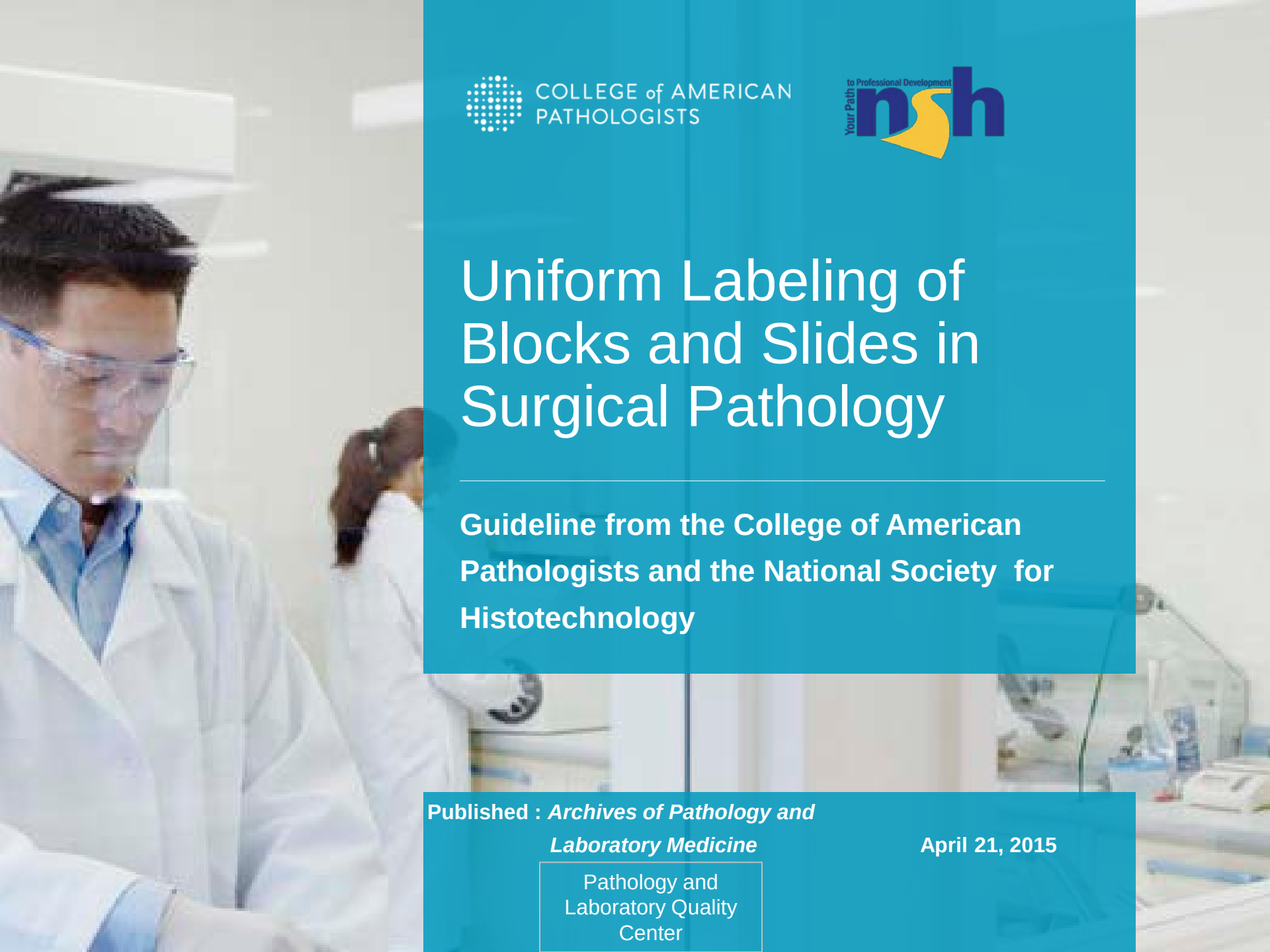

COLLEGE of AMERICAN PATHOLOGISTS

Your Path to Professional Development nsh

Uniform Labeling of Blocks and Slides in Surgical Pathology

Guideline from the College of American Pathologists and the National Society for Histotechnology

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Pathology and Laboratory Quality Center

Background

- **Labeling practice varies from institution to institution; this variation introduces a potential risk of misdiagnosis due to pre-analytic errors**
- **A consistent, standardized method for labeling blocks and slides derived from patient specimens is desirable as it would facilitate consultation between institutions and mitigate the risk of identification errors**

