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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-15-39-CLIA

DATE: **May 15, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Release of the Individualized Quality Control Plan (IQCP) Workbook

Memorandum Summary

The Centers for Medicare & Medicaid Services (CMS) announces the release of Clinical Laboratory Improvement Amendment's (CLIA) Workbook, co-authored with Centers for Disease Control and Prevention (CDC): **IQCP, Individualized Quality Control Plan, Developing an IQCP, A Step-by-Step Guide.**

Introduction

This workbook is designed to assist laboratories in developing an IQCP for one or more test systems. Using an example scenario, the workbook serves as a guide through a step-by-step process to develop an IQCP that can be sustained and modified, as needed, over time. Laboratory staff will evaluate current quality activities and develop an IQCP worksheet which, when completed, can serve as the laboratory's IQCP document.

The workbook will be located on the CLIA website at http://www.cms.gov/CLIA/. State and Regional CLIA surveyors are requested to direct laboratories to the CLIA IQCP Workbook website upon request.

Workbook Highlights

- This educational workbook is a guide that provides instruction and templates to create an IQCP.
- A scenario is included that assists the reader with his/her decision making process to assess risks, develop a quality control plan and document quality assessment activities.
- Blank Worksheet templates are available for the reader to use as a tool and documentation of the IQCP process.

- Laboratories are not required to use the workbook to implement IQCP. The approach outlined in this workbook is not mandatory or the only format for documentation, but is one example that can be used. The clinical laboratory is free to develop its own format to meet individualized needs.

- At the completion of this workbook, the laboratory will have performed a Risk Assessment (RA), created a Quality Control Plan (QCP), and conducted a Quality Assessment for the test system being evaluated for an IQCP.

- This workbook is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations, and rulings. For more information, you may access the regulations on the internet at http://www.cdc.gov/clia/ .

Contact: If you have any questions regarding this memo, please direct them to the IQCP mailbox at IQCP@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachment:
IQCP Individualized Quality Control Plan, Developing an IQCP, A Step-by-Step Guide

cc: Survey and Certification Regional Office Management
Regional Office CLIA Surveyors

IQCP

INDIVIDUALIZED QUALITY CONTROL PLAN

DEVELOPING AN IQCP

A STEP-BY-STEP GUIDE

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

U.S. Department of Health and Human Services

INTRODUCTION

OVERVIEW

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a laboratory to have quality control (QC) procedures to monitor the accuracy and precision of the complete testing process. A QC option is now available that provides you the opportunity to tailor an individualized quality control plan (IQCP) for your unique testing environment and your patients. The IQCP option offers your laboratory flexibility for meeting regulatory QC requirements appropriate for the testing you perform and when you add a new test.

IQCP is an all-inclusive approach to assuring quality. It includes many practices that your laboratory already uses to ensure quality testing beyond requiring that a certain number of QC materials be tested at a designated frequency. IQCP can be applied to all nonwaived testing performed, including existing and new test systems. All CLIA specialties and subspecialites except Pathology are eligible for IQCP.

Adoption of an IQCP will not necessarily reduce your QC testing practices. It will allow you to develop customized QC for your laboratory specific to specimens you test, your test system, reagents, environment, and testing personnel.

Prior to going through this workbook, you may find it beneficial to review CLIA brochures #11, 12, and 13 developed by The Centers for Medicare & Medicaid Services (CMS) for a general overview of IQCP.
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

PURPOSE

This workbook is designed to assist in developing an IQCP for one or more test systems. Using an example scenario, the workbook will guide you through a step-by-step process to develop an IQCP that can be sustained and modified, as needed, over time. You will evaluate your current quality activities and develop an IQCP worksheet which, when completed, can serve as your IQCP document. The approach outlined in this workbook is not mandatory or the only format for documentation, but is one example that can be used. You are free to develop your own format that meets the needs of your laboratory.

At the completion of this workbook you will have performed a Risk Assessment, created a Quality Control Plan, and conducted a Quality Assessment for the test system being evaluated for an IQCP.

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DISCLAIMER:

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WHY DO AN IQCP?

An IQCP offers flexibility in achieving QC compliance and allows you to:

- ✓ Customize a QC Plan for each nonwaived test in its unique environment
- ✓ Optimize the use of electronic/integrated controls
- ✓ Adapt testing practices for advances in technology
- ✓ Incorporate other sources of quality information into the QC Plan
- ✓ Strengthen partnerships with manufacturers
- ✓ Formalize the risk management data already maintained within the laboratory
- ✓ Provide equivalent quality testing to meet the CLIA QC regulations

The IQCP approach is voluntary. If you do not choose to adopt an IQCP, your laboratory must test two levels of external controls on each test system for each day of testing and follow all specialty/subspecialty requirements in the CLIA regulations for nonwaived tests.

WHAT ARE THE 3 STEPS OF THE IQCP?

The IQCP process includes: Risk Assessment, Quality Control Plan (QCP), and Quality Assessment (QA). An IQCP must address the potential failures and errors identified in the entire testing process: preanalytic, analytic and postanalytic phases of testing.

1. RISK ASSESSMENT

A Risk Assessment identifies and evaluates potential failures and sources of errors in your testing process. It must include, at a minimum, an evaluation of the following five components:

- Specimen
- Test system
- Reagent
- Environment
- Testing personnel

2. QUALITY CONTROL PLAN (QCP)

A Quality Control Plan is a written document describing the practices and procedures performed by your laboratory to reduce the chance of possible failures and errors in your test processes. The QCP must ensure that the accuracy and reliability of test results, for a specific process, are appropriate for patient care. Practices, procedures, and resources that you incorporate in your QCP may include, but are not limited to:

- Electronic controls
- Internal controls
- Proficiency testing (PT)
- Calibration
- Maintenance
- Training and competency assessment

3. QUALITY ASSESSMENT (QA)

Quality Assessment is the continuous process of monitoring the effectiveness of the QCP. Practices, processes, and resources to consider for monitoring effectiveness of a QCP may include, but are not limited to:

- QC reviews
- PT performance reviews
- Chart reviews
- Specimen rejection logs
- Turnaround time reports
- Complaint reports

WHAT ARE WE ALREADY DOING?

Gather and review information already available to your laboratory about the testing process, such as manufacturer's information, data you obtained through verification or establishment of performance specifications, historical QC and PT data, as applicable.

The steps listed below will help you determine if your current quality procedures are adequate or if additional or different activities are needed to reduce potential failures and errors.

1. Review the preanalytic, analytic, and postanalytic phases of the testing process.
2. Break down each phase into steps, so that potential failures and errors can be identified.
3. Analyze the information gathered to see if control activities can be put into place to reduce the identified potential failures and errors.

Step 1: Risk Assessment

A risk assessment is the process of identifying and evaluating the potential failures and errors that could occur during the **preanalytical** (before testing), **analytical** (testing), and **postanalytical** (after testing) phases of testing.

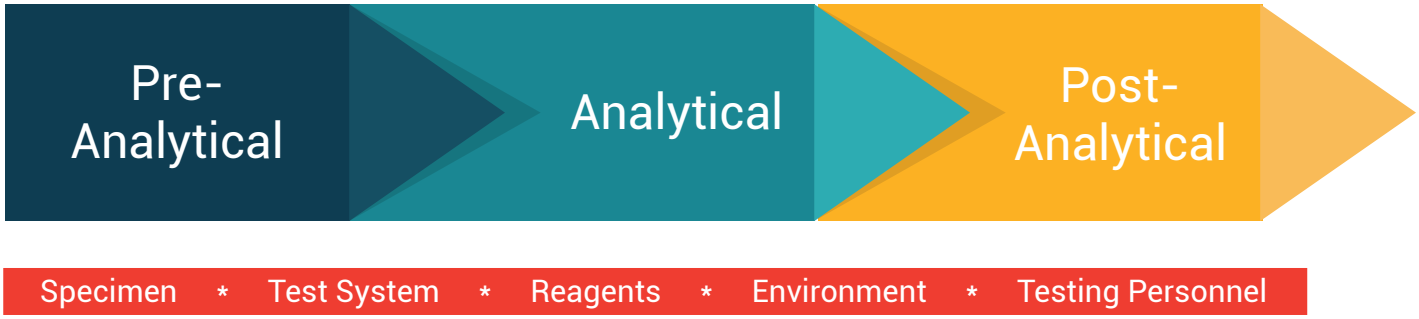
At a minimum, evaluate the following five components of the testing process for potential failures and errors:

- specimen
- test system
- reagent
- environment
- testing personnel

Some risks could fit under more than one of the five risk assessment components. When conducting the risk assessment, identify the risks under the component that is most appropriate for your laboratory.

