

- 1) Miller RT, Kubier P. Blocking of endogenous avidin-binding activity in immunohistochemistry: the use of egg whites. *Appl Immunohistochem* 1997; 5: 63-66
- 2) Miller RT, Kubier P, Reynolds B, Henry T. Blocking of endogenous avidin-binding activity in immunohistochemistry: the use of skim milk as an economical and effective substitute for commercial biotin solutions. *Appl Immunohistochem & Molec Morphol* 1999;7:63-65
- 3) Clinical and Laboratory Standards Institute. *Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays: Approved Guideline*. 2nd ed. CLSI Document I/LA28-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2011.
- 4) Allen M. Gown, MD. Diagnostic Immunohistochemistry: What Can Go Wrong and How to Prevent it. *Arch Pathol Lab Med*. 2016;140(9):893-898.

BAP.05357 Control Slide Review**Phase II**

The biorepository director or designee reviews all control slides each day specimens are stained.

NOTE: Records of this review must be retained and clearly show that positive and negative controls for all antibodies stain appropriately. Control records must be retained for two years.

The control slides must be readily available upon request. The location of the slides should be stated in the procedure manual.

Evidence of Compliance:

- ✓ Records of worksheets with control results

REFERENCES

- 1) Shellhorn N. IHC troubleshooting tips. *Advance/Lab*. 2000;9(1):33-37

****REVISED** 12/26/2024**

BAP.05360 Validation/Verification - IHC Antibody Testing**Phase II**

The biorepository has records of validation/verification of new antibodies, including introduction of a new clone, prior to sample characterization.

NOTE: The performance characteristics of each assay must be appropriately validated/verified before being made available as characterization data for the specimen type. The initial goal is to establish the optimal antibody titration, detection system, and antigen retrieval protocol. Once optimized, a panel of tissues must be tested to determine the assay's sensitivity and specificity. The scope of the validation/verification is at the discretion of the biorepository director and will vary with the antibody.

Means of validation/verification may include, but are not limited to: 1) correlating the results using the new antibody with the morphology and expected results; 2) comparing the results using the new antibody with the results of prior testing of the same tissues with a validated/verified assay in the same laboratory; 3) comparing the results using the new antibody with the results of testing the same tissue in another laboratory with a validated/verified assay; or 4) comparing the results using the new antibody with previously validated/verified non-IHC tests or testing previously graded tissue challenges from a formal proficiency testing program.

For an initial validation/verification, biorepositories should receive at least 90% overall concordance between the new test and the comparator test or expected results.

*For validation of **laboratory-developed or modified FDA-cleared/approved assays**, the validation must be performed on a minimum of 10 positive and 10 negative tissues.*

*For verification of **unmodified FDA-cleared/approved assays**, the biorepository must follow the instructions provided by the manufacturer. If the instructions do not list a minimum number of samples for assay verification, the verification must be performed on a minimum of 10 positive and 10 negative tissues.*

If the biorepository director determines that fewer validation/verification cases are sufficient for a specific marker (eg, a rare antigen or tissue), the rationale for that decision needs to be recorded. Positive cases in the validation/verification set should span the expected range of clinical results (expression level), especially for those markers that are reported quantitatively.