Decalcification Endpoint Testing - Educational SOP Template

A structured template for monitoring calcified specimens and preventing under- or over-decalcification.

This is not a laboratory-approved SOP. Adopt only after review by laboratory leadership, safety, and quality systems. Follow the decalcifier IFU and local validation.

1. Purpose

To define documented methods for determining when mineral removal is sufficient for processing and microtomy while minimizing damage from excess decalcifier exposure.

2. Required documentation

Item	Record
Specimen identifier and type	_____
Thickness / gross dimensions	_____
Fixative and fixation window	_____
Decalcifier, concentration, lot, and volume	_____
Start date/time and temperature	_____
Solution-change schedule	_____
Expected downstream tests	_____
Endpoint method and acceptance criteria	_____

3. Endpoint methods

Method	Procedure summary	Acceptance concept	Limitations
Radiography	Image the specimen at defined intervals using a validated setting.	No residual radiopaque mineral in the required plane/region.	Equipment and specimen geometry affect interpretation.
Chemical calcium test (acid solutions)	Use a validated aliquot-based calcium precipitation method, such as alkalinization followed by ammonium oxalate, under an approved SOP.	No calcium precipitate during the validated observation period.	Can be unreliable with some solutions, including chelators; use method-specific validation.
Physical probing / flexibility	Gently assess only when permitted and away from diagnostic tissue.	Uniform softness consistent with validated endpoint.	Subjective, potentially damaging, and may miss residual mineral islands.
Weight / other analytical method	Track specimen or solution using a validated laboratory method.	Stable endpoint according to method validation.	Not routine in many clinical laboratories.

4. Monitoring workflow

1. Confirm fixation is complete and specimen thickness is appropriate before decalcification.
2. Place the specimen in sufficient fresh decalcifier according to the validated method.
3. Record each solution change and monitoring time point.
4. Perform endpoint testing at the validated interval; increase frequency as the specimen approaches completion.
5. When endpoint criteria are met, remove the specimen promptly and rinse/neutralize according to the decalcifier IFU and local SOP.

6	Proceed to processing using a schedule validated for the specimen and decalcification method.
7	Document deviations, overexposure concerns, and downstream-test limitations in the quality record.

5. Stop and escalate

Stop and seek supervisory/pathologist review when the endpoint is uncertain, the specimen is irreplaceable, the tissue is unexpectedly soft or friable, exposure exceeds the validated window, or sensitive IHC/ISH/molecular testing is requested after an unvalidated acid treatment.

6. Endpoint log

Date/time	Solution changed?	Endpoint method	Observation/result	Initials

References: Published bone-tumour histopathology guidance and studies comparing radiographic and chemical endpoint assessment. Use the local laboratory-approved procedure as the final authority.