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Introduction

CAP and NSH convened an expert panel of pathologists and histotechnologists to systematically review published documents and develop evidence-based recommendations

- **Closely followed the IOM Standards for Developing Trustworthy Clinical Practice Guidelines**
  - **Establish transparency**
  - **Manage conflicts of interest**
  - **Establish multidisciplinary panel**
  - **Perform systematic review**
  - **Rate strength of recommendations**
  - **Articulate the recommendations**
  - **Include external review**

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Expert panel

- **Richard W. Brown, MD,FCAP: CAP Co-Chair**
- **Vincent Della Speranza, MS,HTL(ASCP): NSH Co-Chair**
- **Janice Olivia Alvarez, HT(ASCP), NSH**
- **Richard N. Eisen, MD,FCAP**
- **David P. Frishberg, MD,FCAP**
- **Juan Rosai, MD,FCAP**
- **Jerry Santiago, HTL(ASCP), NSH**
- **Janet Tunnicliffe, ART, MLT, NSH**
- **Christina Lacchetti, MHSc, Consultant Methodologist**
- **Nicole E. Thomas, MPH, CT(ASCP)^{cm}, CAP Staff**

Systematic evidence review

- **Identify key questions**
- **Conduct literature search**
- **Perform data extraction**
- **Develop proposed recommendations**
- **Execute open comment period**
- **Complete considered judgment process**
  - **Consider risks and benefits, cost, regulatory requirements, preferences, etc.**

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Uniform Labeling of Blocks and Slides overarching question

- **What are the essential elements for the proper labeling of paraffin blocks and microscopic slides in the routine practice of surgical pathology?**

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Key questions

1. **What are the unique patient identifiers required for the unambiguous labeling of blocks and slides?**
2. **What elements are required for the unambiguous labeling of blocks and slides with site of origin (specimen and, within the specimen, correlation with gross description)?**
3. **When additional studies (deeper sections, histochemical stains, immunohistochemistry) are requested, what information should be included on the resulting slides?**

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Key questions continued

3a. How should you identify the different types of slides that have been cut? (ie, step sections have different meanings across labs)

3b. How would one determine the appending of numbers of subsequent slides?

3c. What standards should apply for the unique labeling of slides that have been stained with histochemical or immunohistochemical techniques?

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Key questions continued

4. **What is the value of standardizing the abbreviations and conventions used in key question #3?**
5. **In what order should the “essential” elements appear on the slide and, if space precludes inclusion of all, what is the priority?**
6. **How should you label blocks and slides received in consultation?**

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Systematic review results

- **Literature search**
  - **January 2002 – January 2013**
  - **456 articles met search term requirements**
  - **10 articles underwent data extraction**
  - **Grey literature included regulatory documents**
- **Public comment period**
  - **November 4 – December 6, 2013**
  - **302 respondents, 539 comments**

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Quality assessment and grading of evidence

- **Strength of evidence** **is determined by the level of evidence, quantity, size of the effect, quality of the studies, and quality assessment (risk of bias) of included studies. Also taken into account were consistency, generalizability and applicability to labeling of blocks and slides.**
- **Due to low level study designs, the overall strength of evidence was designated inadequate.**

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Definitions of strength of recommendation ratings

Designation	Recommendation	Rationale
Strong Recommendation	Recommend For or Against a particular glass slide or paraffin block labeling practice (Can include must or should)	Supported by high (convincing) or intermediate (adequate) quality of evidence and clear benefit that outweighs any harms
Recommendation	Recommend For or Against a particular glass slide or paraffin block labeling practice (Can include should or may)	Some limitations in quality of evidence (intermediate [adequate] or low [inadequate]), balance of benefits and harms, values, or costs but panel concludes that there is sufficient evidence to inform a recommendation.
Expert Consensus Opinion	Recommend For or Against a particular glass slide or paraffin block labeling practice (Can include should or may)	Serious limitations in quality of evidence (low [inadequate] or insufficient), balance of benefits and harms, values or costs, but panel consensus is that a statement is necessary.
No Recommendation	No recommendation for or against a particular block or slide labeling practice	Insufficient evidence, confidence, or agreement to provide a recommendation

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Guideline statement one

- **Laboratories should ensure that all blocks and slides are unambiguously labeled using two patient identifiers.**
  - **Recommendation**

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Rationale one | Laboratories should ensure that all blocks and slides are unambiguously labeled using two patient identifiers.

