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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Contents

Contents (Continued)

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

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]

8.4.2 Reporting Nonconforming Events

Focusing attention on patient and specimen ID error events has been shown to lower error rates.[4] Only by documenting all occurrences of ID errors can laboratories understand when and where NCEs are happening, as well as the magnitude of the problem. Diligently reporting NCEs helps determine the need for root cause analysis, which will identify the process modifications necessary to prevent future occurrences. Even near-miss events, which are defined as errors that do not result in injury or harm but have the potential to do so, must be reported.[27] They signal to the organization the process issues that need attention. Each NCE involving patient and/or specimen ID must be reported and include at least the following information:

- Date and time of occurrence
- Patient name and ID information
- Patient location
- Health care professional's details
- Name, role, and department of person reporting the occurrence
- Time and place of error detection, eg:
  - During registration
  - During collection (discrepancy between labels, examination requests, ID bands, and/or verbal information from the patient)
  - Upon receipt in the laboratory (discrepancy between sample and examination request)
  - Pretransfusion ID check
  - Before release of results
  - At the time of results review (delta check or clinically inexplicable results)
  - At the discovery of an adverse patient event
- Immediate correction and any follow-up action

See CLSI document QMS11[25] for more information on reporting NCEs.

NOTE:

Diligently reporting NCEs and near-miss events helps determine the need for root cause analysis, which will identify the process modifications necessary to prevent future occurrences.[27]

8.4.3 Responding to Nonconforming Events

When a patient or specimen ID error is discovered, appropriate action must be taken.

8.4.3.1 Immediate Action

Each laboratory must have a documented procedure describing the immediate steps necessary to prevent any additional harm and to mitigate any harm that could already have occurred. Immediate action must be

NOTE:

Immediate action must be taken when an error is discovered to prevent and/or minimize injury to the patient.

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