test system.

This overview is then followed by a series of focus articles that provide detailed discussions of the steps involved in the implementation IQCP for COLA laboratories, and how this is reflected by changes in compliance requirements.

**Highlight Article #1** discusses the Risk Assessment processes involved in the development of an IQCP, and which new IQCP COLA criteria apply.

**Highlight Article #2** reviews the requirements for the Quality Control Plan developed from the information learned through the Risk Assessment information, and the IQCP criteria that apply.

**Highlight Article #3** reviews the Quality Assessment that must be performed to assure the continuing effectiveness of IQCP in maintaining quality patient care; and the IQCP criteria that apply.

**Highlight Article #4** summarizes all thirteen of the new IQCP criteria as the unified approach by COLA to ensure IQCP has been properly developed, implemented and monitored.

**Highlight Article #5** summarizes which of the present specialty specific QC criteria are replaced by the new IQCP criteria when IQCP is used for any analyte and test system.

On a different note, we also feature a discussion of the *Impact of Urine Drug Screens*. This is a procedure readily performed in all types and sizes of laboratories; but especially in physician office settings. Its simplicity and portability belies its importance and impact, as test results can be used to enhance workplace safety, monitor patients' medication compliance and detect drug abuse. We discuss the reasons for ordering urine drug screens (medical, legal/forensic; employment/workplace; and sports/athletics); factors leading to false positive and false negative test results; and when confirmatory testing is needed. We close with a summary of the benefits and risks involved when evaluating the use of urine drug screen testing.

This issue of Insights provides important information about the impact of adopting the IQCP option for your laboratory, both in terms enabling you to achieve the most effective quality control, and to be in compliance with the new IQCP criteria. In addition, the discussion of urine drug screen testing has shown that this has ramifications beyond diagnostic healthcare, into the legal, forensic and workplace arenas. I hope that you will share this issue with your staff and that this will be a catalyst for further discussions and learning.



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# Risk Assessment Processes and Applicable COLA Criteria

An Individualized Quality Control Plan for a specific test system consists of three components:

- The Risk Assessment
- The Quality Control Plan (QC Plan)
- The Quality Assessment Review – as a component of your (QA) Plan

This article focuses on the Risk Assessment Component, and the COLA IQCP criteria applicable to this section:

## **Risk Assessment:**

**Definition:** this is the means of identifying and evaluating the risk of potential problems or errors that may occur in your testing process.

The testing process encompasses all phases of testing: beginning with the specimen collection (pre analytic) and continues through the analysis of the specimen (analytic) until the final test result is reported (post analytic).

**Applicable Criteria: QC 31.5: Did the Risk Assessment include all three phases of testing (pre-analytic, analytic, and post-analytic) when identifying potential errors?**

The first step in developing your IQCP for a test is to gather as much information as possible about all phases of the testing process. This information will be used to identify and evaluate potential risks (i.e., errors with the potential to cause harm).

These risk assessments must include, at a minimum, an evaluation of the following five components of the testing process:

- Specimens
- Environment
- Reagents
- Test System
- Personnel

The right **specimen** on the right patient is essential. Review instructions provided to patients regarding preparation and test requirements for specimens that they collect themselves.

**Applicable Criteria: QC 31.6 R: Did the Risk Assessment evaluate potential errors related to the specimen?**

*Include consideration of applicable elements such as patient preparation, specimen collection, specimen labeling, specimen storage and transport, specimen processing, and unacceptable specimens.*

Information about the **environment** is also needed where the test system is used.

**Applicable Criteria: QC 31.7 R: Did the Risk Assessment evaluate potential errors related to the environment?**

*Include consideration of applicable elements such as temperature, ventilation, available light, noise and vibration, humidity, altitude, dust, utilities, water quality, and space.*

**Reagents**, including calibrators and controls, must be considered as part of the testing process. Errors that can compromise reagents can occur during shipment, handling and storage and processing.

**Applicable Criteria: QC 31.8 R: Did the Risk Assessment evaluate potential errors related to the reagent(s)?**

*Include consideration of applicable elements such as shipping and receipt, storage conditions, expiration dates, and reagent preparation. This includes controls and calibrators as well as reagents.*

In addition, gather information about the testing process by examining the **test system** (measuring system, instrument or test device). Much of this information is supplied by the manufacturer in the package insert and/or operator's manual. The test system may have safeguards such as lock-out functions and error codes that detect and prevent errors. Consider historical data as well.

**Applicable Criteria: QC 31.9 R: Did the Risk Assessment evaluate potential errors related to the test system?**

*Include consideration of applicable elements such as sampling requirements, clot detection, detection of interfering substances, calibration, mechanical failures, maintenance and function checks, and software.*

Information about the **personnel** performing the test must be examined. Review documentation of training, competency assessment, education and experience.

**Applicable Criteria: QC 31.10 R: Did the Risk Assessment evaluate potential errors related to testing personnel?**

*Include consideration of training, competency, cross-functional responsibilities, and adequacy of staffing.*

**Documentation** of Risk Assessment data and evaluation must be maintained for two years after the date that an IQCP is discontinued, or 10 years after the date that an IQCP is discontinued for Immunohematology tests. The Risk Assessment process must involve the laboratory's own testing personnel.

**Applicable Criteria: QC31.4R: Does the lab have documentation to support the Risk Assessment component of the IQCP?**

*Data that can be used includes, but is not limited to, performance specification studies, historical QC data, previously performed EQC qualifying studies, PT data, and QA documentation. Manufacturer's data may be used but not as the only data for the Risk Assessment. The documentation must demonstrate that a representative sample of the lab's own testing personnel were involved in the risk assessment process.*

Identifying, evaluating, and controlling potential errors that are relevant to your laboratory by implementing targeted quality control measures is the cornerstone of IQCP. What you learn from your risk assessment will be used to develop your individualized quality control plans<sup>2</sup>.

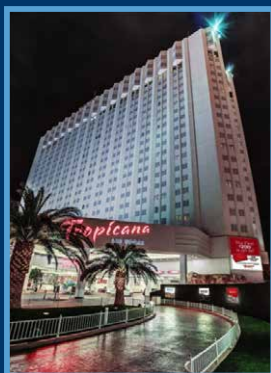
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RESOURCES:

1. IQCP Brochure 13, What is an IQCP? November 2014. What is Risk Assessment? IQCP@cms.hhs.gov.
2. Individualized Quality Control Plan (IQCP) Implementation Guide. What Is IQCP? Pp 11. COLAResources, Inc. 2013.

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# The *Individualized* Quality Control Plan and Applicable COLA Criteria

## Quality Control Plan (QC Plan)

The completion of the Risk Assessment process to identify, evaluate, and control potential errors relevant to your laboratory by the implementation of targeted quality control measures is the cornerstone of IQCP. What you learn from your risk assessment is then used to develop your individualized quality control plans.

