Microwave devices are used in accordance with manufacturer's instructions.

***REVISED** 12/26/2024*

BAP.06856 Microwave Monitoring **Phase I**

Microwave devices (used for any purpose) are monitored for reproducibility at least annually.

NOTE: For some devices, reproducibility may be evaluated by monitoring the temperatures of identical samples after microwave processing. For those microwave devices (particularly those incorporated into histology processing equipment) that use temperature-independent methods to evaluate reproducibility, the reproducibility must be assessed following instrument manufacturer's instructions.

The microwave device must be tested for radiation leakage if there is visible damage to the device. A description of the specific damage along with the result of the test must be recorded.

Evidence of Compliance:

- ✓ Records of monitoring the diagnostic quality of specimens processed using microwaves **AND**
- ✓ Records of reproducibility testing for microwave use

BAP.06858 Microwave Container Venting **Phase I**

All containers used in microwave devices are vented or are used in compliance with manufacturer's instructions for the microwave instrumentation used.

NOTE: Venting of containers is necessary so that processing occurs at atmospheric pressure, to prevent explosion. For procedures using pressure above that of the atmosphere, specialized containers must be used, with strict adherence to manufacturer's instructions.

BAP.06865 Microwave Venting **Phase I**

Microwave devices are properly vented and the effectiveness of ventilation is monitored at least annually.

NOTE: Some types of microwave devices need to be operated in an appropriate ventilation hood to contain airborne chemical contaminants and potentially infectious agents. Before operation of the microwave device, flammable and corrosive reagents must be removed from the hood to prevent fire or chemical damage to the electronic components of the device. Microwave devices used outside a fume hood must have an integral fume extractor certified by the manufacturer for use in a clinical laboratory.

This checklist item does not apply to microwave devices that are designed by the manufacturer to operate without venting. It also does not apply if non-hazardous reagents (as defined in the safety data sheets) and non-infectious specimens (eg, paraffin specimens) are used in the device.

Evidence of Compliance:

- ✓ Records of annual evaluation of ventilation effectiveness

BAP.07110 Automated Stainer **Phase II**

The biorepository changes the solutions in automated stainers following a defined schedule.

NOTE: Solutions must be changed at intervals appropriate for the biorepository's workload. Cleaning of the stainers must be recorded when performed.

Evidence of Compliance:
- ✓ Records for solution changes

BAP.07120 Incubator QC **Phase II**

Incubators are monitored for temperature, CO_2 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