

# Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory



This document specifies the way bar coded sample identification labels are applied to clinical specimen containers.

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# NCCLS...

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### VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

## **Preface**

In 2001, ASTM Committee E31 decided to restructure its operations, with the intent of focusing on standards-development issues such as security, privacy, and the electronic health record. Part of the reorganization plan was to explore the option of transferring responsibility for nine E31.13 standards to NCCLS.

The NCCLS Area Committee on Automation and Informatics, at its meeting in April 2002, reached a positive assessment of the value of the ASTM standards and encouraged the NCCLS Executive Offices staff to pursue negotiations with ASTM on transferring these standards to NCCLS.

Following this transfer, these nine standards (formerly ASTM E792; E1029; E1238; E1246; E1381; E1394; E1466; E1639; and E2118) have been redesignated as NCCLS standards LIS1 through LIS9.

The Area Committee on Automation and Informatics has assumed responsibility for maintaining the documents and will revise or update each document in accord with NCCLS Administrative Procedures.

This document is the equivalent of ASTM E1466-92(1999) but has been redesignated and is now maintained by NCCLS. This document has been approved as an American National Standard (ANSI/ASTM E1466-92(1999)).

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## Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory

### 1. Scope

1.1 This specification specifies the way bar coded sample identification labels are applied to clinical specimen containers. It documents the form, placement, and content of bar code labels on specimen tubes that are used on clinical laboratory analyzers. It enables Laboratory Information System vendors to produce reliable bar coded symbols that are readable by any complying clinical laboratory analyzer vendor.

1.2 This specification is intended to apply to all clinical settings where specimens are collected from patients for examination or analysis in health care laboratory operations. It is complementary to, and extends, the Health Industry Business Communication Council (HIBCC). The document covers requirements that include the symbology, print quality measurement (wavelength of light), module width, symbol size, placement and orientation of the label, and data form and content.

1.3 The values stated in SI units are to be regarded as the standard. The values given in parentheses are provided for information only.

### 2. Referenced Documents

#### 2.1 ANSI Standard:

X3.182-1990 Bar Code Print Quality Guidelines<sup>1</sup>

#### 2.2 Other Documents:

USS-39 Uniform Symbology Specification-39<sup>2</sup>

USS-128 Uniform Symbology Specification-128<sup>2</sup>

Provider Applications Standard<sup>3</sup>

Guideline for the Uniform Labeling of Blood and Blood Components<sup>4</sup>

### 3. Terminology

3.1 The terminology found in X3.182-1990 shall be used where applicable.

### 4. Significance and Use

4.1 Bar code label printers and readers have been provided to accompany laboratory instruments and clinical laboratory information systems with increasing frequency in recent years. In other areas of health care, bar code technology has been successfully used to track radiographs, patient paper charts, supply requisitions, and administrative documents. In the clinical laboratory, use of the printing and reading equipment for bar codes to effectively track requests for services, specimens, and laboratory work has been impeded by the lack of common conventions. This specification provides for the use of bar codes in the management of laboratory specimens.

4.2 This specification should be used by manufacturers and vendors who configure either instruments or information handling systems for the clinical laboratory in order to provide the capabilities described in this specification. It should be used by laboratorians to develop procurement proposals that require this specification and operating procedures which utilize, to the fullest, the noted capabilities. If both audiences conscientiously adhere to this course, the greatest benefit will be obtained within the clinical laboratory through use of conforming components. Alternative considerations in making use of this specification in developing operation procedures best suited to the specific laboratory are available.<sup>5</sup>

### 5. Requirements

#### 5.1 Symbologies:

5.1.1 *Code 39*—Code 39 shall be the symbology for printing and reading bar coded labels applied to specimen containers. The standard check digit shall be used.

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<sup>1</sup>Available from American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036.

<sup>2</sup>Available from Automatic Identification Manufacturers, 634 Alpha Drive, Pittsburgh, PA 15238-2802.

<sup>3</sup>Available from Health Industry Business Communication Council, 5110 N. 40th Street, Suite 120, Phoenix, AZ 85018.

<sup>4</sup>Available from American Blood Commission, 1600 Wilson Blvd., Suite 905, Arlington, VA 22209.

<sup>5</sup>Tilzer, Lowell L., and Jones, R., *Archives of Pathology and Laboratory Medicine*, Vol 12, 1988, pp. 1200–1202; Neely, W., MLO (*Medical Laboratory Observer*), March 1990, pp. 24–27; Whisler, K., *Laboratory Medicine*, Vol 21, 1990, pp. 7–11.

5.1.2 *Code 128*—Code 128 shall be allowed and should be encouraged as a symbology for use in the future (Code 128 includes an inherent check character). Most bar code printers should have the ability to print both Code 39 and Code 128.

5.1.3 Where not explicitly defined in this specification, Specifications USS-39 or USS-128 shall apply.

5.1.4 Future readers on laboratory analyzers should be able to decode both Code 39 and Code 128 symbologies.

5.2 *Symbol Dimensions:*

5.2.1 *Length*—The length of the bar code symbol shall not exceed 60 mm (2.36 in.) including the required minimum quiet zone of 5 mm (0.20 in.) at each end of the symbol (see Fig. 1).

5.2.2 *Height*—The height of the bar code symbol (see Fig. 1) on the collection tube shall not be less than 10 mm (0.40 in.).

5.3 *Data Content:*

5.3.1 The entire 43 character set for Code USS-39 may be used (A–Z, 0–9, space – . \$ / + %). The entire 43-character set supported for Code 39 shall be used for Code USS-128. Full ASCII character set shall not be used for specimen identification. Leading and trailing space characters shall not be used.

