

Evidence of Compliance:

- ✓ Records for solution changes

BAP.07120 Incubator QC**Phase II****Incubators are monitored for temperature, CO₂ level, and humidity on each day of use.**

NOTE: The procedure manual must specify the allowable limits for each type of culture. Readings must be recorded each day that cultures are incubated. There must be records of corrective action if the allowable limits are exceeded.

Evidence of Compliance:

- ✓ Instrument QC records

BAP.07200 Tissue Processor Solutions**Phase II****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) 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.

BAP.07210 Tissue Processing Programs - Validation**Phase II****Tissue processing programs are validated.**

NOTE: To validate new processing programs, the biorepository 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 equal or better quality before being put into use.

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

Evidence of Compliance:

- ✓ Records of validation

BAP.07220 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