

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

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• **Context.**—The labeling of paraffin blocks and microscopic glass slides in the practice of surgical pathology varies from institution to institution and introduces potential risk of preanalytic error. Currently there are no evidence-based guidelines regarding the uniform labeling of these materials.

Objective.—To develop recommendations that will address the need for adequate patient identification and provide a consistent method of identifying slides originating from a particular block.

Design.—The College of American Pathologists Pathology and Laboratory Quality Center and the National Society for Histotechnology convened a panel of pathologists and histotechnologists with expertise in histology laboratory quality practices to develop labeling recommendations. A systematic evidence review was conducted to address 6 main key questions. Recommendations were

derived from strength of evidence, open comment feedback, and expert panel consensus.

Results.—Twelve guideline statements were established to assist pathology laboratories in developing standardized block and slide labeling practices. These guidelines call for the use of 2 patient identifiers, 1 of which includes the accession number and case type, on all paraffin blocks and slides. Recommendations were also developed to address the order and format in which identifying elements should appear.

Conclusions.—Uniform labeling of paraffin blocks and slides derived from patient specimens will provide an important enhancement to patient safety by assuring that all preparations derived from a patient's tissue can be uniquely and unambiguously linked to that patient. Adoption of standardized practices additionally will improve patient care by facilitating interpretation of histologic sections when they are referred in consultation to a second institution.

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The diagnosis of biopsy and surgical tissue samples depends to a great extent and often entirely on the interpretation by the pathologist of the microscopic features of the case as evaluated in sections obtained from paraffin blocks and placed on glass slides. It is therefore imperative for these blocks and slides to be identified in a fashion that is informative and clearly understandable to all of the individuals handling that material. This applies not only to the laboratory and institution where those blocks and slides have been produced, but also to individuals from other institutions who may be requested to review them for medical care purposes as an institutional or personal consultation. It is therefore highly desirable for the blocks and slides to be labeled in a uniform and consistent fashion in order to avoid potentially serious errors; to increase efficiency in the distribution, examination, filing, and retrieval of the material; and to facilitate communication among institutions.

Surgical pathology is a complex process that begins with receipt of a labeled specimen and requisition, followed by accessioning of that specimen into the laboratory with assignment of an alphanumeric accession designation unique to that patient and case, and examination of the specimen with submission of tissue samples into labeled tissue cassettes, which are then processed into paraffin blocks and subsequently cut to produce tissue sections adhered to labeled glass slides. These slides are then microscopically examined by a pathologist. In most laboratories this involves at least 6 handoffs of the specimen, or preparations derived from it, to various personnel. Different personnel may, in some cases, separately hand label the blocks and slides. This complex system is vulnerable to error; therefore, an unambiguous method of identifying a patient's tissue and all preparations derived from it is essential if disastrous misidentifications are to be avoided.

The histology laboratory had not been identified as a source of error in the literature until relatively recently. In a study of medical malpractice cases against pathologists, Troxel¹ noted that 4 of 218 claims were attributable to patient misidentifications at some point in the surgical pathology process, and in a follow-up study,² he noted a sharp increase in histology errors, with 13 of 272 claims attributable to specimen mix-ups and 2 of 272 to mislabeled slides. More recently, in a study of 227 root cause analyses in the Veterans Health Administration, Dunn and Moga³ identified 8 cases in which mislabeling of anatomic pathology specimens, slides, or tissue cassettes led to significant patient harm, including unnecessary surgery (lung lobectomy, prostatectomy, hysterectomy), delays in diagnosis, and necessity for repeat procedures. One of the most comprehensive evaluations of labeling errors was performed through a Q-Probes study of the College of American Pathologists (CAP), reported in 2011. This study,⁴ involving 136 institutions, reported a labeling error rate of 1.1 per 1000 cases, with mislabeling rates of 1.0, 1.7, and 1.1 per 1000 for specimens, blocks, and slides, respectively. Similar studies within a single institution have reported labeling error rates ranging from 0.03% to 0.21% of slides and 0.057% to 0.068% of blocks to 1.7 labeling errors per 1000 cases.⁵⁻¹⁰

The importance of avoiding labeling errors in the laboratory has received increased attention by regulatory and accrediting agencies. The Patient Safety Goals of the Joint Commission, the primary accrediting agency for hospitals in the United States, call for the use of at least 2 patient identifiers on every specimen when providing laboratory services.¹¹ This is reflected in the laboratory general checklist of the College of American Pathologists Laboratory Accreditation Program, which specifically requires the use of 2 patient identifiers on all specimen containers (checklist question GEN.40491). Similarly, the Laboratory Accreditation Program checklist for cytopathology requires 2 patient identifiers on glass slides submitted to the laboratory (checklist question CYP.33333). A more general Laboratory Accreditation Program requirement in anatomic pathology (checklist question ANP.11500) is that the identity of a patient specimen should be maintained at all times during the processing and examination steps.¹² The Clinical and Laboratory Standards Institute has published specific standards for the labeling of laboratory specimens.^{13,14} Notably, however, the Clinical and Laboratory Standards Institute guidelines do not state specific requirements for the labeling of blocks and slides in surgical pathology.