A strong, well-documented individualized QC Plan will establish control procedures that reduce the likelihood of providing an inaccurate patient test result in your laboratory. Your QC Plan must at least 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. It's possible that you may find your customized QC Plan will be less than the CLIA control requirements. However, at a minimum, your QC Plan must not be less stringent than the manufacturer's instructions for testing QC. The QC Plan may also describe the use of electronic controls, procedural controls, training and competency assessment and all other QC activities.<sup>1</sup>

### As with traditional QC plans, your QC Plan must:

- Detect immediate errors that occur due to test system failure, adverse environment conditions, and operator performance.
- Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.
- Meet all applicable regulatory requirements. In addition to the federal CLIA regulations, your laboratory may be subject to more stringent requirements such as state laws, Accrediting Organization criteria, or facility/organization Quality Control protocols that must be followed<sup>2</sup>.

A distinguishing characteristic of IQCP is that the QC Plan is developed from a risk assessment that includes steps that your laboratory must take to prevent errors in the pre-and post analytic phases of testing in addition to the analytic phase that is the focus of traditional QC plans.

### **Applicable Criteria: QC 31.11 R: Does the lab's Risk Assessment support the number, type, and frequency of QC testing described in the QC Plan?**

*Your Individualized Quality Control Plan should reflect the steps necessary to reduce the risk of errors identified in the Risk Assessment, and should be aligned with the performance and stability of the test over time, as demonstrated in the data you reviewed as part of the Risk Assessment.*

***The Risk Assessment and resulting QC Plan must address the corresponding eligible COLA criterion that is being replaced by the use of IQCP. (This will be addressed in Highlight Article #5)***

As with all your other quality control plans, monitoring your IQCPs must be part of your laboratory's overall **Quality Assessment Plan**. Conduct a review anytime you discover a problem, but also conduct periodic reviews specifically to evaluate the effectiveness of each of your IQCPs.

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#### RESOURCES:

1. IQCP Brochure 13, What is an IQCP? November 2014. IQCP QC Plan. [IQCP@cms.hhs.gov](mailto:IQCP@cms.hhs.gov).
2. Individualized Quality Control Plan (IQCP) Implementation Guide. Developing a Plan to Minimize Risk. P 44. COLA Resources, Inc. 2013.

# IQCP QA Review and Applicable COLA Criteria

## Quality Assessment (QA)

IQCP is intended to provide effective quality control that ensures accurate and reliable test results. Ensuring effective QC requires ongoing monitoring, corrective actions as needed, and follow up that quality is maintained.

Monitoring your IQCPs must be part of your laboratory's overall Quality Assessment Plan. The concept is the same as the quality assessment reviews that you perform for other elements in your laboratory's operations. Conduct a review anytime you discover a problem, but also conduct periodic reviews specifically to evaluate the effectiveness of each of your IQCPs.

To accomplish this, add regular, documented reviews of each of your IQCPs to your existing Quality Assessment Plan. The monitoring must include, but is not limited to, each required component of IQCP (testing personnel, environment, specimens, reagents, and test system). At regular intervals you should review each of the elements that your plan incorporates to prevent errors and ensure accurate results, including review of:

- QC results and graphs,
- other quality measures you have implemented,
- proficiency testing results,
- incidence of specimen rejection,
- concerns or complaints from providers; and
- any incidents related to this test.<sup>1</sup>

You may also create specific monitors, unique to the test system, that answer how often or how many times (within a time period for example) did a particular error occur? You are not limited to the number of monitors used to verify the continued performance of a testing process. Keep in mind that your QA monitors may indicate a need to reevaluate the effectiveness of your IQCP.<sup>2</sup>

**Applicable Criteria: QC 31.12 R: Has the laboratory included an annual review of all IQCPs in the Quality Assessment Plan?**

*Your lab's IQCPs must be reviewed for effectiveness at least annually. This review should include a review of the PT performance, staff competency, specimen rejection incidents, QA monitors, complaints, and any other data that could serve as an indicator for the effectiveness of the IQCP. The evaluation must include a review of all components reviewed in the Risk Assessment (specimen, testing personnel, environment, reagents, test system), and the QC Plan. It must indicate whether the IQCP has been effective, and if not, what adjustments are necessary to consistently assure quality.*

When the laboratory discovers a testing process failure, the laboratory must conduct an investigation to identify the cause of the failure, its impact on patient care, and make appropriate modifications to their QC Plan, as applicable. The investigation must include documentation of all corrections, corresponding corrective actions for all patients affected by the testing process failure, and evaluation of the effectiveness of the corrective action(s). The laboratory must implement the correction(s) and corresponding corrective action(s) necessary to resolve the failure and reduce the risk of recurrence of the failure in the future. If necessary, the laboratory must update the risk assessment with the new information and modify the QC Plan, as needed.<sup>3</sup>

**Applicable Criteria: QC 31.13 R: Following any quality failures, or when there have been significant changes in any aspect of the original risk assessment, has the laboratory re-evaluated the QC Plan and made adjustments, if necessary?**

*When a quality failure occurs, the laboratory must determine the cause of failure, its impact on patient care, and make any necessary adjustments to the risk assessment.*

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## RESOURCES:

1. IQCP Brochure 13, What is an IQCP? November 2014. IQCP QC Plan. IQCP@cms.hhs.gov.
2. Individualized Quality Control Plan (IQCP) Implementation Guide. Developing a Plan to Minimize Risk. P 44. COLA Resources, Inc. 2013.
3. IQCP Interpretive Guidelines Memorandum Aug. 6, 2013. Attachment #1: Individualized Quality Control Plan: Quality Assessment. IQCP@cms.hhs.gov.

# Summary of New IQCP Criteria

The transition period from EQC to IQCP as an acceptable QC option ends on January 1, 2016. After that date, EQC will no longer be an acceptable QC alternative for COLA laboratories. During this transition period, COLA laboratories using EQC will need to transition away from the EQC protocol and either implement the regulatory QC requirements (typically two levels of external QC each day of patient testing) OR implement IQCP.

COLA has developed new criteria for evaluating a laboratory's IQCP protocol, processes, and implementation; these are under new QC 31 with thirteen subsections (QC 31.1 – QC 31.13). These will permanently replace EQC criteria QC 24 (24.1 – 24.4) on January 1, 2016.

