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*

5. *Preparation of records*
6. *Utilization (number of times sectioned)*
7. *Storage*

BAP.05600 Preparation - Tissue Microarray **Phase II**

There are records describing the tissue types and purpose for the tissue microarray (TMA), including the size and placement of the tissue cores as well as control tissue cores.

NOTE: Criteria for selection and records of the tissue cases are required. The usefulness and analysis of tissue microarray cores can be affected by the location (edges versus center) and loss of tissue cores as the tissue microarray block is thin sectioned. Consideration of size, frequency, and location of cores therefore, should be considered and recorded to match the intended use of the tissue microarray. Examples of the intended purpose of the TMA include, but are not limited to, disease-specific TMA, disease-progression TMA, tissue staining control TMA, cell line TMA, etc.

BAP.05700 Original Paraffin Tissue Block - Tissue Microarray **Phase II**

The biorepository has criteria for determining the extent to which the original paraffin tissue block lesion can be removed.

BAP.05800 Tissue Core Selection - Tissue Microarray **Phase II**

A qualified anatomic pathologist selects the appropriate tissues (paraffin block and tissue region of interest) to make a tissue microarray.

BAP.05900 Core Selection - Tissue Microarray **Phase II**

There is a defined process for selecting the regions of interest in the tissue and clearly communicating the instructions to the tissue microarray technologist.

BAP.06000 Number of Cores - Tissue Microarray **Phase II**

The methods for determining the relevant number of cores to accurately represent the parent tissue block are recorded.

NOTE: The biorepository must follow a written procedure to determine the optimum number of cores required per tissue microarray, as dictated by each study protocol.

BAP.06100 Tissue Placement - Tissue Microarray **Phase II**

Personnel follow a defined process for ensuring that the correct tissue is placed in the correct location of the tissue microarray (TMA) (eg, a TMA map identifying tissue type, key ID, and location in the TMA).

NOTE: This includes the placement and location of tissue controls and orientation markers.

There is software available to manage the map of a TMA. This resource is very useful in helping the pathologist evaluate and read results from the TMA after it has been stained.

REFERENCES

1) Clinical and Laboratory Standards Institute. *Fluorescence in Situ Hybridization Methods for Clinical Laboratories; Approved Guideline.* 2nd ed. CLSI Document MM07-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2013.