A number of surgical pathology laboratories have published process flow modifications that lead to reduction in labeling errors, including the handling of only one specimen and tissue cassette at a time during specimen accessioning and examination; elimination of prelabeling and/or batch labeling of tissue cassettes and glass slides; implementation of instrumentation for automated block and slide labeling, particularly when interfaced with the hospital and laboratory information systems; and the handling of a single tissue cassette and single glass slide only at the time of cutting.^{7,10,15-17} However, the most significant reductions in specimen misidentification and labeling errors of blocks and slides have been achieved through the implementation of bar coding on all specimen containers, blocks, and slides.^{7,8,10,15} When coupled with the process flow modifications above, laboratories have reported block and slide error rates approaching zero.^{7,10} Unfortunately, however, this technology is not available to all institutions at this time and, even in laboratories with this technology, there may be occasions when a barcode is unreadable because of hardware malfunction, computer downtime, or incompatibility with an institution referring blocks and/or slides in consultation; therefore, it is essential that human-readable labels for blocks and slides are optimized.

In order to address the apparent lack of uniform standards for the labeling of blocks and slides, the CAP Pathology and Laboratory Quality Center convened an expert panel in partnership with the National Society for Histotechnology (NSH). This document outlines the work of this panel. In addition to the review of regulatory standards, the expert panel systematically reviewed the literature regarding surgical pathology practices. Although a few authors described or illustrated suggestions for optimal specimen labeling,^{8,18} no published studies were identified in which a specific nonbarcoded label content was demonstrated to reduce errors in identification. Most publications regarding histology quality practices and process flow do not specifically reference the content of block and slide labels at all. In view of this lack of standardized practices, it is not surprising that review of slides produced by pathology laboratories throughout the country in the consultation practice of one of the authors has revealed a high degree of variability in the type and amount of information contained in the slide labels, and in the way that such information is displayed. The recommendations presented here are an attempt to reach some degree of standardization of this important practice.

METHODS

A detailed description of the methods and systematic review (including engagement of vendors that manufacture labeling equipment for cassettes and slides, quality assessment, and complete analysis of the evidence) used to create this guideline can be found at www.archivesofpathology.org in the December 2015 table of contents.

Panel Composition

The CAP Pathology and Laboratory Quality Center convened an expert panel consisting of members with expertise in surgical pathology and histotechnology. Panel members included pathologists, histotechnologists, a methodologist consultant, and CAP staff. The CAP and NSH approved the appointment of the project cochairs and panel members. These panel members served as the expert panel for the systematic evidence review.

Conflict of Interest Policy

Prior to acceptance on the expert panel, potential members completed the CAP conflict of interest disclosure process, whose policy and form (in effect April 2010) require disclosure of material financial interest in or potential for benefit of significant value from the guideline's development or its recommendations 12 months prior through the time of publication. Potential members completed the conflict of interest disclosure form, listing any relationship that could be interpreted as constituting an actual, potential, or apparent conflict. Everyone was required to disclose conflicts prior to beginning and continuously throughout the project's timeline. Disclosed conflicts of the expert panel members are listed in the Appendix. Both the CAP and NSH provided funding for the administration of the project; no industry funds were used in the development of the guideline. All panel members volunteered their time and were not compensated for their involvement. Please see the supplemental digital content for full details on the conflict of interest policy.

Objective

The panel addressed the overarching question, "What are the essential elements for the proper labeling of paraffin blocks and microscopic slides in the routine practice of surgical pathology?" The key questions are as follows:

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?
 - a. How should you identify the different types of slides that have been cut? (ie, step sections have different meanings across laboratories)
 - b. How would one determine the appending of numbers of subsequent slides?
 - c. What standards should apply for the unique labeling of slides that have been stained with histochemical or immunohistochemical techniques?
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?

Literature Search and Selection

The literature search strategy involved searching the following electronic databases from January 2002 through October 2013: Ovid MEDLINE, Ovid MEDLINE In-Process & Other Non-indexed Citations, PubMed, and Web of Science. Relevant meeting abstracts and pathology journal tables of contents were hand searched (2011–2013). Applicable pathology monographs were identified (2002–2012). The bibliographies of identified articles were reviewed for relevant reports, and citation reports (Scopus, Web of Science) for included articles were also reviewed. (Please see the supplemental digital content for the complete literature search strategy.)