For example, an **inadequate specimen volume** (i.e. 0.5 ml of whole blood might be collected instead of 1.0 ml as specified by the manufacturer's instructions) could fall under more than one risk assessment component:

1. **Specimen**- manufacturer's instructions specify a minimum of 1.0 ml whole blood for the test system, or
2. **Test System**- wrong specimen volume would result in the reporting of wrong result or test system procedural error, or
3. **Reagent**- incorrect specimen volume would result in the test kit reagents performing improperly and producing incorrect test results.

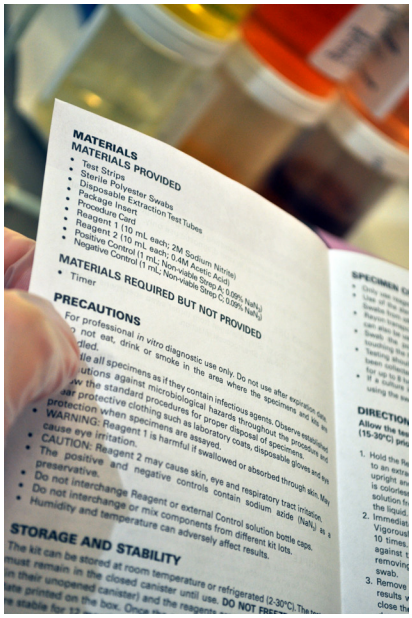


STEP 1: RISK ASSESSMENT

HOW DO I GET STARTED?

To begin your risk assessment, review and assess all manufacturers' information and other applicable resources including, but not limited to:

- ✓ Laboratory procedures/standard operating procedures (SOPs)
- ✓ Manufacturer's instructions/package inserts
- ✓ Instrument and troubleshooting manuals
- ✓ Manufacturer's alerts and bulletins
- ✓ Calibration data
- ✓ Data obtained through verification or establishment of performance specifications
- ✓ FDA alerts
- ✓ Historical QC data, including data from a previously conducted equivalent quality control study
- ✓ Instrument correlation data
- ✓ PT results and data
- ✓ Records of complaints and corrected reports
- ✓ Regulatory and accreditation requirements
- ✓ Scientific publications
- ✓ Test process flow charts or maps
- ✓ Testing personnel training and competency records



- Pay special attention to the following package insert sections: intended use, patient preparation, limitations, environmental requirements, QC frequency, specimen requirements, reagent storage, maintenance, calibration, interfering substances.

- If you have questions concerning the manufacturer's instructions or need additional information, contact the manufacturer directly.

- In laboratories with multiple, identical test systems (same make and manufacturer), a single risk assessment may be performed. However, differences in testing personnel and environments where the test systems are used must be taken into consideration. Due to these differences, you should determine if you need to perform a risk assessment for each individual location and/or device.

STEP 1: RISK ASSESSMENT

WHAT IS HAPPENING IN MY LABORATORY?

The following is an example scenario for you to refer to throughout this workbook. The example is based on a fictitious laboratory and test system. It contains information about the laboratory, test system, and other pertinent information the laboratory has or can acquire in order to develop and implement an IQCP.

Scenario

Dr. Martin is the laboratory director for the Happy Day Physicians Group. She is considering implementing an IQCP for her laboratory. To determine if IQCP is a good option for Happy Day Physicians Group's laboratory to meet CLIA QC requirements, Dr. Martin has asked her laboratory supervisor, Kim, to take the lead in performing a risk assessment.

Kim decided to evaluate the test for magnesium performed on the Acme Chemotrific System-Magnesium because the manufacturer's instructions recommended performing external QC less frequently than required by CLIA. She gathered supporting data to review what her laboratory is currently doing to reduce potential sources of error.

Supporting Data

- ✓ Test system is FDA cleared and moderate complexity under CLIA
- ✓ Laboratory follows the CLIA regulatory requirements for QC - two control materials of different concentration each day of patient testing
- ✓ Acme Chemotrific System-Magnesium ***package insert includes:***
  - Specimen collection time and collection tube requirements
  - Limitations of the test
  - Criteria for acceptable results
  - Use of an internal control process that performs internal QC on every reagent disc
  - Recommendations for performing external controls at least every 30 days; when there is a significant change in laboratory conditions; training or retraining of personnel is indicated; or when test results do not match patient symptoms or clinical findings
- ✓ Two years of successful PT performance reports
- ✓ Test performance specification verification studies demonstrating the test system's accuracy and stability
- ✓ **Specimen** - Review of specimen receipt logs for the past two years demonstrates gaps in documentation when requesting re-collection of specimens.

STEP 1: RISK ASSESSMENT

- ✓ **Instrument maintenance (Test System)-**
  - Review of instrument maintenance logs show no problems with test system's instrument mechanics for the past two years
  - Review of patient test results and two levels of external QC results for the past two years demonstrates no problems with the test system. QC outliers were resolved with corrrective actions.
  - Review of troubleshooting logs demonstrate no indication of problems with the test system or patient results reporting for the past two years

- ✓ **Reagent**- Review of lot-to-lot reagent logs demonstrates no problems or indications of problems for past six months

- ✓ **Environment:**
  - **Room temperature logs**- Review of temperature logs demonstrates no problems with temperature for past year
  - **Refrigerator and freezer temperature log**- Review demonstrates minimal outlier temperature points with investigation and appropriate corrective action for the past year

- ✓ **Testing personnel training and competency** – Review of personnel training records for the past two years demonstrates no personnel turnover.

*NOTE REGARDING SUPPORTING DATA: Support your risk assessment with available data that include, but are not limited to, test performance specifications, manufacturer's package inserts, PT performance data, QC logs/data, specimen receipt and rejection logs, to determine a QC plan that will reduce potential sources of error.

Now let's review your supporting data

Gather the supporting data for your laboratory and record your findings below.

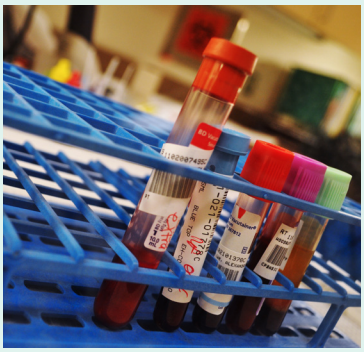
STEP 1: RISK ASSESSMENT

ASSESSING THE SPECIMEN RISKS

"Let's talk about the specimen…" *Review the manufacturer's instructions, technical bulletins, your policies and procedures, patient instructions, and any other documents associated with the specimen. As you review these documents, stop and think about when and where in the testing process a potential error associated with the specimen may occur.*

Specimen Scenario

Let's take a closer look at how Happy Day Physicians Group identified sources of error for the risk assessment component, specimen.



Kim reviewed the specimen receipt logs for the past two years and noted that, according to the laboratory's policy, not all personnel had properly documented requests for re-collection of specimens. Additionally, Kim noted some specimens remained unprocessed for more than 60 minutes without being properly stored.

A review of the refrigerator and freezer logs for the past year showed a few recorded temperatures outside of the acceptable range; however, they had been investigated and appropriate corrective actions were taken.

Kim identified the possible sources of error and recorded her findings in the Risk Assessment Worksheet.

Instructions needed to follow the Happy Day Physicians Group Risk Assessment Worksheets:

For each risk assessment component, Kim has gathered and reviewed the data sources and used the information to consider ***"What could go wrong?"*** during the entire testing process to complete the Happy Day Physicians Group Risk Assessment Worksheets:

In column 2, Kim recorded the identified possible sources of error, and considered how these errors could be reduced.
In column 3, Kim indicated "**yes**" or "**no**" if there were actions the laboratory could take to reduce the sources of error.
In column 4, Kim recorded the actions the laboratory staff could implement to reduce the identified errors.

