

Clinical Laboratory Improvement Amendments (CLIA)

Equivalent Quality Control Procedures

Brochure #4

What are they, and when can I use them?

*Information to assist your laboratory in meeting this
CLIA quality control requirement option for
nonwaived (moderate and high complexity) test systems!*

NOTE: On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published laboratory regulations (CLIA) that became effective April 24, 2003. A summary of equivalent quality control options is included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings. For more complete information, you may access the regulations on the Internet at <http://www.phppo.cdc.gov/CLIA/regs/toc.asp>.



BACKGROUND

What is quality control (QC)?

QC consists of the procedures used to detect errors that occur due to 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.

What are equivalent quality control procedures?

For each test system, the laboratory must test, at a minimum, two levels of external QC materials each day it performs a nonwaived test. However, the regulations now also allow the laboratory to reduce the frequency of testing external QC materials (equivalent QC procedure) for certain test systems.

Advances in laboratory technology have led to test systems that often include internal monitoring systems or controls that check all or a portion of the test system's analytic components each time the test is performed. Also, some test systems are capable of maintaining stable performance specifications and are minimally influenced by adverse environmental conditions (such as temperature and humidity) and operator handling or variance (minor differences in testing personnel techniques). In these situations, the CLIA regulations provide laboratories alternatives to the traditional daily testing of two levels of external QC materials.

For eligible test systems, an equivalent QC procedure may be used by the laboratory if it successfully completes a QC evaluation process approved by CMS that demonstrates the stability of the test system over time.

What is the difference between external QC and internal monitoring systems?

In general, external QC is the testing of control material that is not built into the test system. The control material is sampled and tested by the test system in much the same way a patient specimen is sampled and tested; therefore, it checks all components of the test system's analytic process.

Internal monitoring systems are a part of or built into the test system and may be called electronic, internal, or procedural controls. Electronic controls may only monitor a test system's electronic components. 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.

What are the analytic components of a test system?

The analytic components of a test system are defined by the test system's manufacturer. Examples of analytic components include, but are not limited to, sample addition, sample/reagent interactions, and test completion time. The test system's package insert should state which components of the test system are checked by its internal monitoring systems. If this information is not available or is unclear, seek written guidance from the test system's manufacturer and include this information in your laboratory's records.

What is the equivalent QC procedure evaluation process?

It is an evaluation the laboratory must perform to demonstrate that a test system is stable and can generate correct test results over time. If the test system's results are acceptable during the evaluation period, the laboratory may reduce the frequency of testing external QC materials (see Table 1). The laboratory may only use an evaluation process approved by CMS and published in *The State Operations Manual*, Appendix C--Interpretive Guidelines (CMS Pub. 7).

EQUIVALENT QC PROCEDURES

How many equivalent QC procedure options are there?

At this time, there are three equivalent QC procedure options. The options are based on whether the test system has an internal monitoring system and if so, whether it checks all or only some of the test system's analytic components. As further technological advances are made and additional data become available, other options may be included or existing options revised.

Table 1 Equivalent QC options for eligible test systems

EQUIVALENT QC OPTIONS				
Equivalent QC Option	Test System Description	Evaluation Process:		Equivalent QC Procedure Testing Frequency
		Internal Monitoring Systems*	Test Two Levels of External Controls	
Option 1	Test Systems with Internal Monitoring System that Checks ALL <u>Analytic</u> Components	Daily testing with acceptable results	Results acceptable for 10 consecutive testing days	Testing external controls at least once per calendar month and daily testing by the internal monitoring system*
Option 2	Test Systems with Internal Monitoring System that Checks SOME <u>Analytic</u> Components	Daily testing with acceptable results	Results acceptable for 30 consecutive testing days	Testing external controls at least once per calendar week and daily testing by the internal monitoring system*
Option 3	Test Systems WITHOUT Internal Monitoring System	N/A	Results acceptable for 60 consecutive testing days	Testing external controls at least once per calendar week

* Internal monitoring system checks must be performed in accordance with the manufacturer’s instructions, but not less frequently than daily.

Is the test system I’m using eligible for an equivalent QC procedure?

To determine eligibility for an equivalent QC procedure, the laboratory must consider the following:

Test System Criteria: Whether or not the test procedure includes an extraction step, and the specialty/subspecialty of the test procedure, affect the test system’s eligibility for equivalent QC procedures. Table 2 will help you to determine if a test system is eligible for equivalent QC and if so, which options might be used.

Manufacturer’s Instructions: Manufacturers’ test system instructions must always be followed. Therefore, if the test system instructions require testing external control materials more frequently than required by equivalent QC procedures, or testing more than two levels of external control materials, the test system is not eligible for equivalent QC.

Excluded Methods: Test systems that use molecular amplification, thin layer chromatography, or electrophoretic procedures are not currently eligible for equivalent QC procedures.

Table 2 Determining test system eligibility for equivalent QC

TEST SYSTEM MEETS THESE CRITERIA			
Subject to specialty/ subspecialty requirements for routine chemistry and hematology?*	Subject to specialty/ subspecialty requirements other than routine chemistry and hematology?	Test Procedure includes an extraction phase?***	TEST SYSTEM ELIGIBLE FOR THESE EQUIVALENT QC OPTIONS (refer to Table 1):
No	No	No	Options 1, 2, or 3
Yes	No	No	Options 1 or 2
Yes	No	Yes	Options 1 or 2
No	No	Yes	Options 1 or 2
No	Yes	Yes	None
No	Yes	No	None

* Test systems subject to specialty/subspecialty requirements for routine chemistry or hematology must have an internal monitoring system to be eligible for equivalent QC.