Any laboratory that has already replaced EQC with IQCP will be surveyed utilizing the QC 31 criteria. These are summarized below and grouped by IQCP Process Impact:

## **QC 31 Individualized Quality Control Plan (IQCP) Criteria**

### **General**

#### **QC 31.1 R**

**For any eligible test system with a manufacturer's QC protocol which is less stringent than the CLIA regulatory requirement, has the laboratory developed and implemented an IQCP that adheres to the manufacturer's QC protocol, at a minimum?**

*The IQCP must include the Risk Assessment, the QC Plan, and monitoring the effectiveness as part of the laboratory's QA Plan. If IQCP is not implemented, the default CLIA regulatory requirements must be met.*

#### **QC 31.2 R**

**For Laboratory Developed Tests, if the laboratory has opted to implement IQCP to identify and mitigate errors, are the CLIA regulatory QC requirements still met, at a minimum?**

*COLA encourages the use of IQCP for these tests in order to supplement, rather than replace, the CLIA regulatory QC requirements.*

#### **QC 31.3 R**

**If the lab has implemented IQCP, have all QC Plans been**

**approved, signed and dated by the Laboratory Director prior to implementation?**

### **Risk Assessment**

#### **QC 31.4 R**

**Does the lab have documentation to support the Risk Assessment component of the IQCP?**

*Data that can be used includes, but is not limited to, performance specification studies, historical QC data, previously performed EQC qualifying studies, PT data, and QA documentation.*

*The documentation must demonstrate that a representative sample of the lab's own testing personnel were involved in the risk assessment process.*

#### **QC 31.5 R**

**Did the Risk Assessment include all three phases of testing (pre-analytic, analytic, and post-analytic) when identifying potential errors?**

#### **QC 31.6 R**

**Did the Risk Assessment evaluate potential errors related to the specimen?**

*Include consideration of applicable elements such as patient preparation, specimen collection, specimen labeling, specimen storage and transport, specimen processing, and unacceptable specimens.*

#### **QC 31.7 R**

**Did the Risk Assessment evaluate potential errors related to the environment?**

*Include consideration of applicable elements such as temperature, ventilation, available light, noise and vibration, humidity, altitude, dust, utilities, water quality, and space.*

#### **QC 31.8 R**

**Did the Risk Assessment evaluate potential errors related to the reagent(s)?**

*Include consideration of applicable elements such as shipping and receipt, storage conditions, expiration dates, and reagent*



preparation. This includes controls and calibrators as well as reagents.

#### **QC 31.9 R**

**Did the Risk Assessment evaluate potential errors related to the test system?**

*Include consideration of applicable elements such as sampling requirements, clot detection, detection of interfering substances, calibration, mechanical failures, maintenance and function checks, and software.*

#### **QC 31.10 R**

**Did the Risk Assessment evaluate potential errors related to testing personnel?**

*Include consideration of training, competency, cross-functional responsibilities, and adequacy of staffing.*

### **Quality Control Plan**

#### **QC 31.11 R**

**Does the lab's Risk Assessment support the number, type, and frequency of QC testing described in the QC Plan?**

*The Quality Control Plan should reflect the steps necessary to reduce the risk of errors identified in the Risk Assessment, and should be aligned with the performance and stability of the test over time, as demonstrated in the data you reviewed as part of the Risk Assessment.*

### **Quality Assessment**

#### **QC 31.12 R**

**Has the laboratory included an annual review of all IQCPs in the Quality Assessment Plan?**

*Your lab's IQCPs must be reviewed for effectiveness at least annually. The evaluation must include a review of all components reviewed in the Risk Assessment (specimen, testing personnel, environment, reagents, test system), and the QC Plan. It must indicate whether the IQCP has been effective, and if not, what adjustments are necessary to consistently assure quality.*

#### **QC 31.13 R**

**Following any quality failures, or when there have been**

**significant changes in any aspect of the original risk assessment, has the laboratory re-evaluated the QC Plan and made adjustments, if necessary?**

*When a quality failure occurs, the laboratory must determine the cause of failure, its impact on patient care, and make any necessary adjustments to the risk assessment.*

**Note:** During this transition period, if a laboratory is still following an EQC protocol or is in the process of implementing their IQCP, criteria QC 31.1 will be cited and the laboratory will be required to submit a written statement clarifying their plans to implement IQCP or to revert back to regulatory standards; if the laboratory has documentation that they have begun to develop their IQCP, then criteria QC 31.1 will be cited, but no additional documentation will be needed; if IQCP has been fully implemented, then they will be evaluated for compliance with each of the QC 31 criteria.

# Summary of Present QC Criteria Replaced by IQCP Criteria

COLA QC criteria apply to those tests for which quality control is performed in accordance with CLIA standards, generally at two levels of external quality control daily. When laboratory tests are eligible for IQCP as the QC option, and IQCP is enacted, these quality control criteria no longer apply; instead, compliance is measured in accordance with the new COLA IQCP criteria (under QC 31).

The following table lists standard QC-related COLA criteria that are eligible for replacement by the IQCP option. All other COLA criteria not listed in this table are not eligible for IQCP replacement.

COLA Criteria Grouping	Criteria
Quality Control (QC)	QC 15 QC 17 - 23
Hematology (HE)	HE 3
Coagulation (CO)	CO 3
Chemistry (C)	C 1 C 3 - C 7
Microbiology (M)	M 5 M 8 - M 9
Bacteriology (BA)	BA 3 - BA 7
General Susceptibility (SU)	SU 4
Mycobacteriology (MYCB)	MYCB 1 - MYCB 3
Mycobacteriology	Mycobacteriology
Mycology (MYC)	MYC 1 - MYC 3
Parasitology	PA 3
Virology (VI)	VI 1
Immunohematology (IH)	IH 5 - IH 6 IH 8 - IH 11
Transfusion Services (TS)	TS 24 - TS 25 TS 27 - TS 30

**These COLA Criteria are detailed below and grouped by category**

## Quality Control (QC)

QC 15 E: If you perform quantitative tests, are two different control concentrations performed each day of patient testing?

QC 17 E: If you perform qualitative tests, are positive and negative controls performed each day of patient testing?

QC 18 R: If you perform any direct antigen tests with an extraction phase included, do you check the test system with 2 control materials (including one capable of detecting errors in the extraction process) each day of patient testing?

QC 19 E: If you perform an immunology test which includes titering, is a positive control of known titer or graded reactivity and a negative control run each day a patient test is performed?

QC 20 E: If you use fluorescent and /or immune-histochemical stains, are the stains checked for positive and negative reactivity each time of use?

QC 21 R: Are stains (other than gram or acid-fast stains) checked for positive and negative reactivity (if applicable), and to ensure they provide the expected characteristics on each day of use?

QC 22 E: If you perform a molecular amplification procedure, are two control materials run each day a patient test is performed?

QC 23 E: If you run electrophoresis tests, do you perform at least one control, concurrent with each patient run, which contains all substances being identified or measured?

## Hematology (HE)

HE 3 E: If you perform automated hematology, (CBC's, reticulocyte counts, and/or body fluid cell counts) are a minimum of two levels of commercial control run each day of patient testing?

## Coagulation (CO)

CO 3 E: Are two levels of controls run and documented at least every 8 hours of testing?