Note: To complete the risk assessment worksheet, consider your testing process in its entirety; from the time the order is placed, through collection, processing, analysis, and reporting (preanalytic, analytic and postanalytic processes). One of many possible examples to document your risk assessment follows. The information provided in this example should not be considered all-inclusive of potential risks, QC and QA procedures, and CLIA requirements that may apply for your laboratory.

STEP 1: RISK ASSESSMENT

Happy Day Physicians Group Risk Assessment Worksheet

1	2	3	4
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	Documentation of specimen re-collection. Manufacturer's instructions: • Use lithium heparin tubes for whole blood or plasma specimens • Use no additive or serum separator tubes for serum specimens	Yes	Retrain testing personnel on re-collection policy. Train testing personnel to verify use of proper specimen collection tubes.
	Testing time frame/stability of specimen. Manufacturer's instructions: • Whole blood - run within 60 minutes of collection • Store serum or plasma in capped tubes at 2°C to 8°C for 48 hours or at -10°C for up to 5 weeks	Yes	Train testing personnel to verify and document: • Collection time and time of receipt in laboratory • Proper storage and processing of specimen

STEP 1: RISK ASSESSMENT

General Specimen Questions to Consider in Your Laboratory

Think about your laboratory and your entire testing process as it relates to the specimen.

Do you see a potential risk of an error in test results if:	Answer
The manufacturer's instructions for specimen requirements including, but not limited to, specimen tube or container type, patient preparation, or specimen storage are not followed?	*Yes ___ No ___*
The current version of the manufacturer's instructions is not used?	*Yes ___ No ___*
The specimen is improperly labeled?	*Yes ___ No ___*
The specimen isn't accurately identified throughout the testing process?	*Yes ___ No ___*
Criteria for specimen rejection are not established and followed?	*Yes ___ No ___*

Note: For the purposes of this example, not all questions to consider have been identified or included above. Additional example questions can be found in Appendix D.

In the spaces below, record questions to consider for your laboratory that relate to incorrect test results associated with the **specimen** risk assessment component.

Record Your Specimen Risk Assessment Questions/Findings

STEP 1: RISK ASSESSMENT

Steps to complete your laboratory's risk assessment worksheets:

After reviewing the example worksheet for each component, take **your** identified sources of error from the **"Risk Assessment Questions/ Findings"** for each component section, and follow the process taken by Kim to complete **your** laboratory's risk assessment worksheet.

Risk Assessment Worksheet

Laboratory Name_____ Test System Name _____

1	2	3	4
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			

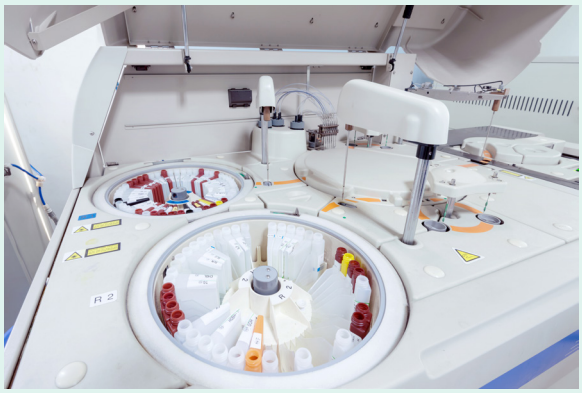
STEP 1: RISK ASSESSMENT

ASSESSING THE TEST SYSTEM RISKS

"Let's talk about the test system…" *Review the manufacturer's instructions, technical bulletins, your policies and procedures, and any other documents associated with the test system. As you review these documents, stop and think about when and where in the testing process a potential error associated with the test system may occur.*

Test System Scenario:

Let's take a closer look at how Happy Day Physicians Group identified sources of error for the risk assessment component, test system.



Kim reviewed external QC log sheets for the last two years. Although she identified a couple of outliers, corrective actions were performed and QC results following the corrective actions were acceptable. Her review suggests that the test system is stable. She also noted the test system performs an internal control with each reagent disc; however, an unacceptable internal control does not prevent a patient result from being reported. The manufacturer has built in safeguards to help reduce the likelihood of test system errors, including the detection of sampling errors.

Kim completed the Risk Assessment Worksheet for the test system using the instructions given on page 12.

STEP 1: RISK ASSESSMENT

Happy Day Physicians Group Risk Assessment Worksheet

1	2	3	4
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
TEST SYSTEM	QC Results: Manufacturer's instructions - test system does not prevent patient results from being reported when QC is unacceptable.	Yes	Assure testing personnel review each QC result upon completion of the test run. Document QC results in QC log. Report patient results only when QC is acceptable.
	Specimen volume.	N/A	The test system will not perform the test if the specimen volume does not meet the minimum volume requirement.

STEP 1: RISK ASSESSMENT

General Test System Questions to Consider in Your Laboratory

Think about your laboratory and your entire testing process as it relates to the test system.

Do you see a potential risk of producing incorrect test results if:	Answer
Maintenance procedures are not consistent with the manufacturer's instructions?	*Yes* ___ *No* ___
The test is performed outside of its intended use as described in the manufacturer's instructions?	*Yes* ___ *No* ___
The limitations to the test system are ignored. For example, do lipemia or medications interfere with the test systems performance?	*Yes* ___ *No* ___
Built-in monitors do not exist for the test system, e.g. the ability to detect inadequate specimen volume?	*Yes* ___ *No* ___
The laboratory information system (LIS) isn't transmitting results or other information accurately?	*Yes* ___ *No* ___
The test system doesn't have a means to ensure positive patient identification, such as a functioning bar code reader?	*Yes* ___ *No* ___
There is no mechanism, such as an operator lockout, to ensure only trained personnel use the test system?	*Yes* ___ *No* ___

Note: For the purposes of this example, not all questions to consider have been identified or included above. Additional example questions can be found in Appendix D.

In the spaces below, record questions to consider for your laboratory that relate to incorrect test results associated with the **test system** risk assessment component.

Record Your Test System Risk Assessment Questions/Findings

STEP 1: RISK ASSESSMENT

Instructions needed to complete this worksheet can be found on page 15.

Risk Assessment Worksheet

Laboratory Name_____ Test System Name _____

1	2	3	4
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
TEST SYSTEM			

STEP 1: RISK ASSESSMENT

ASSESSING REAGENT RISKS

***"Let's talk about the reagent**…" Review the manufacturer's instructions, technical bulletins, your policies and procedures, and any other documents associated with the reagent. As you review these documents, stop and think about when and where in the testing process a potential error associated with the reagent may occur.*

Reagent Scenario

Let's take a closer look at how Happy Day Physicians Group identified sources of error for the risk assessment component, reagent.

Kim reviewed the lot-to-lot reagent logs for the past six months and found no indications of problems. She noticed that some testing personnel took out multiple packs of reagent discs and left them on the work bench for several days at a time. Kim has received several complaints from testing personnel about the warmer laboratory conditions during the early afternoon hours, which could affect the stability of the reagent discs. She reviewed the room temperature logs and found no issues with the daily room temperatures recorded in the past year, as part of the daily morning maintenance. Kim recorded this as a possible source of error in the risk assessment worksheet.

Kim completed the Risk Assessment Worksheet for the reagent using the instructions given on page 12.

STEP 1: RISK ASSESSMENT

Happy Day Physicians Group Risk Assessment Worksheet

1	2	3	4
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
REAGENT	Reagent storage - prevent reagent degradation during storage and use. Manufacturer's instructions - do not allow discs to remain at room temperature longer than 48 hours prior to use.	Yes	Monitor storage conditions of discs daily for refrigerated storage (2°-8°C). Monitor room temperature (20° - 25°C) each day of testing. Document date and time on reagent discs when removed from refrigerator. Do not use reagent discs that are at room temperature beyond 48 hours.
	Reagent expiration date - the test system's QC does not detect the use of expired reagents prior to testing. Manufacturer's instructions - do not use discs after expiration date.	Yes	Train testing personnel to check reagent expiration dates prior to using them for testing.
	Testing the external normal and abnormal controls. Manufacturer's instructions: • Test and document external normal and abnormal controls: ◦ Every 30 days ◦ At change of reagent disc lot number ◦ Whenever laboratory conditions have changed significantly ◦ When training or retraining of personnel is indicated ◦ Whenever test results do not match patient symptoms or clinical findings	Yes	Train testing personnel to perform external QC procedures, as described in the manufacturer's instructions.

