

*immunocytostaining, the Immunochemistry section of the Cytopathology Checklist should be used to inspect that laboratory section.*

*The term immunohistochemistry (IHC) used within this section also includes immunocytochemistry.*

*Please refer to the Definition of Terms section in the All Common (COM) Checklist for definitions of analytical validation and analytical verification.*

## Inspector Instructions:

 <b>READ</b>	<ul style="list-style-type: none"> <li>Sampling of IHC policies and procedures</li> <li>Sampling of new antibody validation/verification records</li> <li>Sampling of new reagents/shipment confirmation of acceptability records</li> <li>Sampling of antibody QC records</li> <li>Sampling of buffer pH records</li> <li>Sampling of batch control records</li> </ul>
 <b>OBSERVE</b>	<ul style="list-style-type: none"> <li>Sampling of slides (quality)</li> </ul>
 <b>ASK</b>	<ul style="list-style-type: none"> <li>How does your laboratory validate/verify new antibodies?</li> <li>How does your laboratory confirm the acceptability of new reagent lots?</li> <li>How does your laboratory distinguish non-specific false-positive staining from endogenous biotin?</li> </ul>

### ANP.22300 Specimen Modification

Phase II



**If the laboratory performs immunohistochemical staining on specimens other than formalin-fixed, paraffin-embedded tissue, the written procedure defines appropriate modifications, if any, for other 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 (CLSI). *Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays; Approved Guideline - Second Edition*. CLSI document I/LA28. Clinical and Laboratory Standards Institute, Wayne, PA; 2011.

### ANP.22500 Buffer pH

Phase II

**The pH of the buffers used in immunohistochemistry is routinely monitored.**

*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**

### ANP.22550 QC - Antibodies

Phase II