## Chemistry (C)

C 1 E: If your blood gas analyzer doesn't verify itself every 30 minutes, is a calibrator or control run and documented with each patient batch?

C 3 E: Is at least one blood gas control run and documented at a minimum every eight hours during each day of testing?

C 4 R: Are a variety of levels of blood gas controls and calibrators (high, low, normal) performed and documented each day of testing?

(THIN LAYER CHROMATOGRAPHY)

C 5 R: If your laboratory performs thin layer chromatography do you spot each plate or card with at least one sample of calibration material which contains all of the drug groups which you report?

C 6 R: If your laboratory performs thin layer chromatography do you run at least one control sample with each plate or card?

C 7 R: If your laboratory performs thin layer chromatography is the control sample used processed through each step of patient testing, including any extractions performed?

## Microbiology (M)

M 5 R: Is each batch or shipment of media checked to show that it:

- Has no visible contamination; AND
- Supports, selects, or inhibits bacterial growth, (as appropriate based on type of media), OR
- Has the biochemical reactivity that is expected?

Documentation available to show that the manufacturer has checked all of these specifications according to the standards of the Clinical Laboratory Standards

M 8 R: Where applicable, are positive, negative, and graded reactivity checked with each batch, lot number and shipment of microbiology reagents, discs, stains, and anti-sera when prepared or opened?

M 9 R: Are positive and negative or graded reactivity checked with each batch, lot number and shipment of identification systems when prepared, received, or when first opened?

## Bacteriology (BA)

BA 3 R: If you perform beta lactamase testing using methods other than Cefinase, do you use control organisms that provide positive and negative reactivity each day of testing and document the results obtained?

BA 4 R: If you perform Gram stains, do you check for positive and negative reactivity with control organisms each week of use and document the results obtained?

BA 5 R: If you use antisera:

BA 5.1: Do you check the antisera for positive and negative reactivity with control organisms with each new batch, lot number and shipment when prepared or opened and document the results obtained?

BA 5.2: Do you check for positive and negative reactivity with control organisms every 6 months and document the results obtained?

BA 6 R: Is susceptibility quality control performed each day of patient testing, or weekly, if the laboratory has met the requirements to qualify for weekly QC?

BA 7 R: Weekly QC option:

Did the laboratory satisfactorily complete & document results of either a 20 or 30 consecutive testing day study prior to instituting weekly QC?

## General Susceptibility (SU)

SU 4 R: Do the laboratory records show that each new batch of media and each new lot and shipment of anti-microbial/anti-fungal drugs (disks) are tested prior to or concurrent with initial use, using appropriate control organisms to ensure appropriate reactivity?

## Mycobacteriology (MYCB)

MYCB 1 R: If you perform an iron uptake test for mycobacteria, are at least one positive and one negative acid-fast organism checked each day of use and the results documented?

MYCB 2 R: Are all reagents and stains used in mycobacteriology testing procedures checked for reactivity

with a positive and negative acid-fast organism each day of use and the results documented?

MYCB 3 E: If you perform anti-mycobacterial susceptibility tests, are all antimicrobial agents checked for appropriate reactivity with a positive control organism each week of use and the results documented?

### **Mycology (MYC)**

MYC 1 R: If you use auxanographic media for nitrate assimilation as part of mycological testing, is the nitrate reagent checked with a peptone control each day of use and the results documented?

MYC 2 R: If lactophenol cotton blue is used for mycological identification, is each batch, lot number, and shipment checked for intended reactivity with a control organism when placed in use and are the results documented?

MYC 3 E: If you perform anti-mycological susceptibility testing, is at least one positive control organism used each day of testing and the results documented?

### **Parasitology (PA)**

PA 3 R: If you use permanent stains for parasite identification, are these stains checked with a fecal control sample containing leukocytes and parasites each month and the results documented?

### **Virology (VI)**

VI 1 E: If you perform viral identification in your laboratory, do you document the use of un-inoculated cells or cell substrate controls cultured simultaneously with patients' specimens as a negative control?

### **Immunohematology (IH)**

IH 5 E: Are ABO antisera checked with a positive control each day of use and are the results documented?

IH 6 E: Are Rh antisera checked with positive and negative controls each day of use and are the results documented?

IH 8 E: Are all other antisera in use checked with positive and negative controls each day of use and are the results documented?

IH 9 E: Are ABO reagent red cells checked with a positive control each day of use and are the results documented?

IH 10 E: Are all antibody screening cells checked with a positive control containing at least one known antibody each day of use and are the results documented?

IH 11 E: Are anti-human globulin (AHG) reagents (Coombs serum) checked with positive and negative controls each day of use and are the results documented?

### **Transfusion Services Quality Control**

TS 24 E: Are ABO antisera checked with a positive control each day of use and are the results documented?

TS 25 E: Are Rh antisera checked with positive and negative controls each day of use and are the results documented?

TS 27 E: Are all other antisera in use checked with positive and negative controls each day of use and are the results documented?

TS 28 E: Is ABO reagent red cells checked with a positive control each day of use and are the results documented?

TS 29 E: Are antibody screening cells checked with a positive control containing at least one known antibody each day of use and are the results documented?

TS 30 E: Are anti-human globulin (AHG) reagents (Coombs serum) checked with positive and negative controls each day of use and are the results documented?



# The Impact of Urine Drug Screens

## Introduction

A drug test is defined as an examination of biologic material to detect the presence of specific drugs and to determine prior drug use.

Urine is the preferred specimen for drug testing primarily because it is non-invasive. Drug levels in blood only reflect the presence of a drug at a given point in time, and levels may be high enough to be detected only for a relatively short period of time. Urine specimens may contain detectable levels of drug over an extended period and at much higher concentrations than in blood. Urine may also contain higher levels of drug metabolites than blood, providing further evidence of drug use.<sup>1</sup>

As a laboratory procedure readily performed in physician office settings, the simplicity of urine drug screening belies its importance and impact, as test results can be used to enhance workplace safety, monitor patients' medication compliance, and detect drug abuse.<sup>2</sup>

It is important to be sure that the drug testing occurs at a reputable and certified laboratory. Any credible drug screening program will involve a two-step process. Initial (immunoassay) and confirmatory (gas chromatography-mass spectrometry [GC-MS]) testing are the methods most commonly utilized to test for drugs. Using a combination of both tests allows a high level of sensitivity and specificity, meaning there is an extremely low chance for false positives or false negatives.

The immunoassay (EMIT, ELISA, and RIA are the most common) is performed first and is often used as a screening method. If the immunoassay is negative, no further action is required, and the results are reported as negative. A "dipstick" drug testing method which provides screening test capabilities to field investigators has been developed as well. The latter is gaining wide use in physician offices due to its simplicity of design and utilization.

