DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-20-CLIA

DATE: **April 8, 2016**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Policy Clarification on Acceptable Control Materials Used when Quality Control (QC) is Performed in Laboratories

Memorandum Summary

The Centers for Medicare & Medicaid Services (CMS) is providing clarification regarding the policy on acceptable control materials, which includes:

- **Acceptable control materials:** Acceptable control materials will now include on-board controls, i.e. ampules or cartridges containing the same QC material that would traditionally be considered as external QC.
- **Function checks and procedural controls**: Instrument/electronic function checks and procedural controls **do not** fulfill the regulatory requirement for control materials.
- **Guidance for surveyors:** The laboratory Director is responsible for the determination of what control materials to use in his/her laboratory. Surveyors will ensure that the laboratory is following its own established policies, specifically its QC procedures, in the context of the Outcome Oriented Survey Process.

Background

Quality control is performed on a laboratory test to ensure that the test is performing within the required analytic perameters prior to and during patient testing.

The Clinical Laboratory Improvement Amendments (CLIA) Interpretive Guidelines (IGs) for the regulation at §493.1256(c) state that laboratories have traditionally tested two levels of external control materials daily, and that such testing of external controls meets the requirement for monitoring test system components, environment, and operator performance. External control materials, as described in the IGs, have 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, and they may be provided as part of the test system, provided separately, or prepared in-house.

The IGs do not state that external control materials are the only way to meet the requirement. We believe that on-board control materials, when used as described below, can also fulfill the

regulatory requirement. However, we believe that electronic function checks or procedural controls, as described below, do not fulfill the regulatory requirement.

Acceptable control materials

Control materials that go through all elements of the analytic process must be run for each procedure per §493.1256(d)(3)(i)-(iii). With the advances in technology, certain instruments have introduced the use of on-board controls, that is, ampules or cartridges containing the same QC material that would traditionally be considered as external QC. For example, on-board control materials that have a similar matrix to that of patient specimens, are treated in the same manner as patient specimens, and go through all elements of the analytic process as applicable, will be considered acceptable to meet the regulatory requirement for control materials. The laboratory Director is responsible for the determination of what control materials to use in his/her laboratory. Surveyors will ensure that the laboratory is following its own established policies, specifically its QC procedures, in the context of the Outcome Oriented Survey Process.

Applicability

Control materials are referenced throughout the CLIA regulations. For sections §493.1256(d)(3)(iv)-(v), (4)-(10), and (e)-(h); also sections §493.17, 19, 1252, 1255, 1267, 1269, and 1278 (all mentioning the term "control material"), specific control materials are **not** specified by the regulation. These regulations are included in the scope of this memo allowing the laboratory director flexibility in selecting the control materials to meet these regulations. For sections §493.1264 and §493.1265, regulation specifies the control material to be used. Therefore, they are not within the scope of this memo.

Controls activities that are not considered to be acceptable as control materials to meet the regulatory requirements

Function checks, instrument/electronic checks, and procedural controls do not fulfill the regulatory requirements for testing control materials. These types of checks only verify the electronic components and detection function of the instrument and may only monitor a portion of the analytic process, such as sample addition, instrument/reagents interaction, or test completion, not the performance of the entire test system. Accordingly, they do not go through all elements of the analytic process as applicable.

Guidance for surveyors

Laboratories that intend to perform less QC than the regulatory requirements must develop and implement an Individualized Quality Control Progam (IQCP) that supports their QC plan. It will be the decision of the laboratory director to determine what control materials to use.
CLIA Surveyors will continue to follow established Outcome Oriented Survey Process policies and protocols to ensure that the laboratory is following its own established policies, specifically its own QC procedures.

Contact: Questions related to this policy memorandum may be submitted to: LabExcellence@cms.hhs.gov.

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

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management