Inclusion Criteria

Published studies were selected for full-text review if they met each of the following criteria:

1. Surgical pathology studies
2. Original research addressing the labeling of blocks and/or microscopic slides
3. English-language articles of any study design
4. Animal and human studies

Exclusion Criteria

Studies that did not include original data regarding the labeling of blocks or microscopic slides, autopsy or cytopathology studies, and studies that focused exclusively on specimen container labeling were excluded. Editorials, letters, commentaries, invited opinions, articles not written in English, and articles that did not address any key question were also excluded.

Quality Assessment

Articles meeting the inclusion criteria were assessed for strength of evidence, methodologic rigor, and confirmation of validity by a contracted methodologist. The quality assessment of the studies was informed by several instruments, based on study design.^{19–21} The other components of evidence such as generalizability and applicability to labeling of blocks and slides in surgical pathology were also considered when determining the strength of evidence.

For strength of the evidence, the panel considered the level of evidence, its quantity, and quality of included studies. The level of evidence was based on the study design as follows: level I was evidence from systematic reviews of appropriate level II studies; level II was evidence from good-quality randomized controlled trials; level III was evidence from low-quality comparative studies; level IV was evidence from studies without a comparator. In general, level I and II evidence is considered most appropriate to answer clinical questions, but in the absence of such high-quality evidence, the panel considered data from lower-quality studies. The quantity of evidence refers to the number of studies and number of cases included for each outcome in the recommendation. The quality of studies reflects how well the studies were designed to eliminate bias and threats to validity.

The methodologic quality of preimplementation and postimplementation studies was assessed using 4 elements of the Ramsay et al²¹ quality criteria for interrupted time series designs. Scientific quality assessment of prospective case series was informed by the Centre for Reviews and Dissemination's guidance for reviews.¹⁹ The 3 elements considered included the representativeness of the sample, the sufficiency of the follow-up period, and the application of objective criteria to assess study outcomes. Finally, the qualitative study was assessed for methodologic quality using 5 components of the National Institute for Health and Clinical Excellence's 2009 methodology checklist for qualitative studies.²⁰ The appropriateness of the study design and data collected, relevance and clarity of findings, and adequacy of conclusions were evaluated. Each study was assessed individually, and then studies were summarized by study type. Finally, a summary of the overall quality of the evidence was given considering the evidence in totality.

Assessing the Strength of Recommendations

Development of recommendations required that the panel review the identified evidence and make a series of key judgments. Grades for strength of recommendations were developed by the CAP Pathology and Laboratory Quality Center and are described in Table 1.

Guideline Revision

This guideline will be reviewed every 4 years, or earlier in the event of publication of substantive and high-quality evidence that could potentially alter the original guideline recommendations. If necessary, the entire panel will reconvene to discuss potential changes. When appropriate, the panel will recommend revision of the guideline to the CAP and NSH for review and approval.

Disclaimer

The CAP developed the Pathology and Laboratory Quality Center as a forum to create and maintain evidence-based practice guidelines and consensus statements. Practice guidelines and consensus statements reflect the best available evidence and expert consensus supported in practice. They are intended to assist

Table 1. Grades for Strength of Recommendations

Designation	Recommendation	Rationale
Strong recommendation	Recommend for or against a particular block or slide 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 block or slide 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 block or slide 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

physicians and patients in clinical decision making and to identify questions and settings for further research. With the rapid flow of scientific information, new evidence may emerge between the time a practice guideline or consensus statement is developed and when it is published or read. Guidelines and statements are not continually updated and may not reflect the most recent evidence. Guidelines and statements address only the topics specifically identified therein and are not applicable to other interventions, diseases, or stages of diseases. Furthermore, guidelines and statements cannot account for individual variation among patients and cannot be considered inclusive of all proper methods of care or exclusive of other treatments. It is the responsibility of the treating physician or other health care provider, relying on independent experience and knowledge, to determine the best course of treatment for the patient. Accordingly, adherence to any practice guideline or consensus statement is voluntary, with the ultimate determination regarding its application to be made by the physician in light of each patient's individual circumstances and preferences. The CAP and NSH make no warranty, express or implied, regarding guidelines and statements and specifically exclude any warranties of merchantability and fitness for a particular use or purpose. The CAP and NSH assume no responsibility for any injury or damage to persons or property arising out of or related to any use of this statement or for any errors or omissions.

RESULTS

Of the 456 studies identified by the systematic literature review, 10 peer-reviewed articles met inclusion criteria and underwent data extraction. However, these studies ultimately failed to meet the minimum quality standards, presented incomplete data, or only included information based on expert opinion. As the overall body of available evidence was deemed inadequate to inform the guidelines, the panel relied on expert consensus opinion to formulate 10 of the 12 recommendations. Two of the recommendations were informed by existing regulatory requirements and were further guided by the clinical experience of the panel, resulting in a strong consensus.

