

CAP offers comment period on IHC guideline

The [College of American Pathologists Pathology and Laboratory Quality Center \(the Center\)](#) develops and maintains evidence-based guidelines and consensus statements.

The CAP welcomes participation in the [open comment period](#) through July 29, on the Center guideline recommendations for [Immunohistochemical \(IHC\) Assays: Principles of Analytic Validation](#).

IHC testing is an essential component of the pathologic evaluation of many specimens and increasingly provides key information that helps determine how patients are treated. As with any laboratory test, laboratories must validate all IHC assays before they are used to test patient specimens. Unfortunately, recent studies have found significant interlaboratory variation in validation practices and revealed that many laboratories do not follow consistent procedures.

The expert and advisory panels, chaired by Patrick L. Fitzgibbons, MD, addressed the overarching question:

What is needed for initial analytic assay validation before placing any immunohistochemical test into clinical service and what are the revalidation requirements?

In addition, the panel is exploring the following questions:

- When and how should validation assess analytic sensitivity, analytic specificity, accuracy (assay concordance), and precision (inter-run and inter-operator variability)?
- What is the minimum number of positive and negative cases that need to be tested to analytically validate an immunohistochemical assay for its intended use(s)?
- What parameters should be specified for the tissues used in the validation set?
- How do certain preanalytic variables influence analytic validation?
- What conditions require assay revalidation?

The expert panel drafted recommendations following a systematic review of about 100 publications covering nearly 1,500 citations in the context of their own expert judgments.

The final recommendations after consideration of the public comments, further discussion, and analysis will be presented at the [CAP '13 Course](#) and published in the [Archives of Pathology & Laboratory Medicine](#).

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