If the sample is positive, an additional confirmatory GC-MS analysis is performed on a separate portion of the biological sample. The more specific GC/MS is used as a confirmatory test to identify individual drug substances or metabolites and quantify the amount of the substance. Confirmatory tests, such as GC-MS should be utilized prior to reporting positive

drug test results. False positive samples from the screening test will almost always be negative on the confirmation test. Samples testing positive during both screening and confirmation tests are reported as positive to the entity that ordered the test. Most laboratories save positive samples for some period of months or years in the event of a disputed result or lawsuit.<sup>3</sup>

## Reasons for ordering urine drug screens<sup>4</sup>

### Medical Screening

Medical screening for drugs of abuse is primarily focused on determining what drugs or combinations of drugs a person may have taken so that the person can receive proper treatment. A drug's overall effect on a particular person depends on the response of the person's body to the substance, on the quantity and combination taken, and when it was taken.

### Legal or Forensic Screening

Drug testing for legal purposes primarily aims to detect illegal or banned drug use in a variety of situations. Sample collection procedures for this type of testing are strictly controlled and documented to maintain a legal "chain-of-custody." The donor provides a sample that is closed and secured with a tamperproof seal in his or her presence. Specific chain-of-custody paperwork then accompanies the sample throughout the testing process. Each person who handles and/or tests the sample provides their signature and the reason for the sample transfer. This creates a permanent record of each step of the process.

### Employment or Workplace Drug Screening

Drug testing is often done when applying for employment, especially for positions that may involve federal transportation, airline industries, railways, and other workplaces where public safety is of the utmost importance. However, workplace drug testing is now common in general for many U.S. employers to lessen the impact from drug abuse and lower productivity in the workplace. Workplace drug screening is primarily limited to drugs with the potential for abuse, including some prescription drugs, and alcohol.

Prescription drug abuse has been reported as a growing problem in the U.S. Deaths from prescription painkillers have also quadrupled since 1999, killing more than 16,000 people in the U.S. in 2013. Nearly two million Americans, aged 12 or

older, either abused or were dependent on opioids in 2013.<sup>5</sup>

### Sports/Athletics Screening

While conventional drug testing is performed on competitive athletes, the primary focus is on doping, the use of drugs and/or supplements intended to promote muscle growth and/or to improve strength and endurance. On a local level, sports testing may be limited, but on a national and international level, it has become highly organized.

Screening programs randomly perform out-of-competition drug tests on athletes during the training season to look for anabolic steroids, such as testosterone, that promote increased muscle growth. During competitions, testing is frequently done both randomly and on all winners. Testing includes categories such as stimulants, narcotics, anabolic agents, and peptide hormones.<sup>6</sup>

### A summary of the many reasons that urine drug screens may be ordered:<sup>7</sup>

- Pre-employment
- Suspicion of drug abuse (e.g., unexplained negligence/impairment/behavior)
- Random testing outlined in employment contract
- Military service
- Sports participation
- Legal/criminal (e.g., post-accident, parole, date-rape)
- Drug-therapy compliance monitoring
- Drug abuse rehabilitation monitoring
- Postmortem investigation

Because of the personal, occupational, and legal implications that accompany drug testing, family physicians who perform urine drug screenings must be confident in their ability to interpret screening results and respond appropriately to that interpretation.

Ordering and interpreting urine drug screenings requires an understanding of the test procedure, the detection times for specific drugs, and the common reasons for false-positive and false-negative test results.<sup>8</sup>

The first consideration is the length of time drugs of abuse can be detected in the urine:

Drug/drug class	Detection time
Alcohol	7 to 12 hours
Amphetamine	48 hours
Methamphetamine	48 hours
Barbiturates Short-acting Long-acting	24 hours 3 weeks
Benzodiazepine Short-acting Long-acting	3 days 30 days
Cocaine metabolites	2 to 4 days
Marijuana Single use Moderate use (4x/week) Daily use Long-term heavy smoker	3 days 5 to 7 days 10 to 15 days >30 days
Opiates	
Codeine	48 hours
Heroin (morphine)	2 to 4 days
Hydromorphone	2 to 4 days
Methadone	3 days
Morphine	48 to 72 hours
Oxycodone	2 to 4 days
Propoxyphene	6 to 48 hours
Phencyclidine	8 days

## THE IMPACT OF URINE DRUG SCREENS

CONTINUED FROM PAGE 15

The next consideration is to be aware of the possibilities of false negative and false positive results:

### Possible reasons for false negative results:

False negatives are uncommon but can occur as a result of low drug concentrations in the urine, tampering, and in other situations. Possible reasons for false-negative results include:

- Dilute urine (excess fluid intake, diuretic use, pediatric sample)
- Infrequent drug use
- Prolonged time since last use
- Recent ingestion
- Insufficient quantity ingested
- Metabolic factors
- Inappropriate test used
- Elevated urine lactate
- Tampering:
  - Tetrahydrozoline (eye drops)
  - Bleach
  - Vinegar
  - Soap
  - Ammonia
  - Lemon juice
  - Drain cleaner
  - Table salt

### Possible Reasons for false positive results:

Although immunoassays are very sensitive to the presence of drugs and drug metabolites, specificity and accuracy varies depending on the assay used and the substance for detection. This limitation may result in false-positives from substances cross-reacting with the immunoassay. Many prescription and nonprescription substances have been reported to cross-react with immunoassays and cause false-positives. Most have only been documented in case reports. The frequency of false-positives varies, depending on the specificity of immunoassay used and the substance under detection.

### Reporting The Test Result

A positive initial drug screening means that the person tested has a substance in his or her body that falls into one of the drug classes and is above the established cutoff level. If secondary testing confirms a positive result, it means that the person has indeed taken this drug. In some cases, this result

indicates a window of time in which the person took the substance and its approximate quantity, but in most circumstances, that information is not necessary. Interpretation of when and how much drug was consumed can be challenging because the concentration of many drugs varies, as do people's rates of metabolism.

If testing reveals no drugs, or drugs in amounts below the established cutoffs, then the results are usually reported as "not detected" or "none detected." A negative result does not necessarily mean that the person did not take a drug at some point. The drug may be present but below the established cutoff, the drug may have been already metabolized and eliminated from the body, or the test method does not detect the particular drug present in the sample.

