

Evidence of Compliance:

- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

SPECIMEN ANALYSIS

Inspector Instructions:



- Sampling of specimen analysis policies and procedures

BAP.05440 Area of Analysis

Phase II



A qualified pathologist selects or confirms the appropriate areas for analysis prior to reporting the results, as applicable.

NOTE: Specimens that do not represent "in situ" samples embedded in paraffin may not require pathologist review. Examples include cultured preparations and direct preparations of liquid specimens including blood, urine, pleural fluid, etc.

BAP.05445 Analysis Guidelines

Phase II



There are written guidelines for identification of appropriate areas and cells for analysis.

NOTE: Evaluation of heterogeneous cell populations requires use of specific guidelines and procedures to ensure analysis of the appropriate areas and/or cells, particularly if there is background or nonspecific staining, or if there is cell debris, endogenous pigment, and/or artifacts of aging, sectioning or preparation.

Test results may be affected by fixation parameters, including time of fixation, type of fixative used, hemorrhage, necrosis, and autolysis of tissue.

PERSONNEL

Inspector Instructions:



- Records of personnel education and experience

BAP.05450 Testing Personnel Qualifications

Phase II

Personnel who are responsible for evaluating the imaging system data are qualified as high-complexity testing personnel.

NOTE: Refer to the Laboratory General Checklist for high complexity testing personnel (GEN.54750) and general supervisor (GEN.53600) qualifications. Detailed information on