

Communications Materials – IHC Validation Survey

Letter to Non-CAP Participants (letter to be sent via mail with paper copy of IHC Validation survey)

Dear Laboratory Director:

The College of American Pathologists (CAP) is collaborating with the Centers for Disease Control and Prevention (CDC) on a cooperative agreement, “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics.” The CAP and the CDC invite your laboratory to assist us in accomplishing our goal by examining the current state of immunohistochemistry (IHC) validation practices and procedures by completing this important survey. Your participation is completely voluntary.

The CAP conducted a baseline survey in 2010 with customers enrolled in certain proficiency testing products. The results were published in *Archives of Pathology and Laboratory Medicine*¹. In response to gaps identified, the CAP Pathology and Laboratory Quality Center initiated an evidence-based guideline to address specific questions regarding IHC validation processes. The final recommendations were also published in *Archives*².

The CAP and the CDC will publish the post-survey overall results as part of the CDC cooperative agreement. Your responses will remain anonymous and not be used to identify any laboratory or individual. The unique identifier provided is so that we can connect your survey answers to demographic data on file and to ensure that only one response per laboratory is received. All information collected in this survey will be kept in a secure manner. No individual answers will be shared with the CDC. The final report in the planned publication will not contain any identifying information, preventing the linkage of specific laboratories with survey results. At some future time, your laboratory may be invited to participate in a focus group.

Survey Instructions

The anticipated time to complete the enclosed survey is 20 minutes. We recommend having your current laboratory procedures available during completion of the survey. We kindly ask participants to complete the survey by **faxing the result form to 866-FAX-2CAP (866-329-2227). The survey will remain open until (date TBD and will be finalized upon OMB approval).**

Please note that this survey does not apply to the validation of HER2, ER, and PgR assays as separate guidelines for those markers have already been established.

Thank you for responding to the 2015 IHC Validation Practices and Procedures Survey. If you have any questions, please email the CAP Pathology and Laboratory Quality Center at center@cap.org.

Sincerely,

Raouf Nakhleh, MD, FCAP,
Chair, CAP Guidelines Metric Expert Panel

Lisa Fatheree, SCT(ASCP)
Director, CAP Pathology and Laboratory Quality Center

¹ Hardy LB, Fitzgibbons PL, Goldsmith JD, et al. Immunohistochemistry validation procedures and practices: a College of American Pathologists survey of 727 laboratories. *Arch Pathol Lab Med.* 2013;137(1):19–25.

² Fitzgibbons PL, Bradley LA, Fatheree LA, et al. Principles of analytic validation of immunohistochemical assays: guideline from the College of American Pathologists Pathology and Laboratory Quality Center. *Arch Pathol Lab Med.* 2014;138(11):1432-1443.

Surveys Program – Half Page Insert Sent to Surveys Participants for IHC VAL(Possibly include each one separately and specify mailings and instructions on completing if they enroll in multiple Surveys)



COLLEGE of AMERICAN
PATHOLOGISTS

**Important Notice:
UPCOMING Survey of Immunohistochemistry Validation
Practices and Procedures**

HQIP A Final Critique

The College of American Pathologists (CAP) is collaborating with the Centers for Disease Control and Prevention (CDC) on a cooperative agreement, “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics.” The CAP invites your laboratory to assist its goal of examining the current state of immunohistochemistry validation practices and procedures by completing an upcoming survey in the B mailing of HQIP. Only one response per laboratory is needed so if you also participate in the PIP-C mailing or the HER2-B mailing, you will not need to re-submit. Duplicate results from laboratories will be not included.

The results of the CAP and the CDC cooperative agreement will be published in the future. Your laboratory information and responses will be kept anonymous preventing the linkage from specific laboratories to survey data.

Please email the CAP Pathology and Laboratory Quality Center at center@cap.org.

PIP B Final Critique

The College of American Pathologists (CAP) is collaborating with the Centers for Disease Control and Prevention (CDC) on a cooperative agreement, “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics.” The CAP invites your laboratory to assist its goal of examining the current state of immunohistochemistry validation practices and procedures by completing an upcoming survey in the C mailing of PIP. Only one response per laboratory is needed so if you completed in the HQIP-B mailing or participate in the HER2-B mailing, you will not need to re-submit. Duplicate results from laboratories will be not included.

The results of the CAP and the CDC cooperative agreement will be published in the future. Your laboratory information and responses will be kept anonymous preventing the linkage from specific laboratories to survey data.

Please email the CAP Pathology and Laboratory Quality Center at center@cap.org.

HER2A Final Critique

The College of American Pathologists (CAP) is collaborating with the Centers for Disease Control and Prevention (CDC) on a cooperative agreement, "Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics." The CAP invites your laboratory to assist its goal of examining the current state of immunohistochemistry validation practices and procedures by completing an upcoming survey in the B mailing of HER2. Only one response per laboratory is needed so if you completed in the HQIP-B or the PIP-C mailing, you will not need to re-submit. Duplicate results from laboratories will be not included.

The results of the CAP and the CDC cooperative agreement will be published in the future. Your laboratory information and responses will be kept anonymous preventing the linkage from specific laboratories to survey data.

