IQCP for the PAMG-1 Test

It’s Time to Develop an Individualized Quality Control Plan (IQCP), ARE YOU READY?

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SCHOOL OF MEDICINE AND PUBLIC HEALTH
MADISON, WI
Today’s Webinar

IQCP Topics

• Update of the CMS (CLIA) new QC option
• CMS, CAP, TJC and COLA Requirements
• Example of developing an IQCP for the PAMG-1 Assay

Disclosures

• Not a representative of CMS or any professional accrediting agency
• Seminar content reflects my views
• Seminar is sponsored by QIAGEN
Today’s Objectives

- Discuss methods to help you determine whether or not you will need to create an IQCP for your testing systems
- Explain the updated IQCP regulations put forth by CLIA and its accrediting agencies
- Illustrate the creation and documentation all three components of the IQCP: a Risk Assessment, a Quality Control Plan and a Quality Assessment
- Guide you through the process of customizing the IQCP to your lab and to your non-waived testing device(s)
- Review the tools and templates available to you to create an IQCP
A question for you…
Should an IQCP for the PAMG-1 Test be considered?

- PAMG-1 test is classified as CLIA moderately complex (i.e., non-waived)
- Regardless of accreditation all non-waived testing requirements must be met (follow your accreditation agency)
- QC options will change Jan. 1, 2016
So, It’s Time to Consider IQCPs

<table>
<thead>
<tr>
<th>QC Options</th>
<th>Now</th>
<th>Jan. 1, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Default (2 levels external QC/day)</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>EQC (Equivalent QC)</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>IQCP (Individualized QC Plan)</td>
<td>●</td>
<td>●</td>
</tr>
</tbody>
</table>

Does IQCP development leave you feeling like this?
Forget the Panic Button: IQCP seems “Kinder and Gentler”
Quick IQCP Review
Purpose of IQCPs …

- Ensure quality throughout the testing
- Allow “customization” of QC
- Allow use of manufacturers’ built-in quality assessments to meet the required daily QC requirements
  - Avoid the default QC of 2 levels of external QC/test/day of testing
    - Can reduce daily QC to less than default, but never less than what the test manufacturer specifies
New CMS (CLIA) Approach to Quality

August 16, 2013

Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option

Effective Jan. 1, 2016

• Revisions to SOM, Appendix C- Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services (CLIA)

• Removal of references to CLSI standards and guidance documents

• Patient access to test reports, PT changes, D-tags, ABMG

CMS (CLIA) and Accrediting Agencies’ IQCPs

Make sure to follow the requirements appropriate for your test site
IQCP Reminder

**Is it voluntary?**
Yes, UNLESS:
- QC is *less* stringent than CLIA’s (2 external QC/day of testing)
- You want to use manufacturers’ built-in quality assessments to meet daily QC

**What testing is eligible?**
- Non-waived testing
- All specialties *except* pathology and cytology
- Used in states that allow IQCPs

**What is involved?**
- Risk assessment
- Quality control plan
- Quality assessment for ongoing effectiveness
Every patient deserves the GOLD STANDARD...

All Common Checklist
CAP Accreditation Program

College of American Pathologists
325 N. Halsted Street
Chicago, IL 60654-2799
www.cap.org
07.28.2015

http://www.cap.org
CAP: Updated July 2015 Checklists

- All Common Checklist
  - New IQCP section with 5 new requirements
    - COM.50200, .50300, .50400, .50500, .50600

- Other Checklists (e.g., POCT)
  - Revisions to existing QC requirements
  - Provisions for EQC removed

- CAP’s IQCP is more restrictive in some areas
  - Must employ internal QC, e.g., electronic, procedural, or built-in

- Labs can develop their own model for IQCP
Make sure the IQCP is inspection ready!

Inspector Instructions:

- Policies and procedures for the implementation of an IQCP
- Sampling of IQCP records with emphasis on tests with IQCPs implemented in the past two years for the following:
  - Risk assessment including laboratory data and summary of findings
  - Manufacturer’s product inserts and published data
  - Signed quality control plan defining all aspects monitored
  - Ongoing quality assessment monitoring records for QC, instrument/equipment maintenance and function checks, complaints, errors, and corrective actions
  - Reassessment of quality control plan at least annually

If an IQCP is in use, the laboratory is required to complete the following forms provided by the CAP and provide a copy to the inspector:

- List of Individualized Quality Control Plans by Instrument/Device/Test - identifies all tests, instruments and devices using an IQCP
- Individualized Quality Control Plan Summary - provides key information on implementation and monitoring of the IQCP

Use the completed forms to identify an appropriate sampling of records to review.

Sampling of IQCP records to include: 1) a mix of manual and automated tests using an IQCP in the last two years; 2) a mix of tests using an IQCP where there are variations in the testing environment, personnel, multiple testing devices, etc.; and 3) a mix of tests using an IQCP that have had recurring problems with proficiency testing, quality control, instrument failure, errors, or physician complaints.

