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# AUTO12-A

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

**SAMPLE**

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.

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

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

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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.

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## 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.<sup>1</sup> 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

SAMPLE

## **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.

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 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 for all labels throughout the enterprise, as well as on specimens ultimately forwarded to reference laboratories that are outside the hospital system.

### **1.3 Character Set and Font Typographical Class**

A principal limitation is that only the Latin-1 character set is specified in this standard. However, it is anticipated that future versions of this standard might encompass other character sets, and that LIS vendors or others who may deal with multiple character sets might wish to account for this future possibility as they implement this standard. This standard also specifies the use of a sans serif font (see Section 4.2), although a specific font is not specified. The document development committee believes that serifs make the characters harder to read and can contribute to errors.

### **1.4 Preprinted Labels**

Some laboratories now use tubes that the tube manufacturer provides with unique bar code ID numbers printed on labels the manufacturer affixes to tubes. Although these bar codes are useful to these laboratories, this standard does not support them.

### **1.5 Aliquots, Daughter Tubes, and Other Derivative Specimens**

Many laboratory automation systems (LASs) have automated aliquotters that print bar coded labels that are affixed to the tubes that are used in the aliquotters. Usually, these systems are interfaced to the laboratory's LIS, and the bar code on the labels affixed to the daughter tubes is the same laboratory accession number that was on the mother tube. In addition, the label stock used in these automated systems is often limited in size.

This standard requires that the labels on all specimens, including aliquot tubes, daughter tubes, and derivative specimens, comply with at least the minimal requirements of two unique identifiers as detailed in Section 5.3. These identifiers are the patient name (considered the primary identifier) and a second unique identifier, eg, a medical record number (MRN), the patient's financial/account number, or an episode number. It is recognized that some unlabeled aliquots are made and analyzed within a completely closed system. However, in all instances in which these specimens will be transported around the laboratory or shipped to a reference laboratory, and are no longer contained within a confined automated system or work system, these aliquots must be labeled as defined here.

There are other examples within the laboratory (eg, microbiology, anatomic pathology, hematology, mass spectrometry, and molecular diagnostics) in which derivative specimens (eg, sample cups, microvials, pilot tubes, microtiter plates, and slides) may be prepared and the labeling employed may be limited in size and space. It is a recognized reality of laboratory medicine that many tests use such derivative specimens. This standard acknowledges that reality, and requires only the minimal labeling requirements stated in the previous paragraph when feasible. However, it is expected that laboratories using such derivative specimens with limited label space have established an auditable procedure that prevents labeling errors.

### **1.6 Container and Source Limitations**

This standard addresses labels that are used in a clinical laboratory setting. However, it does not address paraffin blocks, labels for slides that might be used in anatomic pathology, hematology, or microbiology,



## The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI document HS01—*A Quality Management System Model for Health Care*. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are:

Documents and Records Organization Personnel	Equipment Purchasing and Inventory Process Control	Information Management Occurrence Management Assessment—External and Internal	Process Improvement Customer Service Facilities and Safety
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AUTO12-A addresses the QSEs indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Documents and Records	Organization	Personnel	Equipment	Purchasing and Inventory	Process Control	Information Management	Occurrence Management	Assessments—External and Internal	Process Improvement	Customer Service	Facilities and Safety
			AUTO01 AUTO02	H03	X AUTO02 GP33 H03 MM13						H03

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

### Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow, which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

AUTO12-A addresses the clinical laboratory path of workflow steps indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
H03	X GP33 H03 MM13	H03 MM13	X GP33 H03 MM13	X GP33 H03	H03		GP33	X MM13

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

## Related CLSI Reference Materials\*

- AUTO01-A**     **Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard (2000).** This document provides standards for the design and manufacture of specimen containers and carriers used for collecting and processing liquid samples, such as blood and urine, for clinical testing in laboratory automation systems.
- AUTO02-A2**     **Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition (2005).** This document provides specifications for use of linear bar codes on specimen container tubes in the clinical laboratory and for use on laboratory automation systems.
- GP33-A**         **Accuracy in Patient and Sample Identification; Approved Guideline (2010).** This guideline describes the essential elements of systems and processes required to ensure accurate patient identification. The principles in this document may be applied to manual or electronic systems. Design considerations covered include criteria for accuracy, differences in inpatient vs outpatient settings that impact patient identification, language and cultural considerations, and standardization of processes across the health care enterprise.
- H03-A6**         **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition (2007).** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.
- MM13-A**         **Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline (2005).** This document provides guidance related to proper and safe biological specimen collection and nucleic acid isolation and purification. These topics include methods of collection, recommended storage and transport conditions, and available nucleic acid purification technologies for each specimen/nucleic acid type.

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\* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

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