NOTE: When isotopes and internal standards are measured by ICP/MS, interferences (isobaric and polyatomic species) and relative abundances must be considered and described in written procedures and/or assay validation materials.

CHM.21200 Contamination **Phase I**

Laboratory processes minimize and detect contamination of results obtained by ICP/MS.

NOTE: Potential sources of contamination include specimen collection, reagent handling, carryover between samples, and engineering controls within the analytical environment.

CHM.21300 Gas/Reagent Purity **Phase I**

The purity of each gas and reagent used with ICP/MS is defined and appropriate for the intended use.

NOTE: Purity of gasses and reagents (including water) used with ICP/MS should be defined and validated to identify and minimize interferences and sources of contamination.

CHM.21400 Controls/Calibrators/Blanks **Phase I**

Controls, calibrators and blanks are matrix-matched to the sample type.

NOTE: The matrices of controls, calibrators and blanks may affect the ions generated and should be considered in the design and validation of each ICP/MS assay. If matrices are not an issue, the laboratory should have a record that matrix-matching is not necessary.

IMAGING MASS SPECTROMETRY

Imaging Mass Spectrometry (IMS) is an emerging technology used to provide molecular information on tissue section specimens through visualization of the spatial distribution of proteins, lipids and other molecules by their molecular masses. It is used in conjunction with other pathology findings to make a tissue diagnosis or provide other information on the tissue specimen.

IMS combines the following methods to evaluate the tissues:
- *Whole slide imaging*
- *Matrix-assisted laser desorption ionization mass spectrometry (MALDI MS)*
- *Individual molecular mapping of a tissue*
- *Data analysis process*

This checklist section is not applicable to use of MS imaging for education or research-only use.

Inspector Instructions:

READ

- Sampling of imaging Mass Spectrometry policies and procedures
- Sampling of calibration and maintenance records
- Sampling of quality control records

CHM.21405 Instrument Calibration **Phase II**

The laboratory calibrates each test system and reviews calibration records for acceptability.

NOTE: The manufacturer provides detailed instructions for this process along with minimum specifications for each instrument. This basic calibration should be performed each time the instrument is cleaned or serviced with a record of performance retained by the laboratory.

Evidence of Compliance:
- ✓ Records of service and calibration at defined frequency

CHM.21410 Mass Spectrometer Tuning — Phase II

The mass spectrometers are tuned each day of patient/client testing, or according to manufacturer's recommendations, and tuning records are retained.

NOTE: Acceptable tolerance limits for tune parameters must be defined, and tuning records retained. A specific suitable standard sample covering the m/z range of the patient samples must be used.

Evidence of Compliance:
- ✓ Records of tuning parameters

CHM.21415 Mass Spectrometry Calibration — Phase II

A calibration consisting of at least five standard compounds is included on each target used for patient testing within the m/z range acquired from patient samples. Calibration is performed with each insertion of the target plate, and these records are retained.

NOTE: Tolerance limits for calibration parameters must be defined in accordance with instrument specifications.

Evidence of Compliance:
- ✓ Records of calibration

CHM.21420 MS Performance Evaluation for Patient Samples — Phase II

Exogeneous standards are placed on like tissue (with respect to the type of patient tissue to be analyzed) on each day of patient testing to measure signal-to-noise and overall performance specifications for one or more analytes.

NOTE: For MS/MS (tandem MS) assays, identification criteria for tandem mass spectrometry (MS/MS) are validated and recorded. For MS tests using multiple reaction monitoring (MRM) there is at least one transition monitored for the internal standard and another for the analyte.

Evidence of Compliance:
- ✓ Records of performance values and test records

REFERENCES

1) Kaletas BK, van der Wiel IM, Stauber J, et al. Sample preparation issues for tissue imaging by imaging MS. *Proteomics.* 2009; 9(10):2622-33.

CHM.21425 Mass Spectrometer Control Tissue — Phase II

Appropriate control tissues are tested on each day of patient testing representing the diagnostic state being considered.

NOTE: Control tissue must be subjected to the same testing conditions throughout the testing procedure as patient specimens.