

Reports of outside consultations on laboratory cases (whether or not requested by the laboratory)	10 years after the date that the original report was issued
Fluorochrome-stained slides	At the discretion of the laboratory director
Images or permanent slides of ISH studies	10 years for neoplastic disorders 20 years for constitutional disorders (Subject to Note 4 below)
Images for Circulating Tumor Cells	10 years
Digital images used for primary diagnosis	10 years if original glass slides are not available; may not replace glass slides
Datasets from In-Vivo Microscopy (IVM) or Ex Vivo Microscopy (EVM) systems used to aid in interpretation or diagnosis	10 years - data must be retrievable for this period (Subject to Note 5 below)

* *Pathology reports may be retained in either paper or electronic format. If retained in electronic format alone, the reports must include a secure pathologist electronic signature. Images of paper reports, such as microfiche or PDF files are acceptable.*

NOTE 2: Paraffin blocks used for patient diagnostic, prognostic and/or predictive purposes must be kept for at least 10 years and be stored in a manner that preserves their identity and integrity. Tissue blocks must be stored in a temperature-controlled, pest-free environment to maintain tissue integrity. The CAP recommends (but does not require) ambient temperatures in block storage areas to be less than 27°C.

Paraffin blocks may be released for research purposes if all of the following criteria are met:

1. For laboratories subject to US regulations, formal written authorization is obtained in accordance with the requirements of HIPAA if identifiable patient information is released.
2. The laboratory retains sufficient blocks to support the diagnosis for the full 10-year period. After a patient has been deceased for two years, only one block containing normal tissue (if it exists) needs to be retained for the full 10-year period.
3. Provision is made for retrieval by the laboratory of any blocks or material that remain after use in research, if the blocks or material are needed for diagnostic, legal, or other legitimate purposes. After a patient has been deceased for two years, only one block containing normal tissue (if it exists) must be retrievable for the full 10-year period.
4. In the event of limited material (eg, only one diagnostic block), tissue microarray (TMA) cores or portions of the block may be released for research or clinical trials, as long as the original lab retains control or access to the diagnostic material if clinically needed.
5. The laboratory meets other relevant requirements including but not limited to the requirements of the institution, the directives of any applicable institutional review board (IRB) or similar entity; and state and local laws and regulations.

The restriction on release of blocks does not prohibit release of blocks for purposes of treatment, diagnosis, prognosis, etc., for patients on research protocols as long as release is consistent with patient privacy regulations (eg, HIPAA) and applicable state and local regulations; and there is IRB approval, as applicable.

NOTE 3: Given that patient survival rates are increasing and the continued emergence of treatment based on biomarker testing, which at times may be required on the original tissue, it is recommended that, whenever feasible, tissue block retention from patients with diagnosed malignancies be retained beyond the 10 year requirement.

NOTE 4: There is no retention requirement for images of slide preparations when the source slides remain readable for the required retention period. If slides are expected to become unreadable before the end of the required retention periods (for example, FISH slides), then images that adequately represent findings on the slides must be retained.

If representative images of chromosome ISH slides are retained, those with a normal result must include an image of at least one cell illustrating the normal probe signal pattern, and those with