- What sources of information are used to perform a risk assessment prior to IQCP implementation?
- What steps were taken to ensure that tests already in place with internal quality control processes for daily QC (e.g. equivalent quality control) are in compliance with the IQCP requirements?
- How is the ongoing assessment of the IQCP quality control plan performed?
- How are physician complaints about the validity of test results for tests using an IQCP handled?
- What is the process to review errors for tests using an IQCP?
- Have there been any adverse patient events related to a test using an IQCP?

- Review an IQCP and confirm that all elements of the quality control plan are being monitored
- Review an IQCP that is shared by more than one testing location to verify that the risk assessment included an evaluation of each site or location and that each location is monitored as defined in the IQCP
- Review IQCP risk assessment summary, supporting data and approved quality control plan to confirm that the plan was approved by the laboratory director prior to implementation
- Review ongoing quality assessment data and error/incident logs to confirm that effective corrective actions have been taken

www.cap.org
IQCP worries? Help with what ends and begins

Anne Paxton

July 2015—Technically, it’s true: The Centers for Medicare and Medicaid Services’ new program, the Individualized Quality Control Plan, is a voluntary, alternative option that clinical laboratories can use to customize their QC plans according to test method, patient population, environment, and personnel competency.

For much of the laboratory community, however, “optional” is the last word association they would make with “IQCP.” What many see is an entirely new quality control framework to grapple with every day; a looming cutoff date when the old, reliable system will become extinct; and potentially a major drain on their workday time and energy to cope with unfamiliar concepts of risk assessment.

It’s no wonder that, as CMS’ Jan. 1, 2016 implementation date nears, some laboratory directors are considering an Ativan prescription. But as a service to CAP-accredited labs—and with the aim of keeping panic at bay—the CAP has marshaled an array of resources to ease laboratories’ transition to IQCP. Already available are workbooks, algorithms, templates, lists of frequently asked questions, and other guidance from the CMS, the CAP, the Clinical and Laboratory Standards Institute, and the American Society for Microbiology. Now, the CAP Laboratory Accreditation Program has integrated IQCP requirements into the 2015 edition of the All Common Checklist, which at CAP TODAY press time was scheduled for release at the end of July.

“Four those who are writing individualized plans using IQCP, the Laboratory Accreditation Program wants to provide support, and so we’re offering nuts-and-bolts help,” says checklist commissioner Gerald A. Hoeltge, MD. “The All Common Checklist will have a brand-new section on IQCP that will itemize all the pieces that must be in place, and you can go to the College’s ‘Frequently Asked Questions’ page for a really clear preview of what you’ll need to do.”

There’s really nothing mandatory about IQCP, Dr. Hoeltge emphasizes. “Labs can continue to do the traditional two controls each day of testing. But we’re getting toward the end of the transition period, and more labs are going to be thinking about IQCP and working toward it.”

IQCP’s downside is undeniable. Establishing an IQCP in a laboratory involves a significant amount of work compared with what was required to implement the Equivalent Quality Control (EQC) program as developed by CLSI, says Adrienne Malta, MT(ASCP), MBA, senior manager of inspection services for the College.
Quality Control
Like the CLIA requirements, COLA laboratories must establish a QC program for all tests performed in the lab.

COLA, like CLIA, now allows *Individualized Quality Control Plans (IQCP)*
See QC 31 and associated criteria.

http://www.criedu.org
Prepublication Requirements

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semianual updates to the print manuals (as well as in the online E-dition), accredited organizations and paid subscribers can also view them in the monthly periodical The Joint Commission Perspectives®. To begin your subscription, call 800-746-6578 or visit http://www.jointcommission.org.

Issued June 23, 2015

New and Revised Standards for Individualized Quality Control Plans (IQCP)

Applicable to Laboratories

Effective January 1, 2016

Quality System Assesment for Nonstandard Testing (QSA)

Standard QSA.02.01.01
The laboratory verifies tests, methods, and instruments in order to establish quality control procedures.

Note: This standard also applies to instruments on loan when the original instrument is under repair.

Element of Performance for QSA.02.01.01

A.7. The laboratory’s quality control procedure for each testing system or methodology includes the following:
- The range of quality control values used
- The frequency of quality control testing
- Adherence to the manufacturer’s recommendations
- The predicted instability based on history
- The stability and susceptibility requirements

Note: If the manufacturer’s quality control requirements are absent or less stringent than the requirements outlined in Standard QSA.02.01.01, the laboratory develops an individualized quality control plan (IQCP) to meet the requirements in Standard QSA.02.01.01.

Standard QSA.02.04.01
The laboratory evaluates instrument-based testing with elecrometric or automated systems prior to using them for routine quality control.

Element of Performance for QSA.02.04.01

A.1. When the laboratory evaluates instrument-based testing with elecrometric or automated systems, the test being performed is a moderately complex test in routine chemistry or hematology.