In short, the importance and impact of urine drug screen results on the life of the individual tested requires a heightened awareness of both the strengths and limitations of the methodologies used.<sup>9</sup>

### Advantages of Urine Drug Screens

- Non-invasive
- Ample volume
- Drugs and drug metabolites found in urine are usually stable
- Drugs and their metabolites are often present in higher concentrations in urine than in other biological materials
- Detectable in urine for relatively long period of time
- Presence of metabolites (in addition to parent drug) provides further evidence of drug use
- Readily preserved by refrigeration or freezing
- Analysis relatively simple because of absence of proteins and cellular material in urine
- Wide availability of commercial reagents and analytical systems

### Disadvantages of Urine Drug Screens

- Drug levels in urine do not correlate well with levels in other body fluids
- Drug levels may vary widely depending on fluid intake, voiding pattern, and time lapse since drug intake
- Urine drug excretion continues after physiologic effect of

the drug ceases, resulting in lack of correlation of drug level with intoxication

- May be difficult to obtain specimen if test subject cannot void (catherization?)
- Urine specimens are easily substituted, diluted, or adulterated
- Direct observation may be an invasion of privacy
- Urine may be unstable if not properly handled and stored

### Summary

All positive results on immunoassay are presumptive until confirmed using GC-MS. An extensive medication history including prescription, nonprescription, and herbal medications should be obtained from the patient. Medication histories are important in order to anticipate false-positives as well as differentiate between drugs used for legitimate medical purposes and drugs of abuse. It is important for the ordering physician, law enforcement representative, forensic professional, government entity, insurance agent, employer, and sports organization as well as for the person being tested to understand what exactly is included in the testing, how it is done, and how the results may or may not be interpreted.<sup>10</sup>

### RESOURCES:

1. Urine Drug Testing: Approaches to Screening and Confirmation Testing. Gifford Lum, MD and Barry Mushlin, MA. Laboratory Medicine. June 2004 No.6 V. 35.
2. Drug Information Group. University of Illinois, Chicago College of Pharmacy. Feb. 2011. <http://dig.pharm.uic.edu/faq/2011/Feb/faq1.aspx>
3. Drugs.com. Drug testing FAQs. <http://www.drugs.com/article/drug-testing.html>
4. AACC Lab Tests Online. Drugs of Abuse Testing . 2015 (Last modified Nov 2013). <http://labtestsonline.org/understanding/analytes/drug-abuse/tab/test/>
5. <http://www.cdc.gov/drugoverdose/data/index.html>
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7. Drug Information Group. University of Illinois, Chicago College of Pharmacy. Feb. 2011. <http://dig.pharm.uic.edu/faq/2011/Feb/faq1.aspx>
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9. Urine Drug Testing: Approaches to Screening and Confirmation Testing. Gifford Lum, MD and Barry Mushlin, MA. Laboratory Medicine. June 2004. No.6 V. 35.
10. Drug Information Group. University of Illinois, Chicago College of Pharmacy. Feb. 2011. <http://dig.pharm.uic.edu/faq/2011/Feb/faq1.aspx>.

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# IQCP – COLA Criteria and Implementation

## Introduction

Performing Quality Control (QC) gives healthcare professionals confidence that test results obtained on patient specimens are accurate and reliable. It is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results.

Concepts of what makes for effective quality control have continued to evolve since the original requirements were defined by the Clinical Laboratory Improvement Act of 1988, and became effective in 1992. At that time the minimum requirement for most tests was established as two levels of external control materials each day of patient testing (due to specialty specific requirements, exceptions are made for Coagulation, Arterial Blood Gas studies, and Microbiology). However, CLIA Interpretive Guidelines have always allowed for an alternative to daily external Quality Control requirements as long as “equivalent quality testing” is assured. Since 2004, this alternative has been Equivalent Quality Control (EQC). Even though many laboratories implemented EQC without difficulty, there were a number of potential errors that could lead to inaccurate results that were not detected by the test system's internal controls or by the EQC qualifying studies.

Out of these concerns, and after a summit conference attended by accrediting organizations, industry representatives, professional organizations and the government, the concept of quality control based on Risk Management was developed. CMS named this policy the “Individualized Quality Control Plan” (IQCP).

COLA has officially adopted IQCP as the acceptable QC option to CLIA mandated standards.

The present transition period from using EQC to using IQCP as an acceptable QC option ends on January 1, 2016. After that date, EQC will no longer be the acceptable QC alternative for COLA laboratories. During this transition period, laboratories using EQC will need to transition away from the EQC protocol and either implement the regulatory QC requirements (typically two EQC levels of external QC each day of patient testing for most tests) OR implement IQCP.

## How is IQCP an improvement over traditional QC as an internal monitor for laboratory quality?

IQCP is effective QC: Quality Control is most effective when it

takes into consideration all of the circumstances that are unique to each laboratory. That is exactly what IQCP does, allowing the laboratory to develop a QC plan that is customized for how the test is performed on site while maintaining compliance with the applicable regulations.

An Individualized Quality Control Plan for a specific test system consists of three components:

- The Risk Assessment
- The Quality Control Plan (QC Plan)
- The Quality Assessment Review – as a component of your (QA) Plan

## The Risk Assessment:

This is the means of identifying and evaluating the risk of potential problems or errors that may occur in your testing process. The testing process encompasses all phases of testing beginning with the specimen collection (pre analytic) and continues through the analysis of the specimen (analytic) until the final test result is reported (post analytic).<sup>1</sup>

These risk assessments must include, at a minimum, an evaluation of the following five components of the testing process:

- Specimens
- Environment
- Reagents
- Test System
- Personnel

Identifying, evaluating, and controlling potential errors that are relevant to each laboratory by implementing targeted Quality Control measures is the cornerstone of IQCP.

What you learn from your Risk Assessment will be used to develop your Individualized Quality Control Plans.

## The Quality Control Plan

A strong, well-documented *individualized* QC Plan will establish control procedures that reduce the likelihood of providing an inaccurate patient test result in your laboratory. Your QC Plan must at least include the number, type and frequency of testing, and criteria for acceptable result(s) of the quality control(s). Your lab's own data must support the

rationale for the number, type and frequency of testing. It's possible that you may find your customized QC Plan will be less than the CLIA control requirements. However, at a minimum, your QC Plan must not be less stringent than the manufacturer's instructions for testing QC. The QC Plan may also describe the use of electronic controls, procedural controls, training and competency assessment and all other QC activities.<sup>2</sup>

As with traditional QC plans, your QC Plan must:

- Detect immediate errors that occur due to test system failure, adverse environment conditions, and operator performance.
- Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.
- Meet all applicable regulatory requirements. In addition to the federal CLIA regulations, your laboratory may be subject to more stringent requirements such as state laws, Accrediting Organization criteria, or facility/organization Quality Control protocols that must be followed.<sup>3</sup>

#### **IQCP Evaluation and Monitoring (Quality Assessment)**

Ensuring effective quality control requires ongoing monitoring, corrective actions when needed, and follow up to ensure that quality is maintained. A review should be conducted any time a problem is discovered, or a failure occurs, but annual reviews must be conducted specifically to evaluate each of your IQCPs.

To accomplish this, add regular, documented reviews of each of your IQCPs to your existing Quality Assessment Plan. The monitoring must include, but is not limited to, each required component of IQCP (testing personnel, environment, specimens, reagents, test system, post-analytic (Result Interpretation and Reporting)). At regular intervals review each of the elements that your plan incorporates to prevent errors and ensure accurate results, including reviews of QC results and graphs, other quality measures implemented, proficiency testing results, incidence of specimen rejection, concerns or complaints from providers; and any incidents related to this test.