STEP 1: RISK ASSESSMENT

General Reagent Questions to Consider in Your Laboratory

Think about your laboratory and your entire testing process as it relates to the reagents.

Do you see a potential risk of producing incorrect test results if:	Answer
Storage requirements for reagents are not followed?	*Yes ___ No ___*
Integrity of reagents are not checked when received? (e.g. some manufacturers ship reagents on dry ice or icepacks to maintain required temperatures.)	*Yes ___ No ___*
There is a delay in storing reagents upon receipt?	*Yes ___ No ___*
Reagents are shipped to the laboratory at a time when staff are not available to ensure proper storage (e.g. a weekend or holiday)?	*Yes ___ No ___*
Reagents with different lot numbers are mixed? (Consider if the test system has a mechanism to identify reagent lot numbers or if the laboratory will need to track them manually.)	*Yes ___ No ___*
Manufacturer's instructions for reagent preparation are not followed? (e.g. reconstitution of reagents or bringing to room temperature)	*Yes ___ No ___*
The specified type of water required by the test system is not used?	*Yes ___ No ___*

Note: For the purposes of this example, not all questions to consider have been identified or included above. Additional example questions can be found in Appendix D.

In the spaces below, record questions to consider for your laboratory that relate to incorrect test results associated with the **reagent** risk assessment component.

Record Your Reagent Risk Assessment Questions/Findings

STEP 1: RISK ASSESSMENT

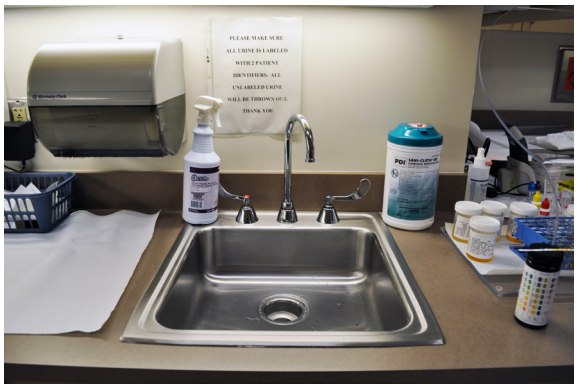
Instructions needed to complete this worksheet can be found on page 15.

Risk Assessment Worksheet

Laboratory Name_____ Test System Name _____

1	2	3	4
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
REAGENT			

ASSESSING ENVIRONMENT RISKS



***"Let's talk about the environment**…" Review the manufacturer's instructions, technical bulletins, your policies and procedures, and any other documents associated with the environment. As you review these documents, stop and think about when and where in the testing process a potential error associated with the environment may occur.*

Environment Scenario

Let's take a closer look at how Happy Day Physicians Group identified sources of error for the risk assessment component, environment.

Kim has received several complaints from testing personnel about the warmer laboratory conditions during the early afternoon hours. She reviewed the room temperature logs and found that room temperatures recorded each morning for the past year were within the acceptable range.

Kim had also noticed that the Acme Chemotrific System-Magnesium was located directly under the air conditioning vent. She was concerned that the location of the test system could lead to fluctuations in temperature that could affect test results.

Kim recorded her findings in the Risk Assessment Worksheet using the instructions given on page 12.

STEP 1: RISK ASSESSMENT

Happy Day Physicians Group Risk Assessment Worksheet

1	2	3	4
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
ENVIRONMENT	Room temperature: Manufacturer's instructions - operate test system at temperatures between 20°C and 25°C.	Yes	Record room temperature daily in the morning and afternoon, and adjust as needed to maintain 20° - 25°C.
	Proper ventilation of instrument: Manufacturer's instructions - do not locate test system in front of room air in-take and out-take flow vents.	Yes	Move test system to a location away from air conditioning vents to meet manufacturer's requirements.

STEP 1: RISK ASSESSMENT

General Environment Questions to Consider in Your Laboratory

Think about your laboratory and the testing process as it relates to the environment.

Do you see a potential risk of producing incorrect test results if:	Answer
The manufacturer's instructions for space and the testing environment are not followed?	*Yes* ___ *No* ___
The manufacturer's ventilation and airflow requirements are not adhered to?	*Yes* ___ *No* ___
There is insufficient lighting and space for workflow and the test system?	*Yes* ___ *No* ___
The manufacturer's instructions for maintaining the appropriate temperature and humidity for the test system are not followed?	*Yes* ___ *No* ___
Workspace is not free of clutter, dust, or debris?	*Yes* ___ *No* ___

Note: For the purposes of this example, not all questions to consider have been identified or included above. Additional example questions can be found in Appendix D.

In the spaces below, record questions to consider for your laboratory that relate to incorrect test results associated with the **environment** risk assessment component.

Record Your Environment Risk Assessment Questions/Findings

STEP 1: RISK ASSESSMENT

Instructions needed to complete this worksheet can be found on page 15.

Risk Assessment Worksheet

Laboratory Name_____ Test System Name _____

1	2	3	4
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
ENVIRONMENT			

ASSESSING TESTING PERSONNEL RISKS

***"Let's talk about testing personnel**…" Review the manufacturer's instructions, technical bulletins, your policies and procedures, and any other documents associated with testing personnel. As you review these documents, stop and think about when and where in the testing process a potential error associated with testing personnel may occur.*

Testing Personnel Scenario

Let's take a closer look at how Happy Day Physicians Group identified sources of error for the risk assessment component, testing personnel.

Kim reviewed the personnel training records for the past two years. There were no personnel changes during that time. Kim recognized that some testing personnel had not been properly trained on the test system, but had signed off on and reported results. A review of the laboratory competency assessment revealed that the assessment did not include all elements required by CLIA.

Kim also noted that the laboratory policy did not prohibit verbal reporting of test results before entry into the laboratory information system (LIS). Concerned that this practice could potentially be an additional source of error related to testing personnel, she recorded her findings in the Risk Assessment Worksheet.

Kim completed the Risk Assessment Worksheet for the test personnel using the instructions given on page 12.

STEP 1: RISK ASSESSMENT

Happy Day Physicians Group Risk Assessment Worksheet

1	2	3	4
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
TESTING PERSONNEL	Improperly trained personnel.	Yes	Train testing personnel on specimen requirements, and proper performance of test according to manufacturer instructions.
	Competency assessment does not include all CLIA required elements.	Yes	Evaluate competency assessment policy and procedures, rewrite to include all CLIA required elements. Perform and document competency assessment for all testing personnel. Competency assessments required for new employees at least every six months, and annually thereafter, or when test methodology and test system changes.
	Verbal reporting of test results prior to LIS entry.	Yes	Update policy to require testing personnel do not verbally release results until they are entered into the LIS.

STEP 1: RISK ASSESSMENT

General *Testing Personnel* Questions to Consider in Your Laboratory

Think about your laboratory and the testing process as it relates to testing personnel.

Do you see a potential risk of an error in test results if:	Answer
Laboratory personnel do not have a formal certification or license if required by the state?	*Yes ___ No ___*
The laboratory does not have adequate personnel to perform patient testing in a safe and timely manner?	*Yes ___ No ___*
There is no documentation of CLIA-required competency assessment for all laboratory personnel?	*Yes ___ No ___*
Laboratory personnel are not trained on specimen requirements (collection and type) required for the test system?	*Yes ___ No ___*
Laboratory personnel are not trained to follow the manufacturer's instructions in their entirety?	*Yes ___ No ___*
Laboratory personnel make transcription errors when reporting results, either written or when using an LIS?	*Yes ___ No ___*

Note: For the purposes of this example, not all questions to consider have been identified or included above. Additional example questions can be found in Appendix D.

