CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

CLSI AUTO14™

Use of 2-Dimensional Bar Coding in Clinical and Anatomic Pathology Laboratories

CLSI AUTO14 provides a context and framework for the use of 2-dimensional bar codes in clinical and anatomic pathology laboratories. The long-term goal of CLSI AUTO14 is to replace linear bar codes currently in use in laboratories, because they are known to have unacceptably high error rates that could lead to significant patient safety issues, such as misidentified patients and incorrect tests.

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

CLSI AUTO14-Ed1
September 2026

Use of 2-Dimensional Bar Coding in Clinical and Anatomic Pathology Laboratories

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Abstract

CLSI AUTO14—*Use of 2-Dimensional Bar Coding in Clinical and Anatomic Pathology Laboratories* provides a context and framework for the use of 2-dimensional (2D) bar codes in clinical and anatomic pathology laboratories. The long-term goal of CLSI AUTO14 is to replace linear bar codes currently in use in laboratories. The current linear bar codes are known to have unacceptably high error rates and could lead to significant patient safety issues, such as misidentified patients and incorrect tests. CLSI AUTO14 specifies a particular 2D symbology that meets requirements. CLSI AUTO14 specifies the data content of the code, how codes are to be printed and subsequently decoded, and how the content is to be used. Finally, there is a guide for users on how CLSI AUTO14 should be implemented.

CLSI. *Use of 2-Dimensional Bar Coding in Clinical and Anatomic Pathology Laboratories*. 1st ed. CLSI standard AUTO14 (ISBN 978-1-68440-336-3 [Print]; ISBN 978-1-68440-337-0 [Electronic]). Clinical and Laboratory Standards Institute, USA, 2026.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Suggested Citation

CLSI. *Use of 2-Dimensional Bar Coding in Clinical and Anatomic Pathology Laboratories*. 1st ed. CLSI standard AUTO14. Clinical and Laboratory Standards Institute; 2026.

CLSI AUTO14-Ed1

ISBN 978-1-68440-336-3 (Print)

ISBN 978-1-68440-337-0 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 46, Number 16

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Foreword

Correct patient identification is critical to timely and appropriate patient care in all areas of health care, including pathology and laboratory medicine. Prior CLSI standards addressed the use of a linear bar code (see CLSI AUTO02[1]), the content of linear bar codes (see CLSI AUTO07[2]), and the format of the human-readable content on clinical pathology specimen labels (see CLSI AUTO12[3]). CLSI AUTO14, which covers the use of 2-dimensional (2D) bar codes on specimen labels for both anatomic and clinical pathology, greatly improves patient identification in several ways. First, 2D matrix bar codes have an exponentially lower error rate than linear bar codes, because error correction technology is used. Second, 2D bar codes occupy significantly less label space than that required by linear bar codes, which enables laboratories to encode and check multiple identifiers inside 1 bar code. Third, the use of structured encoded content that includes identification of the laboratory location as well as the patient, specimen, and aliquot lays the foundation for a global identification system. When incorporated into laboratory software, such a global identification system makes it possible for multiple laboratories to use the same bar code to identify the patient and specimen without relabeling. CLSI AUTO14 requires the use of the Data Matrix (ECC 200 version) 2D bar-code symbology.[4] Rectangular Data Matrix symbols are required for curved surfaces with small diameters (eg, specimen tubes), but Data Matrix square symbols can be used elsewhere on flat items and on curved surfaces with larger diameters. Flexibility has been provided in CLSI AUTO14 to enable its application to all specimens, whether from the clinical laboratory, anatomic pathology, pediatric specimens, etc.

NOTE: The content of CLSI AUTO14 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

automation

bar code

identification

patient safety

Chapter 1

Introduction

Use of 2-Dimensional Bar Coding in Clinical and Anatomic Pathology Laboratories

1 Introduction

1.1 Scope

CLSI AUTO14 specifies the requirements and recommendations for use of 2-dimensional (2D) bar-coding technology in both anatomic and clinical laboratories for the labeling of specimens, aliquots, blocks, slides, associated documents, etc. The encoded content of this 2D bar code is highly structured and includes multiple elements to maximize patient identification within and between laboratories.

For laboratories, CLSI AUTO14 shall be used for:

- Parent specimen containers and all derivative sample containers in settings where the container represents a specimen from an individual patient (eg, anatomic pathology specimen to blocks to slides, blood specimen to white cell pellet to extracted nucleic acid)
- Documents and records in which the document or record represents something about an individual specimen or case (eg, specimen requisition)
- Labeling of autopsy patients (eg, toe tag) and their specimens
- Referral laboratory testing
- Vendor-provided prelabeled containers with a globally unique identifier (ID)
- Specimen containers tested with *in vitro* diagnostic (IVD) instruments and non-IVD instruments in the clinical setting
- Specimens collected for the purposes of blood bank and transfusion medicine testing, when compatible with the specimen labeling requirements in the International Society of Blood Transfusion 128 (ISBT 128) standard[5]
- Specimens collected from donated products (eg, blood products, stem cells), when compatible with the specimen labeling requirements in the ISBT 128 standard

The encoded content string defined by CLSI AUTO14 may also be used for identifying the specimen and patient being analyzed in digital records (eg, next-generation sequencing data files, analysis files, electronic requisitions).

The intended users of CLSI AUTO14 are clinical laboratory and anatomic pathology personnel, bar-code vendors, IVD manufacturers, LIS vendors, electronic health record system vendors, and other personnel involved in collecting specimens from patients (nurses, physicians, advanced practice professionals, laboratorians, etc.) in all patient care areas (clinics, laboratories, hospital units, emergency departments, blood bank personnel, tissue banks, etc.).

CLSI AUTO14 is not intended for use by areas that do not use bar codes in the health care setting. CLSI AUTO14 does not:

- Cover identification of items containing specimens from multiple patients (eg, transport bags, specimen racks, slide trays, tissue microarrays, multiwell plates, multiplexed next-generation sequencing assay chips, flow cells) or items containing multiple specimens from the same patient in which the individual specimens have more than 1 case number or accession number.