AUTO12-P
Vol. 30 No. 2

Specimen Labels: Content and Location, Fonts, and Label Orientation; Proposed Standard

PLEASE

▼▼▼
▼▼
▼

This proposed document is published for wide and thorough review in the new, accelerated Clinical and Laboratory Standards Institute (CLSI) consensus-review process. The document will undergo concurrent consensus review, Board review, and delegate voting (ie, candidate for advancement) for 60 days.

Please send your comments on scope, approach, and technical and editorial content to CLSI.

Comment period ends

15 March 2010

The subcommittee responsible for this document will assess all comments received by the end of the comment period. Based on this assessment, a new version of the document will be issued. Readers are encouraged to send their comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; Fax: +610.688.0700, or to the following e-mail address: standard@clsi.org.

▲
▲▲
▲▲▲

COMMENT

The purpose of this standard is to reduce human errors currently associated with the lack of standardization of labels on clinical laboratory specimens. The standard identifies the required human-readable elements to appear on specimen labels and specifies the exact locations, fonts, and font sizes of these elements.

A standard for global application developed through the Clinical and Laboratory Standards Institute consensus process.

Clinical and Laboratory Standards Institute

Advancing Quality in Health Care Testing

Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related health care issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient testing and health care services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, we provide an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

A document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that was not subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The CLSI voluntary consensus process is a protocol establishing formal criteria for

- The authorization of a project
- The development and open review of documents
- The revision of documents in response to comments by users
- The acceptance of a document as a consensus standard or guideline

Most documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed A consensus document undergoes the first stage of review by the health care community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Approved An approved standard or guideline has achieved consensus within the health care community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (ie, that comments on earlier versions were satisfactorily addressed), and to identify the need for additional consensus documents.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI's established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are addressed by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Health care professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

AUTO12-P
ISBN 1-56238-715-4
Volume 30 Number 2
ISSN 0273-3099

Specimen Labels: Content and Location, Fonts, and Label Orientation; Proposed Standard

Charles D. Hawker, PhD, MBA, FACB
Yashpal Agrawal, MD, PhD
Ulysses J. Balis, MD
Imelda M. Catalasan, MA, MT(ASCP)
Patricia Charache, MD
Quynh H. Vantu, MS, MT(ASCP)BB
Elizabeth A. Wagar, MD

Abstract

Clinical and Laboratory Standards Institute document AUTO12-P—*Specimen Labels: Content and Location, Fonts, and Label Orientation; Proposed Standard* was developed to reduce the unacceptably high incidence of mislabeled specimens in clinical laboratories. The standard specifies five required human-readable elements that must appear on the label for each clinical laboratory specimen (except labels with limited space, eg, slides and pediatric specimens), a standard label size of 1 × 2 inches (2.54 × 5.08 cm), and the exact required location and format on this label for each element. The patient's name was judged to be the single most important element in correct specimen identification and is always to be in the top left corner on each label. The standard also specifies rules for truncation for long patient names, the location and size of the bar code on each label, a list of the most commonly used variable elements that can appear on specimen labels, and the required orientation of labels on specimen tubes.

Clinical and Laboratory Standards Institute (CLSI). *Specimen Labels: Content and Location, Fonts, and Label Orientation; Proposed Standard*. CLSI document AUTO12-P (ISBN 1-56238-715-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2010.

Suggested Citation

CLSI. *Specimen Labels: Content and Location, Fonts, and Label Orientation; Proposed Standard.* CLSI document AUTO12-P. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

Proposed Standard

January 2010

ISBN 1-56238-715-4
ISSN 0273-3099

Committee Membership

Area Committee on Automation and Informatics

David Chou, MD
Chairholder
University of Washington Medical Center
Seattle, Washington, USA

Andrzej J. Knafel, PhD
Vice-Chairholder
Roche Diagnostics Ltd
Forrenstrasse, Switzerland

Ed Heierman, PhD
Abbott
Irving, Texas, USA

David A. Lacher, MD, MEd
National Center for Health Statistics
Hyattsville, Maryland, USA

William Neeley, MD, FACP, DABCC
Detroit Medical Center University Laboratories
Detroit, Michigan, USA