** Contact the manufacturer if it is unclear from the manufacturer’s package insert if the test procedure includes an extraction phase.

What should I consider before choosing to evaluate a test system for equivalent QC?

In general, test systems that have a history of infrequent QC failures, and that are simple to use, very stable, and routinely performed in your laboratory, are the most suitable for equivalent QC procedures. Therefore, you should take into account the following:

- *Instrumentation and reagents*—Test systems using reliable and easy-to-maintain instruments, and reagents that are stable and do not require special handling or storage are good candidates for equivalent QC procedures.
- *Technique dependence of the test method*—Test methods with few and uncomplicated procedural steps are less prone to operator error.
- *Frequency and volume of test performance*—Frequently performed tests or high volume tests are more familiar to the laboratory’s testing personnel, making them less prone to operator error.
- *Frequency of control failures*—Test systems with few control failures over time are more suited for equivalent QC procedures.
- *Testing personnel*—Well-trained, proficient testing personnel are essential for quality test performance.

May I use data from the test system’s manufacturer to establish an equivalent QC procedure?

No. Although manufacturers may assist laboratories by providing quality control instructions, the laboratory is ultimately responsible for the establishment, performance, documentation and evaluation of its quality control procedures, which take into account the laboratory’s particular testing environment and personnel.

EQUIVALENT QC EVALUATION PROCESS

I have determined that my test system is eligible for an equivalent QC procedure. What are my next steps?

As stated previously, an evaluation process must be performed by the laboratory to demonstrate that the test system is stable and can generate correct test results over time.

5.

If the test system’s control results are acceptable throughout the evaluation you may begin using the equivalent QC procedure. The evaluation process consists of the following:

1. Two levels of external control materials must be tested for the number of consecutive testing days specified in the option chosen (see Table 1). The control results must be acceptable.
2. For options 1 and 2, internal monitoring systems must be checked, at a minimum, daily for the number of consecutive testing days specified in the option chosen. The results must meet the test system’s instructions for acceptability.
3. For option 3, during the evaluation process, all personnel who are likely to perform the test and report patient test results must participate in the evaluation process.

What do I do if an internal or external control fails during the evaluation process?

If any internal or external control result is unacceptable during the evaluation process, the laboratory must re-test the unacceptable control one time. If the repeat control result is acceptable, no further corrective action is necessary and the laboratory may continue the evaluation process. If the repeat control result is unacceptable, the laboratory must identify the problem and take appropriate corrective action. This includes evaluating all patient test results obtained in the unacceptable test run, and since the last run with both internal and external acceptable QC to determine if the patient test results were adversely affected, before reporting the results and/or, if necessary, issuing corrected reports. Once appropriate corrective action has been taken, the laboratory must restart the evaluation process from the beginning.

Note: If more than two restarts are required for an evaluation process without success and you have verified that you are performing the test correctly, you should reconsider using equivalent QC for the test system.

What do I have to do if I want to use an equivalent QC procedure for multiple instruments that perform the same test?

An evaluation must be performed for each instrument that performs the test, even if it is the exact same make and model. This ensures that each individual instrument or test system exhibits the necessary stability to qualify for equivalent QC.

6.

If I have historical (existing) QC data for my test system, may I immediately reduce the frequency of testing external control materials?

Yes. If a laboratory's existing QC data for the test system successfully fulfills the requirements of the applicable equivalent QC evaluation process, the laboratory may immediately begin the reduced frequency for testing external control materials.

May I reduce the frequency of internal monitoring system checks to less than once a day after I have successfully completed the evaluation process?

No. Internal monitoring system checks must be performed as specified by the manufacturer, but not less frequently than once each day of testing.

REMINDER: The laboratory must document all of its equivalent QC evaluation process activities and retain the records for 2 years.

MONITORING EQUIVALENT QC PROCEDURES

What do I do if an internal or external control result is unacceptable after I have implemented the equivalent QC procedure? May I continue reporting patient test results?

If any internal or external control result is unacceptable, the laboratory must re-test the unacceptable control one time. If the repeat result is acceptable, no further corrective action is necessary. If the repeat control result is unacceptable, the laboratory must identify the problem and take appropriate corrective action before reporting patient test results. This includes evaluating all patient test results obtained in the unacceptable test run and since the last run with both internal and external acceptable QC to determine if the results were adversely affected, before reporting the results and/or issuing corrected reports, if necessary. The laboratory must repeat and successfully complete the evaluation process before again reducing the frequency of testing external controls.

Are there any other quality monitoring activities I have to perform?

The laboratory must continue to perform the following on-going assessments:

- Quality assessment activities
- Proficiency testing
- Analytic system quality assessment
- Personnel competency assessments
- Calibration verification

What do I do if one of the on-going assessment indicators fails?

If unacceptable results are obtained for any of the above assessment activities, the laboratory must discontinue using the equivalent QC procedure, investigate, identify the problem, and document the actions taken to correct the problem. The evaluation process will have to be repeated and successfully completed before the laboratory may resume using the equivalent QC procedure.

REMINDER: Even though the laboratory has implemented an equivalent QC procedure, it is still responsible for testing external control materials with each complete change of reagents, with each new lot number or shipment of reagents, following major preventive maintenance, or following replacement of critical parts that may influence the test system's test performance.

Where can I find additional information about the CLIA requirement pertaining to equivalent QC?

You may refer to the State Operations Manual, Appendix C—Interpretive Guidelines, §493.1256(d), available on the CMS web site at: www.cms.hhs.gov/clia.

Links to other laboratory-related resources can be found at these websites:

CDC: www.phppo.cdc.gov/clia/default.asp

FDA: www.fda.gov/cdrh/CLIA/index.html (for a listing of waived, moderate complexity and high complexity tests).