A.2. For each test system, the laboratory evaluates the accuracy, including precision, tracing, and comparison, and determines whether the elecrometric or automated quality controls monitor the entire analytical process on a portion of the analytical process. The results are documented.

Note: This information may also be evaluated in the CQMS and documented in the CQMS.

A.3. The laboratory conducts an evaluation of the elecrometric or automated quality controls by testing internal controls. If the test system with the elecrometric or automated quality control meets the following:
- 10 consecutive days of testing for test systems that monitor the entire analytical process
- 20 consecutive days of testing for test systems that monitor a portion of the analytical process
The evaluation of the elecrometric or automated quality controls is documented.

Note: Consecutive days include only those days when

http://www.jointcommission.org/assets/1/18/LAB_IQCP_2016_Prepub.pdf
The Joint Commission

Accepted: Revisions Related to IQCP Option for Clinical Laboratories

Effective January 1, 2016, The Joint Commission will implement a new voluntary quality control (QC) option for clinical laboratories. The Individualized Quality Control Plan (IQCP) will allow laboratories to customize QC policies and procedures based on a risk assessment of their health care setting, and it will be applicable to all specialties and subspecialties except pathology.

This new option is a result of the Centers for Medicare & Medicaid Services (CMS) January 2014 introduction of IQCP, which will replace the existing Equivalent Quality Control (EQC) plan. The Joint Commission’s initial IQCP initiative will also identify all EQC. In order for The Joint Commission to maintain its deeming authority, its standards and elements of performance (EPs) must meet or exceed CMS’s Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) regulations. Consequently, The Joint Commission has made the following revisions to the “Quality System Assessment for Nonwaived Testing” (QSA) chapter of the Comprehensive Accreditation Manual for Laboratory and Pathology Care Testing (CAMILAB):
- Partial or full EPs specific to IQCP:
  - Standard QSA.02.04.01, EP 1-3:
    - Standard QSA.02.05.01, EPs 1–3:
  - Additions of new and revised EPs (Standard QSA.03.04.01, EP 1-3) that address the IQCP Interpretive Guidelines, including the following:
    - Components of an IQCP
    - Elements to include in a risk assessment and quality assessment
    - Development of a quality control plan
    - Review of the IQCP or changes prior to implementation by the laboratory director

As previously announced in Perspectives (see “Revised Laboratory Requirements: Immunohematology and Microbiology” on pages 4 and 5 of the July issue), The Joint Commission has revised Standard QSA.04.04.01, EP 2 to reflect the January 1, 2015, revision to the CMS CLIA ’88 Interpretive Guidelines that removed all references to the Clinical Laboratory Standards Institute (CLSI) and CLSI documents. With the deletion of the reference to the CLSI document on QC for Commercial Microbial Identification Systems Approved Guidelines (MS-A), laboratories are now required to either comply with all Joint Commission QC requirements or implement IQCP.

There are additional requirements that are eligible for IQCP located in the QSA chapter of the CAMILAB. A list of all IQCP-eligible requirements will be included in Appendix C: IQCP-Eligible Requirements. Laboratories will be able to filter and display only the IQCP-eligible requirements in the Edition.*

IQCP is an optional quality control for clinical laboratories, and it may not be accepted in some states. As IQCP will no longer be an acceptable option for QC compliance beginning January 1, 2016, Joint Commission–accredited laboratories will have the following QC options:

- Follow all Joint Commission quality control requirements as written.
- Implement IQCP as described in Standard QSA.03.04.01, EP 1-3 and Appendix C: IQCP-Eligible Requirements. Laboratories that choose to implement IQCP are still required to follow all other non-IQCP-eligible Joint Commission accreditation requirements.
- With the removal of the streamlined QC option for microbiology, laboratories are required to either comply with all Joint Commission QC requirements or implement IQCP.

The following information about the IQCP model includes selected content from the March 2014 Perspectives.

The Individualized Quality Control Plan (IQCP) will allow laboratories to customize QC policies and procedures based on a risk assessment of their health care setting, and it will be applicable to all specialties and subspecialties except pathology.

The IQCP Model

The IQCP Interpretive Guidelines (available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationCenterDownloads/Survey-and-Cert-Letter-3-S-56.pdf) outline a risk assessment model for establishing the quality control frequency that will replace IQCP. IQCP comprises the following three steps:

Step 1: Risk Assessment
- The risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process. To meet the requirements of IQCP, the risk assessment must cover all three phases of testing: pre-analytic, analytic, and post-analytic and include the following five components:
  1. Specimen
IQCP Goal: Quality Testing Processes for Quality Test Results. Sites need to...

