

When possible, biorepositories should use tissues that have been processed using the same fixative and processing methods as cases that will be tested clinically. If IHC is regularly done on specimens that are not fixed or processed in the same manner as the tissues used for validation/verification (eg, alcohol fixed cell blocks, cytologic smears, formalin post fixed tissue, or decalcified tissue), the biorepository should test a sufficient number of such tissues to ensure that assays consistently achieve expected results. The biorepository director is responsible for determining the number of positive and negative cases and the number of markers to test.

Evidence of Compliance:

- ✓ Records of validation/verification, if applicable

REFERENCES

- 1) Hsi ED. A practical approach for evaluating new antibodies in the clinical immunohistochemistry laboratory. *Arch Pathol Lab Med.* 2001;125:289-294
- 2) Clinical and Laboratory Standards Institute. *Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays; Approved Guideline - Second Edition.* CLSI document I/LA28-A2. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA; 2011.
- 3) Allen M. Gown, MD. Diagnostic Immunohistochemistry: What Can Go Wrong and How to Prevent it. *Arch Pathol Lab Med.* 2016;140(9):893-898.
- 4) Uhlen M, Bandrowski A, Carr S, et al. A proposal for validation of antibodies. *Nat Methods.* 2016; 13(10):838-7.
- 5) Goldsmith JD, Troxell M, Roy-Chowdhuri S, et al. Principles of analytic validation of immunohistochemical assays: guideline update. *Arch Pathol Lab Med.* 2024. <https://doi.org/10.5858/arpa.2023-0483-CP>

BAP.05361 IHC Assay Performance

Phase I

Biorepositories confirm assay performance when conditions change that may affect performance.

NOTE: A change in antibody clone requires full revalidation/verification of the assay (equivalent to initial analytic validation/verification - see BAP.05360).

Biorepositories must confirm assay performance with at least two known positive and two known negative cases when an existing validated/verified assay has changed in any of the following ways: antibody dilution, antibody vendor (same clone), or the incubation or retrieval times (same method).

A more extensive study to confirm acceptable assay performance in accordance with published guidelines must be performed when any of the following have changed: fixative type, antigen retrieval protocol (eg, change in pH, different buffer, different heat platform), antigen detection system, tissue processing or testing equipment, environmental conditions of testing (eg, biorepository relocation), or biorepository water supply. This study must include a representative sampling of the assays affected by the change and an appropriate number of positive and negative cases per assay, sufficient to confirm acceptable assay performance. The biorepository director is responsible for determining the extent of the study. The rationale for the assays selected and number of positive and negative cases checked per assay must be recorded.

REFERENCES

- 1) Goldsmith JD, Troxell M, Roy-Chowdhuri S, et al. Principles of analytic validation of immunohistochemical assays: guideline update. *Arch Pathol Lab Med.* 2024. <https://doi.org/10.5858/arpa.2023-0483-CP>

BAP.05363 New Reagent Lot Confirmation of Acceptability

Phase II



The performance of new lots of antibody and detection system reagents is compared with old lots before or concurrently with being placed into service.

NOTE: Parallel staining is important to control for variables such as disparity in the lots of detection reagents or instrument function. New lots of primary antibody and detection system reagents must be compared to the previous lot using an appropriate panel of control tissues. This comparison must be made on slides cut from the same control block.

Evidence of Compliance:

- ✓ Records of confirmation of new reagent lots