REFERENCES
1) Annesley TM. Ion Suppression in Mass Spectrometry. *Clin. Chem.* 49, pp. 1041-1044 (2003).
2) Krull I, and Swartz M. Quantitation on Method Validation. *LC-GC,* 16. pp. 1084-1090 (1998).

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

FDT.25210 Matrix Effect Assessment of Mass Spectrometry Assays - Routine Monitoring **Phase II**

The laboratory evaluates mass spectrometry assays for possible ion-suppression or enhancement in donor samples during routine testing.

NOTE: Ion suppression (or less frequently, ion enhancement) is a recognized analytical anomaly in mass spectrometry assays. Such suppression can lead to false negative results or poor quantitative analyses (especially near assay limit of quantitation). While difficult to predict and observe from specimen to specimen, certain precautions should be used to try to detect ion suppression or enhancement.

Routine monitoring of the signal intensity of internal standard(s) is an effective way to recognize signal suppression/enhancement in a single patient sample, due to unexpected interfering components of the matrix. Internal standards to be used are those that cover the areas of the elution profile where matrix effects are most pronounced, and that the suitability of these internal standards has been determined (ie, with acceptance limits) during assay development and validation. Internal standard abundance acceptance criteria may be based on signal to noise ratio or may be compared to internal standard abundance in QC samples. As an example, for isotopically-labeled internal standards, if there is poor recovery of the internal standard, a signal to noise ratio greater than 3:1 should still suffice for acceptance of the specimen in question. If recovery of the isotopically-labeled internal standard is considered poor, then an alternate analysis should be considered, eg, the method of standard addition. For analogue-type internal standards, internal standard recovery may be used as a guide for identification of ion suppression/enhancement, although another option, such as the method of standard addition, would be a reasonable alternative. It should be noted that even isotopically-labeled internal standards do not always readily identify ion suppression or enhancement.

Evidence of Compliance:

✓ Records of monitoring using internal standards **OR** records for alternative methods used

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Liquid Chromatography-Mass Spectrometry Methods;* 2nd ed. CLSI document C62. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

FDT.25280 Reinjection/Reanalysis **Phase II**

The laboratory defines situations when reinjection or reanalysis is required.

PERSONNEL

The laboratory must be staffed by appropriately qualified and trained personnel under the guidance of the laboratory director. Records of the qualifications and training must be kept and be available for review. Minimum personnel qualifications for analytical testing in the FDT laboratory must be equivalent to those defined in the Personnel section of the Laboratory General Checklist (GEN.54750).

The laboratory must have an organizational chart, personnel policies, and job descriptions that define qualifications and duties for all positions. Personnel files must contain qualifications and continuing education records for each employee.

Ideally, these files should be located in the laboratory. However, they may be kept in the personnel office or health clinic if the laboratory has ready access to them (ie, easily available to the inspector).

Please consult the Laboratory General Checklist for additional details relating to personnel that are not covered in this FDT Checklist.

LABORATORY DIRECTOR

Inspector Instructions:

	• Records of laboratory director education and experience
	• Interaction of laboratory director with laboratory supervisory personnel and laboratory staff
	• How does your laboratory choose the individual(s) who perform certifying scientist responsibilities?

FDT.26830 Laboratory Director Qualifications **Phase II**

The laboratory director meets at least one of the following qualifications.

1. **MD certified in clinical and/or forensic pathology with at least two years' experience in analytic toxicology**
2. **PhD in a chemical and/or biological discipline with at least two years' experience in analytic toxicology**
3. **Scientific director of a CAP FDT accredited laboratory on January 1, 1997 or before**

NOTE: The experience requirement is deemed to be satisfied if the individual is board certified by the American Board of Forensic Toxicology or the American Board of Clinical Chemistry in Toxicological Chemistry.

Evidence of Compliance:

✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

FDT.27030 Laboratory Director Experience **Phase II**

The laboratory director has appropriate experience in forensic applications of analytical toxicology, such as in-court testimony, attendance at relevant continuing education programs, research, and publications in analytical toxicology.

Evidence of Compliance:

✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field