<table>
<thead>
<tr>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify possible sources of error (risk) in the entire testing process</td>
</tr>
<tr>
<td>Determine whether or not <em>current</em> practices and protocols are eliminating these errors</td>
</tr>
<tr>
<td>Decide how to reduce all significant errors identified <em>but not eliminated with current practices</em></td>
</tr>
<tr>
<td>Develop a QCP plan by identifying practices/protocols to address findings and have QCP approved by director</td>
</tr>
<tr>
<td>Assess these practices/protocols for on-going effectiveness</td>
</tr>
</tbody>
</table>
IQCP Development Process
(CLIA, CAP, TJC, COLA)

IQCP based on FACTS
medical, regulatory, device, test setting

Risk Assessment (RA)

Quality Assessment (QA)

Quality Control Plan (QCP)

IQCP
An in-house activity conducted by in-house personnel:

- Review entire testing process to identify potential risks (failures/errors) that impact test result quality. Must at least review:
  - Specimen, testing personnel, environment, reagent, and test system

Think, but don’t over think!!
Clues for Review: Inspector Probes (§493.1256(d)): Specimen*

Has lab identified and evaluated the pre-analytical phase, as applicable, for:

- Patient preparation
- Specimen collection
- Specimen labeling
- Specimen storage, preservation, and stability
- Specimen transportation
- Specimen processing
- Specimen acceptability and rejection
- Specimen referral

Clues for Review: Inspector Probes (§493.1256(d)): Operator *

Has lab assessed risks associated with testing personnel by evaluating:

- Training
- Competency
- Appropriate education and experience qualifications
- Adequate staffing

Has lab evaluated environmental conditions which may affect test system performance including, but not limited to:

- Temperature
- Airflow/ventilation
- Light intensity
- Noise and vibration
- Humidity
- Altitude
- Dust
- Water
- Utilities (electrical failure or supply variance/surge)
- Adequate space

Clues for Review: Inspector Probes (§493.1256(d)): Reagent*

Factors to consider for reagents, QC materials, calibrators, etc., may include, but are not limited to:

- Shipping/Receiving
- Storage condition requirements
- Expiration date (may differ based on storage requirements)
- Preparation

Factors to consider for analyte and test system, may include, but are not limited to:

- Inadequate sampling
- Clot detection capabilities
- Interfering substances detection
- Mechanical/electronic failure
- Optics, pipettes or pipettors, barcode readers
- Failure of system controls and function checks
- Built-in procedural and electronic controls, external or internal liquid QC, temperature monitors and controllers
- Software/Hardware
- Transmission of data to LIA
- Result reporting

IQCPs will be inspected; they are regulatory!

Be ready…

Document (as you go) the collected facts, data [charts, graphs, tables], staff involved, processes, memos, instrument proof sheets, reported studies, etc.
Remember, often…

A “picture” is worth a 1000 words!
Fish Bone Diagram (a tool) to Identify *Potential* Errors/Risks from RA

Errors Impacting Quality

- Samples
- Operators
- Test Environment

Quality Test Results

- Reagents
- Test System
Risk Assessment (RA)
1. Identify risks

Example of common risks in the testing process
IQCP Goal: Quality Test Results 
Eliminate All *Significant* Risks

- ** Samples 
- ** Operators 
- ** Test Environment 

Errors Impacting Quality

Quality Test Results

- ** Risks

- ** Risks

- ** Reagents 
- ** Test System
CDC/CMS Example: Worksheet to Compile RA Process/Findings

<table>
<thead>
<tr>
<th>Laboratory Name</th>
<th>Test System Name</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
</table>
| **Risk Assessment Components** | **What are our possible sources of error?**
What can go wrong? | **Can our identified sources of error be reduced?** | **How can we reduce the identified sources of error?** |
| Gather information, from the manufacturer’s instructions and other resources, on how we should be performing the testing process. | Yes/No Not Applicable (N/A) | Indicate how to reduce possible error sources.
- Internal controls
- Actions taken by laboratory
- Safeguards in the test system or laboratory practices |
| **SPECIMEN** | | | |

Another Example: To Compile RA Process/findings

<table>
<thead>
<tr>
<th>Risk Assessment Component</th>
<th>Potential failure/error</th>
<th>Potential Cause</th>
<th>Mitigated/Detected? Yes/no</th>
<th>For yes, How?</th>
<th>Changes needed to detect/eliminate unmitigated failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test System</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operator</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Environment</td>
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</tr>
<tr>
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<td></td>
</tr>
</tbody>
</table>
# PAMG-1 Test - Worksheet to Document RA Process/Findings*

