



- What is your course of action if calibration is unacceptable?
- What is your course of action when preparing calibrators/controls in-house?
- How does your laboratory matrix match calibrator/control materials?
- What is your course of action if using expired RSCC materials?
- When was the last time you performed a calibration procedure and how did you verify calibration?

FDT.07600 RSCC Validation Phase II



The laboratory follows a written procedure that describes the system for monitoring of RSCC preparation or receipt by the laboratory and the verification of same against previously verified RSCC before they are placed into service.

FDT.17190 RSCC Labeling Phase II



RSCC are properly labeled, as applicable and appropriate, with the following elements.

1. Content and quantity, concentration or titer
2. Storage requirements
3. Date prepared or reconstituted by laboratory
4. Expiration date
5. Safety precautions or warnings

NOTE: The above elements may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log. While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc.

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7164 [42CFR493.1252(c)]
- 2) Gonzales Y, Kampa IS. The effect of various storage environments on reagent strips. *Lab Med*. 1997;28:135-137
- 3) Clinical and Laboratory Standards Institute (CLSI). *Developing and Managing Laboratory Documents*. 7th ed. CLSI guideline QMS02. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.

FDT.17210 RSCC Expiration Phase II



Outdated RSCC are discarded and replaced routinely.

NOTE: Certain reagents may warrant use after the labeled expiration date. In such cases, the laboratory must have a clearly defined, written policy specifying such reagents, the circumstances under which extended usage is permitted, the control procedures for such usage, and the persons authorized to extend the usage of the RSCC.

FDT.17220 Calibration/Control Materials Phase II

High quality drug calibration standards and control materials are used whenever possible.

NOTE: Calibrators or calibration standards are test materials with defined values that establish the relationship between the response measurement and the output values. "Calibration standard" refers to a primary reference material that is of fixed or known composition. "Calibrators" are secondary materials and are the test materials most often used by laboratories for calibration. Control materials should have known values, and be independent of the calibrators provided by the manufacturer of a method system, if possible.