	• Instruments/equipment (clean and well-maintained)
	• How does your laboratory prevent cross-contamination between specimens or cases at the processing, embedding, and microtomy stations? • Please explain your process for refilling tissue processor solutions
	• If problems are identified during the review of instruments and equipment, or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions • Select a representative assay and follow the entire process from specimen receipt to final result reporting

ANP.23100 Tissue Processor Solutions **Phase I**

Tissue processor solutions are changed at intervals appropriate for the workload.

NOTE: When solutions are changed, they must be entirely replaced with new solution and not just "topped off."

Evidence of Compliance:

✓ Records of solution changes at the defined frequency

REFERENCES
1) Baunoch DA, *et al*. Troubleshooting problems in processing, staining. *Advance/Lab*. 1999(Oct));8(10):59-64
2) Compton CC, Robb JA, Anderson MW, et al. Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. *Arch Pathol Lab Med.* 2019;143(11)1346-63.

ANP.23120 Tissue Processing Programs - Validation **Phase II**

Tissue processing programs are validated.

NOTE: To validate new processing programs, laboratories should run tissue samples of the same size, thickness and fixation in duplicate. Reagents on the processor(s) should be comparable, eg, all fresh reagents. Process, embed, cut, and stain slides at the same time and evaluate the quality of the blocks, eg, firmness, ease of cutting. The slides should be evaluated by the pathologist without knowledge of which processing program was used and graded on quality of section and staining. The new processing program must be of adequate quality before being put into use.

This method may also be used to verify a routine processing program before putting a new processor into clinical service.

For tissue programs in place prior to July 31, 2012, ongoing records of acceptable tissue processing may be used to demonstrate compliance with this requirement.

Evidence of Compliance:

✓ Validation records of processing program changes

ANP.23130 Tissue Processing Programs **Phase I**

Specific tissue processing programs are available for different types and sizes of specimens.

NOTE: To achieve acceptable results for diagnostic purposes, processing programs may be needed for different sizes and types of specimens. Biopsy specimens may be processed on a shorter schedule than larger specimens; large, dense or fatty specimens and brain specimens will not process adequately on a shorter schedule. A variety of processing programs should be defined and used to achieve good processing results.

Evidence of Compliance:

✓ Defined processing programs for various types and sizes of specimen tissues

ANP.23350 Paraffin Baths, Flotation Baths, and Embedding Stations Phase II

Paraffin baths, flotation baths, and embedding stations are clean and well-maintained.

NOTE: Instruments must be clean and well-maintained (eg, tissue processors, embedding centers, dispensers, flotation baths, stain lines, coverslipping equipment). The temperature of the paraffin dispenser and paraffin baths must be correct for the type of paraffin used. At a minimum, the equipment must be maintained according to the manufacturer's instructions and paraffin temperatures recorded.

The CAP recommends the use of high-quality paraffin with a melting point <60°C. The benefit of low-melt paraffin is that it is removed more efficiently during de-paraffinization and/or antigen retrieval. Efficient paraffin removal is essential for all molecular analyses.

REFERENCES
1) Gephardt GN, Zarbo RJ. Extraneous tissue in surgical pathology. A College of American Pathologists Q-Probes study of 275 laboratories. *Arch Pathol Lab Med.* 1996;120:1009-1014
2) Compton CC, Robb JA, Anderson MW, et al. Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. *Arch Pathol Lab Med.* 2019;143(11)1346-63.

ANP.23400 Microtome Maintenance Phase I

Microtomes and microtome knives are clean and well-maintained.

NOTE:

1. *Microtomes must be clean, properly lubricated, and without excessive play in the advance mechanism*
2. *Knives must be sharp and free of nicks*

ANP.23410 Cryostat Decontamination Phase II

The cryostat is decontaminated at defined intervals and under defined circumstances.

NOTE: The cryostat must be defrosted and decontaminated by wiping all exposed surfaces with tuberculocidal disinfectant. The cryostat should be at room temperature during decontamination unless otherwise specified by the manufacturer. Decontamination must be done at an interval appropriate for the institution; this must be weekly for instruments used daily. Trimmings and sections of tissue that accumulate inside the cryostat must be removed during decontamination. Although not a requirement, cut-resistant gloves should be worn when changing knife blades.

Evidence of Compliance:

✓ Records of cryostat decontamination

REFERENCES
1) Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline.* 4th ed. CLSI Document M29-A4. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.
2) US Environmental Protection Agency: Antimicrobials Products Tested or Pending Testing. https://www.epa.gov/pesticide-registration/antimicrobials-products-tested-or-pending-testing Accessed April 19, 2018.

ANP.23420 ISH Slide Processing System Temperature Checks Phase II