



CAP IHC Telephone Interview Script

Attachment C1

Form Approved
OMB No. 0920-1067
Exp. Date: xx/xx/20xx

Hello,

- I'm Ron Brooks calling on behalf of the College of American Pathologists (the CAP) in collaboration with the Centers for Disease Control and Prevention (the CDC) to assess the status of our cooperative agreement for improving the impact of laboratory practice guidelines.
In 2013, the CAP published a study that identified a gap in practice consistency across laboratories when validating and re-validating immunohistochemistry (IHC) assays.
In 2014, the CAP published a new evidence-based guideline, "Principles of Analytic Validation of Immunohistochemical Assays," which was designed to support accurate and consistent validation and re-validation of IHC assays and addresses diagnostic markers and predictive markers other than ER (Estrogen Receptor)/PR (Progesterone Receptor) and HER2 (human epidermal growth factor receptor 2 for breast cancer).
Note: IF the individual requests additional information about the guideline, Mr. Brooks will provide the 2014 press release summary and a copy of the guideline summary at time of call or afterwards depending on the individual's preference (attachments Ci and Cii). Mr. Brooks will also offer to have CAP Center Director to follow up with them on any issue, question or concern the individual may have.
In 2015, the CAP together with the CDC distributed a questionnaire to collect current IHC validation practice data and your laboratory returned the completed survey. We thank you for your responses.
Would you be willing to participate in a short, follow-up telephone interview designed to be completed within 15 minutes? Is this a good time or would it be better to reschedule this for another time? Our focus is to understand if and how the IHC evidence-based guideline has impacted your laboratory and what additional support from CAP might be helpful.
Please note that this initiative and telephone interview revolve around evidence-based guidelines and is not associated with the CAP Laboratory Accreditation Program (LAP). Your participation is completely voluntary and we respect the value of your time. No individual laboratory responses will be shared with the CDC and CAP. Your responses will be recorded in an anonymous way and no individual will be identified in any resulting report or publication.

CDC estimates the average public reporting burden for this collection of information as 20 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-1067)



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Topic 1: Awareness/Adoption:

The following questions are designed to determine your laboratory's level of awareness, mode of dissemination by which awareness was achieved and a high-level query of adoption.

- A. Were you aware of the published guideline on IHC Validation prior to this call?
- 1 Yes
 - i. How did you hear about it?
 - ii. Are you familiar with the recommendations?
 - Yes (Cascade to Topic 1B)
 - No (Cascade to Topic 1 A2)
 - 2 No
 - i. Would you like to receive a follow-up email or phone call from CAP describing the guideline recommendations on IHC validation in further detail?
 - ii. How can CAP or CDC assist with helping you learn about future laboratory practice guidelines?

If the laboratory was not aware of the guideline and did not want any follow-up on this subject, Mr Brooks will capture the response and end the telephone interview after asking Topic A2ii.

- B. Have you incorporated any (-more-) of the guideline recommendations into your procedures?
Yes or No (Cascade to Topic 1B1)
- 1 Were any of the recommendations already in place in your institution?
Yes
 - Probe: Could you describe which ones?
No (Cascade to Topic 1B2)
 - 2 Were there any recommendations that aren't applicable to your laboratory?
Yes
 - Probe: Could you describe which ones?
No (Cascade to Topic 1 B3)
 - 3 Did you have any disagreements with some of the recommendations?
Yes
 - Probes: Which recommendations did you disagree with?... Why did you disagree with the recommendations?
No (Cascade to Topic 1B4)
 - 4 Have you revised or updated your written procedures based on the guideline?
Yes
 - Probes: When did you revise your procedure? ... How did the guideline assist you in your revisions? ... Which recommendations were most helpful in your laboratory?
No (Cascade to Topic 2)



If the laboratory did not incorporate any of the guideline recommendations and did not want any follow-up on this subject, Mr Brooks will capture the response and end the telephone interview after asking B3.

Topic 2: Impact (Facilitators and Barriers):

The following questions are designed to examine the factors that may have influenced your decisions to implement in your laboratory. *Some questions will be omitted for respondents who didn't adopt some of the recommendations.*

- A.** Why did you decide to implement (-or not implement-) (-some-most-all-none-) of the recommendations?
- 1 Has your laboratory introduced a new IHC assay within the last 2 years?
 - How did the guideline improve or hinder your validation process?
 - 2 At the time of implementation, what was/were your biggest challenge(s) with the initial validation recommendations?
 - Probe: Could you explain further? ...What did you do to overcome these challenges?
 - 3 In your experience, what was/were the biggest challenge(s) with adopting the revalidation recommendations?
 - Probe: Could you explain further?... What did you do to overcome these challenges?
 - 4 What other experiences did you have with implementing the recommendations (ie, complexity, barriers, costs etc)?
 - Probe: Could you explain further?... What did you do to overcome these challenges?
 - 5 Did you have adequate institutional support in implementing the recommendations?
 - Probe: Could you explain further?
- B.** Did the guideline assist or provide clarity for developing or updating your written procedures for initial validation and revalidation?
 - Probe: If so, how did it assist OR Why didn't it assist?
- C.** Would you agree or disagree that the guideline recommendations were clearly written?
 - Probe: Could you explain further?
- D.** Could you describe any instances where you perceive this guideline (-certain recommendations-) had a concrete impact on patient outcomes?
 - Probe: Which recommendations had the most/least impact on patient outcomes?

Topic 3: Opportunities:

This last series of questions are designed to assess and collect opportunities (both enhancements and improvements) for CAP to deliver helpful items or to remove duplicate or burdensome items.

- A.** In our conversation, you mentioned -XYZ – (paraphrased based on interview). What opportunities would you like to see CAP explore for the future to help laboratories implement the specific recommendation(s) and/or guideline?
- 1 Would an electronic or paper-based template to document your validation processes be helpful?
 - 2 What clarification of wording and/or actions recommended in the evidence-based guideline are needed to assist your laboratory to either implement or develop a metric to assess the impact?



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- B. CAP plans to review and potentially revise this guideline on IHC validation testing according to updated literature. Would you be inclined to adopt the new or revised recommendations in the future?
 - Probe: Why or why not?
- C. What suggestions do you have to improve the guideline for future revisions?

Closure question:

- A. What other thoughts or comments do you have?

Thank you (name of interviewee) for taking the time today out of your busy schedule. Your participation was valuable to both the CAP and the CDC. They will publish the final outcome as part of the cooperative agreement and all information collected during this call will remain anonymous. Have a good day.