CLINICAL AND LABORATORY STANDARDS INSTITUTE®

April 2011

AUTO12-A

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

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.

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AUTO12-A
Vol. 31 No. 7
ISBN 1-56238-748-0
Replaces AUTO12-P
ISSN 0273-3099
Vol. 30 No. 2

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

Volume 31 Number 7

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Abstract

Clinical and Laboratory Standards Institute document AUTO12-A—*Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard* was developed to reduce the unacceptably high incidence of mislabeled specimens in clinical laboratories. The standard specifies locations and formats for the 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 2 × 1 inches (50.8 × 25.4 mm), and an exact required location and format on this label for other commonly used elements. The patient's name is 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; Approved Standard*. CLSI document AUTO12-A (ISBN 1-56238-748-0). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.

Suggested Citation

CLSI. *Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard.* CLSI document AUTO12-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Proposed Standard
January 2010

Approved Standard
April 2011

ISBN 1-56238-748-0
ISSN 0273-3099

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Acknowledgment

CLSI and the Consensus Committee on Automation and Informatics gratefully acknowledge the following individual for her contributions during the development of this approved-level document:

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Contents

Foreword

Correct patient identification 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.[1] 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 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, which 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.

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; Approved 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 Sections 1.1 to 1.7, 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, and 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 LIS accession number. The document development committee acknowledges that two-dimensional (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. However, institutions wishing to implement 2D bar codes before widespread adoption in the industry may do so by using, at their option, any of the space on the label that has not been reserved for the fixed label elements (see Sections 5.1.1 and 6.2). Institutions may still have to retain linear bar codes in parallel to 2D bar codes until all analytical and automation systems they may be using have implemented 2D technology. In those circumstances in which the implementer chooses to add 2D technology in addition to the Code 128 bar code specified in this standard, it is up to the implementer to validate that all bar codes are correctly decoded according to the application to ensure that no inappropriate information is decoded into the wrong application. 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 the first category 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.