In the spaces below, record questions to consider for your laboratory that relate to incorrect test results associated with the **testing personnel** risk assessment component.

Record Your Testing Personnel Risk Assessment Questions/Findings

STEP 1: RISK ASSESSMENT

Instructions needed to complete this worksheet can be found on page 15.

Risk Assessment Worksheet

Laboratory Name_____ Test System Name _____

1	2	3	4
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
TESTING PERSONNEL			

STEP 1: RISK ASSESSMENT

Completed EXAMPLE

The example below shows the complete Risk Assessment containing the merged information from all five components for Happy Day Physicians Group's Acme Chemotrific System-Magnesium test system.

Happy Day Physicians Group Risk Assessment Worksheet Acme Chemotrific System-Magnesium (Showing all 5 components)

1	2	3	4
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	Documentation of specimen re-collection. Manufacturer's instructions: • Use lithium heparin tubes for whole blood or plasma specimens • Use no additive or serum separator tubes for serum specimens	Yes	Retrain testing personnel on re-collection policy. Train testing personnel to verify use of proper specimen collection tubes.
	Testing time frame/stability of specimen. Manufacturer's instructions: • Whole blood - run within 60 minutes of collection • Store serum or plasma in capped tubes at 2°C to 8°C for 48 hours or at -10°C for up to 5 weeks	Yes	Train testing personnel to verify and document: • Collection time and time of receipt in laboratory • Proper storage and processing of specimen

continued on next page...

STEP 1: RISK ASSESSMENT

1	2	3	4
TEST SYSTEM	QC Results: Manufacturer's instructions - test system does not prevent patient results from being reported when QC is unacceptable.	Yes	Assure testing personnel review each QC result upon completion of the test run. Document QC results in QC log. Report patient results only when QC is acceptable.
	Specimen volume.	N/A	The test system will not perform the test if the specimen volume does not meet the minimum volume requirement.
REAGENT	Reagent storage - prevent reagent degradation during storage and use. Manufacturer's instructions - do not allow discs to remain at room temperature longer than 48 hours prior to use.	Yes	Monitor storage conditions of discs daily for refrigerated storage (2°-8°C). Monitor room temperature (20° - 25°C) each day of testing. Document date and time on reagent discs when removed from refrigerator. Do not use reagent discs that are at room temperature beyond 48 hours.
	Reagent expiration date - the test system's QC does not detect the use of expired reagents prior to testing. Manufacturer's instructions - do not use discs after expiration date.	Yes	Train testing personnel to check reagent expiration dates prior to using them for testing.
	Testing the external normal and abnormal controls. Manufacturer's instructions: • Test and document external normal and abnormal controls: ◦ Every 30 days ◦ At change of reagent disc lot number ◦ Whenever laboratory conditions have changed significantly ◦ When training or retraining of personnel is indicated ◦ Whenever test results do not match patient symptoms or clinical findings	Yes	Train testing personnel to perform external QC procedures, as described in the manufacturer's instructions.

continued on next page...

STEP 1: RISK ASSESSMENT

1	2	3	4
ENVIRONMENT	Room temperature: Manufacturer's instructions - operate test system at temperatures between 20°C and 25°C.	Yes	Record room temperature daily in the morning and afternoon, and adjust as needed to maintain 20° - 25°C.
	Proper ventilation of instrument: Manufacturer's instructions - do not locate test system in front of room air in-take and out-take flow vents.	Yes	Move test system to a location away from air conditioning vents to meet manufacturer's requirements.
TESTING PERSONNEL	Improperly trained personnel.	Yes	Train testing personnel on specimen requirements, and proper performance of test according to manufacturer instructions.
	Competency assessment does not include all CLIA required elements.	Yes	Evaluate competency assessment policy and procedures, rewrite to include all CLIA required elements. Perform and document competency assessment for all testing personnel. Competency assessments required for new employees at least every six months, and annually thereafter, or when test methodology and test system changes.
	Verbal reporting of test results prior to LIS entry.	Yes	Update policy to require testing personnel do not verbally release results until they are entered into the LIS.

LET'S REVIEW...

So far, the workbook has guided you through the steps of performing a risk assessment.

Before you move to the next step, you should:

- ✓ Review your Risk Assessment and make sure it includes all three phases of the testing process (preanalytic, analytic and postanalytic).
- ✓ Ensure that your Risk Assessment includes the five components (specimen, test system, reagent, environment and, testing personnel).
- ✓ Determine if your current practices are sufficient to detect the sources of error or failure in your test system.
- ✓ Determine whether your identified risks need to be monitored or controlled regularly in the testing process.

Step 2: Quality Control Plan

WHAT IS A QUALITY CONTROL PLAN?

A Quality Control Plan (QCP) describes practices, procedures and resources needed by your laboratory to ensure the quality of a testing process. The QCP includes measures to assure the accuracy and reliability of test results, and that the quality of testing is adequate for patient care.

The QCP must provide for immediate detection of errors that occur due to test system failure, adverse environmental conditions, and operator performance. It must also monitor, over time, the accuracy and precision of test performance that may be influenced by changes in the specimen, test system, reagent, environment, or variance in operator performance.

Create a plan that includes activities to reduce the likelihood of failures and errors identified from your risk assessment. Consider the amount of QC necessary based on the frequency and volume of patient testing.

NOTE: Laboratories cannot establish QC procedures that are less stringent than those specified by the manufacturer of the test system.

WHAT IS INCLUDED IN A QCP?

At a minimum, your QCP must include the number, type, and frequency of testing control materials, as well as criteria for acceptable quality control.

If indicated by the risk assessment, your QCP may also incorporate the use of:

- Electronic controls
- Equipment maintenance
- Internal controls
- Personnel training and competency assessment
- Equipment calibration
- Other specified quality control activities

STEP 2: QUALITY CONTROL PLAN

DEVELOPING YOUR QCP

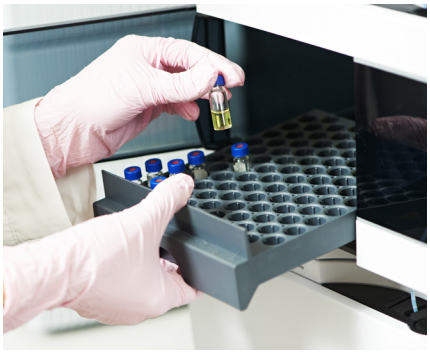
The development and implementation of QCPs may be delegated (in writing) to a qualified individual. However, the laboratory director has the ultimate responsibility for the proper development and implementation of a QCP. There must be documented evidence that the laboratory director has approved, signed and dated the QCP. The laboratory director must consider the laboratory's clinical and legal responsibility for providing accurate and reliable patient results prior to implementing a QCP.

Quality Control Plan Scenario:

Kim, the laboratory supervisor for the Happy Day Physicians Group, reviewed the findings from the risk assessment and is ready to develop her new QCP.

Kim found several opportunities to improve the QCP, in order to reduce the risk of failures and errors. Kim identified instances where testing personnel had not verified sample acceptability or followed proper storage recommendations, and she noted fluctuations in room temperature that had not been addressed. Additionally, internal QC was not being documented as acceptable for each patient test performed prior to reporting patient results.

Putting it all together



Kim used the information she reviewed to consider ***"What could go wrong?"*** during the entire testing process. Using the Happy Day Physicians Group Risk Assessment Worksheet:

- ✓ Kim reviewed the potential failures and errors that were entered in **column 2** of the Happy Day Physicians Group **risk assessment** worksheet.
- ✓ She determined that the activities that were identified in **column 4** of the **risk assessment** worksheet will adequately detect and reduce the identified potential sources of failure and error.
- ✓ Kim reviewed the QC activities in column 4. She noted some of the QC activities could be performed immediately to resolve potential errors in the future. For example, moving the test system to a better location in the laboratory immediately resolved airflow and temperature fluctuations. (You may also encounter similar QC activities that can immediately resolve the potential for errors in your own laboratory.) Kim decided all other QC activities would be incorporated into her QCP, which will be monitored on an ongoing basis.