#### **The New IQCP COLA Criteria**

##### **COLA adopted IQCP in mid-2014 as the acceptable QC option to replace EQC.**

As a result, COLA has developed new accreditation criteria for evaluating a laboratory's IQCP protocol, processes, and implementation. These are under the new QC 31 with thirteen subsections (QC 31.1 – QC 31.13). These will permanently replace EQC criteria QC 24 (24.1 – 24.4) on January 1, 2016.

These criteria are designed to evaluate the development, implementation, and effectiveness of all three components of the IQCP processes. They are thus organized in the same order as the IQCP process:

**Criteria QC 31.1 – QC 31.3** are designed to answer basic questions of whether the laboratory has implemented or plans to implement IQCP, either to replace EQC or as an option to previously performed QC by CLIA standards; and if the Laboratory Director has approved, signed and dated the IQCP Plan prior to implementation.

**Criteria QC 31.4 – QC 31.10** evaluate whether the laboratory, in the performance of the Risk Assessment, has included all five components of each test system under study, over all phases of the testing process, and whether the laboratory testing personnel were directly involved. QC 31.4 specifically requires that the laboratory use its own data.

**Criteria QC 31.11** Requires that the lab's own data must support the risk assessment and the resulting QC Plan.

**Criteria QC 31.12 – QC 31.13** evaluate how well IQCP is monitored as a part of ongoing Quality Assessments; documentation of corrective actions taken when needed, and follow up to ensure continued effectiveness of the IQCP.

#### **Please note:**

##### **Certain analyte specific COLA QC Criteria are replaced when IQCP is utilized:**

Present COLA QC criteria apply to those tests whose quality control is performed in accordance with CLIA standards, generally at two levels of external quality control daily. When laboratory tests are eligible for IQCP as the QC option, and IQCP is enacted, these quality control criteria no longer apply; instead, compliance is measured in accordance with the new

#### COLA IQCP criteria (under QC 31).

The following table lists standard QC-related COLA criteria that are eligible for replacement by the IQCP option. All other COLA criteria not listed in this table are not eligible for IQCP replacement.

COLA Criteria Grouping	Criteria
Quality Control (QC)	QC 15 QC 17 - 23
Hematology (HE)	HE 3
Coagulation (CO)	CO 3
Chemistry (C)	C 1 C 3 - C 7
Microbiology (M)	M 5 M 8 - M 9
Bacteriology (BA)	BA 3 - BA 7
General Susceptibility (SU)	SU 4
Mycobacteriology (MYCB)	MYCB 1 - MYCB 3
Mycobacteriology	Mycobacteriology
Mycology (MYC)	MYC 1 - MYC 3

Parasitology	PA 3
Virology (VI)	VI 1
Immunohematology (IH)	IH 5 - IH 6 IH 8 - IH 11
Transfusion Services (TS)	TS 24 - TS 25 TS 27 - TS 30

Thus the introduction and utilization of IQCP affects your laboratory in many ways, from improving the effectiveness of your quality control through risk identification, evaluation and mitigation, to greater involvement by your testing staff in the evaluation of the testing process, the decisions made as to the level of QC performed, the requirements and standards of the new COLA IQCP criteria.

Additional articles in this edition of Insights discuss the implementation of IQCP, and the application of the new COLA accreditation criteria in greater detail.

#### RESOURCES:

1. IQCP Brochure 13, What is an IQCP? November 2014. What is Risk Assessment? IQCP@cms.hhs.gov.
2. IQCP Brochure 13, What is an IQCP? November 2014. IQCP QC Plan. IQCP@cms.hhs.gov.
3. Individualized Quality Control Plan (IQCP) Implementation Guide. Developing a Plan to Minimize Risk. P 44. COLA Resources, Inc. 2013.

Visit COLA's booth at the upcoming AACC Conference in Atlanta, July 26-30th. We hope to see you there!



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# MARK YOUR CALENDARS

## **The COLA Survey “Sweet Sixteen” Most Frequently Cited Criteria of 2014 – 2015**

This presentation is a discussion of the most frequently cited criteria during surveys of COLA accredited labs during the 2014-2015 period. While this list originated as a “Top Ten” many years ago, the growing specificity of criteria for Laboratory Director, as well as the introduction of new categories, including Waived Testing, has necessitated including additional criteria under each category. In addition, three frequently cited “educational” or “transitional” criteria are discussed, even though their citing does not constitute a deficiency.

**Tuesday, June 23, 2015**  
**2:00 – 3:00pm EST**  
**FREE to COLA LABS**

### **Continuing Education Credit**

1.0 P.A.C.E. Continuing Education Credit will be awarded after completion of the webinar and evaluation.

### **Objectives**

- Identify and summarize the “Sweet Sixteen” most frequently cited COLA criteria;
- Illustrate non-compliant scenarios;
- Formulate the implementation of appropriate corrective actions to achieve compliance;
- Identify the educational and transitional criteria frequently cited, and the response options.

### **Speaker**

#### **Kathy Nuclfora, MPH, MT (ASCP)**

Kathy Nucifora received her Bachelor’s degree in Medical Technology from Ball State University, and her Master of Public Health (MPH) Degree from Wichita State University. She has a wide range of experience managing clinical laboratories, including large and small POLs, and large and small hospital laboratories. She currently serves as Accreditation Division Director at COLA.

### **Webinar Access**

A new version of the recording, with visible slides and answers to all questions, are now available on LabUniveristy.



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## Follow CRI's Pathway to navigating the new IQCP transition period.

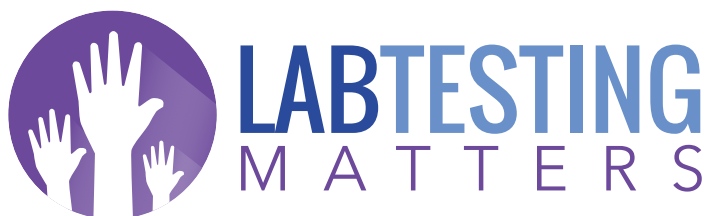
5 Key milestones to transition from EQC to IQCP by end of 2015



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## Stories from the Front Lines: How a lab test literally saved my life

**Name:** Greg Clark, PhD

**Title:** Vice President, National Esoteric Reference Laboratory Services

**Employer:** Pathology Associates Medical Laboratories, Spokane, WA

I studied Chemistry in college and graduate school, and when faced with the choice of pursuing a clinical lab track versus industrial applications, I chose labs because I wanted to make a difference in people's lives. I boarded in Clinical Chemistry, and have been managing labs since 1991. I've always been passionate about what I do, but after an incident in 2004, this commitment became deeply personal.