The expert panel met 12 times through teleconference webinars from April 2012 through March 2014. Additional work was completed via electronic mail. The panel met in person August 17, 2013, to review evidence to date and draft recommendations and March 22, 2014, to draft the manuscript. An open comment period was held from November 4 through December 6, 2013. Thirteen draft recommendations were posted online on the NSH web site.

"Agree" and "disagree" responses were captured for every proposed recommendation. The Web site also received 539 written comments. Ten of 13 recommendations achieved more than 80% agreement; the other 3 achieved 78% to 79% agreement. Each expert panel member was

assigned 3 or 4 draft recommendations for which to review all comments received and provide an overall summary to the rest of the panel. One draft recommendation was maintained with the original language, 10 were modified with minor changes and/or additions for clarification, and 2 of the draft recommendations were combined, for a total of 12 final recommendations. Resolution of all changes was obtained by majority consensus of the panel using nominal group technique (rounds of teleconference webinars, e-mail discussion, and multiple edited recommendations) among the panel members. The final recommendations were approved by the expert panel with a formal vote. The panel considered laboratory efficiency and the feasibility of the recommendations throughout the entire process. A formal analysis of cost or cost effectiveness was not performed.

An independent review panel, masked to the expert panel and vetted through the conflict of interest process, provided final review of the guideline and a recommendation for approval by the CAP and NSH. The final recommendations are summarized in Table 2.

Guideline Statements

1. Recommendation.—Laboratories should ensure that all blocks and slides are unambiguously labeled using 2 patient identifiers.

There were insufficient published data to inform this recommendation; however, current regulatory requirements, extensive clinical experience, and a strong expert consensus were deemed *adequate* to support this recommendation.

Standards set by accrediting and regulatory agencies, including the CAP, the Joint Commission, and state agencies, require that all specimens submitted to the laboratory be labeled with 2 patient identifiers.^{11,12,14,22} Maintaining specimen identity at all steps in the processing and examination of specimens is an accreditation requirement of pathology laboratories accredited by the College of American Pathologists (checklist questions ANP.11500 and ANP.21050) and similar accrediting entities and is a key element to ensuring patient safety. In the anatomic pathology laboratory, it is generally accepted that the specimen accession designation, commonly called the *accession number*, serves as the primary means of unambiguously linking a specimen, as well as all tissue blocks and slides that derive from that specimen, to the patient. Therefore, this accession designation must appear on all of these preparations. In order to maintain specimen identity, there must be a manual or computer-generated log that serves as a link between this accession number and the full

Table 2. Guideline Statements and Strength of Recommendations

Guideline Statement	Strength of Recommendation
1. Laboratories should ensure that all blocks and slides are unambiguously labeled using 2 patient identifiers.	Recommendation
2. 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. Example: S14-9999 (surgical case–year–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
3. 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
4. When an accession number has not yet been assigned (eg, frozen sections or intraprocedural consultations), laboratories should label the blocks and slides with at least 2 patient identifiers, 1 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
5. Laboratories should label each specimen container with a unique alphanumeric designation that incorporates the accession designation. Each block and slide from that specimen container should be labeled with the same unique alphanumeric designation.	Expert consensus opinion
6. Laboratories should label each block obtained from a single specimen sequentially with a unique alphanumeric 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. Example: For specimen A, blocks are labeled 1, 2, 3 . . . (S14-9999 A1, A2, A3 . . .) For specimen 1, blocks are labeled A, B, C . . . (S14-9999-1A, 1B, 1C . . .)	Expert consensus opinion
7. 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. Example: S14-9999-A1-1, S14-9999-A1-2, S14-9999-A1-3 Note: The laboratory may determine the exact labeling format for multiple slides.	Expert consensus opinion
8. The laboratory should label the slides with the histochemical, immunohistochemical, 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. Examples: S14-9999-A1-1 FS S14-9999-A1-1 Cytokeratin (AE1/AE3) S14-9999-A1-1 AFB (Ziehl-Neelsen, Wade-Fite, etc) 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-eosin 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
9. No recommendation is made regarding standardization of abbreviations and conventions.	No recommendation
10. 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
11. 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
12. 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

patient demographic information. Arriving specimens are checked for labeling accuracy against accompanying documentation to ensure that the identity of each sample is confirmed.

