BAP.05338 Slide Quality **Phase II**

Slides are of sufficient quality for diagnosis.

NOTE: Histopathology slides must be of adequate technical quality to be diagnostically useful. Criteria to evaluate include adequate tissue fixation, processing, thickness of sections, absence of interfering tissue folds and tears, and good staining technique and coverslipping. For hematoxylin and eosin and other routine stains, the patient slide serves as the internal control to ensure adequate staining technique. The sections must be cut from sufficient depth in the block to include the entire tissue plane.

BAP.05342 Specimen Modification **Phase II**

If the biorepository performs immunohistochemical staining on specimens other than formalin-fixed, paraffin-embedded tissue, the written procedure defines appropriate modifications, if any, for specimen types.

NOTE: Such specimens include frozen sections, air-dried imprints, cytocentrifuge or other liquid-based preparations, decalcified tissue, and tissues fixed in alcohol blends or other fixatives.

REFERENCES
1) Perkins SL, Kjeldsberg CR. Immunophenotyping of lymphomas and leukemias in paraffin-embedded tissues. *Am J Clin Pathol* 1993:99(4):362-373
2) 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.

BAP.05345 Buffer pH **Phase II**

The pH of the buffers used in immunohistochemistry is monitored at defined intervals.

NOTE: pH must be tested when a new batch is prepared or received.

Evidence of Compliance:
- ✓ Records of initial and subsequent QC on each buffer

*****REVISED** 12/26/2024***
BAP.05348 QC - Antibodies **Phase II**

Positive controls are used for each antibody.

NOTE: Positive controls assess the performance of the immunohistochemistry assay (including impact of fixation and antigen retrieval) and can assess the sensitivity of the assay. They should, whenever possible, be subjected to the same processing, antigen retrieval, and immunostaining protocol as donor tissue.

Results of controls must be recorded, either in internal biorepository records, or in the donor report. A statement in the report such as, "All controls show appropriate reactivity" is sufficient.

For tissue-based positive controls, the ideal control is of the same specimen type as the donor test specimen (eg, small biopsy, large tissue section, cell block), and is processed and fixed in the same manner (eg, formalin-fixed, alcohol-fixed, decalcified) as the donor specimen. However, for most biorepositories, it is not practical to maintain separate positive control samples to cover every possible combination of fixation, processing and specimen type. Thus, it is reasonable for a biorepository to maintain a bank of formalin-fixed tissue samples as its positive controls; these controls can be used for donor specimens that are of different type, or fixed/ processed differently, providing that the biorepository can show that these donor specimens exhibit equivalent immunoreactivity. This can be accomplished by parallel testing a small panel