- **Evidence from the clinical laboratory, not specifically reviewed in the preparation of this guideline, has clearly established the utility of using two identifiers on all specimens submitted to the laboratory**
- **This is a requirement of the Joint Commission and the CAP Laboratory Accreditation Program (checklist question GEN.40491)**
- **The accession designation (also known as the "accession number") serves as the primary means of unambiguously linking all blocks and slides to a patient specimen; this designation should appear on all preparations**
- **A second identifier has not been traditionally used in the histology laboratory; however, this practice reduces the possibility of a reading error that can occur when a single identifier is used**

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Guideline statement two

- **Laboratories should ensure that the accession designation used on the surgical pathology report, and all blocks and slides from that accession, includes the case type (surgical pathology versus cytology or autopsy), the year, and a unique accession number.**
- ***Note:*** **Laboratories may position the information in a different format (eg, 14-9999S, 14S-9999) and may include additional letters that reflect the hospital or clinic site of origin.**
  - **Expert consensus opinion**

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Rationale two | Laboratories should ensure that the accession designation used on the surgical pathology report, and all blocks and slides from that accession, includes the case type (surgical pathology versus cytology or autopsy), the year, and a unique accession number.

- **The essential elements of an accession designation are:**
  - **A sequential, unique accession number that can be linked by the laboratory information system (LIS) or manual log to the patient specimen and a requisition containing complete patient demographic information**
  - **The year, typically written as the last two digits; this prevents confusion between identical accession numbers generated in different years**
  - **The specimen type (surgical [S], cytology [C], or autopsy [A]) if the laboratory processes more than one type of specimen**

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Rationale two continued | Laboratories should ensure that the accession designation used on the surgical pathology report, and all blocks and slides from that accession, includes the case type (surgical pathology versus cytology or autopsy), the year, and a unique accession number.

- **A preferred order of these three elements is not specified in this guideline as there is no evidence to support the efficacy of a specific format and the format may be limited by the programming of the LIS**
- **Alternating letters and numbers may add clarity to the designation (15-S-9999)**
- **Laboratories may choose to add a hospital or clinic designation as well (HS-15-9999)**

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Guideline statement three

- **If the patient's name is used as one of the patient identifiers, laboratories should ensure that the name format will link the blocks and slides to the correct patient.**
- ***Note:*** **Possible formats include, but are not limited to, full last and first name, full last name with first initial, or an appropriate number of letters of the last and first names.**
  - **Expert consensus opinion**

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Rationale three | If the patient's name is used as one of the patient identifiers, laboratories should ensure that the name format will link the blocks and slides to the correct patient.

- **Although names are not unique identifiers, they provide a clear visual contrast with the primarily numerical accession designation, minimizing the potential for transposition or other reading errors that may occur with use of an accession number alone**
- **Use of the full name is not necessary as long as the combination of letters from the first and last names can be clearly linked to the patient**

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Guideline statement four

- **When an accession number has not yet been assigned (eg, frozen sections or intra-procedural consultations), laboratories should label the blocks and slides with at least two patient identifiers, one of which is the patient name.**
- ***Note:*** **Possible additional identifiers include, but are not limited to, date of birth, medical record number, or unique health identification number.**
  - **Recommendation**

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Rationale four | When an accession number has not yet been assigned (eg, frozen sections or intra-procedural consultations), laboratories should label the blocks and slides with at least two patient identifiers, one of which is the patient name.

- **In the absence of an accession designation or barcode generated by the LIS, blocks and slides that are produced by the laboratory require two OTHER patient identifiers**
- **The LAP checklist question ANP.11800 specifically requires use of the patient name**
- **Other patient identifiers include, but are not limited to, date of birth, medical record number, or unique health identification number**

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Guideline statement five

- **Laboratories should label each specimen container with a unique alpha-numeric designation that incorporates the accession designation. Each block and slide from that specimen container should be labeled with the same unique alpha-numeric designation.**
  - **Expert consensus opinion**

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Rationale five | Laboratories should label each specimen container with a unique alpha-numeric designation that incorporates the accession designation. Each block and slide from that specimen container should be labeled with the same unique alpha-numeric designation.

