- How does your laboratory identify possible ion-suppression or enhancement?
- How does your laboratory ensure appropriate extracted calibrator(s) are analyzed?
- When are reinjection or reanalysis procedures required?

***REVISED** 08/24/2023*

FDT.24430 Instrument Calibration **Phase II**

The laboratory calibrates the mass spectrometer and reviews calibration records for acceptability.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline - Second Edition.* CLSI Document C43-A2. (ISBN 1-56238-720-0). Clinical and Laboratory Standards Institute, 940 West Valley Road, Wayne, PA 19087-1898, USA, 2010.
2) Clinical and Laboratory Standards Institute (CLSI). *Liquid Chromatography-Mass Spectrometry Methods;* 2nd ed. CLSI document C62. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

***REVISED** 08/24/2023*

FDT.24630 Mass Spectrometer Tuning **Phase II**

The mass spectrometers are tuned as defined based on the particular platform in use, assay performance requirements, and specimen types tested.

NOTE: Instruments must be tuned at least as frequently as recommended by the manufacturer. Acceptable tolerance limits for tune parameters must be defined, and tuning records retained.

Evidence of Compliance:

✓ Records of tuning

FDT.24880 Extracted Calibrators **Phase II**

Appropriate extracted calibrator(s) are analyzed with each batch of samples.

NOTE: At least one extracted calibrator at the commonly accepted cutoff for single-point calibration, or multiple calibrators above and below the commonly accepted cutoff for multipoint calibration, must be analyzed with each run.

***NEW** 08/24/2023*

FDT.24950 Validation, Monitoring, and Annual Verification of MS Data Analysis Tools **Phase II**

The laboratory validates data analysis tools used for compound identification and quantification when first installed and after any modifications, as applicable, and verifies performance at least annually.

NOTE: Data analysis tools may be used for various processes, such as integration of targeted and untargeted peaks, evaluating acceptability of calibration and control performance, stability of baseline, calculation of ion mass ratios, discrimination of positive and negative results, and assessing risk of carryover. Data analysis tools (eg, software or code-based rules, algorithms, machine learning) used for automated data analysis must be verified using defined acceptability criteria. Version control of custom data analysis tools is required. Reassessment of lower limit of quantification (LLOQ) and other decision points may be used to ensure that a shift has not occurred due to instrument performance or another factor impacting assay performance.

Customized data analysis tools, and modifications to that software, should be appropriately documented and records should allow for tracking to identify persons that have added or modified that software. The purpose of the computer program, the way it functions, and its