STEP 2: QUALITY CONTROL PLAN

HAPPY DAY PHYSICIANS GROUP QUALITY CONTROL PLAN

After reviewing the Acme Chemotrific System-Magnesium risk assessment worksheet, Kim used the information that she gathered to develop the following QCP for Happy Day Physicians Group. The examples below show how you can use the information that you obtain from the risk assessment to create a QCP.

These examples are not meant to be all inclusive of all possible QC procedures that may apply to your laboratory.

1 Type of Quality Control	2 Frequency	3 Criteria for Acceptability (Range of Acceptable Values)
Temperature Checks Room Refrigerator Freezer A	Record room temperature daily, in the morning and afternoon. Record refrigerator and freezer each day of patient testing.	20°C – 25°C (Room) 2°C – 8°C (Refrigerator) -10°C – -20°C (Freezer) Recorded on temperature log sheets
Verify specimen collection tubes for acceptability upon receipt in the laboratory.	With each specimen	Refer to Specimen Rejection Policy and record all improperly collected tubes on specimen rejection log sheet.
Verify specimen collection time and time received by the laboratory.	With each specimen	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).
Internal Quality Control	Performed with each reagent disc.	Must be documented as acceptable on quality control log sheet prior to reporting results.
External Quality Control Normal value Abnormal value	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 ran when: • laboratory conditions have changed significantly • training or retraining of personnel is indicated • test results do not match patient symptoms or clinical findings	Acceptable range printed in the manufacturer's package insert. Results must be recorded on quality control log sheet prior to reporting results.
Reagent Disc Storage	With each reagent disc	Document date and time on reagent discs when removed from refrigerator. Do not use reagent discs that are at room temperature beyond 48 hours.

continued on next page...

STEP 2: QUALITY CONTROL PLAN

1 Type of Quality Control	2 Frequency	3 Criteria for Acceptability (Range of Acceptable Values)
Training	With each new testing personnel and when indicated.	Successful demonstration of test performance. Document training activities.
Competency Assessment	Six months and one year after initial training, annually thereafter.	All testing personnel must successfully meet all six CLIA elements for competency assessment.

There are many options for documenting your QCP. See the example of how Kim documented her Acme Chemotrific-Magnesium QCP using a different format.

HAPPY DAY PHYSICIANS GROUP QUALITY CONTROL PLAN

***NOTE*: The example provided below does not represent a complete QCP. It is NOT meant to represent every QC procedure that you may need to implement in your laboratory.**

1. Document temperatures for the refrigerator and freezer each day of patient testing. Document the room temperature, morning and afternoon, each day of patient testing. The acceptable criteria for temperature ranges must be included in the temperature logs.
2. Verify specimen collection tubes for acceptability upon receipt in the laboratory. Document improperly collected specimens following established Specimen Rejection Policy.
3. Verify specimen collection and receipt times on the test order forms prior to loading the sample on the disc. Specimens that are not tested within 60 minutes of collection must be separated into plasma or serum and store in capped sample tubes at 2^0C to 8^0C for 48 hours or store at -10^0C in a freezer without a self-defrost cycle for up to five weeks. Train testing personnel regarding specimen collection and storage.
4. Test and document reagent stability by running external normal and abnormal controls per manufacturer's instructions for the following: every 30 days, at change of reagent disc lot number, whenever laboratory conditions have changed significantly, when training or retraining of personnel is indicated, and when test results do not match patient symptoms or clinical findings.
5. Verify and document Internal QC as "acceptable" for each patient test performed before patient results are reported.
6. Document the date and time when reagent discs are removed from the refrigerator. Do not use reagent discs that have been at room temperature beyond 48 hours.
7. Verify that training of testing personnel, upon hire and when indicated, documents successful demonstration of competency as indicated by laboratory policy and regulations. *CLIA Regulation 493.1451 (b)(8)i-vi and (9)*

After reviewing how Kim completed the QCP worksheet above for Happy Day Physicians Group, develop a QCP worksheet for your laboratory.

STEP 2: QUALITY CONTROL PLAN

General Quality Control Questions to Consider for Your Laboratory's QCP

Think about your laboratory and your QC process.

Do the QC activities identified in your Risk Assessment:	Answer
Provide for immediate detection of errors for each phase of the testing process (i.e. before, during, and after testing) for the test?	*Yes ___ No ___*
Specify the number, type, and frequency of testing QC material(s)?	*Yes ___ No ___*
Contain criteria to determine acceptable QC results?	*Yes ___ No ___*
Require the laboratory perform QC as specified by the manufacturer's instructions, but not less than the manufacturer's instructions?	*Yes ___ No ___*
Indicate that your Laboratory Director has reviewed, signed and dated the QCP document?	*Yes ___ No ___*

STEP 2: QUALITY CONTROL PLAN

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

QUALITY CONTROL PLAN WORKSHEET

Laboratory Name_____ Test System Name _____

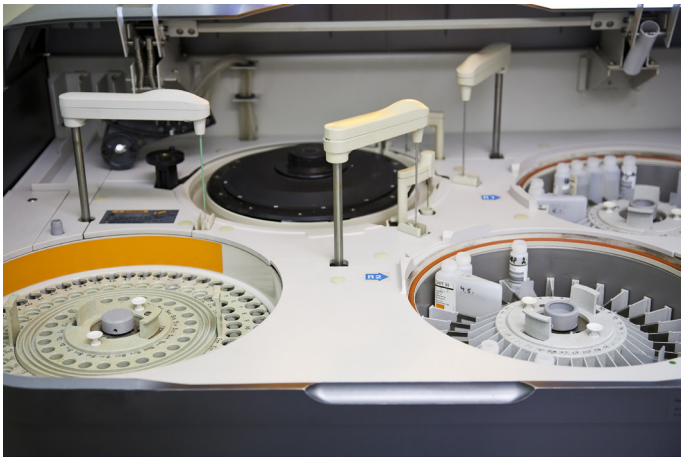
1 Type of Quality Control	2 Frequency	3 Criteria for Acceptability (Range of Acceptable Values)

Laboratory Director Signature_____ Date _____

LET'S REVIEW

TIPS TO REMEMBER:

A complete QCP must:



- ✓ Provide for immediate detection of errors for each phase of the testing process (i.e. before, during, and after testing) for the test.
- ✓ Specify the number, type, and frequency of testing QC material(s).
- ✓ Contain criteria to determine acceptable QC results.
- ✓ Require the laboratory perform QC as specified by the manufacturer's instructions, but not less than the manufacturer's instructions.
- ✓ Indicate that your Laboratory Director reviewed, signed, and dated the QCP document.

If your QCP does not address all five items listed above, you do not have a QCP.

Go back and investigate what is missing.

Step 3: Quality Assessment

WHAT IS QUALITY ASSESSMENT?

Quality Assessment (QA) can be described as a multi-part activity.

Monitor and Assess

The laboratory must establish and follow written policies and procedures to monitor and assess, and when indicated, correct problems identified. The monitoring should include, but is not limited to, the following risk assessment components: specimen, test system, reagents, environment, and testing personnel.

Corrective Action

The QA must also include a review of the effectiveness of corrective actions taken to resolve problems identified. The laboratory must update the risk assessment and modify the QCP, as necessary based on the information obtained from the QA.

QA vs. QC

Now that we have defined QA and before we begin to discuss QA activities, let's take a look at the differences between QC and QA activities.

Below is an example that explains the difference between a QC activity and a QA activity.

Example of a QC activity:

- ✓ Recording the room temperature on a log sheet
- ✓ Documenting controls on log sheets
- ✓ Documenting personnel training

Example of a QA activity:

- ✓ Reviewing the room temperature log sheet for problems and evidence of corrective actions
- ✓ Reviewing control documents for out of range values and corrective actions taken
- ✓ Reviewing personnel training records for completion of required trainings and competency assessments

STEP 3: QUALITY ASSESSMENT

Without Quality Assessment (QA), you don't have a complete IQCP

Once QA has been incorporated into your IQCP, the three parts of the IQCP may be viewed as a continuous cycle of improvement, as depicted above.