<table>
<thead>
<tr>
<th>Source of Error</th>
<th>Potential Failure</th>
<th>Pre-Analytical, Analytical, or Post-Analytical</th>
<th>Existing Standards/Documentation Addressing Source of Error</th>
<th>Severity</th>
<th>Probability</th>
<th>Risk Index Before</th>
<th>Assessment of Residual Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Test is performed in incorrect patient population</td>
<td>False result may occur if test is run in women who are not complaining of signs or symptoms of ROM</td>
<td>Pre-Analytical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>Vaginal sample is taken 12 hours or later after rupture</td>
<td>False negative result may occur if sample is taken 12 hours or later after rupture due to obstruction of rupture by fetus or necrotic of amniotic sac</td>
<td>Pre-Analytical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Swab is inserted into vagina for less than 1 minute</td>
<td>False result may occur if sample collection swab is placed in vagina for less than one minute</td>
<td>Pre-Analytical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>Swab is rotated in test vial solvent for less than 1 minute</td>
<td>False result may occur if sample collection swab is rotated in the solvent solution for less than one minute</td>
<td>Pre-Analytical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5</td>
<td>Specimen is applied to test strip incorrectly</td>
<td>False result may occur if specimen is incorrectly applied to test strip (e.g., poured onto sample pad)</td>
<td>Pre-Analytical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.6</td>
<td>Sample is collected earlier than 6 hours after vaginal disinfectants or medications were removed</td>
<td>False results may occur if vaginal disinfectants or medications were applied less than 6 hours before sample collection</td>
<td>Pre-Analytical</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>1.7</td>
<td>Sample is collected in presence of menstruation, anti-fungal creams or suppositories, K-Y Jelly, Monistat, Baby Powder (Fash and Telco), Rainelle, or Baby Oil</td>
<td>False results may occur if sample is collected in presence of menstruation, anti-fungal creams or suppositories, K-Y Jelly, Monistat, Baby Powder (Fash and Telco), Rainelle, or Baby Oil</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td>Incorrect collection swab is used</td>
<td>Test is swab-specific. Use of different swab from same manufacturer, may result in incorrect results.</td>
<td>Pre-Analytical</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>1.9</td>
<td>Test is run more than 30 minutes after sample collection</td>
<td>False result may be reported if user waits more than 30 minutes to run test after sample has been collected and diluted</td>
<td>Pre-Analytical</td>
<td></td>
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*Available from AmniSure, a QIAGEN Company; www.whitehat.com.com/amnisure
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<tr>
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# PAMG-1 Test - Worksheet to Document RA Process/Findings: Specimen

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</tbody>
</table>
## PAMG-1 Test - Worksheet to Document RA Process/Findings*: Operator

| Source of Error | Potential Failure | Pre-Analytical, Analytical, or Post-Analytical | Existing Standard Documentation Addressing Source of Error | Severity | Probability | Risk Index Before | Assessment of Residual Risks | Solutions to Minimize Residual Risks | Risk Index After |
|-----------------|-------------------|-----------------------------------------------|----------------------------------------------------------|----------|-------------|------------------|--------------------------|-----------------------------------|----------------|---|
| 5.1             | User tries to interpret test result quantitatively |  |  |  |  |  |  |  |  |  |
| 5.2             | User inserts test strip incorrectly (upside down) or insufficiently (strip doesn’t touch solvent) |  |  |  |  |  |  |  |  |  |
| 5.3             | Results are misinterpreted |  |  |  |  |  |  |  |  |  |
| 5.4             | Results are reported incorrectly |  |  |  |  |  |  |  |  |  |

* Available from AmniSure, a QIAGEN Company
PAMG-1 Test - Worksheet for RA Process/Findings*:
Environment, Reagents, Test System

<table>
<thead>
<tr>
<th>Source of Error</th>
<th>Potential Failure</th>
<th>Pre-Analytical, Analytical, or Post-Analytical</th>
<th>Existing Standard Documentation Addressing Source of Error</th>
<th>Severity</th>
<th>Probability</th>
<th>Risk Index Before</th>
<th>Assessment of Residual Risks</th>
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</thead>
<tbody>
<tr>
<td><strong>2.0 ENVIRONMENT</strong></td>
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<tr>
<td>2.1</td>
<td>Test kits are exposed to excessively high or low temperatures</td>
<td>Test kits may not function as expected if exposed to excessively high or low temperatures</td>
<td>Pre-Analytical</td>
<td></td>
<td></td>
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<tr>
<td>2.2</td>
<td>External controls are exposed to excessively high or low temperatures</td>
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<tr>
<td>2.4</td>
<td>Sterile swab touches something prior to sample collection</td>
<td>Prior exposure to other environmental factors may contaminate the swab and prevent proper sample collection</td>
<td>Pre-Analytical</td>
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<tr>
<td><strong>3.0 REAGENTS</strong></td>
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<tr>
<td>3.1</td>
<td>Swab is washed in incorrect solvent</td>
<td>Test may report false results if any solvent is used in place of provided solvent in test kit</td>
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<tr>
<td><strong>4.0 TEST SYSTEM</strong></td>
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</tr>
<tr>
<td>4.1</td>
<td>Test strip is exposed to excessive moisture</td>
<td>Test may not function properly if test strip is exposed to moisture outside testing procedure</td>
<td>Pre-Analytical</td>
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<tr>
<td>4.2</td>
<td>Accidental mechanical damage to the test strip</td>
<td>Accidentally damaged test strip may become dysfunctional</td>
<td>Pre-Analytical</td>
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</tr>
<tr>
<td>4.3</td>
<td>Test strip is not removed from solvent solution by 10 minutes</td>
<td>An incorrect result may occur if test strip is not removed from solvent solution by 10 minutes after inserting strip into solvent well</td>
<td>Analytical</td>
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</tr>
<tr>
<td>4.4</td>
<td>Test system is damaged during manufacture or delivery of test kits</td>
<td>Test may report invalid or false results if components of test system are damaged during production or delivery</td>
<td>Pre-Analytical</td>
<td></td>
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</tbody>
</table>

