

**D5441**

**(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)**

**§493.1256 Standard: Control procedures**

**(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.**

**(b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in §493.1253(b)(3).**

**(c) The control procedures must--**

**(c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.**

**(c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.**

#### **Interpretive Guidelines §493.1256(a)-(c)**

For each test system, the laboratory is responsible for monitoring the accuracy and precision of each phase of the analytic testing process by using control procedures that will detect immediate errors and errors occurring over time. Errors may occur due to test system failure, change in environmental conditions, and operator performance.

#### **TEST SYSTEM**

Test system failures may result from reagent contamination or deterioration, reagent lot variation, reaction temperature fluctuations, inadequate sampling, improper or loss of calibration, electronic or mechanical failure, power supply variances, etc.

#### **ENVIRONMENT**

Environmental conditions that may affect test system performance include temperature, airflow, light intensity, humidity, altitude, etc.

#### **OPERATOR (TESTING PERSONNEL)**

Operator (testing personnel) performance that may affect testing includes improper specimen preparation and handling, incorrect test interpretation, failure to follow the manufacturer's test system instructions, etc. Operator training prior to testing is critical and competency assessment over time is necessary to ensure continued appropriate test performance. (See subpart M.)

#### **Interpretive Guidelines §493.1256(c)**

#### **CONTROL PROCEDURES**

In determining the control procedures, including the frequency of testing controls that detect immediate errors and monitor test performance over time, the laboratory needs to consider the following:

- Control procedures specified by the test system's manufacturer;
- Test system instrument reliability and reagent stability (e.g., relocation);
- Frequency and volume of test performance;
- Technique dependence of the method;
- Frequency of quality control failures; and
- Training, experience, and competency of person(s) performing the test.

Traditionally, laboratories have tested two levels of external control materials daily to monitor the accuracy and precision of the analytic test system components. External control materials having a similar matrix to that of patient specimens, are treated in the same manner as patient specimens, and go through all analytic phases of testing as applicable. External control materials may be provided as part of the test system, provided separately or prepared in-house. Testing external controls meets the requirement for monitoring test system components, environment, and operator performance. External control materials may be:

- Commercially or in-house prepared controls;
- Proficiency testing specimens for which results have been confirmed;
- Reference or control strains of microorganisms;
- Calibrators of different lot numbers and concentration than those used to calibrate the system; or
- Previously tested patient specimens provided the laboratory determines the acceptable performance level for the patient specimens.