- 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Outdated RSCC are discarded and replaced routinely.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.

Evidence of Compliance:
- ✓ Records of calibration/control materials

FDT.17230 Quality of Calibration Standards **Phase II**

The quality of drug calibration standards is recorded.

NOTE: The laboratory may use manufacturer's certification data for the purity of the drug calibration standards, but must still independently record the quantitative accuracy of any calibrator solutions created from the calibration standard. If manufacturer's certification of purity is not available, then the laboratory must validate the purity by determining if any significant extraneous compounds are present, using the appropriate analytical methods. Minimum requirements would be the analysis of a pure drug standard solution using GC/MS (or the same method used for drug confirmation analysis) to demonstrate that no interfering compounds are present.

Evidence of Compliance:
- ✓ Records of calibration materials

FDT.17330 Calibrator Preparation **Phase II**

If the laboratory prepares calibrators and controls in-house, different sources or lot numbers of drug calibration standards are used (when possible) for the creation of calibrators and controls, or these materials are prepared separately, at minimum.

FDT.17363 Control Matrix **Phase II**

Control material is matrix-matched or validated against the matrix by the laboratory.

NOTE:
1. *Urine: Urine based matrix*
2. *Oral-Fluid: Buffer/preservative solution from the collection device or purified saliva as appropriate*
3. *Hair: Negative hair digest or extract*
4. *Blood: Whole blood, plasma, or serum based matrix, as appropriate*
5. *Other materials may be used if validated by the laboratory and shown to be equivalent to the above*

Evidence of Compliance:
- ✓ Records of validation when differing matrices are used

FDT.17396 Calibrator Matrix **Phase II**

Calibration material is matrix-matched or validated against the matrix by the laboratory.

NOTE:
1. *Urine: Urine based matrix*
2. *Oral-Fluid: Buffer/preservative solution from the collection device or purified saliva as appropriate*
3. *Hair: Negative hair digest or extract*
4. *Blood: Aqueous calibrators when appropriate*
5. *Other materials may be used if validated by the laboratory and shown to be equivalent to the above*

Evidence of Compliance:
- ✓ Records of validation when differing matrices are used