QSA.13.03.01

The laboratory documents its receipt of surgical specimens and maintains the identity of the specimens throughout processing and storage. The laboratory receives, processes, evaluates, and stores surgical specimens.

Elements of Performance (EPs) for QSA.13.03.01

1. The laboratory establishes a time frame for transport of surgical specimens to the laboratory for gross examination, dissection, and fixation.
   Note: Delayed fixation can lead to inaccurate immunohistochemical staining results and diminished immunoreactivity. For these reasons, fixation should start immediately after surgical removal of the tissue.

QSA.13.06.01

The equipment, methods, and stains used in producing microscopic slides provide tissue sections that facilitate a diagnosis.

Elements of Performance (EPs) for QSA.13.06.01

5. For laboratories that develop immunohistochemistry tests that include primary antibodies commercially distributed as analyte-specific reagents (ASRs), the laboratory establishes the clinical performance characteristics of the assay using patient specimens that test the reportable range of the assay.
   Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document I/LA28 (Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays).

QSA.13.08.01

The histopathology laboratory conducts surveillance of patient results and related records as part of its quality management plan.

The histopathology laboratory follows its written quality management plan.

Elements of Performance (EPs) for QSA.13.08.01

1. The histopathology laboratory’s quality management plan addresses the following:
   - Documentation of verbal orders and reports
   - Management of all consultation and peer case review
   - Prevention of cross-contamination during grossing
   - Criteria for adequacy of each surgical slide specimen for diagnosis
   - Correlation with ancillary studies (for example, immunohistochemistry, special stains, cytology, flow cytometry, cytogenetics, molecular testing)
   - Authentication of interpretive surgical pathology reports (See also DC.02.03.01, EP 2)
- Quality control of each surgical specimen (See also QSA.13.06.01, EPs 2 and 3)
- Periodic maintenance and decontamination of cryostat and other equipment used in
  the histopathology laboratory (See also EC.02.04.03, EP 7)

2. The histopathology laboratory's written policies and procedures for Mohs surgery
   specify processing of Mohs frozen sections, reporting of each Mohs surgical
   procedure, and the associated quality control procedures specific to Mohs surgical
   specimens.