

LIS7-A

Vol. 23 No. 13

Formerly ASTM E1466-92(1999)

---

# 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.

---



# NCCLS...

## Serving the World's Medical Science Community Through Voluntary Consensus

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 healthcare 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 healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

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

### PUBLICATIONS

An NCCLS 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 has not been subjected to consensus review and is released by the Board of Directors.

### CONSENSUS PROCESS

The NCCLS 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 NCCLS 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 (i.e., "tentative") consensus level.

**Proposed** An NCCLS consensus document undergoes the first stage of review by the healthcare 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.

**Tentative** A tentative standard or guideline is made available for review and comment only when a recommended method has a well-defined need for a field evaluation or when a recommended protocol requires that specific data be collected. It should be reviewed to ensure its utility.

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

NCCLS 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 NCCLS's established consensus procedures. Provisions in NCCLS 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 NCCLS 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 responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any NCCLS document. Address comments to the NCCLS Executive Offices, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

### 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)).

This publication is protected by copyright. No part of it may be reproduced, stored in a retrieval system, transmitted, or made available in any form or by any means (electronic, mechanical, photocopying, recording, or otherwise) without prior written permission from NCCLS, except as stated below.

NCCLS hereby grants permission to reproduce limited portions of this publication for use in laboratory procedure manuals at a single site, for interlibrary loan, or for use in educational programs provided that multiple copies of such reproduction shall include the following notice, be distributed without charge, and, in no event, contain more than 20% of the document's text.

Reproduced with permission, from NCCLS publication LIS7-A—*Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory* (ISBN 1-56238-495-3). Copies of the current edition may be obtained from NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA.

Permission to reproduce or otherwise use the text of this document to an extent that exceeds the exemptions granted here or under the Copyright Law must be obtained from NCCLS by written request. To request such permission, address inquiries to the Executive Director, NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA.

Copyright ©2003. The National Committee for Clinical Laboratory Standards.

### **Suggested Citation**

(NCCLS. *Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory*. NCCLS document LIS7-A [ISBN 1-56238-495-3]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.)

### **Published**

April 2003

ISBN 1-56238-495-3  
ISSN 0273-3099

## 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.

<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.