At the time, I was working for a major reference laboratory in Los Angeles, CA. As employees, we were offered free wellness testing. I didn't think I needed to do it, but a colleague encouraged me. When I received the results, my blood tests showed I was definitely anemic. But since I was otherwise fit, and worked out a lot, I didn't think much about it.

Around that same time, I also donated blood, where once again, I tested low in hemoglobin levels. I was then re-tested and considered healthy enough to donate a unit. Now I had two tests that suggested something was amiss, but again, I didn't act on the results.

A short time later, I experienced a respiratory problem, and went to urgent care. I was eventually

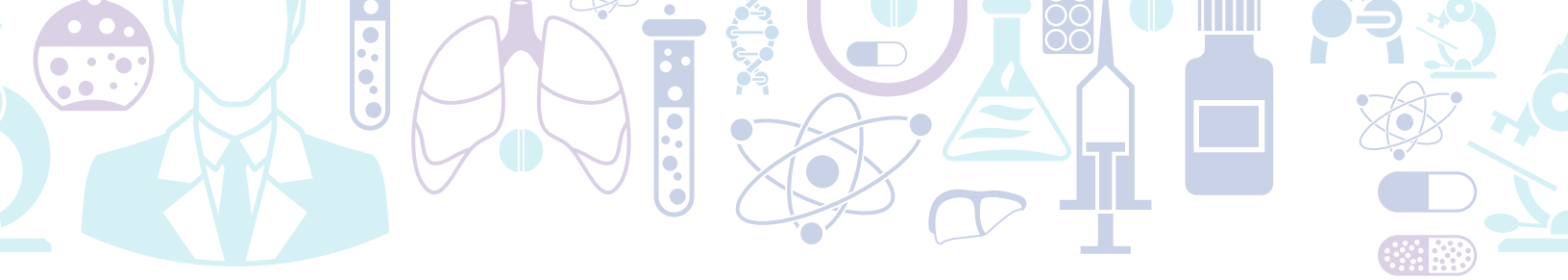
sent home, after they examined me and assured me I didn't have pneumonia.

Two months after that initial wellness exam, I happened to discover a lump near my left clavicle. My doctor immediately sent me for a CT scan, which included a contrast dye. Later that evening, he called to tell me that I had "lit up like a Christmas tree" on the scan, which was suggestive of lymphoma disease. He immediately sent me for a biopsy and, once again, laboratory testing provided an answer: I had mixed cellularity Hodgkin lymphoma disease.

My doctors recommended a course of chemotherapy and radiation. But first, I underwent more lab testing to determine my sensitivity to certain types of chemotherapy. Once that was established, I began chemo treatments twice a month for six months; each time I had a blood test



**Greg Clark, Ph.D**



first to make sure my white blood cell count was sufficiently high to receive treatment. Again, the lab came to my rescue: at one point, the results of my CBC (Complete Blood Count) test revealed that my white blood cell count was too low, and I was prescribed a drug to build up my white blood cells.

And still later, after I had completed my radiation treatments, a lab tested picked up that I had hypothyroidism, for which again I was prescribed treatment.

Thankfully, all my treatments were successful, and I have been clear of disease for 10 years. I continued to work with several clinical laboratories, and now work for a national reference laboratory headquartered in Spokane, Washington that is ranked among the top in the nation. I still love what I do, but it's not as much of an intellectual pursuit anymore, because I often think back to how lab tests literally saved my life – from my first wellness test, and the diagnostic pathology testing that confirmed my lymphoma type, to the chemo sensitivity testing, CBC test, and the hypothyroid diagnosis.

The reality is that lab testing contributes to about 70 percent of all diagnostic decisions. While many of us in the lab profession labor behind the scenes, with our work largely unseen, I can personally attest to its importance.

Visit [LabTestingMatters.org](https://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 Victoria Farrell at [vfarrell@cola.org](mailto:vfarrell@cola.org) or [submit your story online](#).

# *inSights* SPOTLIGHT:

## LABORATORY EXCELLENCE AWARD



*Angela M. Franklin, CPT; Amy C. Reilly, CPT; Ann F. Costello, CLS; Mary A. Agne, CLS; Emily L. Cardey, MS/TS; Not pictured: Sheila A. Hendry, PhD, HCLD (behind the camera); Regina C. MacKay, CLS; Iris J. Underwood, CLS; Rebecca A. Arriola, CPT.*

### THE IGO MEDICAL GROUP LABORATORY

SAN DIEGO, CA

LABORATORY MANAGER:  
SHEILA A. HENDRY, PHD, HCLD

Founded in 1979, IGO Medical Group is one of San Diego's oldest and most respected medical practices. IGO strives to provide high-quality medical care to women and, where appropriate, to their partners, including obstetrical, gynecological, menopausal, and infertility services. We seek to ensure patient comfort, confidentiality, and timely care by offering appropriate and cost-effective ancillary medical services through a quality laboratory, digital mammography, bone densitometry and ultrasound. IGO's goal is to be known for excellence in all aspects of its operations and for outstanding service to our patients and our community.

The IGO Medical Group Laboratory is a COLA accredited and California licensed clinical laboratory facility. Founded in 1982 in order to provide convenience for our patients and rapid turn-around times for hormone results,

it has grown to be a full service laboratory. With everything on-site within our office suite, we can conveniently and confidentially obtain specimens for laboratory testing and we can schedule laboratory test performance to provide results in a timely fashion to facilitate medical decisions and optimize patient care. This is particularly important for our patients undergoing infertility treatment, fine-tuning their hormone therapy for menopause treatment or following patients through a high-risk pregnancy. Test menus include endocrinology, microbiology, hematology, blood chemistry, urinalysis, blood typing, antibody testing and complete semen analysis.

The clinical laboratory is staffed by a group of highly-trained and licensed Clinical Laboratory Scientists with many years of providing precise and accurate laboratory test results with an acute sensitivity to the needs of our patients and physicians. Our Certified Phlebotomists are very skilled at obtaining blood specimens quickly and painlessly; and have a special rapport with patients to help them feel at ease in a

situation that can sometimes be stressful. The andrology section of the IGO Medical Group Laboratory, which is a licensed California Tissue Bank, is staffed by a highly trained Andrologist who has specialized training and years of experience with andrology and assisted reproductive technology procedures. It provides complete andrology services to our patients including complete semen analysis, antisperm antibody testing, sperm washing for intrauterine insemination and therapeutic donor inseminations using cryopreserved semen specimens from an outside commercial sperm bank selected by the patient.

The dedication and professionalism of our staff are the heart of the laboratory which is reflected in the excellent performances during our COLA surveys. Since first applying for accreditation in 1989, our laboratory staff and the physicians it supports have been extremely pleased with the expertise and resources COLA provides both through the inspection process every two years and intermittently via COLAcentral. Thank you COLA.