5.3.2 There shall be a minimum of three data characters in the bar code.

5.3.3 The maximum number of encoded data characters permitted shall be eleven.

NOTE 1—Numeric data may be compacted for additional content, in which case base 36 should be used. If a lower density printer is used, the maximum number of data characters depends on the number of data characters that fit in a symbol which does not exceed the 60 mm (2.36 in.) limit in length, including quiet zone.

5.3.4 For specimen identification conforming to HIBCC-PAS (Provider Application Standard), the bar code shall contain, in addition to the start/stop characters and a check character specific to the symbology, the *where/what* flag characters “CD” preceding the unique specimen identification data characters. Where label length or number of specimen identification characters is limited, or in a closed identification system, the “CD” may be deleted from the sample identification and be nonconforming to HIBCC-PAS.

5.4 *Human Readable Information:*

5.4.1 Included on the collection tube in human readable form shall be all encoded data characters except start, check character and stop codes. If a compaction routine is used, then as a minimum the compacted data in human readable form shall be printed on the label.

5.4.2 The bar coded label to be affixed to the collection tube shall include an identifier that links the sample to the patient and may also include other identifiers such as the patient name, patient identification, sample identification number, date, and priority (stat, routine, ASAP, etc.) according to standard regulatory requirements. The total size of the label may be more than 10 by 60 mm (0.39 by 2.36 in.) to allow for human readable information to be printed.

5.5 *Bar Code Label Orientation*—The label shall be placed with the bars perpendicular to the axis of the tube (see Fig. 2). The label skew shall be less than  $\pm 5^\circ$  with respect to the axis of the sample container.

5.6 *Bar Code Placement*—Instrument readers shall accommodate a bar code symbol including quiet zone placed within a zone of 0 to 62 mm (0 to 2.44 in.) from rim of sample container. The label shall be applied to the cylindrical portion of the tube below the rim, skirt, or cap of the sample container.

5.7 *Module Dimension (Narrow Element Dimension)*—The narrow element dimension of the bar code symbol shall be nominally 0.19 to 0.51 mm (0.0075 to 0.02 in.).

5.8 *Bar Code Reader Wavelength:*

5.8.1 *Wavelength of Light*—The wavelength of light used for reading bar code labels should be 630 to 990 nanometers. Future instrument readers should conform to visible light range as suggested by Specifications USS-39 and USS-128.

5.9 *Print Quality of Measurement:*

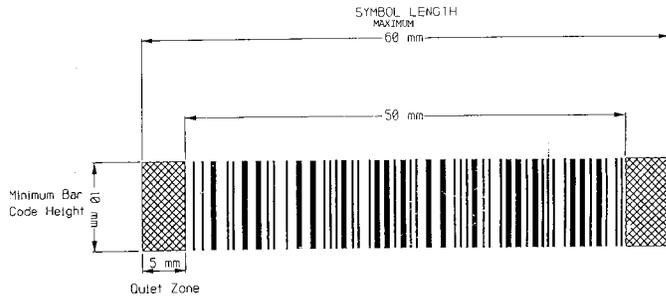
5.9.1 *Wavelength of Light*—The wavelength of light used for measuring bar code labels shall be 900 nanometers  $\pm 10\%$ .

5.9.2 *Measuring Aperture*—The measuring aperture shall be 0.13 mm (0.005 in.)  $\pm 10\%$ .

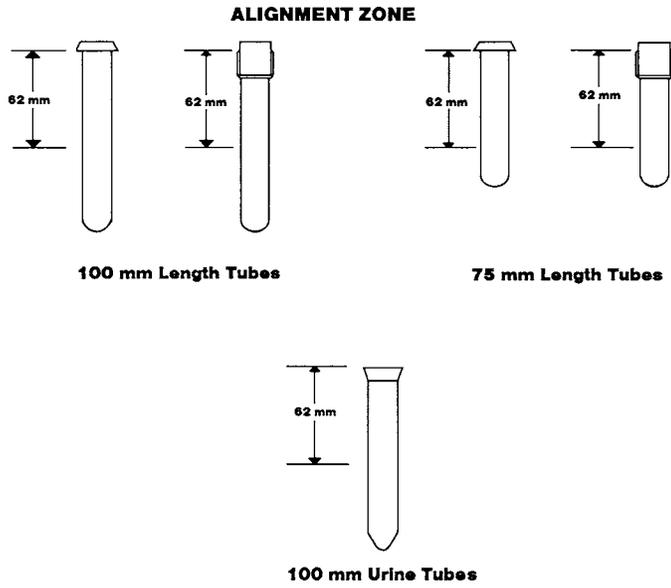
5.9.3 *Symbol Grade*—The minimum acceptable symbol grade shall be “C” as defined by ANSI X3.182-1990.

5.9.4 *Print Quality of Measurement*—Where not explicitly defined in this specification, ANSI X3.182 shall apply for aspects with regard to bar code print quality.

5.10 *Other Bar Code Symbols*—There shall be no other vertically oriented bar code symbols on the specimen container.



**FIG. 1 Symbol Dimension**



**FIG. 2 Bar Code Label Placement**

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NCCLS ▼ 940 West Valley Road ▼ Suite 1400 ▼ Wayne, PA 19087 ▼ USA ▼ PHONE 610.688.0100  
FAX 610.688.0700 ▼ E-MAIL: [exoffice@nccls.org](mailto:exoffice@nccls.org) ▼ WEBSITE: [www.nccls.org](http://www.nccls.org) ▼ ISBN 1-56238-495-3

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