The expert panel concludes that the requirement for 2 identifiers on primary containers should be extended to the labels on tissue blocks and slides in order to ensure patient safety. Two identifiers should be placed onto each tissue cassette (or block) and each slide prepared from that tissue

block. This reduces the possibility of a reading error that can occur when only a single identifier is used (Figure 1). Possible second identifiers include patient name, medical record number, financial or encounter number, date of birth, or a computer-generated barcode. One study demonstrated that human recognition of data strings is more accurate when both alphabetic and numeric data elements are used.¹⁸ Because the accession designation is primarily numerical, use of a patient name, or a portion of it, as the second

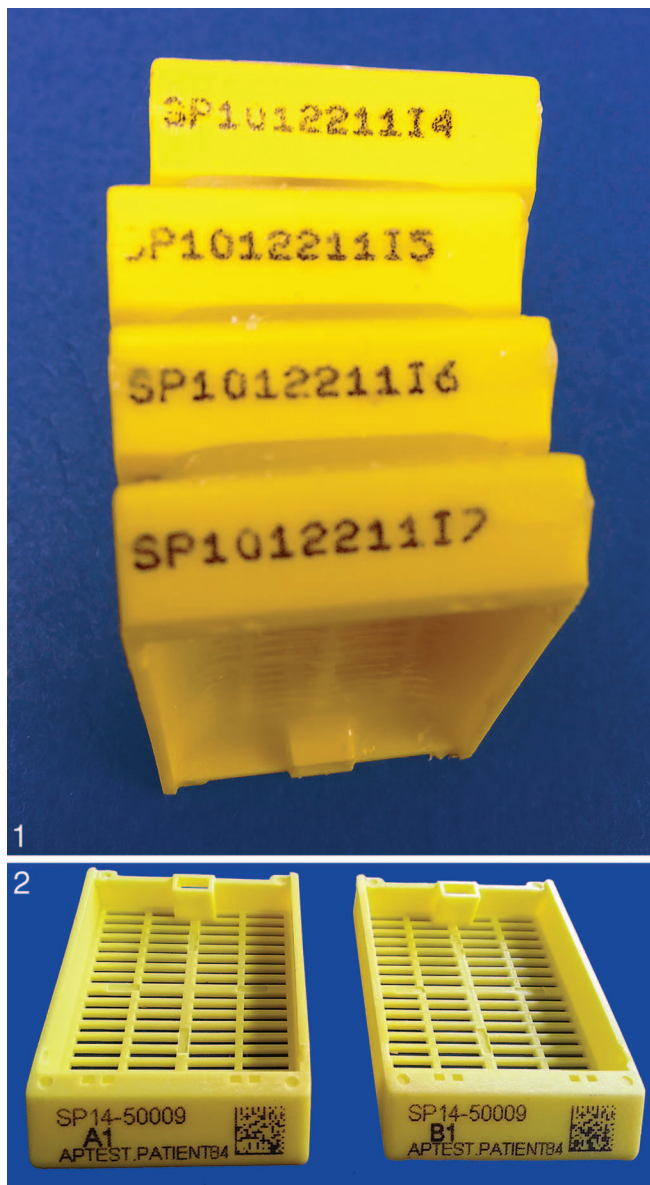


Figure 1. The use of a single identifier, typically the laboratory accession number, on tissue cassettes may yield a monotonous string of characters that can lead to read errors, particularly in high-volume laboratories in which hundreds of cassettes are handled in a single day.

Figure 2. Modern cassette labelers can provide clear and distinctive labeling with 2 or more identifiers.

identifier (when the second identifier is not a barcode) may be optimal as it provides a clear visual contrast.

The use of 2 identifiers on tissue cassettes is limited by the available labeling surface area. Instrumentation for high-volume applications is available that is capable of legibly printing 2 or more identifiers onto cassettes (Figure 2). In laboratories where cassettes are labeled by hand, the sides of the cassette may be used for the second identifier (Figure 3). The use of 2 patient identifiers on microscopic slides is less challenging because of the larger labeling area (Figures 4 and 5).

The use of barcode technology, which is beyond the scope of this guideline, has been shown to reduce human error; however, a barcode has some limitations when used as a

second identifier: (1) computer downtime or malfunction of the hardware used in barcode generation and scanning can lead to loss of operations, (2) physical damage to the barcode may render it unusable, and (3) when blocks and/or slides are referred in consultation to a second institution, the barcode may not be readable at that site. Therefore, the expert panel recommends that when a laboratory uses barcode technology, 2 human-readable identifiers should be included on all blocks and slides, in addition to the barcode, whenever this is technically feasible.

During the open comment period some respondents expressed concern that the use of patient names as a second identifier might represent a violation of the federal Health Insurance Portability and Accountability Act; however, the use of protected health information by health care workers during the delivery of care is permissible under this legislation. The law does require that the laboratory take steps to ensure that protected health information cannot fall into the possession of individuals who are not authorized to have this information. This may require laboratories to store blocks and slides labeled with patient names in a secure area.

2. Expert Consensus Opinion.—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.

Example: S14-9999 (surgical case–year–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.

There were insufficient published data to inform this recommendation; the strength of evidence was *inadequate* to support a specific labeling format.