Quality Assessment Monitoring and Review

Quality Assessment (QA) is used to determine if the quality activities you have put in place are working according to your QCP.

The laboratory personnel must establish a review system for the ongoing monitoring of the effectiveness of their QCP. The monitoring should include, but is not limited to, the following components: specimen, test system, reagent, environment, and testing personnel. Reevaluate the QCP when changes occur in any of the above components.

How frequently will you monitor your QCP?

Your QA plan should include a schedule for evaluating your QCP to ensure it continues to provide accurate and reliable test results. If necessary, you must update any portion of the risk assessment with new information and modify the QCP as needed.

STEP 3: QUALITY ASSESSMENT

DOCUMENTS TO CONSIDER FOR QUALITY ASSESSMENT MONITORING AND REVIEW MAY INCLUDE, BUT ARE NOT LIMITED TO:

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

Quality Assessment helps you:

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

Corrective Actions

When the laboratory discovers a testing process failure, the laboratory must conduct an investigation to identify the cause of the failure and its impact on patient care. The investigation must include documentation of all corrections, corresponding corrective action(s) for all patient results affected by the testing process failure, and evaluation of the effectiveness of the corrective action(s) taken. The laboratory must implement the correction(s) and corresponding corrective action(s) necessary to resolve the failure and reduce the risk of recurrence in the future. If necessary, the laboratory must update the risk assessment with the new information and modify the QCP, as needed.

Always review your QCP to ensure that your customized plan is working and modify the plan if it is not adequately detecting or preventing errors. A plan that may have seemed appropriate, based upon the available evidence when it was established may turn out to be insufficient to address all possible errors upon the next evaluation.

STEP 3: QUALITY ASSESSMENT

DOES YOUR QA DO THE FOLLOWING?

- ✓ **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?

Remember - QA is used to determine if the quality activities you have put in place are working.

QA Scenario:
The quality assessment activities **below** are currently implemented at Happy Day Physicians Group for the Acme Chemotrific System-Magnesium assay.

Happy Day Physicians Group QA

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/ documentations 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*

STEP 3: QUALITY ASSESSMENT

QA Scenario:

Let's take a closer look at how Happy Day Physicians Group identified new QA monitors.

As a result of her QA reviews, Kim discovered testing personnel had been performing an external control run and not including controls on patient specimen runs. The laboratory's standard operating procedure (SOP) indicated controls should be run at the same time as patient specimens. Kim identified additional QC activities to reduce this risk of error and included them in the laboratory's updated QCP.

Kim also added a monthly supervisory review of the instrument print-outs to ensure that controls are simultaneously run with patient specimens. She will initiate periodic remedial training for all testing personnel, annually assess personnel performance, and review competency assessments based on compliance with the updated policy. Additionally, Kim will review the instrument print-outs to ensure controls are properly tested as indicated in the laboratory's SOP, and there are no indications of errors. If abnormalities are identified during the review, Kim will document them and develop a corrective action plan to address the errors. Going forward, Dr. Martin, the laboratory director, will now review and sign all QC logs quarterly.

The new QA activities Kim identified in the scenario above are now listed in the Happy Day Physician Group's QA worksheet below. You may use this worksheet as an example of how to document your QA activities or you can develop your own.

STEP 3: QUALITY ASSESSMENT

Note: The information provided in this worksheet should not be considered all-inclusive of processes and CLIA requirements that may apply to your laboratory.

HAPPY DAY PHYSICIANS GROUP QA WORKSHEET

QA ACTIVITY (TO MONITOR)	FREQUENCY	ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)	CORRECTIVE ACTION (WHEN INDICATED)
Supervisor reviews and signs instrument print-outs and QC logs	Monthly	Yes	Remedial training of testing personnel Reassess testing personnel performance
Competency Assessment	Annually after first year of employment	No	Rewrite competency assessment training program to ensure it is up to date.
Laboratory Director reviews and signs QC logs	Quarterly	No	N/A

In the blank spaces below, record your current QA activities and/or those activities that could reduce potential errors in testing.

Record Your Quality Assessment Activities/Findings

STEP 3: QUALITY ASSESSMENT

OPTIONAL 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 _____

QA ACTIVITY (TO MONITOR)	FREQUENCY	ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)	CORRECTIVE ACTION (WHEN INDICATED)

LET'S REVIEW

Now that you have seen all parts of an IQCP and sample scenarios, you are ready to apply this process to your laboratory's test systems for which you choose to implement the IQCP process.

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.

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!!

For more information please visit the websites listed below:

CDC CLIA Website
http://wwwn.cdc.gov/clia/default.aspx

CDC IQCP Workbook and Resources
http://wwwn.cdc.gov/CLIA/Resources/IQCP/

CMS CLIA Website
http://www.cms.gov/CLIA/

CLIA Federal Regulations
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html

CLIA Brochures
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

Additional questions may be directed to the electronic mailbox
IQCP@cms.hhs.gov

APPENDIX A

RISK ASSESSMENT WORKSHEET

Laboratory Name_____ Test System Name _____

1	2	3	4
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			
TEST SYSTEM			
REAGENT			
ENVIRONMENT			
TESTING PERSONNEL			

APPENDIX B

QUALITY CONTROL PLAN WORKSHEET

Laboratory Name_____ Test System Name _____

Type of Quality Control	Frequency	Criteria for Acceptability (Range of Acceptable Values)

APPENDIX C

QUALITY ASSESSMENT WORKSHEET

Laboratory Name_____ Test System Name _____

QA ACTIVITY TO MONITOR	Frequency	ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)	CORRECTIVE ACTION (WHEN INDICATED)

APPENDIX D

ADDITIONAL RISK ASSESSMENT QUESTIONS

The following questions are a mixture of requirements under the CLIA regulations and recommended good laboratory practices. These questions are provided to help guide you as you consider the types of issues that contribute to your laboratory's potential risk of incorrect test results. The questions listed are not intended to be all-inclusive but are intended to stimulate your thinking when considering potential risks that could lead to incorrect test results in your laboratory setting.

***Note*:** Good laboratory practices may be representative of laboratory practices that are more stringent than CLIA regulations.

Specimen

1. Are specimens collected in the correct container, with proper preservatives?
2. Are the manufacturer's instructions followed for proper centrifugation (time and speed) to ensure proper and adequate separation of cells from serum or plasma?
3. Are written procedures followed for managing unacceptable specimens?
4. Are the manufacturer's instructions followed for proper specimen collection and use of specimen collection containers?
5. Are there written procedures for specimen referral to other laboratories?

Test System

1. Does the laboratory have an established range for an acceptable calibration that includes a minimum (or zero), midpoint, and a maximum value near the upper limit of the range that verifies the laboratory's reportable range?
2. Is the laboratory able to detect mechanical or electronic errors on this test system?
3. Does the laboratory define and document mechanisms to detect test system optical, pipette, or barcode reader errors?
4. Does the laboratory perform system controls and function checks according to the manufacturer's instructions, to include checks for:
   - Built-in procedural and electronic controls (internal controls)?
   - External or internal liquid quality control (assayed vs. unassayed)?
   - Temperature monitors and systems?
5. Does the laboratory utilize hardware/software that is current and appropriate for the needs of the facility?
6. Is an evaluation of instrument and reagent stability performed following relocation of instruments?
7. Does the laboratory have established corrective action policies and procedures, to include corrective action for out of range controls and calibrations?
8. Does the laboratory document corrective actions taken, to include resolutions, and review and share with testing personnel?
9. Does the laboratory have an adequate manual or electronic system(s) in place to accurately and reliably transmit patient results in a timely manner from data entry point to final report destination?
10. Are final results reviewed by a laboratory supervisor within 24 hours?
11. Does the laboratory have a Laboratory Information System (LIS)? If so, are there procedures to monitor the accuracy and completeness of the information being transmitted to the LIS?