Jeff Quint, PhD
Beckman Coulter, Inc.
Brea, California, USA

Eugene T. Reilly
FDA Center for Devices and Radiological Health
Rockville, Maryland, USA

Richard S. Seaberg, MT(ASCP)
North Shore University Hospital
Manhasset, New York, USA

Advisors

Michael G. Bissell, MD, PhD, MPH
Ohio State University
Columbus, Ohio, USA

Suzanne H. Butch, MA, MT(ASCP), SB
The University of Michigan
Ann Arbor, Michigan, USA

Randy R. Davis
Siemens Healthcare Diagnostics
Bear, Delaware, USA

Arden W. Forrey, Jr, PhD, FACB
University of Washington
Seattle, Washington, USA

Charles D. Hawker, PhD, MBA, FACB
ARUP Laboratories, Inc.
Salt Lake City, Utah, USA

David A. Herold, MD, PhD
VA (San Diego) Medical Center
San Diego, California, USA

Gary W. Kramer, PhD
National Institute of Standards and Technology
Gaithersburg, Maryland, USA

Rodney S. Markin, MD, PhD
University of Nebraska Medical Center
Omaha, Nebraska, USA

Richard A. McPherson, MD
Medical College of Virginia Hospital
Richmond, Virginia, USA

Paul J. Mountain, MSc, MT(ASCP)
Flamborough, Ontario, Canada

David O'Bryan, PhD
Hibernia Consulting
Portsmouth, New Hampshire, USA

Hiroshi Sekiya
Olympus America Inc.
Irving, Texas, USA

Russell H. Tomar, MD
Chicago, Illinois, USA

Subcommittee on Specimen Labels: Content and Location, Fonts, and Label Orientation

Charles D. Hawker, PhD, MBA, FACB
Chairholder
ARUP Laboratories, Inc.
Salt Lake City, Utah, USA

Yashpal Agrawal, MD, PhD
New York Presbyterian Hospital – Cornell Campus
New York, New York, USA

Ulysses J. Balis, MD
University of Michigan
Ann Arbor, Michigan, USA

Imelda M. Catalasan, MA, MT(ASCP)
Armed Forces Institute of Pathology
Washington, District of Columbia, USA

Donna Urmston, MT(ASCP), MBA
Misys
Raleigh, North Carolina, USA

Quynh H. Vantu, MS, MT(ASCP)BB
Department of Veterans Affairs, Central Office
Washington, District of Columbia, USA

Craig Vorwald, MT(ASCP)
Quest Diagnostics
Collegeville, Pennsylvania, USA

Elizabeth A. Wagar, MD
UCLA School of Medicine
Los Angeles, California, USA

Advisors

Kathleen Allen, MD
Quest Diagnostics, Inc.
Pittsburgh, Pennsylvania, USA

Leann Bauer, MT(ASCP)
University of Virginia Medical Center
Charlottesville, Virginia, USA

Patricia Charache, MD
Johns Hopkins Medical Institutions
Baltimore, Maryland, USA

Aaron Cousins
BD Diagnostics
Oxford, United Kingdom

Nancy Erickson, PBT(ASCP), CPT(NHA)
Phlebotomy Education LLC
Allen Park, Michigan, USA

Contents

Foreword

Correct patient identification (ID) is critical to timely and appropriate patient care in all areas of health care including laboratory medicine. Published data have shown an unacceptably high rate of mislabeled specimens in US laboratories. At present, no standard format exists for clinical laboratory specimen labels, and the lack of such a standard is believed to be a significant contributor to the current rate of mislabeled specimens. This standard was developed to address the lack of a standard format for specimen labels in order to lower the mislabel error rate in laboratories and health care institutions. The primary focus of this standard is to identify the five required human-readable elements that must appear on each label and to specify the location, font, and font size of each of those elements. Additionally, the standard specifies the location and size of the bar code on each label and provides adequate space for other label elements frequently used by laboratories that are listed in the standard. Adoption of this standard by laboratories and all health care providers who collect and handle clinical laboratory specimens will contribute to a reduction of mislabeled specimens, ensuring higher quality of reporting and faster delivery of results. It is expected that all organizations involved in the licensing and accrediting of laboratories will refer to this standard in their accreditation checklists used during laboratory inspections.

