

**Survey of Immunohistochemistry Validation Practices and Procedures  
PILOT Questions**

CAP Pathology Laboratory Quality Center: Cooperative Grant with Centers for Disease Control and Prevention

Results for the pilot test post-survey for **Immunohistochemistry Validation Practices and Procedures**.

Pilot responses and questionnaire responses reviewed by Drs Nakhleh, Fitzgibbons, Ms Souers and Ms Fatheree via conference call on 1-5-15.

**Pilot Tester Information**

|   |   |
|---|---|
| <b>Institution Name and Address</b>                                     | <b>7 Respondents</b><br><b>4 MDs (IHC Directors)</b><br><b>3 Histology Supervisors</b><br><br><b>2 Non-Respondents (CDC contacts, non CAP PT customers)</b>                         |
| <b>Time to complete IHC Validation survey (not including this form)</b> | <b>Average: 25 minutes</b><br><b>Range: 15 – 60 minutes</b><br><b>2 @ 15</b><br><b>1 @ 25</b><br><b>1 @ 30</b><br><b>2 @ 20</b><br><b>1 @ 60 (most time spent finding the data)</b> |

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**Survey Introduction**

|   | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
|---|-------------------|----------|---------|-------|----------------|
| After reading the introduction, my interest in continuing the survey is high<br><b>Average: 4</b><br><b>Range: 2-4</b>  | 1                 | 2        | 3       | 4     | 5              |
| The introduction helped me understand what to expect from this survey.<br><b>Average: 4</b><br><b>Range: 3-4</b>  | 1                 | 2        | 3       | 4     | 5              |
| The amount of detail provided was adequate.<br><b>Average: 4</b><br><b>Range: 3-4</b>   | 1                 | 2        | 3       | 4     | 5              |
| What recommendations do you have for the Introduction? <ul style="list-style-type: none"> <li>• <b>List of definitions is a bit off-putting – can you put them somewhere else –like end- but clearly refer to them?</b></li> <li>• <b>I hardly read directions –note I had seen elements of survey before</b></li> </ul> <p>Recommendation by Biostats to leave definitions at beginning for consistency.</p> |                   |          |         |       |                |

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**Section I: IHC Validation Procedure survey questions 1-7**

**Summary: Questions 1-7 all ACCEPTABLE from respondents except for following comments on #5**

| Q #. | Elements                               |  | Specific Observations/Other Comments |
|------|--|--|--------------------------------------|
| 1.   | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |                                      |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |                                      |
| 2.   | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |                                      |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |                                      |
| 3.   | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |                                      |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |                                      |

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| Q #. | Elements                               |  | Specific Observations/Other Comments   |
|------|--|--|--|
| 4.   | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
| 5.   | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision | <p><b>How is this different from Q3 – I know you are trying to split out predictive markers but seems redundant</b><br/>           Modified answers for clarity.</p> |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision | <p><b>Typo – stray “ in question stem</b><br/>           Corrected.</p>  |
| 6.   | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
| 7.   | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |

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**Section II: Re-Validation Procedures survey questions 8-9**

**Summary: Both acceptable except for comments listed below:**

**Revised order of questions for better flow. These are the original pilot question numbers.**

| Q #. | Elements                               |  | Specific Observations/Other Comments  |
|------|--|--|---|
| 8.   | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |   |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |   |
| 9.   | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision | <ul style="list-style-type: none"> <li>• <b>Suggest breakdown into 2 separate questions</b> <ul style="list-style-type: none"> <li>○ Done</li> </ul> </li> <li>• <b>If you want respondents to list number of cases they used for revalidation, add an empty box in the Number of Cases column</b> <ul style="list-style-type: none"> <li>○ Taken care of by Forms Dept</li> <li>○ <b>Answer boxes for ‘change incubation or retrieval time’ is missing. Taken care of by Forms Dept</b></li> <li>○ <b>This is a complex question and could be confusing to some. The Number of cases will have to look like a blank or answer box. Taken care of by Forms Dept</b></li> </ul> </li> <li>• <b>Also there should be a comment field. Instructing “0” when number not specified in protocol is not fair. Guideline leaves discretion for lab director in many of the options and this could be formulated prior to –illegible-project. Added additional responses to address</b></li> </ul> |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |   |

