




immunocytochemical staining, the Immunocytochemistry 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:

	<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>
	<ul style="list-style-type: none"> <li>• Sampling of slides (quality)</li> </ul>
	<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

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### ANP.22550 QC - Antibodies

Phase II