



News Release

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New IHC Validation Guideline Improves Patient Safety by Ensuring Consistent Lab Test Results

NORTHFIELD, ILL. — Physicians and patients rely on accurate laboratory test results to guide treatment decisions. To ensure the accuracy of laboratory tests and reduce variation in laboratory practices, the College of American Pathologists has developed the first evidence-based guideline to validate all immunohistochemical (IHC) assays. The guideline, "[Principles of Analytic Validation of Immunohistochemical Assays](#)", is now available in the online edition of *Archives of Pathology & Laboratory Medicine*.

"IHC testing is an essential component of the pathologist's evaluation of a tissue sample. It serves a critical need in patient care as the results from IHC testing often directly guide treatment," said Patrick L. Fitzgibbons, MD, FCAP, lead author of the guideline and a pathologist at St. Jude Medical Center in Fullerton, Calif. "Implementation of the guideline provides pathologists and laboratory professionals a set of standardized procedures to ensure consistency among all laboratories for all specimens."

Guideline Recommendations

The new guideline outlines 14 evidence-based and expert consensus recommendations that help ensure that an IHC test accurately measures the analyte of interest and that validation is appropriate for the test's intended use. Recommendations are also provided for verifying that an existing validated assay continues to perform as expected when there has been a change in laboratory location, test methods, or equipment.

With the guideline, laboratories can be assured they are following consistent procedures based upon recent scientific evidence and expert consensus opinion. This consistency promotes patient safety by ensuring laboratories achieve the various steps required by regulatory and accreditation agencies before performing testing on a patient specimen.

To develop the guideline, the CAP convened an expert panel of pathologists and histotechnologists to conduct a systematic review of more than 125 publications covering almost 1,500 citations in the context of open comment feedback, quality of evidence, and their own expert judgments in the field of immunohistochemistry. The CAP Pathology and Laboratory Quality Center provided the forum for the guideline development. The guideline will be updated as new scientific evidence becomes available.

Future Applications

"As laboratory testing moves toward personalized medicine, the new IHC validation guideline may also provide a framework for validating molecular and genomic-based assays," added Dr. Fitzgibbons. "Pathologists can take the lead by implementing the guideline in their hospitals and into their practices."

Additional Resources

The CAP offers [tools and resources](#), including a [summary of the recommendations](#), frequently asked questions ([FAQs](#)), a [video](#), and a [teaching PowerPoint](#) for pathologists and laboratory professionals.

About the College of American Pathologists

As the leading organization for board-certified pathologists, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. With more than 18,000 physician members, the CAP has led laboratory accreditation for more than 50 years with more than 7,600 CAP-accredited laboratories in 50 countries. Find more information about the CAP at cap.org. Follow CAP on Twitter: [@pathologists](https://twitter.com/pathologists).

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