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.

In general, targets are not to be reused. In formats of testing where a target is reused, a blank control needs to be run after each cleansing to assess the cleanliness of the target (demonstrating lack of peaks prior to testing).

Evidence of Compliance:
- ✓ QC records at defined frequency

CHM.21430 Mass Spectrometer Reagent Grade **Phase II**

Reagents and solvents are of HPLC-grade, MS-grade, or equivalent quality.

NOTE: HPLC-grade and MS-grade solvents with certification from the manufacturer (when available) are acceptable. If lesser grade reagents are used, the laboratory must document equivalent performance.

Evidence of Compliance:
- ✓ Reagent logs and test records

CHM.21435 Mass Spectrometer Consumables **Phase II**

Consumables appropriate to the instrument and assay are used.

NOTE: Consumables (eg, auto-pipettes and tips, solvents, target glass slides) utilized may be specified by the manufacturer. Other types of consumables must be validated.

Evidence of Compliance:
- ✓ Consumable logs **AND**
- ✓ Validation of alternative consumables not specified by the manufacturer

CHM.21440 Area of Analysis **Phase II**

A qualified pathologist selects or confirms the appropriate areas for analysis.

NOTE: The identity of the individual determining the areas for analysis must be recorded. For specific tissue types, a specialist in the related area may perform this duty (eg, dermatologist for skin biopsies).

Evidence of Compliance:
- ✓ Record of review by a qualified individual

CHM.21445 Analytical Data Analysis Procedure **Phase II**

The algorithms and steps that make up the data analysis process used to analyze, interpret, and report test results are defined.

NOTE: This data analysis process includes all algorithms, software, scripts, and reference databases, whether in-house, vendor-developed, or open source.

The written procedure must include:
- *Individual applications and databases used with versions and appropriate command line flags, or other configuration items needed to compile, install, and run the process*
- *Additional scripts or steps used to connect discrete applications in the process*
- *Name and version number of the source codes for algorithms used*
- *Description of input and output data files or information (eg, parameters/flags and values) in each process step*
- *Criteria and specific thresholds used*
- *Acceptance and rejection criteria for the results generated by the data analysis process. Criteria must be based on metrics and quality control parameters established during test*