- **During a surgical or biopsy procedure multiple specimens may be obtained**
- **A mechanism is necessary to link all blocks and slides derived from a single patient specimen with that specimen**
- **A unique, sequential letter or number designation provides that direct link and should be added after the accession designation (First specimen S15-9999-A or S15-9999-1); this identifier should be associated with the specimen on the paper requisition and in the LIS**

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Guideline statement six

- **Laboratories should label each block obtained from a single specimen sequentially with a unique alpha-numeric designation that can be unambiguously linked to a gross description within the pathology report. The order should be accession designation, specimen identifier and block identifier. Laboratories may select the format of the specimen/block identifier.**
  - **Expert consensus opinion**

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Rationale six | Laboratories should label each block obtained from a single specimen sequentially with a unique alpha-numeric designation that can be unambiguously linked to a gross description within the pathology report. The order should be accession designation, specimen identifier and block identifier. Laboratories may select the format of the specimen/block identifier.

- **Multiple tissue blocks may be submitted from a single specimen. It is essential that all of these blocks are unambiguously linked to that specimen and are clearly differentiated from each other**
- **The use of sequential block letters or numbers provides that link; the additional identifiers should follow the accession designation and specimen identifier**
- **For visual clarity, the specimen and block identifiers should be alternately alpha and numerical (eg, S-15-9999 A1,A2, A3 or S-15-9999 1A, 1B, 1C)**

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Rationale six continued | Laboratories should label each block obtained from a single specimen sequentially with a unique alpha-numeric designation that can be unambiguously linked to a gross description within the pathology report. The order should be accession designation, specimen identifier and block identifier. Laboratories may select the format of the specimen/block identifier.

- **The site of origin for each block should be listed in a section code within the gross description so that each block and the slides derived from it can be appropriately interpreted both within the laboratory and by external reviewers**
- **For example, a section code for a uterus might be:**

  1A cervix

  1B endomyometrium

  1C serosa

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Guideline statement seven

- **When multiple slides are cut from a single block, laboratories should label each slide sequentially in order of cutting. This slide identifier should come after the specimen identifier and block identifier.**
- ***Note:*** **The laboratory may determine the exact labeling format for multiple slides.**
  - **Expert consensus opinion**

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Rationale seven | When multiple slides are cut from a single block, laboratories should label each slide sequentially in order of cutting. This slide identifier should come after the specimen identifier and block identifier.

- **Sequential numbering of all slides obtained from a single paraffin block allows the pathologist to interpret the findings in the context of the entire tissue surface**
- **For example, if tumor is present in the first H&E slide but not in the immunostains, it is of importance to know if there have been multiple sections obtained between the two preparations**
- **Sequential numbering also allows the pathologist and any outside consultants interpreting the case to determine if all slides have been accounted for**

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Guideline statement eight

- **The laboratory should label the slides with the histochemical, immunohistochemical (IHC), and/or special procedure (eg, FS for frozen section, TP for touch preparation, AFB for acid fast bacteria) after the accession, specimen, block and slide identifiers. The histochemical technique or specific antibody used should also be included when it may affect the interpretation.**
- ***Note:*** **The panel concludes that surgical pathology slides labeled with terms such as "recut," "level," or "deeper" and slides without an explicit stain name are inherently implied to be a hematoxylin and eosin (H&E) stain; no additional labeling is required. The panel also concludes that the labeling of control slides or control tissue on test slides is beyond the scope of this guideline; however, the panel concludes that laboratories should establish a clear and standardized method for distinguishing control tissues from patient tissues that can be understood internally and externally.**
  - **Expert consensus opinion**

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Rationale eight | The laboratory should label the slides with the histochemical, immunohistochemical, (IHC) and/or special procedure (eg, FS for frozen section, TP for touch preparation, AFB for acid fast bacteria) after the accession, specimen, block and slide identifiers. The histochemical technique or specific antibody used should also be included when it may affect the interpretation.

- **Clear identification of the stain or procedure on the slide label is essential to ensure that there is no confusion as to what stain procedure has been used**
- **Use of "H&E" is not necessary for routine preparations; however, if this is not the stain routinely employed, then that stain should be specified**
- **Proper interpretation of immunohistochemical stains requires knowledge of the antigen target (eg, melanoma, pan-keratin) as many cases lack an internal control**

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Rationale eight continued | The laboratory should label the slides with the histochemical, immunohistochemical (IHC) and/or special procedure (eg, FS for frozen section, TP for touch preparation, AFB for acid fast bacteria) after the accession, specimen, block and slide identifiers. The histochemical technique or specific antibody used should also be included when it may affect the interpretation.

- **It is not necessary to include the histochemical stain technique or antibody clone routinely; however, these additions are recommended when this information may impact the interpretation (eg, “keratin” AE1/AE3 versus “keratin” Cam 5.2, Wade-Fite versus Ziehl-Neelsen)**
- **There is potential for misinterpretation of control tissue as part of the patient tissue; therefore, it is essential that the control tissue should be clearly identified and demarcated from patient tissue, particularly when they are present on the same slide**

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Guideline statement nine

- **No recommendation is made regarding standardization of abbreviations and conventions.**
  - **No recommendation**

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Rationale nine | No recommendation is made regarding standardization of abbreviations and conventions.