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9. **Please answer:** Note: If your laboratory does not have separate procedures for predictive and non-predictive assays please enter your responses in the non-predictive section

| Are the following changes explicitly specified in the validation procedure? (Note: *No of cases refer to minimum number cases required to test in validation set. If no minimum number is specified in procedure, enter 0 in the number column.) | <i>Non-FDA approved, <u>non-predictive</u> IHC assays (e.g., cytokeratin, S100, CD45)</i> |                |                          |                          | <i>Non-FDA approved <u>predictive</u> marker IHC assays other than HER2, ER/PgR (e.g., CD20)</i> |                |                          |                          |
|--|---|----------------|--------------------------|--------------------------|--|----------------|--------------------------|--------------------------|
|  | Yes   | *No of case(s) | No                       | Unsure                   | Yes  | *No of case(s) | No                       | Unsure                   |
| Introduction of a new lot of antibody  | <input checked="" type="checkbox"/>   | 2              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | 2              | <input type="checkbox"/> | <input type="checkbox"/> |
| Change in antibody dilution  | <input checked="" type="checkbox"/>   | 4              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | 4              | <input type="checkbox"/> | <input type="checkbox"/> |
| Change in antibody vendor (same clone)   | <input checked="" type="checkbox"/>   | 4              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | 4              | <input type="checkbox"/> | <input type="checkbox"/> |
| Change in antibody clone   | <input checked="" type="checkbox"/>   | 20             | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | 40             | <input type="checkbox"/> | <input type="checkbox"/> |
| Introduction or change in antigen retrieval method   | <input checked="" type="checkbox"/>   | *              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | *              | <input type="checkbox"/> | <input type="checkbox"/> |
| Change in incubation or retrieval times (same method)  | <input checked="" type="checkbox"/>   | 4              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | 4              | <input type="checkbox"/> | <input type="checkbox"/> |
| Change in antigen detection system   | <input checked="" type="checkbox"/>   | *              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | *              | <input type="checkbox"/> | <input type="checkbox"/> |
| Change in fixative type  | <input checked="" type="checkbox"/>   | *              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | *              | <input type="checkbox"/> | <input type="checkbox"/> |
| Change in tissue processing equipment  | <input checked="" type="checkbox"/>   | *              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | *              | <input type="checkbox"/> | <input type="checkbox"/> |
| Change in testing equipment  | <input checked="" type="checkbox"/>   | *              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | *              | <input type="checkbox"/> | <input type="checkbox"/> |
| Change in environmental conditions (e.g., laboratory relocation)   | <input checked="" type="checkbox"/>   | *              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | *              | <input type="checkbox"/> | <input type="checkbox"/> |
| Change in water supply   | <input checked="" type="checkbox"/>   | *              | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/>  | *              | <input type="checkbox"/> | <input type="checkbox"/> |

\* medical Director to assess case-by-case + develop plan

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**Section III: Documentation Procedures survey questions 10-11**

**Summary: Both acceptable except for comments listed below:**

| Q #. | Elements                               |  | Specific Observations/Other Comments   |
|------|--|--|--|
| 10.  | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
| 11.  | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision | <ul style="list-style-type: none"> <li>• Suggest breakdown into 2 separate questions</li> <li>• Same as comments for number 9</li> </ul> Done                                |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision | <ul style="list-style-type: none"> <li>• Answers misaligned</li> <li>• Same as above – with adding empty boxes</li> </ul> Done – added minimum overall concordance rate also |

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**Section IV: General IHC Laboratory Data – Survey Questions 12-16**

**Summary: All Acceptable except for comment on Q16 below**

| <b>Q #.</b> | <b>Elements</b>                        |  | <b>Specific Observations/Other Comments</b> |
|-------------|--|--|---|
| 12.         | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |   |
|             | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |   |
| 13.         | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |   |
|             | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |   |
| 14.         | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |   |
|             | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |   |



