

control(s). For FDA-cleared or approved ISH assays, biorepositories must follow manufacturer's instructions for quality control at minimum.

Evidence of Compliance:

- ✓ Records of QC results

REFERENCES

- 1) American College of Medical Genetics, Standards and Guidelines for Clinical Genetics Laboratories, 2021 edition.
- 2) Clinical and Laboratory Standards Institute (CLSI). *Fluorescence In Situ Hybridization Methods for Clinical Laboratories; Approved Guideline—Second Edition*. CLSI document MM07-A2 (ISBN 1-56238-885-1) Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087-1898 USA, 2013.
- 3) Stupca P, Meyer RG, Dewald GW. Using controls for molecular cytogenetic testing in clinical practice. *J Assoc Genet Tech*. 2005;31:4-8.

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BAP.06780 Image and Slide Retention - ISH

Phase II



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. For an ISH assay with a normal result, retain an image of at least one cell illustrating the normal probe signal pattern. For an ISH assay with an abnormal result, retain images of at least two cells illustrating each relevant abnormal probe signal pattern.

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 period (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, Standards and guidelines for clinical genetics laboratories, 2021 edition.

BAP.06790 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 (CLSI). *Fluorescence In Situ Hybridization Methods for Clinical Laboratories; Approved Guideline*. 2nd ed. CLSI document MM07-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2013.

INSTRUMENTS AND EQUIPMENT

A variety of instruments and equipment are used to support the biorepository. All instruments and equipment should be properly operated, maintained, serviced, and monitored to ensure proper performance. The procedures and schedules for instrument maintenance and function checks must be as thorough and as frequent as specified by the manufacturer. Examples of equipment include, but are not limited to centrifuges, microscopes, incubators, heat blocks, microwaves, etc.

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.