- **Standardized conventions for naming and abbreviations would be desirable in surgical pathology, particularly with regard to histochemical and immunohistochemical stains as this would facilitate interpretation across institutions**
- **With few exceptions (eg, Cluster Designations), however, there are no agreed upon naming conventions**
- **In view of this and the lack of an agency charged with maintaining and updating the list of abbreviations, no recommendation is made**
- **Although it is unlikely that universal standardization can be achieved, the Expert Panel strongly endorses the use of standardized naming conventions and abbreviations *within each institution*, clearly articulated in a policy or procedure, uniformly applied in that institution, and provided to any external clients**

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Guideline statement ten

- **On paraffin blocks, the accession designation should be the most prominent printed element (ie, larger font or bolded) followed by the patient name or other second identifier. As long as the ability to read the accession designation and second identifier is not compromised, additional elements may be included as determined by the laboratory.**
  - **Expert consensus opinion**

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Rationale ten | On paraffin blocks, the accession designation should be the most prominent printed element (ie, larger font or bolded) followed by the patient name or other second identifier. As long as the ability to read the accession designation and second identifier is not compromised, additional elements may be included as determined by the laboratory.

- **This guideline statement emphasizes the relative importance of the information of a paraffin block.**
- **The accession designation is most important and should be clearly identified by a larger or bolded font**
- **The second identifier (patient name, MR number, barcode) is the next most important element**
- **Additional elements (eg, tissue type, embedding symbols) should be added only if they do not compromise the visibility of the two primary identifiers**

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Guideline statement eleven

- **On microscopic slides, the accession designation should be the most prominent printed element (ie, larger font or bolded) followed by the patient name or other second identifier and stain/procedure name. As long as the ability to read these essential elements is not compromised, additional elements may be included as determined by the laboratory.**
  - **Expert consensus opinion**

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Rationale eleven | On microscopic slides, the accession designation should be the most prominent printed element (ie, larger font or bolded) followed by the patient name or other second identifier and stain/procedure name. As long as the ability to read these essential elements is not compromised, additional elements may be included as determined by the laboratory.

- **This guideline statement emphasizes the relative importance of the information on microscopic slides**
- **The accession designation is most important and should be clearly identified by a larger or bolded font**
- **The second identifier (patient name, MR number, barcode) is the next most important element**
- **The third essential element is the stain name, if it is not H&E**
- **Additional elements (eg, tissue type, institution name) should be added only if they do not compromise the visibility of the two identifiers and stain name**

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Guideline statement twelve

- **Laboratories should label blocks and slides received in consultation with their own institution's accession designation. Laboratories should not obscure the original label when relabeling.**
  - **Expert consensus opinion**

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Rationale twelve | Laboratories should label blocks and slides received in consultation with their own institution's accession designation. Laboratories should not obscure the original label when relabeling.

- **Labeling outside material with the consulting laboratory's identifier facilitates the ability to track, cross- reference and return the consultation material to the appropriate referring institution**
- **The presence of the consulting laboratory's accession designation provides the referring laboratory with a permanent record of the consultation and a link to the consultation report**
- **The original label represents the primary identification of the case material and should not be obscured by the consulting laboratory's information**

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Conclusion

- **It is common clinical practice for a patient's blocks and/or slides to be shared with external healthcare organizations to obtain consultative diagnostic opinions or to confirm diagnosis prior to treatment**
- **Standardization of labeling format facilitates interpretation of patient identification information across institutions and may avoid error**
- **Current labeling variability across institutions may result in misinterpretation due to unfamiliar labeling formats.**

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Conclusion continued

- **Although bar code technology can be helpful for avoiding human error, bar codes are often not interpretable outside one's own institution, limiting their utility when cases are referred elsewhere**
- **The standardization of labeling formats for blocks and slides facilitates recognition of labeling elements between institutions**

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References

- ***Archives of Pathology and Laboratory Medicine***
  - **Brown RW, Della Speranza V, Alvarez JO, et al. Uniform labeling of blocks and slides in surgical pathology: guideline from the College of American Pathologists Pathology and Laboratory Quality Center and the National Society for Histotechnology. Arch Pathol Lab Med. 2015;139(12):1515-24.**

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