

CLIA Corner

State Hygienic Laboratory at the University of Iowa

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Iowa CLIA Surveyors: Nancy Grove, BS, MT(ASCP) & Kristine Rotzoll, BS, MT(ASCP)

In This Issue...

• Quality Control Plan (QCP) in Relation to the Individualized Quality Control Plan (IQCP)

A Quality Control Plan (QCP) is the second of three components that must be addressed in any IQCP plan. As stated in the 2014 – Third Quarter CLIA Corner, after the laboratory has identified and evaluated the sources of potential failures and errors for a testing process, and evaluated the frequency and impact of those failures and errors, the resulting risk assessment is used to develop the quality control plan.

Definition:

The Centers for Medicare & Medicaid Services (CMS) defines a QCP as a document that describes the practices, resources and procedures to control the quality of a particular test process. The QCP must ensure the accuracy and reliability of test results, and that the test result quality is appropriate for patient care.

Let's get started!!

Before we begin with the QCP, let's do a quick review of risk assessment since this is the basis for your QCP. Risk assessment must encompass the entire testing process: **pre-analytic, analytic and post-analytic**. When performing risk assessment in regards to IQCP, the risk assessment must include (at a minimum) an evaluation of five risk assessment components: **specimen, environment, reagent, test system and testing personnel**. For more details on Risk Assessment, refer to the *2014 Third Quarter CLIA Corner* located at www.shl.uiowa.edu/publications/.

The laboratory's QCP must provide for the immediate detection of errors that occur due to system failure, adverse environment 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 test system, environmental conditions, or variance in operator performance.

As with the risk assessment, there is no right or wrong way to develop the QCP. **The QCP must at least include the following:**

- **Number, type and frequency of testing of the quality control material(s) [At minimum, perform quality control as specified/required by the manufacturer];**
- **Criteria to determine acceptable quality control results; and**
- **Provide for the immediate detection of errors.**

If indicated by the evaluation of the risk assessment, the QCP may also include:

- Electronic controls;
- Procedural controls;
- Training and competency assessments; and
- Other specified quality control activities (e.g. specimen collection and processing; test system calibration and calibration verification; equipment maintenance and function checks; shipping, testing and storage temperature monitoring; and interpretation and reporting test results).

The laboratory must have a written QCP for each test system that the laboratory implements an IQCP. The task of development and implementation of QCP's may be delegated (in writing) to a qualified individual, i.e., a technical consultant for moderate complexity testing, or technical supervisor or general supervisor for high complexity testing. 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.

Linking the Quality Control Plan to Risk Assessment and Quality Assessment Plan

After the laboratory has identified and evaluated the sources of potential failures and errors for a testing process, and evaluated the frequency and impact of those failures and errors, the resulting risk assessment is used to develop the quality control plan. Once the quality control plan is implemented, the laboratory must establish a review system (quality assessment) for the on-going monitoring of the effectiveness of the quality control plan. When the laboratory discovers a testing process failure, the laboratory must conduct and document an investigation to identify the cause of the failure, its impact on patient care and then make appropriate modifications to the quality control plan.

In summary, establishing a quality control plan is nothing new to the laboratory. However, in order for a laboratory to implement IQCP for one or more its non-waived test systems, the laboratory is required to have a quality control plan based on its risk assessment for each test system.

Example Quality Control Plan (QCP)

Attached is an example of a QCP for a serum pregnancy test kit. *The example is for teaching purposes only and is not to be interpreted as a "CLIA-approved" quality control plan for any specific laboratory or test system. As with the risk assessments, the QCP must be customized for each laboratory.* This example QCP is based on the risk assessment from the 2014 Third Quarter CLIA Corner. Also, this example is a test kit and not an actual analyzer; therefore we did not include information about calibration, calibration verification and instrument maintenance/function checks. Finally, there is no supporting data with the example, as it is a fictional example and we don't have supporting data.

References:

- Centers for Medicare/Medicaid Services (CMS), Center for Clinical Standards and Quality/Survey & Certification Group, Survey & Cert Letter 13-54, Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option, Ref: S&C:13-54-CLIA; Published 08/16/2013.
- CMS CLIA Brochure #11, Individualized Quality Control Plan Introduction
- Food & Drug Administration, Home Medical Devices Device Advice: Comprehensive Regulatory Assistance Guidance Documents (Medical Devices), Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices [Issued 01/30/2008; OMB control number: 0910-0598; Expiration Date: 07/31/2016].

Contact Information:

If you have questions about this publication or suggestions for future issues, please contact Nancy Grove at nancy-grove@uiowa.edu or Kristine "Kristi" Rotzoll at kristine-rotzoll@uiowa.edu.

Qualitative Serum HCG Quality Control Plan

Specimen

- Use only a serum sample. Refer to the laboratory's procedures for serum specimen collection.
- Ensure that the specimen is labeled according to the laboratory's procedure to ensure the patient identification integrity.
- Handle and store specimen(s) according to the manufacturer's instructions and specifications.
- For any unacceptable specimens, refer to laboratory's policy for specimen acceptability and rejection.

Environment

- Each day of operation, monitor and record the refrigerator and room temperatures and humidity, as appropriate. If outside of acceptable range, take and document corrective action.

Reagents/Test Kits

- Use only one kit at a time. Do not interchange the reagents and controls from different kits.
- Check the lot number(s) and expiration date(s). Do not use if the test kit/reagents have exceeded expiration date. Discard expired reagents according to laboratory policy/procedure.
- Document the lot number(s) and expiration dates(s) in laboratory testing records.

Test System

External (Liquid) Controls

- Perform two levels of control materials (positive and negative controls) for the following:
 - Upon receipt of a new shipment and/or lot number of test kits;
 - When a new test kit is opened;
 - When new personnel are trained to perform the test;
 - If the laboratory temperature falls outside the following range: 59-86°F or 15-30°C; and
 - If the patient result is in question.
- Document all control results.
- Take and document corrective action for any unacceptable control results according to the laboratory's procedure.

Internal (Procedural) Control

- Document the acceptability of the internal control with each patient or external control test.
- Take and document corrective action for any unacceptable control results according to the laboratory's procedure.

Test Performance

- Testing personnel must follow the manufacturer's package insert and instructions for performing the test.
- Prior to reporting patient or external control results, check the internal control result for acceptability. If the internal control fails, the patient or external control results may be invalid and corrective action must be taken.

Interpretation of Test Results

- Interpret test results according to the manufacturer's package insert and instructions.
- Check the internal control result for acceptability. If the internal control fails, the patient or external control results may be invalid and corrective action must be taken.
- Document test results according to the laboratory's procedure.

Reporting Test Results

- Report patient test results according to the laboratory's procedure.

Testing Personnel

- Training - Prior to testing patient specimen(s), testing personnel training includes, but is not limited to, the following:
 - Specimen – Positive patient identification; correct specimen collection, labeling, processing and storage
 - Environment – Monitoring work space and storage temperatures and humidity
 - Reagents/Test Kits – Refer to Quality Control Plan (QCP)
 - Test System – Refer to QCP
- Competency – Competency assessment will be completed twice during the first year of testing and annually thereafter. Refer to the laboratory's procedure for competency assessments.
- Document training and competency assessments according to the laboratory's procedure.