BAP.07400 Paraffin Baths, Flotation Baths, and Embedding Stations — Phase II

Paraffin baths, flotation baths, and embedding stations are clean, controlled 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 of <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.

Written procedures must include required water type, fill volume, and optimal temperature range for the type of paraffin used for tissue blocks. Inappropriate temperatures may affect the downstream use of the biospecimen.

Evidence of Compliance:
- ✓ Records of maintenance **AND**
- ✓ Records of temperature checks

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.07600 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 for 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.

BAP.07630 Thermocycler Temperature Checks — Phase II

Individual wells (or a representative sample thereof) of thermocyclers are checked for temperature accuracy before being placed in service and at least annually thereafter.

NOTE: A downstream measure of well-temperature accuracy (such as productivity of amplification) may be substituted to functionally meet this requirement. For closed systems, this function should be performed as a component of the manufacturer-provided preventive maintenance.

Evidence of Compliance:
- ✓ Records of thermocycler verification

REFERENCES

1) Saunders GC, *et al.* Interlaboratory study on thermal cycler performance in controlled PCR and random amplified polymorphic DNA analyses. *Clin Chem.* 2001;47:47-55

STORAGE

This section of storage for a biorepository should be based on the type of equipment, the type of specimen(s) to be stored, the length of time in storage, and the intended use of the specimen(s). Performing visual audits of refrigerators/freezers to assess for clutter, water damage, and mold, along with daily refrigerator/freezer temperature and humidity monitoring would be considered best practice.

TEMPERATURE DEPENDENT STORAGE EQUIPMENT

Inspector Instructions:

	• Sampling of specimen storage policies and procedures • Sampling of preventive and corrective maintenance procedures • Records of storage container calibrations and calibration verifications • Sampling of temperature monitoring records • Sampling of temperature set points
	• Adequate space for storage containers • Active alarm systems in place • Walk-in storage environment • Liquid nitrogen tanks usage monitoring and storage, if applicable
	• What do you do in the event of freezer breakdown? • How do you prevent overflow of storage containers?
	• Have you ever suffered a significant loss of samples? How did you address this and what were the corrective actions that became policy as a result?

BAP.07800 Storage Equipment Calibration/Calibration Verification **Phase II**

The biorepository performs calibration and calibration verification for all applicable storage equipment.

NOTE: The records of calibration and calibration verification include:
1. *Date calibration was performed*
2. *Identity of person who ran the calibration*
3. *Records of results*
4. *Name of the device used against which instrument was calibrated*

Evidence of Compliance:
✓ Records of calibration/calibration verification **OR** manufacturers' certification of calibration