* Available from AmniSure, a QIAGEN Company
## Document changes*

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<th>Solutions to Minimize Residual Risks</th>
<th>Risk Index After</th>
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*Available from AmniSure, a QIAGEN Company
Are Identified Errors/Risks Eliminated?

- Preanalytical
- Analytical
- Postanalytical

Analyze your instrument/manufacturer‘s information
  - Requires in-depth analysis of requirements and features

Review site’s SOPs for adequacy and adherence

Determine if training and competency assessment are adequate

Document your actions as you go!
Review the Performance Data Collected on the Device

- In-house collected method performance data
  - Performance specification verification
    ✓ Accuracy
    ✓ Precision
    ✓ Reportable range
  - QC
  - Proficiency testing
  - EQC evaluation data

- Quality assessment information
  - QA Monitor data
  - Complaints
  - Corrective actions
Review Device’s Features
Some Considerations

- Operator ID lockout?
- System controls?
- Function checks?
- Reagent controls?
  - Reagent dating check
  - Built-in internal, procedural, and/or electronic controls
  - External or internal liquid QC (frequency – discrete or continuous)
- Error detection and elimination?
  - Systematic and/or transient error detection
  - Corrective actions initiated automatically based upon error
  - Confirmation of error mitigation prior to sample testing
- Documentation/report generation?
Review Device’s Features for Post-analytical Risks

Some Considerations

• Positive Patient Identification?
• Interface mitigation features?
• Sample result range alerts?
• Patient History?
• Post-analytical reports?
  ✓ Sample handling → monitor competency
  ✓ Turn-around time
  ✓ Exception → monitor sample integrity
  ✓ Notification → monitor doctor receipt
What about “Leftover” Identified Risks?

“Turkey again, how big was that flaming bird?”
“Leftover,” Residual, Identified Risks?

For those identified in the RA, but NOT detected or eliminated with *current* practices and testing device features—

determine which are *significant*

*but how?*
Identification of significant risks?

Bottom line
It is a judgment!

You decide how to judge!
One Example: RM table to judge significance of leftover identified risks*

- For each leftover (residual) risk, determine the impact of an incorrect, delayed or no result due to the occurrence of the risk
  - Assess the probability of harm from risk
    - Frequent to improbable
  - Assess the severity of harm
    - Negligible to catastrophic
- Significance depends on the combination of the probability of harm and severity

Definitions for Probability of Harm and Severity of Harm*

- Assess the probability of harm from risk

  - Frequent = once/week
  - Probable = once/month
  - Occasional = once/year
  - Remote = once every few years
  - Inconceivable = once in the life of the measuring system

- Assess the severity of harm

  - Negligible = inconvenience or temporary discomfort
  - Minor = temporary injury or impairment not requiring professional medical intervention
  - Serious = injury or impairment requiring professional medical intervention
  - Critical = permanent impairment or life-threatening injury
  - Catastrophic = results in patient death

Risk management table to judge significance of residual risk*

![Risk Matrix Table]

*Available from AmniSure, A QIAGEN Company
Identification of significant risks?

You decide how to judge!
Modify practices to accommodate significant, unmitigated risks

For those risks identified as significant:

• Decide how to detect/eliminate the residual failure/error
• Modify and/or add additional policies and practices
• Modify training and competency assessment activities to accommodate changes

• Make sure to document the modifications/changes
Collect FACTS
medical, regulatory, device, test setting

Risk Assessment (RA)

Quality Assessment (QA)

Quality Control Plan (QCP)

IQCP
CMS §493.1256d: Quality Control Plan

- Documented strategy that is device and site specific for (analytical) quality test results
  - Practices, resources and procedures to control quality
    - Ensures accuracy/reliability and appropriate quality for patient care
    - Provides for immediate error detection due to:
      - Test system failure, adverse environment conditions, operator performance
    - Monitors performance accuracy and precision influenced by changes in test system, environment, and operators

CMS says the QCP...

**Must** at least include the number, type, frequency of testing and criteria for acceptable result(s) of the quality control(s).

**Note:** ...labs are **not** permitted to establish QC procedures that are less stringent than those specified by the manufacturer...

If indicated by...the evaluation of the RA, the QCP **may** also include:

- Electronic controls
- Procedural controls
- Training and competency assessment
- Equipment maintenance, calibrations
- Other specified quality control activities
Quality Control Plan (QCP)

CMS Inspector Probes: QCP

● Does the lab have a written QCP for each test system, as applicable?