It is understood that surgical pathology laboratories label surgical material (blocks and/or slides) and pathology reports with a unique numerical accession designation, but some may not identify the case type in a manner that will clearly link the material to the corresponding report. The report and all material should list the surgical case type (for example, S = surgical, C = cytology, A = autopsy); the year, listed as the last 2 digits of the year in which the procedure was performed (14 = 2014); and the unique accession number (9999).

Most automated labeling platforms will provide all elements of the specimen accession designation, but formats and the ability to alter them may differ from platform to platform. Therefore, it is suggested that all elements of the accession designation be present in the format that is consistent with each laboratory's established format(s), (eg, S14-9999; 14S-9999). The unique accession designation will serve as the primary and simplest link to the specimen. Clearly listing the case type on the report and all material provides an easy method to identify the particular case type as it relates to the report.

3. Expert Consensus Opinion.—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.



Figure 3. Laboratories in which patient identifiers are handwritten can use the sides of tissue cassettes to record additional identifiers.

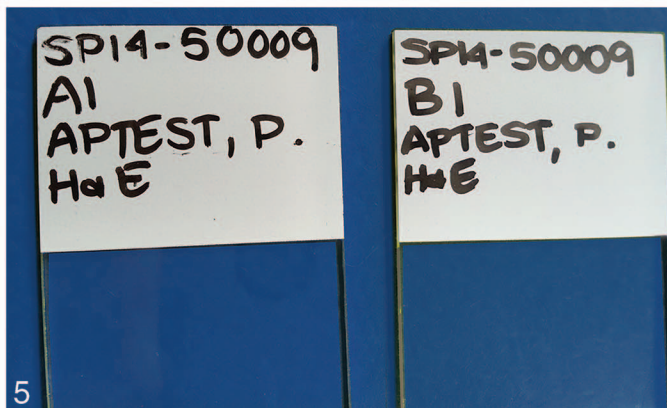


Figure 4. The greater labeling area on microscope slides makes the inclusion of 2 or more identifiers and the stain/procedure name readily achievable using currently available automated instrumentation.

Figure 5. The use of 2 patient identifiers and inclusion of the stain name on handwritten slides is achievable. In this example, the accession number is SP14-50009; A1 designates the specimen and block number. The patient name, designated as APTEST, P., is included as a second identifier in this image.

There were insufficient published data to inform this recommendation; the strength of evidence was *inadequate* to support a specific labeling format.

Although names are the least unique of identifiers, they are valuable as they are easily and quickly recognizable and are less subject to small transposition errors or other problems with manually read, purely numeric identifiers. This is particularly true whenever block or slide labels are checked for accuracy, either within the laboratory or when referred for further testing or consultation.

4. Recommendation.—When an accession number has not yet been assigned (eg, frozen sections or intraprocedural consultations), laboratories should label the blocks and slides with at least 2 patient identifiers, 1 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.

There were insufficient published data to inform this recommendation; however, current regulatory requirements, extensive clinical experience, and a strong expert consensus were deemed *adequate* to support this recommendation.

Use of a laboratory information system (LIS) to generate unique accession numbers is general practice within the pathology laboratory, and the panel acknowledges that

whenever possible all specimens should be assigned an accession number prior to evaluation; however, not all laboratories have an LIS portal accessible at the site of the intraprocedural consultation. Even when LIS access is available, the professional staff completing the frozen section may not have security access to enter patient demographics and generate an accession number. These situations can result in an accession number not being readily available at the time the intraprocedural consultation is being completed, resulting in the need to establish an alternate process for positively identifying all blocks and slides. Positive identification of the blocks and slides with 2 identifiers enables the blocks and slides generated as part of the intraprocedural consultation to be associated in the pathology laboratory with the patient requisition and additional specimen containers at a later time, ensuring an exact match. Even when an accession number is available, it is a CAP Laboratory Accreditation Program checklist requirement to use a second patient identifier: name, date of birth, or medical record number (checklist question ANP.11800).¹²

5. Expert Consensus Opinion.—Laboratories should label each specimen container with a unique alphanumeric designation that incorporates the accession designation. Each block and slide from that specimen container should be labeled with the same unique alphanumeric designation.

There were insufficient published data to inform this recommendation; the strength of evidence was *inadequate* to support a specific labeling format.

When samples are accessioned, the laboratory assigns a unique, internal identifier specific to each case that should consist of an alphabetic designation for the specimen type; a numerical year designation; and a sequential, laboratory-assigned number for that case. If multiple specimens are received for this case, it is essential that the labeling information distinguishes one specimen from another. Each specimen should be assigned an alphabetic or numeric designation, in ascending order. That designation should be paired, on a written requisition or in the electronic record, with a specific specimen source. For example, an accession designation might be S14-9999, where the letter "S" identifies a surgical case, the year is delineated by "14" and the case number is "9999."

