Photographic or digitized images or permanent slides are retained of all in situ hybridization (ISH) assays for an appropriate period.

NOTE: Images or permanent slides of ISH assays for neoplastic disorders must be retained for 10 years; images or permanent slides of ISH assays for constitutional disorders must be retained for 20 years.

There is no retention requirement for retaining 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 of 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 an abnormal result must include images of at least two cells illustrating each relevant abnormal probe signal pattern.

REFERENCES
1) American College of Medical Genetics Laboratory. Standards and guidelines for clinical genetics laboratories, 2021 edition.

ANP.22966 ISH Interpretation **Phase II**

If an in situ hybridization (ISH) study requires consultation with a qualified pathologist and/or a cytogeneticist for an accurate interpretation, the appropriate expert is consulted and their involvement is recorded.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Fluorescence In Situ Hybridization Methods for Clinical Laboratories; Approved Guideline*. 2nd ed. CLSI Document MM07-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2013.

PREDICTIVE MARKERS

The term predictive marker as used in this section refers to immunohistochemical (IHC), immunocytochemical, and in situ hybridization (ISH) biomarkers used independent of histologic findings to identify individuals who are more likely to experience a favorable or unfavorable effect from a specific (targeted) therapy, compared to individuals with the same diagnosis lacking the biomarker. Rather than confirming a specific diagnosis (such as B-cell lymphoma or gastrointestinal stromal tumor), these biomarkers predict responsiveness to a specific treatment among cases of the same diagnosis. For example, this section applies to estrogen receptor testing used to determine eligibility for hormonal treatment of breast carcinoma, but does not apply to estrogen receptor testing used solely to assist in determining the primary site of origin of a metastatic neoplasm.

The current CAP guidelines (https://www.cap.org/protocols-and-guidelines/current-cap-guidelines) relating to predictive marker testing (eg, ASCO/CAP HER2 and ER testing in breast cancer) may be found at http://www.cap.org in the Protocols and Guidelines section. The guidelines are periodically updated based on new evidence. Laboratories should review updated predictive marker guidelines and promptly implement changes for items relating to requirements in the checklists (eg, validation, fixation, scoring criteria).

If digital image analysis is used (eg, quantitative image analysis for HER2 by immunohistochemistry), additional requirements in the Digital Image Analysis section also apply.

Inspector Instructions:

READ

- Predictive markers policies and procedures
- Sampling of patient reports for completeness, including ASCO/CAP scoring when applicable
- Records of annual benchmark comparison for breast predictive markers
- Records of annual analyte-specific quality assessment, as applicable