● Does the QCP specify:
  ○ Number and type of controls?
  ○ Frequency of testing?
  ○ Criteria for acceptable results?

● Does the QCP require the lab to perform QC as specified by manufacturer instructions?
  ○ Remember, labs can always do more, but never less

● Is there documented evidence of lab director approval of the QCP before it was put into use?
CAP Requirements for the QCP

Quality Control Plan Elements – COM.50500

COM.50500  Quality Control Plan Elements  Phase II

The individualized quality control plan must define all aspects monitored based on the potential errors identified during the risk assessment, including the following parameters as applicable:

- The number, type (external and internal quality control systems), and frequency of quality control
- Criteria for acceptable performance
- Monitoring of the testing environment and reagents
- Specimen quality
- Instrument calibration, maintenance, and function checks
- Training and competency of testing personnel
- Provisions for multiple identical devices and variation for uses covered under one IQCP
## Example CMS QCP

**Laboratory Director’s Approval (signature) is mandatory**

---

<table>
<thead>
<tr>
<th>1 Type of Quality Control</th>
<th>2 Frequency</th>
<th>3 Criteria for Acceptability (Range of Acceptable Values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature Checks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Room</td>
<td>Record room temperature daily, in the morning and afternoon. Record refrigerator and freezer each day of patient testing.</td>
<td></td>
</tr>
<tr>
<td>Refrigerator</td>
<td></td>
<td>20°C – 25°C (Room) 2°C – 8°C (Refrigerator) -10°C – -20°C (Freezer) Recorded on temperature log sheets</td>
</tr>
<tr>
<td>Freezer A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verify specimen collection tubes for acceptability upon receipt in the laboratory.</td>
<td>With each specimen</td>
<td>Refer to Specimen Rejection Policy and record all improperly collected tubes on specimen rejection log sheet.</td>
</tr>
<tr>
<td>Verify specimen collection time and time received by the laboratory.</td>
<td>With each specimen</td>
<td>If the time lapse for specimen collection and receipt is greater than 60 minutes, aliquot and store according to manufacturer’s instructions (2°C – 8°C for 48 hrs or freeze at -10°C up to 5 weeks).</td>
</tr>
<tr>
<td>Internal Quality Control</td>
<td>Performed with each reagent disc.</td>
<td>Must be documented as acceptable on quality control log sheet prior to reporting results.</td>
</tr>
<tr>
<td>External Quality Control</td>
<td>Assay normal and abnormal quality control every 30 days or the first day of patient testing each month. In addition to the above, external quality control will be run when:</td>
<td></td>
</tr>
<tr>
<td>Normal value</td>
<td>laboratory conditions have changed significantly</td>
<td></td>
</tr>
<tr>
<td>Abnormal value</td>
<td>training or retraining of personnel is indicated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>test results do not match patient symptoms or clinical findings</td>
<td>Acceptable range printed in the manufacturer’s package insert. Results must be recorded on quality control log sheet prior to reporting results.</td>
</tr>
<tr>
<td>Reagent Disc Storage</td>
<td>With each reagent disc</td>
<td>Document date and time on reagent discs when removed from refrigerator. Do not use reagent discs that are at room temperature beyond 48 hours.</td>
</tr>
<tr>
<td>Training</td>
<td>With each new testing personnel and when indicated.</td>
<td>Successful demonstration of test performance. Document training activities.</td>
</tr>
<tr>
<td>Competency Assessment</td>
<td>Six months and one year after initial training, annually thereafter.</td>
<td>All testing personnel must successfully meet all six CLIA elements for competency assessment.</td>
</tr>
</tbody>
</table>

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Laboratory Director’s Signature ____________________________  
Date

---

Collect FACTS
medical, regulatory, device, test setting

Risk Assessment (RA)

Quality Assessment (QA)

Quality Control Plan (QCP)

IQCP
Quality Assessment: Is the QCP/IQCP effective?

- **RISK ASSESSMENT**: What can go wrong?
- **QUALITY ASSESSMENT**: Is it working?
- **QUALITY CONTROL PLAN**: How do we prevent or detect?

**Plan-Do-Check-Act for Continuous Quality Improvement (CQI)**

- **Plan**
- **Do**
- **Check**
- **Act**

**QA is nothing new**

- Implement the PLAN
- Monitor, verify and improve the PLAN, when needed

CMS (CLIA): Does your QA?

- **Outline** the QA practices for your laboratory?
- **Monitor** continuously for effectiveness?
- **Revise** policies and procedures necessary to prevent recurrence of problems?
- **Discuss** QA reviews with appropriate staff?
- **Document** all QA activities?

CMS suggests useful documents for Quality Assessment

- QC review and PT performance
- Patient results review
- Specimen rejection logs
- Failure investigations
  - Corrective actions, reagent storage records, etc.
- Turnaround time reports
- Complaint logs
- Competency assessment records
Additional “tools” for QA

- Variance Forms,
- Quality Indicators,
- Corrected-Amended Reports (accept/reject feature, flags),
- Corrective action reports (trend “problems”),
- Clinician feedback

Problems?

