CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

CLSI PRE01™

Patient and Laboratory Specimen Identification Processes

CLSI PRE01 establishes procedures to ensure accurate patient and specimen identification. It is meant to eliminate repeating information in individual Clinical and Laboratory Standards Institute documents, which might introduce inconsistencies within the standards and guidelines and confusion for the user.

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

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Replaces CLSI GP33-Ed2

Patient and Laboratory Specimen Identification Processes

Aparna Jha Ahuja, MD
Judith Dixon, MS, MLS(ASCP), BS
Ruben Cudiamat, BSc, MLT(CSMLS), MLS(ASCPi)
Mickayla Karikari, MHA, MLS(ASCP)CM
Milly Keeler, BSMLS(ASCP), CLC(AMT), CCCP
Sean Kocur, PhD, C(ASCP), D(ABFT)FT
Chantia M. McClelland, MLS(ASCP)CM
Terri A. McElhattan, MHA, MLS(HEW), PBT(ASCP)CM, CPI(ACA)
Estelle Ninnemann, MLS(ASCP)
Ghazaleh Pourmahram, PhD, MICR
Matthew Shashack, PhD, DABCC
Jean Tenuta, MS, MBA, MLS(ASCP)CM, DLM, SLS, CQA(ASQ)
Sheryl Thiessen, MA, MLT(CSMLS), MLS(ASCP)

Abstract

Clinical and Laboratory Standards Institute (CLSI) standard PRE01—*Patient and Laboratory Specimen Identification Processes* covers procedures for patient and specimen ID, collection, transport, and handling that are applicable to most medical laboratory specimens. It discusses the critical need for accuracy in examination ordering, patient registration, patient and specimen ID, and specimen labeling and handling throughout the preexamination, examination, and postexamination phases. This standard is intended for providers and health care professionals who collect, label, and process biological specimens for laboratory testing and who train specimen-collection personnel to do so.

CLSI PRE01 is also meant to serve as a resource for individuals who manage ID and labeling processes and develop, validate, and verify electronic patient ID systems, procedures, and practices. This standard seeks to harmonize patient and specimen ID processes throughout the health care industry wherever blood and nonblood specimens are collected and identified. This standard does not include information related to the collection of individual specimen types and takes precedence over all CLSI documents when patient and specimen ID are discussed, except in cases of specimen-specific requirements.

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P: +1.610.688.0100 **F:** +1.610.688.0700 **E:** customerservice@clsi.org **W:** www.clsi.org

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Foreword

Of all preexamination processes, improperly identifying patients and incorrectly labeling specimens have the most potential to cause serious consequences affecting patient safety and compromising the quality of patient care.[1,2] 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 can 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 QMS01.[3] The QSE subchapters in this standard discuss implementing bar-code, radio frequency identification, and biometric technologies, managing nonconforming events (NCEs), and conducting patient and specimen ID audits.

Overview of Changes

This standard replaces CLSI GP33-Ed2, published in 2019. Several changes were made in this edition, including:

- Combining common information on patient and specimen identification to eliminate redundancy and/or potentially contradictory information across CLSI documents
  - **NOTE:** Detailed information for specific measurands and/or specimen types is retained in applicable CLSI documents.
- Updating patient identification process to include obtaining patient consent
- Adding information for general handling and transport to the laboratory or testing facility, including:
  - Packaging specimens for transport within a facility or campus
  - Packaging specimens for public transport
  - Monitoring specimens during external transport
  - Transporting specimens internationally (see Appendix B for a list of national and international agencies that regulate transport of dangerous goods)
- Adding new table providing approaches for greeting the patient
- Adding chapter on QSEs described in CLSI QMS01,[3] including information on personnel management, equipment management, process management, information management, NCE management, assessments, and continual improvement
- Updating Appendixes A and C on placement of labels on tubes and identification of irreplaceable specimens, respectively

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.

Chapter 1

Introduction

Patient and Laboratory Specimen Identification Processes

1 Introduction

1.1 Scope

CLSI PRE01 discusses the critical need for accuracy in examination ordering, patient registration, patient and specimen ID, and specimen labeling throughout the preexamination, examination, and postexamination phases. This standard is intended for providers and health care professionals (HCPs) who collect, label, and process biological specimens for laboratory testing and who train specimen-collection personnel to do so. It is also meant to serve as a resource for those who develop and validate electronic patient ID systems, procedures, and practices, and manage ID and labeling processes.

This standard harmonizes patient and specimen ID processes throughout the health care industry wherever blood and nonblood specimens are collected and identified. It serves as the primary source over other CLSI documents, except when there are specific requirements outlined in those documents. CLSI PRE01 does not include information related to the collection of individual specimen types.

1.2 Background

Despite advances in health care technology, 46% to 68% of all medical mistakes occur in the preexamination phase.[2,4,5] Incorrect patient ID and specimen labeling errors have the highest risk of occurrence.[1] 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" errors did not decrease.[6] The consequences of not standardizing ID procedures can lead to serious patient harm, including medication errors, misdiagnosis, incorrect treatment, failure to treat an existing condition, unnecessary surgery, injury, disability, and death.[1,5,7,8] Some statistics to consider are:

- Mislabeled tubes of blood or failure to properly identify the patient accounts for 11% of all transfusion deaths.[9]
- Patient or specimen ID errors involving the laboratory account for 160 000 adverse patient events each year in the United States.[10]
- Up to 1% of collection tubes are mislabeled.[1,7,8]
- Erroneous or missing information has been observed in 7.4% of patient ID bands.[10]

Technology alone will not eliminate patient ID and specimen labeling errors. Standardized processes with rigid adherence, regular audits, and consequences for noncompliance are necessary to fully protect the public.[1,11]

1.3 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of bloodborne pathogens. Published guidelines are available that discuss the daily operations of diagnostic medicine in humans and animals while encouraging a culture of safety in the laboratory.[12] For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all known infectious diseases, refer to CLSI M29.[13]

2 Patient and Specimen Path of Workflow

The flow chart shown in Figure 1 depicts the patient and specimen identification processes. Chapters 3 and 4 describe activities in the **preexamination** workflow that establish accurate patient and specimen ID. Subchapters 6.2 and 6.3 describe activities in the **examination** and **postexamination** workflows that maintain accurate specimen ID.

[a] Three basic symbols are used in this process flow chart: oval (signifies the beginning or end of a process), arrow (connects process activities), box (designates process activities).

Figure 1. Patient and Specimen Path of Workflow[a]

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