If multiple specimens are received on this patient from the same surgical procedure, each must be assigned a unique identifier that is added to the accession number, such as "A," "B," etc (eg, S14-9999 A, S14-9999 B). Alternately, the specimen identifier may be a number (eg, S14-9999-1, S14-9999-2). Numerical specimen identifiers have the advantage of unlimited sequential numbering in cases with many specimens; however, the sequential letter designations provide a more obvious visual distinction from the accession number. The entire specimen designation, including the specimen identifier, should appear on the body of the specimen container. This information must be carried over to each block and slide label from this case.

6. Expert Consensus Opinion.—Laboratories should label each block obtained from a single specimen sequentially with a unique alphanumeric 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.

Example: For Specimen A, blocks are labeled 1, 2, 3 . . . (S14-9999 A1, A2, A3 . . .).

For Specimen 1, blocks are labeled A, B, C . . . (S14-9999-1A, 1B, 1C . . .).

There were insufficient published data to inform this recommendation; the strength of evidence was *inadequate* to support a specific labeling format.

Unique alphanumeric case, specimen, and block identifiers are essential for documenting sampling site and method as well as accurately correlating macroscopic and histologic findings. The clarity of such documentation becomes paramount when the prosector and the pathologist reviewing the microscopic sections are not the same person and when cases are reviewed by other institutions. Sequential lettering/numbering helps ensure that all specimens and blocks are accounted for. A standardized order (case → specimen → block) also facilitates the task of accounting for all material, and makes interpretation of reports and slides among laboratories less prone to error.

7. Expert Consensus Opinion.—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.

Example: S14-9999-A1-1, S14-9999-A1-2, S14-9999-A1-3

Note: The laboratory may determine the exact labeling format for multiple slides.

There were insufficient published data to inform this recommendation; the strength of evidence was *inadequate* to support a specific labeling format.

All slides cut from a block should be sequentially numbered. This includes all initial orders and subsequent requests for additional hematoxylin-eosin slides and/or ancillary testing. Sequential lettering/numbering helps ensure that all slides are accounted for. Interpretation of subtle histologic findings or limited lesional tissue may benefit from, or even require exact knowledge of, order of preparation. In an era when immunohistochemistry and molecular testing play an increasing role, selection of slides for ancillary, companion diagnostic, or prognostic studies can be optimized by knowledge of exact slide order.

8. Expert Consensus Opinion.—The laboratory should label the slides with the histochemical, immunohistochemical, 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.

Examples:

S14-9999-A1-1

FS

S14-9999-A1-1

Cytokeratin (AE1/AE3)

S14-9999-A1-1

AFB (Ziehl-Neelsen, Wade-Fite, etc)

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-eosin 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.

There were insufficient published data to inform this recommendation; the strength of evidence was *inadequate* to support a specific labeling format.

Clear identification of the stain or procedure on the slide label is essential to ensure there is no confusion as to what stain procedure has been used. In the majority of pathology laboratories, the routine stain used for primary slides is hematoxylin-eosin; therefore, when space on the label is limited, it is more important to include the cutting procedure used (recut, level, or deeper), providing the pathologist with information more valuable to the interpretation of the slides than the stain name. Immunohistochemical staining patterns are often the same; providing the name of the antibody used assists the pathologist in interpretation but also provides a visual confirmation that the correct stain has been performed and that the slide has been correctly labeled.

The majority of the participants (293 of 318 respondents) in the open comment period agreed that the stain name or procedure should be included on the label, especially when multiple techniques or antibody clones are available for use. Respondents who asserted that the stain or antibody designation is available in the pathology report and is therefore not required on the label were forgetting that the pathology report is not created until the slides are reviewed

and interpreted. There is also the potential for initial interpretation and secondary review to be completed more efficiently and with less risk of error when the pathologist can directly read the slide label and not have to refer to metadata stored in the computer or review a printed copy of the pathology report to confirm the stain or antibody designation.

9. No Recommendation.—No recommendation is made regarding standardization of abbreviations and conventions.

The strength of evidence was *inadequate* to support a recommendation for or against standardizing abbreviations and conventions.

The expert panel and the majority of respondents from the open comment period agreed that standardization of abbreviations would be ideal; however, developing and maintaining a list of specialized stain names or procedure abbreviations would be onerous and would require frequent updates, especially for immunohistochemical testing. Additionally, in the absence of a standardized naming system (eg, cluster designation), obtaining agreement on a standardized abbreviation would be problematic. An alternate approach, supported by the respondents and the expert panel, is that each laboratory should develop a list of standardized names/abbreviations to be used in its facility. When the laboratory performs consultation work, a copy of the standardized name/abbreviation list should be provided to the referring laboratories, ensuring that the abbreviations are clearly understood.

