

- 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:

	<ul style="list-style-type: none"> 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
	<ul style="list-style-type: none"> Adequate space for storage containers Active alarm systems in place Walk-in storage environment Liquid nitrogen tanks usage monitoring and storage, if applicable
	<ul style="list-style-type: none"> What do you do in the event of freezer breakdown? How do you prevent overflow of storage containers?
	<ul style="list-style-type: none"> 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