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*

optimization and utilized during validation. These should include criteria for determining when the data analysis process has failed and the data are either re-processed or not further processed.
- *Limitations in the test methodology for each test*
- *Written procedures for any portion of the data analysis process performed by a referral laboratory, if applicable*

REFERENCES
1) Jones EA, Deininger SO, Hogendoorn PC, Deelder AM, McDonnell LA. Imaging mass spectrometry statistical analysis. *J Proteomics.* 2012; 75(16):4962-89.
2) Kriegsmann J, Kriegsmann M, Casadonte R. MALDI TOF imaging mass spectrometry in clinical pathology: a valuable tool for cancer diagnostics (review). *Int J Oncol.* 2015; 46(3):893-906.

CHM.21450 Data Analysis Process Validation — Phase II

The laboratory validates the data analysis process on a control tissue sample and revalidates the entire process and/or confirms the performance of the components of the process as acceptable when modifications are made.

Evidence of Compliance:
- ✓ Records of validation and revalidation and/or confirmation studies, including metrics and QC parameters used to establish and assess performance **AND**
- ✓ Written approval of validations, revalidations and/or confirmation studies **AND**
- ✓ Records of review of referral laboratory, if applicable

REFERENCES
1) Jennings L, et al. Recommended practices and principles for validating clinical molecular pathology tests. *Arch Pathol Lab Med.* 2009; 133(5):743-755.

CHM.21455 Data Analysis Process - Updates — Phase I

The laboratory has a defined process for monitoring, recording, and implementing patch-releases, upgrades, and other updates to the data analysis process.

NOTE: The data analysis processes are composed of multiple components - open source or other software packages, additional scripts, and databases for managing content and aspects of analysis and reporting. Due to the ongoing evolution of the field, laboratories need to establish a procedure for regular monitoring of updates, patch-releases, and other upgrades for each component of the process. Congruent with the procedure, the laboratory must demonstrate that acceptable performance specifications are met when a change to the process is implemented. The extent of revalidation and/or confirmation is modification dependent. Revalidation/confirmation may cover all or a subset of steps in the data analysis process and must designate specific monitoring intervals and address when such updates will be implemented.

Evidence of Compliance:
- ✓ Records of monitoring activities **AND**
- ✓ Records of revalidation/confirmation data including the type of upgrade, metrics, and quality control (QC) parameters monitored to assess analytical run performance **AND**
- ✓ Approval of revalidation/confirmation data by the laboratory director **AND**
- ✓ Dates of implementation

CHM.21460 Data Storage — Phase I

The laboratory retains data necessary to support primary results generated and re-analysis for a minimum of two years and as required by national, federal, state (or provincial), and local laws and regulations.

NOTE: The data retained must include the files necessary to re-review cases as originally performed for original results reporting. Examples include specimen tacking and quality metrics