QA leads to solutions
**OPTIMAL QA WORKSHEET**

Take your identified sources of error from the "Record Your Quality Assessment Questions/Findings" section, and follow the steps taken by Kim to complete your laboratory's QCP worksheet below.

Laboratory Name ___________________________ Test System Name ________________________

<table>
<thead>
<tr>
<th>QA ACTIVITY (TO MONITOR)</th>
<th>FREQUENCY</th>
<th>ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)</th>
<th>CORRECTIVE ACTION (WHEN INDICATED)</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>
1. Review all temperature logs monthly for room, refrigerator, and freezer to ensure temperatures were monitored according to the QCP, and appropriate corrective action(s) were taken for any temperatures that were out of range.

2. Review Specimen Receipt Log weekly for any unacceptable conditions, i.e. rejected samples, to ensure appropriate action(s) were taken. If the number of unacceptable specimens or occurrences exceeds a threshold established by the laboratory, conduct training, or another activity and monitor the effectiveness of the corrective action.

3. Review manufacturer’s instructions with each new lot/shipment of reagent discs or software change. Ensure changes are incorporated into the standard operating procedures as well as monitor any quality control problems found regarding lot-to-lot variability.

4. Review Internal QC Logs monthly to ensure appropriate corrective action(s) were taken for any unacceptable values.

5. Update policy and procedures to outline steps for verbal reporting of patient test results.

6. Update policy and procedures for competency assessment and review personnel records/documentation to ensure competency assessments meet the CLIA required elements.

7. Review scheduled maintenance records/documentation for completeness for the test system(s) per laboratory policies and procedures.

Laboratory Director Signature  ________________________________
Dr. Martin 
Date ________________  mm/dd/yyyy

Finally, Putting “Everything” Together

Collect FACTS
medical, regulatory, device, test setting

Risk Assessment (RA)

Quality Assessment (QA)

Quality Control Plan (QCP)

IQCP
Important Points
Keep these points in mind when developing an IQCP:

✓ The IQCP is unique to your laboratory and is customized for your laboratory’s specific testing considerations.

✓ The risk assessment must include the entire testing process and address all five components: specimen, test system, reagents, environment and testing personnel.

✓ The risk assessment should be updated to include all risk identified in your QA, as some risk originally identified may no longer apply.

✓ The QCP should include the number, type and frequency of testing control materials.

✓ The IQCP should include all activities performed to reduce your risk of failures and errors.

✓ The entire testing process continually evolves and the IQCP will need to be reviewed periodically to identify new sources of errors or failures.

✓ The QCP must be reviewed, approved, and signed by the Laboratory Director.
Put the IQCP Together

- Keep it simple
- Impress the inspector
  - Show all the good work that was done
  - It is essential for inspector “buy-in”
- NO official format
  - Document as appropriate for the situation
Pull it all together!

- Lists, Tables
- Process Flow/Contingency diagrams
- Fishbone diagrams
- Potential Problem Analysis (PPA)
- Process decision program charts
- Word/Excel documents

IQCP: No “wrong” way, if individualized; RA covers all 5 areas; pre-analytical, analytical, and post-analytical phases are evaluated; has supporting documentation; and approved by Medical Director
CONGRATULATIONS!!!

You have completed a Risk Assessment, created a Quality Control Plan and performed a Quality Assessment for the test system being evaluated for an IQCP!!

Putting the IQCP together

Keep it “short” – 1 – 2 pages: (think executive summary)

• Include specifics - testing device/analytes, test site’s name and address, effective date, CLIA number, director, and any other relevant information
• Summarize the RA process - steps, staff, information collected, etc.
• Summarize changes in practice(s) for all 3 phases of testing
• Identify location of supporting documentation/data, SOPs, etc.
• Specify in QCP - at least the CMS mandates for analytical QC
• Include QA approach - monitors, frequency, follow-up, inclusion into lab’s QA plan

Have and show director’s approval of the process and plan

Keep just like all other lab documents (2 years after QCP is discontinued)
Whatever Approach: Make sure… IQCP is controlled, Ready for inspection, Includes all the “right” stuff -- RA, QCP, QA, & signature, And “others” know where it is!
Quality Processes for Quality Test Results

IQCPs Matters!
References

- http://www.jointcommission.org/assets/1/23/Lab_Focus_Two_2015.pdf
- Email IQCP@cms.hhs.gov for questions relating to IQCPs
- CLSI FAQ Sources of Failure Template (Question #12) http://clsi.org/edu/workshops/ep23qa/
- http://www.jointcommission.org/patient_safety_systems_chapter_for_the_hospital_program/
- http://www.cap.org/web/home/lab/eAlerts/eAlert?contentID=11076452&_afrLoop=618964995331847%40%3F_afrLo
Thank you