Invitation for Participation in the Consensus Process

An important aspect of the development of this and all CLSI documents is the consensus process. Within the consensus process, CLSI members and other interested parties (1) have the opportunity to review and comment on CLSI publications in development and (2) are assured that their comments will be given serious consideration. All CLSI documents evolve, as does the technology affecting laboratory and health care procedures, methods, and protocols; therefore, through the operation of the consensus process, CLSI documents are expected to undergo cycles of evaluation and modification.

The Area Committee on Automation and Informatics has attempted to engage the broadest possible worldwide representation in committee deliberations. Consequently, it is reasonable to expect that issues remain unresolved at the time of publication at the proposed level. The review and comment process is the mechanism for resolving such issues.

The CLSI voluntary consensus process depends on the expertise of worldwide reviewers whose comments add value to the effort. At the end of a 60-day comment period, each subcommittee is obligated to review all comments and to respond in writing to all that are substantive. When appropriate, modifications will be made to the document, and all comments along with the subcommittee’s responses will be included as an appendix to the document when it is published at the next consensus level.

Key Words

Aliquot container, bar code, character set, daughter tube, derivative specimen, label size, Latin-1, patient name, quiet zone, specimen collector, specimen label, unique identifier

Specimen Labels: Content and Location, Fonts, and Label Orientation; Proposed Standard

1 Scope

This document presents a standard for specimen label content, format, and placement. This document is intended for health care providers; laboratory information system (LIS) vendors, diagnostic vendors, and vendors that manufacture labels and/or label printers; and for all other entities that collect, prepare, or handle patient specimens and must use, print, or read specimen labels. With some exceptions such as slides and pediatric specimens that have limited label space, this standard is applicable to all laboratory specimens from the point of collection, including all transfers of specimens from one provider to another.

The scope is limited, as described in the following sections, to reduce complexity in both developing and implementing the standard.

1.1 General Scope

This document provides requirements for the format and location of five main elements of every patient specimen label: (1) patient name, (2) a unique patient identifier, (3) date of birth (DOB), (4) specimen collection time and date, and (5) a designated space for the collector's identification (ID) (initials, signature, code) whether this ID is handwritten or printed by an automated portable label printer at the time of collection. This standard reserves adequate space for the institution to use for its specific customized needs on specimen labels such as critical result calling or contact information, the type of tube to be used, the type and volume of specimen to be obtained, specific handling requirements such as for pH or temperature, preservatives, specimen routing, test codes, and order status.

The standard also recommends a general location for the bar-coded identifier that is usually on a specimen label—the laboratory information system (LIS) accession number. The subcommittee acknowledges that 2D bar codes are increasingly being used in pathology systems and some automation systems, but not in analytical systems. Therefore, this standard provides no specifications regarding 2D bar codes. Finally, the standard requires a specific orientation of the label on the specimen tube relative to the cap or stopper on the container.

1.2 Specimen Origination and Information Systems

This standard is to be applied to specimen labels from the time of collection through all phases of laboratory processing and testing, when feasible. Accordingly, this standard was written so as to divide the labeling locations (application points for the standard) into three categories: (1) specimen collection in physician offices, phlebotomy stations, clinics, medical office buildings, and similar facilities, from which the majority of specimens are transported to a laboratory; (2) specimen receipt and/or collection in hospital laboratories or similar laboratories where specimens often come from the sources in category 1 and thus must often be relabeled, although they may also be collected within the facility and the labeling may be controlled by positive patient ID label systems or other systems within the institution; and (3) specimen receipt in reference laboratories, where specimens also must often be relabeled.

It is recognized that specimen collection may be initiated within systems other than the LIS such as a hospital information system (HIS), a computerized provider order entry (CPOE) system, or other systems the health care enterprise uses to support other hospitals, phlebotomy centers, clinics, or physician offices either organizationally affiliated with the laboratory or as reference customers of the laboratory. This standard must be implemented in all such systems so there is consistency in label formats and appearance

