CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

GP33

Accuracy in Patient and Specimen Identification

This standard specifies the processes required to ensure accurate patient and specimen identification in manual and electronic systems across the health care organization. Processes include system design considerations, differences in requirements for patients with or without identification bands, and provisions for patients with communication barriers.

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

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Accuracy in Patient and Specimen Identification

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Abstract

Clinical and Laboratory Standards Institute standard GP33—*Accuracy in Patient and Specimen Identification* specifies the processes required to ensure accurate patient and specimen identification in manual or electronic systems across health care organizations. Processes include system design considerations, differences in requirements for patients with or without ID bands, and provisions for patients with communication barriers. Guidance on bar-code system implementation and user training is included. Validation of patient identification systems or programs and ongoing monitoring as a quality measure are also covered. This standard is intended for providers and health care personnel who collect and label diagnostic samples and who design, select, implement, monitor, and/or evaluate patient and specimen identification systems.

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Foreword

Of all preexamination processes, improperly identifying patients and incorrectly labeling diagnostic specimens have the most potential to result in catastrophic consequences. This standard establishes procedures that prevent such errors and protect patients against medical mistakes that can profoundly affect the care they receive. Although regulatory and accreditation organizations require policies, processes, and procedures to ensure positive identification throughout the laboratory's path of workflow, errors occur frequently. Results reported on the wrong patient have the potential to cause significant harm not only to the misidentified patient but to the patient whose health care decisions are guided by results from the misidentified specimen. Because the risk of harm to both patients is high, laboratories must establish strict policies on patient and specimen ID errors to manage risk and heighten personnel awareness of process errors that lead to patient ID and specimen labeling errors.

This standard contains information related to the quality system essentials (QSEs) described in CLSI document QMS01.[1] The QSE sections in this standard discuss implementing bar-code and radio frequency ID technology, biometrics, managing nonconforming events, and conducting patient and specimen ID audits. Users of this standard are encouraged to comment on the provisions established herein to help make future revisions more applicable, comprehensive, and efficacious.

Overview of Changes

This standard replaces the previous edition of the approved guideline, GP33-A, published in 2010. Several changes were made in this edition, including:

- Reclassified as a standard
- Reformatted with process flow charts and QSEs
- Established more-stringent requirements for identifying patients and labeling specimens
- Expanded Special Considerations chapter
- Added comprehensive label specification and placement guidance
- Included a subsection on labeling anatomic pathology specimens

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

KEY WORDS

ID band

Identification errors

Label

Labeling errors

Misidentification

Mislabeling

Patient identification

Sample

Sample labeling

Specimen

Chapter 1

Introduction

This chapter includes:

- Standard's scope
- Background information pertinent to the standard's content
- Standard precautions information
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the standard
- Abbreviations and acronyms used in the standard

Accuracy in Patient and Specimen Identification

1 Introduction

1.1 Scope

This standard discusses the critical need for accuracy in patient and specimen ID, the process required to maintain accurate patient and specimen ID throughout the preexamination, examination, and postexamination phases, and the verification of patient ID systems. It is intended for all providers and health care professionals who collect, label, and process biological specimens for laboratory testing, including blood and nonblood specimens, and who train others to do so. It is also meant to serve as a resource for those who develop patient ID systems, procedures, and practices, manage ID and labeling processes and specimen-collection personnel, and perform internal assessments.

In addition to ensuring accuracy in patient and specimen ID, this standard also seeks to harmonize patient and specimen ID processes throughout the health care industry wherever diagnostic blood and nonblood specimens are collected and identified. This standard serves as the overarching document to which all CLSI documents defer when discussing patient and specimen ID.

1.2 Background

Despite advances in health care technology, medical mistakes from patient and specimen misidentification continue to occur. Between 2007 and 2015, the use of bar-code systems in health care environments increased from 8% to 38%, yet the rate of "wrong blood in tube" did not decrease.[2] The consequences to the patient of not standardizing ID procedures include over- and undermedication, misdiagnosis, incorrect treatment, failure to treat an existing condition, unnecessary surgery, injury, disability, and death.[3,4] Consider these statistics:

- Eleven percent of all transfusion deaths occur because the health care professional did not properly identify the patient or mislabeled the tube of blood.[5]
- One hundred sixty thousand adverse patient events occur each year in the United States because of patient or specimen ID errors involving the laboratory.[2]
- Up to 1% of collection tubes are mislabeled.[3,6]
- 7.4% of patient ID bands are missing or contain erroneous information.[7]