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

personnel qualifications can be found in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

Evidence of Compliance:

- ✓ Records of qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, or current license (if required) **AND**
- ✓ Work history in related field

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28):[42CFR493.1489].

TISSUE MICROARRAY (TMA)

TMA technology helps expedite discovery of the novel targets important in disease treatment by providing a tool for high-throughput screening of multiple tissues using immunohistochemical, in situ hybridization, and fluorescent in situ hybridization (FISH) analyses. (Reference: https://ccrod.cancer.gov/confluence/display/CCRTARP/About)

Inspector Instructions:

	• Sampling of tissue microarray policies and procedures • Records of methods selected for region of interest of tissue and communication with the microarray technologist
	• System to positively identify specimens, specimen types and aliquots throughout the process
	• Who is responsible for selecting tissues and performing analysis for tissue microarray? • How are the selection and number of cores determined?
	• Follow a tissue specimen for TMA from processing to final analysis. Observe specimen identification, core selection and analysis.

BAP.05500 Specimen Identification - Tissue Microarray **Phase II**

There is a system to positively identify all participant specimens, specimen types, and aliquots through all phases of the analysis.

NOTE: The phases include, but are not limited to:

1. *Specimen receipt*
2. *Specimen ID key*
3. *Tissue core selection from parent paraffin block*
4. *Location and identification within the new tissue microarray recipient tissue block*