Please email the CAP Pathology and Laboratory Quality Center at center@cap.org.

CAP Today for the IHC Post Survey (*The news brief is intended to be included in the Newsbytes section. CAP Today publishes monthly*)

The College of American Pathologists (CAP) is collaborating with the Centers for Disease Control and Prevention (CDC) on a cooperative agreement, "Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics." The CAP invites laboratories to assist us in accomplishing our goal of examining the current state of immunohistochemistry (IHC) validation practices and procedures by completing a survey.

The survey will be sent to customers enrolled in HER2, HQIP, and PIP. Laboratory information and responses provided by survey participants will be kept anonymous. The CAP plans to publish the overall survey findings as part of the CDC cooperative agreement.

The survey is in follow up to one that was sent in 2010 to participants enrolled in certain proficiency testing products to obtain baseline information on IHC testing¹. For more information on recommendations for validating IHC assays, the CAP Pathology and Laboratory Quality Center offers an evidence-based guideline: "[Principles of Analytic Validation of IHC Assays](#)",² which was published in *Archives of Pathology and Laboratory Medicine* in 2014.

¹ Hardy LB, Fitzgibbons PL, Goldsmith JD, et al. Immunohistochemistry validation procedures and practices: a College of American Pathologists survey of 727 laboratories. *Arch Pathol Lab Med.* 2013;137(1):19–25.

² Fitzgibbons PL, Bradley LA, Fatheree LA, et al. Principles of analytic validation of immunohistochemical assays: guideline from the College of American Pathologists Pathology and Laboratory Quality Center. *Arch Pathol Lab Med.* 2014;138(11):1432-1443

CAP Pathology and Laboratory Quality Center Quarterly Newsletter

The CAP Pathology and Laboratory Quality Center is participating in cooperative agreement with the Centers for Disease Control and Prevention (CDC) to increase the effectiveness and adoption of laboratory practice guidelines.

As part of the agreement entitled, “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics,” the Center invites laboratories to assist in the CAP’s goal of examining the current state of immunohistochemistry (IHC) validation practices and procedures by completing a survey. In addition to general questions about IHC testing, the survey also includes questions specific to the adoption of the Center guideline, [Principles of Analytic Validation of IHC Assays](#)¹. The survey is in follow-up to a survey sent in 2010 to obtain baseline information on IHC testing.²

The survey will be sent to customers enrolled in HER2-B, HQIP-B, and PIP-C mailings. All responses and information provided by laboratories will be kept anonymous. Overall survey findings will be published as part of the CDC cooperative agreement and used to help improve adoption of evidence-based laboratory practice guidelines.

¹ Fitzgibbons PL, Bradley LA, Fatheree LA, et al. Principles of analytic validation of immunohistochemical assays: guideline from the College of American Pathologists Pathology and Laboratory Quality Center. *Arch Pathol Lab Med.* 2014;138(11):1432-1443.

² Hardy LB, Fitzgibbons PL, Goldsmith JD, et al. Immunohistochemistry validation procedures and practices: a College of American Pathologists survey of 727 laboratories. *Arch Pathol Lab Med.* 2013;137(1):19–25.

CAPconnect – Blog (Possibly from Raouf E. Nakhleh, MD, FCAP or Patrick L. Fitzgibbons, MD, FCAP for IHCVAL)

Validation of nonwaived test systems is mandated by CLIA'88. Since the introduction of immunohistochemistry this test has been used as an adjunct to morphologic diagnosis and has not been subject to rigorous quality control and quality assurance measures.

To help ensure the accuracy and consistency of IHC test results, the College of American Pathologists (CAP) is collaborating with the Centers of Disease Control and Prevention (CDC) to improve the effectiveness and adoption of evidence based laboratory practice guidelines.

In follow-up to a survey offered in 2010 to participants of the CAP's Surveys program¹, the CAP and the CDC have issued a survey to gather feedback on how IHC testing is performed and if laboratories are implementing either all or part of the CAP's evidence-based guideline, "[Principles of Analytic Validation of IHC Assays](#)"².

Patients are at the heart of the CAP and ensuring test accuracy and patient safety are critical. As a leader in quality assurance, I encourage laboratories to participate in the survey to help advance patient care and laboratory practices.

If you're interested in participating in the survey as part of the CAP/CDC cooperative agreement, "Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics," please contact the CAP Pathology and Laboratory Quality Center at center@cap.org.

¹ Hardy LB, Fitzgibbons PL, Goldsmith JD, et al. Immunohistochemistry validation procedures and practices: a College of American Pathologists survey of 727 laboratories. Arch Pathol Lab Med. 2013;137(1):19–25.

² Hardy LB, Fitzgibbons PL, Goldsmith JD, et al. Immunohistochemistry validation procedures and practices: a College of American Pathologists survey of 727 laboratories. Arch Pathol Lab Med. 2013;137(1):19–25.

[The CAP staff plans to interview Dr. Nakhleh and/or Dr Fitzgibbons for this blog to obtain a more personal account of participation in the survey development and role as a quality assurance leader.]