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| Q #. | Elements                               |   | Specific Observations/Other Comments   |
|------|--|---|--|
| 15.  | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision            |  |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision            |  |
| 16.  | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision            |  |
|      | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input checked="" type="radio"/> Needs revision | <p><b>This needs to allow multiple answers</b></p> <p>Clarified by adding 'primary' to question but multiple answers would be acceptable</p> |

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**Section V: Awareness and Adoption – Survey Questions 17-20**

**Summary: All Acceptable except for comment on Q19 and Q20 below**

|     |  |  |  |
|-----|--|--|--|
| 17. | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
|     | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
| 18. | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
|     | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
| 19. | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
|     | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision | <p><b>Need to stipulate more than one answer is acceptable</b><br/>           Comment meant for Q20 because (check all that apply is there)</p>  |
| 20. | Question clarity                       | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision |  |
|     | Answers (clarity and no. of responses) | <input type="radio"/> Acceptable<br><input type="radio"/> Needs revision | <ul style="list-style-type: none"> <li>• More than one answer acceptable??</li> <li>• Not specified if single or multiple answers are acceptable – implied with ‘most difficult’.</li> </ul> <p>Added “choose up to 3 responses”</p> |

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**Section VI: Conclusion**

**Summary: All Acceptable except for one comment**

| Q #.  | Elements                               | Specific Observations/Other Comments   |   |          |         |       |                |
|---|--|--|---|----------|---------|-------|----------------|
| 21.   | Question clarity                       | <ul style="list-style-type: none"> <li>○ Acceptable</li> <li>○ Needs revision</li> </ul> |   |          |         |       |                |
|   | Answers (clarity and no. of responses) | <ul style="list-style-type: none"> <li>○ Acceptable</li> <li>○ Needs revision</li> </ul> | <p><b>Would be good to specify MD after first 3 choices</b><br/>                     Added clarifying credentials to capture specifics for “ IHC Laboratory Director”</p> |          |         |       |                |
|   |  |  | Strongly Disagree   | Disagree | Neutral | Agree | Strongly Agree |
| The confidentiality information made me comfortable with submitting the survey.<br><b>Average: 4</b><br><b>Range: 3-4</b> |  |  | 1   | 2        | 3       | 4     | 5              |
| The amount of detail provided about the outcome of the survey was adequate.<br><b>Average: 4</b><br><b>Range: 3-4</b>     |  |  | 1   | 2        | 3       | 4     | 5              |
| What recommendations do you have for the Conclusion?<br><b>None</b>   |  |  |   |          |         |       |                |

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**Overall Survey Review  
Goals and Objectives**

|   | Strongly Disagree | Disagree           | Neutral  | Agree    | Strongly Agree |
|---|-------------------|--------------------|----------|----------|----------------|
| The survey questions are easy to understand.<br><b>Average: 4</b><br><b>Range: 4-5</b>              | 1                 | 2                  | 3        | <b>4</b> | <b>5</b>       |
| The answer choices are clearly written.<br><b>Average: 4</b><br><b>Range: 4-5</b>                   | 1                 | 2                  | 3        | <b>4</b> | <b>5</b>       |
| I was always able to find an appropriate answer to choose<br><b>Average: 4</b><br><b>Range: 3-4</b> | 1                 | 2                  | <b>3</b> | <b>4</b> | 5              |
| The order of questions was easy to follow.<br><b>All: 4</b>   | 1                 | 2                  | 3        | <b>4</b> | 5              |
| Overall, the length of the survey was (circle one)<br><b>All: Appropriate</b>                       | too short         | <b>appropriate</b> |          |          | too long       |

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What did you like best about the survey?

- **Survey is well structured and questions are clearly stated**
- **Made you think about what I do**
- **Pretty straight forward**

If given the option to change parts of the survey what changes would you make?

**Need a comment box at end of survey and for Q9 and Q11**

Added free text comment box at end. Changed responses for Q9 and Q11 to address better.

Additional thoughts/comments:

**None**