10. Expert Consensus Opinion.—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.

There were insufficient published data to inform this recommendation; the strength of evidence was *inadequate* to support a specific labeling format.

It is the expert panel's opinion that there is relative importance of the information on the block. The order of priority should be the specimen accession designation, including the specimen and block designations (eg, S14-9999-1A), followed by the patient name or other second identifier. The essential elements of the accession designation and second patient identifier should be large enough to be readable and should not be compromised by the inclusion of any additional elements. These elements may include, but are not limited to, institution name, nonroutine fixative, specific tissue type, specimen site/location or margin (eg, breast, upper outer quadrant, superior), and symbols or text that provide embedding or cutting instructions (eg, on edge). Limitations related to the amount of labeling surface and the font size will determine which of the additional elements a laboratory may decide to use.

11. Expert Consensus Opinion.—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.

There were insufficient published data to inform this recommendation; the strength of evidence was *inadequate* to support a specific labeling format.

It is the expert panel's opinion that there is relative importance of the information on the slide label. The order of priority should be the specimen accession designation, including the specimen, block, and slide designations (eg, S14-9999-1A-1), followed by the patient name or other second identifier and the stain/procedure name. These 3 essential elements should be large enough to be readable and should not be compromised by the inclusion of any additional elements. These elements may include, but are not limited to, institution name, nonroutine fixative, specific tissue type, and specimen site/location or margin (eg, breast, upper outer quadrant, superior). Limitations related to the amount of labeling surface and the font size will determine which of the additional elements a laboratory may decide to use.

12. Expert Consensus Opinion.—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.

There were insufficient published data to inform this recommendation; the strength of evidence was *inadequate* to support a specific labeling format.

Labeling the outside material with the consulting laboratory's own identifier without obscuring or defacing the original institution's label facilitates the ability to track, cross-reference, and return the consultation material to the appropriate outside institution.

Sites should establish an internally standardized process for labeling blocks and slides received in consultation. Blocks may be labeled by affixing a label with the consulting institution's identifier to the back side of the paraffin block. This may be achieved by adding a small amount of molten paraffin before affixing the label to help bond the label to the block. Slide labeling can be achieved by adding the consulting institution's label on the front side of the referred slide, if doing so will not obscure any portion of the diagnostic material. Alternately, the laboratory could place a label on the reverse side of the slide, directly behind the referring institution's label; however, this practice is regarded as significantly less desirable, as it may result in loss of the pathologist's ability to maintain a single plane of focus while examining the slide microscopically.

CONCLUSION

This guideline standardizes the labeling of blocks and slides in surgical pathology in order to assure that all preparations can be unambiguously linked to the patient. Development of the guideline was limited by the absence of published, outcomes-based evidence meeting the methodologic rigor used for the systematic literature review. The first and fourth guideline statements, which recommend the use of 2 patient identifiers on all preparations, are supported by regulatory and accreditation standards. All other recommendations represent the consensus opinion of the expert panel members.

In addition to the use of 2 patient identifiers, the guideline acknowledges the importance of linking each specimen within a case to the report, and to all blocks and slides derived from that specimen, by the use of a unique alphanumeric designation; each tissue block derived from a specimen should be similarly uniquely identified. In order to facilitate standardization and interpretation of block and slide labels, recommendations are also made for the order and format of the recommended elements. The goal is to

improve patient safety and the quality of care by decreasing the opportunity for misidentification within a laboratory and facilitating the identification of blocks and slides referred for ancillary testing and/or consultation.

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APPENDIX Disclosed Interests and Activities March 2012 to March 2014^a

Name	Interest/Activity Type	Entity
Janice O. Alvarez, HT(ASCP)	Board or advisory board	NSH
Richard W. Brown, MD	Other financial interest	Maryland Society of Histotechnologists
	Future expectations	Memorial Hermann Physicians Network
Vincent Della Speranza, MS, HTL(ASCP)	Lecture fees paid by entity	Ventana/Roche Patient Safety Advisory Board
	Royalties	Sakura Finetek, USA
Richard N. Eisen, MD	Board or advisory board	CAP
	Board or advisory board	Society for Applied Immunohistochemistry
David P. Frishberg, MD	Lecture fees paid by entity	Connecticut Society of Pathologists
	Board or advisory board	PathLearning
	Board or advisory board	Genentech
Jerry Santiago, MEd, HTL(ASCP)QIHC	Board or advisory board	XIFIN/PathCentral
	Board or advisory board	NSH
Janet Tunnicliffe, MLT, ART	Board or advisory board	NSH
	Board or advisory board	Diagnostic Accreditation Program for British Columbia
	Royalties	CAP/NSH Histology Quality Improvement Program
		United Kingdom National External Quality Assurance Scheme
		CAP

Abbreviations: CAP, College of American Pathologists; NSH, National Society for Histotechnology.

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