12. Does the laboratory have multiple locations? If so, has a risk assessment been performed for each test system (method) at each location for which an IQCP will be established?
13. Are procedures written according to the manufacturer's instructions for this test?
14. Are commercial tests performed following the manufacturer's instructions and within the laboratory's stated performance specifications?
15. Does the laboratory perform and document calibration procedures following the manufacturer's recommendations and using calibration material appropriate for the test systems (per manufacturer's recommendation)?
16. Does the system recognize when external QC and calibrations are expired and prevent users from reporting results if these are due to be performed?

Reagent

1. Are expiration dates clearly identified and in agreement with manufacturer's recommendations (properly labeled)?
2. Are all reagents, controls, and calibrators used within the manufacturer's designated expiration date?
3. Are all reagents removed from storage and disposed of when they have reached their expiration date?
4. Are lot numbers recorded in a log (when new lots are received and when beginning use of different lot numbers)?
5. Is there a procedure for evaluating new lot numbers before beginning use for patient testing?

Environment

1. Does the laboratory have ventilation adequate for conducting all phases of laboratory testing?
2. Do the manufacturer's instructions specify requirements for ventilation and airflow?
3. Do the manufacturer's instructions specify the type of water required for this testing process?
4. Does the laboratory have adequate space to perform testing, prevent cross contamination, and/or injury?
5. Is lighting adequate to perform visual interpretation of test results, where required?
6. Are surge protectors used to prevent fluctuations of the power source in testing areas?
7. Is the testing area kept clean and clear of clutter and debris that could interfere with the testing process or disrupt airflow?

Testing Personnel

1. Do all personnel who collect specimens and perform testing follow the manufacturer's instructions?
2. Do all testing personnel perform QC and PT?
3. Do all laboratory personnel meet the appropriate educational and training requirements specified by CLIA?
4. Do laboratory personnel have a formal certification or license, if required by their state?
5. Does the laboratory have adequate personnel to perform testing in a safe and timely manner?
6. Does the laboratory have an ongoing and documented competency assessment program that includes the six elements required by CLIA for all personnel categories?

APPENDIX E

QUALITY ASSESSMENT (QA) ACTIVITIES

Below you will find a list of QA activities to help you reduce the occurrence or enhance the detection of potential failures and errors.

- Review all reports, manufacturer's instructions, and procedure manuals to monitor:
  - Accuracy and clarity of results reporting
  - Appropriateness of specimen, specimen collection, specimen handling and transportation
  - Assay accuracy and precision
  - Turnaround time
  - Compliance with policy and procedures
- Ensure there is a written procedure or manufacturer's instructions for each assay performed and that they are all readily accessible to testing personnel. Written procedures should include all information required by CLIA.
- Keep a log of known errors and sources of errors encountered over time for:
  - Specimen collection
  - Temperatures variations
  - Reagent and QC performance
  - Personnel errors
- Ensure all personnel meet the minimum qualifications necessary for performing testing.
- Ensure that there is a formal training period for all new personnel and refresher training for existing personnel.
- Ensure that there are procedures in place to document:
  - Corrective actions taken
  - Record reviews
  - Data entry errors
  - Laboratory investigations of failures and errors, to include actions taken to prevent future occurrences
  - Personnel training and competency assessment
  - Complaints received and actions taken to resolve
- Monitor QC results for shifts and trends.
- Ensure that all personnel participate in performing proficiency testing (PT).
- Monitor and document laboratory conditions that could adversely affect patient testing.

APPENDIX F

GLOSSARY

Glossary Term	Definition
Analytic Phase	A part of the total testing process involving workflows related to preparation and processing of patient specimens, analysis of specimens, and interpretation of test results. CLIA §493.1251-493.1283
Calibration	A process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure. CLIA §493.2
Competency	The ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. CMS CLIA Brochure #10
Competency Assessment	A process to monitor and assess laboratory personnel performance to ensure that they are fulfilling their duties as required by federal regulation. CMS CLIA Brochure #10 CLIA §493.1413(b)(8) or §493.1451(b)(8)
Corrective action	Actions taken to remedy a situation, remove an error, adjust a condition, or prevent recurrence of a problem. Interpretive Guidelines §493.1239(a)(b)(c), §493.1299(a)(b)(c)
Electronic Controls	An internal part of the (analyzer) test system that monitors the electrical or electronic components of the test system. "Good Laboratory Practices for Waived Testing Sites" Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports; November 11, 2005, vol 54(RR13);1-25. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm
Environmental Conditions	Conditions that may affect test system performance. These include, but are not limited to, temperature, airflow, light intensity, humidity, and altitude.
External Controls	Materials that have a similar matrix to patient specimens, are treated in the same manner as patient specimens, and go through all analytic phases of testing. External controls check the operating characteristics of a test system, including instrument stability and calibration. "Good Laboratory Practices for Waived Testing Sites" Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports; November 11, 2005, vol 54(RR13);1-25. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm
Individualized Quality Control Plan (IQCP)	A framework for customizing a quality control (QC) program for your test systems and your laboratory's unique environment. By performing the steps in an IQCP, you will examine the potential sources of error in your preanalytic, analytic and postanalytic phases of testing, as well as establish the appropriate QC and quality practices which reduce the likelihood of errors occurring in your laboratory. CMS CLIA Brochure #13
Internal Controls	Internal or procedural controls may only monitor a portion of the test system's analytic components, for example, a color change that indicates when a patient's specimen or reagent is added correctly. "Good Laboratory Practices for Waived Testing Sites" Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports; November 11, 2005, vol 54(RR13);1-25. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm

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APPENDIX F (CONTINUED...)

Glossary Term	Definition
Manufacturer's Instructions	Written product information usually supplied by the manufacturer with each test kit or test system containing instructions and critical details for performing the test. All of the instructions in the product insert from "intended use" to "limitations of the procedure" must be followed. "Good Laboratory Practices for Waived Testing Sites" Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports; November 11, 2005, vol 54(RR13);1-25. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm
Post-Analytic Phase	Post-analytic is a part of the total testing process occurring after analysis. It includes but is not limited to data entry; follow-up plan; and reporting results to the healthcare provider. CLIA §493.1291- 493.1299
Pre-Analytic Phase	Pre-analytic is a part of the total testing process referring to all steps taken prior to the actual testing of a patient specimen from the test request to the actual testing of the specimen. CLIA Interpretive Guidelines at §493.1240.
Proficiency Test (PT)	Proficiency testing or PT is the testing of unknown samples sent to a laboratory by a CMS approved PT program. CMS CLIA Brochure #8
Quality Assessment (QA)	An ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. The laboratory must establish and follow written policies and procedures to monitor and assess, and when indicated correct problems identified. The QA must also include a review of the effectiveness of corrective actions taken to resolve problems identified. CLIA Interpretive Guidelines at §493.1239, §493.1249, §493.1289, §493.1299
Quality Control (QC)	The procedures used to detect and correct errors that occur because of test system failure, adverse environmental conditions and variance in operator performance, as well as the monitoring of the accuracy and precision of the test performance over time. CMS CLIA Brochure #12
Quality Control Plan (QCP)	A laboratory's standard operating procedure that describes the practices, resources, and procedures to control the quality of a particular test process. S&C: 13-54-CLIA Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option Attachment 1: INDIVIDUALIZED QUALITY CONTROL PLAN
Risk Assessment (RA)	Risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process. Risk assessments for IQCP must include, at a minimum, an evaluation of the following five components (Specimen, Test system, Reagent, Environment, and Testing Personnel). S&C: 13-54-CLIA Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option Attachment 1: INDIVIDUALIZED QUALITY CONTROL PLAN CMS CLIA Brochure #13
Test System	The instructions and all the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results. CLIA §493.2

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APPENDIX F (CONTINUED...)

Glossary Term	Definition
Testing Process	Includes the pre-analytic, analytic, and post-analytic phases of testing. This process includes everything that occurs from the time the physician initiates the test request to the time the test result is entered in the patient's medical record. CLIA §493.2
Verification	The process of the laboratory verifying the manufacturer's analytical claims of a test or test system. The verification of method performance should provide evidence that the accuracy, precision, and reportable range of the procedure are adequate to meet the clients' needs, as determined by the laboratory director and clinical consultant. This process must be completed prior to reporting patient results. CLIA §493.1253(b)(1)