ISSN: 2230-9926

Available online at http://www.journalijdr.com

IJDR

International Journal of Development Research
Vol. 16, Issue, 10, pp.71096-71100, October, 2026
https://doi.org/10.37118/ijdr.31261.10.2026



RESEARCH ARTICLE OPEN ACCESS

SAMPLE RECEPTION IN CLINICAL LABORATORIES: A REVIEW OF SPECIMEN ACCEPTANCE, REJECTION CRITERIA, AND THEIR IMPACT ON PATIENT SAFETY

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ARTICLE INFO

Article History:

Received 20th July, 2026
Received in revised form
25th August, 2026
Accepted 15th September, 2026
Published online 31st October, 2026

Key Words:

Clinical Laboratories; Patient Safety; Sample Reception; Specimen Quality; Preanalytical Errors; Specimen Rejection.

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ABSTRACT

Background: Clinical laboratories contribute to patient safety by providing reliable and timely information for clinical decisions. Sample reception is an important checkpoint for detecting identification discrepancies and unsuitable specimens before testing. **Objective:** To examine the role of clinical laboratories in patient safety, focusing on sample reception, specimen quality, and implications for diagnostic reliability. **Methods:** A preliminary critical narrative synthesis was developed using targeted searches of PubMed-indexed records, publisher websites, and authoritative resources. Four primary studies provided quantitative findings, supported by one systematic review and relevant guidance. Findings were organized thematically; no meta-analysis was performed. **Results:** One study reported 2,178 rejected specimens among 837,862 received (0.26%), with recollection increasing turnaround time by an average of 108 minutes. Common rejection reasons included contamination, unsuitable containers, insufficient quantity, and labeling errors. Three intervention studies reported fewer identification or processing errors following electronic identification and labeling improvements. In one study, processing errors decreased from 0.42% to 0.11%. Evidence primarily addressed process outcomes rather than directly measured diagnostic accuracy or patient harm. **Conclusion:** The selected evidence supports standardized specimen verification, reliable identification, prompt communication, and quality monitoring. A comprehensive literature search and stronger clinical-outcome research are needed to establish the extent of patient benefit.

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Citation: Nada Mabrok Alnajari, Moroje Naji Aljihani, Maryam Mushtak Ahmed, Radwan Ibrahim Alsomali and Atheer Naif Alshehri. 2026. "Sample Reception in Clinical Laboratories: A Review of Specimen Acceptance, Rejection Criteria, and Their Impact on Patient Safety". *International Journal of Development Research*, 16, (10), 71096-71100.

INTRODUCTION

Clinical laboratories are essential to safe healthcare because their results support disease detection, diagnosis, treatment selection, and monitoring. Their contribution extends beyond producing numerical values to ensuring that laboratory information is reliable, timely, and clinically meaningful. Laboratory professionals therefore share responsibility for preventing diagnostic errors throughout the testing process, including activities performed before specimens arrive and after results are reported. A patient-centered approach considers any testing-related failure that could adversely affect care, regardless of where it occurs (Plebani, 2015). The total testing process includes preanalytical, analytical, and postanalytical activities. Although advances in instrumentation have improved analytical performance, errors remain possible across all three phases. Problems involving test requests, patient identification, specimen collection, transportation, and result communication demonstrate that accurate analysis alone cannot guarantee safe care. These stages are interdependent: an unsuitable specimen may undermine an otherwise well-controlled analytical procedure, while delayed communication can reduce the usefulness of a valid result. Laboratory safety consequently requires attention to the complete testing pathway (Plebani, 2015). Within this pathway, sample reception provides an important opportunity to identify problems before testing begins. Reception staff verify specimen identification, check agreement with the test request, assess container suitability and sample quantity, and document receipt. They also assess specimen condition and relevant transport requirements. The World Health Organization (WHO, 2011) emphasizes that laboratories should establish clear procedures for specimen verification, registration, and management of unsuitable samples. These activities support traceability and help prevent compromised specimens from progressing unnoticed through laboratory workflows. Specimen quality problems include hemolysis, clotting, contamination, inadequate volume, labeling discrepancies, and inappropriate collection containers. Their significance depends on the requested examination, specimen type, and degree of compromise. In a retrospective clinical chemistry study involving 837,862 specimens, Cao et al. (2016) reported that 2,178 specimens were rejected, representing 0.26% of those received. Recollection following

rejection increased turnaround time by an average of 108 minutes. These findings illustrate the operational consequences of specimen problems, although their frequency and impact cannot be generalized to every laboratory. Rejecting an unsuitable specimen can protect against unreliable results, but it may also require repeat collection and delay care. Laboratories therefore need documented, test-specific acceptance criteria, prompt communication with clinical teams, and appropriate consultation when specimens are difficult to replace (WHO, 2011). Broader quality management provides the organizational foundation for these decisions. ISO 15189:2022 establishes requirements for medical laboratory quality and competence, while quality indicators offer a means of monitoring weaknesses throughout the testing process (International Organization for Standardization [ISO], 2022; Plebani et al., 2017). Indicators should be interpreted alongside local workflows and acceptance policies. An integrated examination of laboratory responsibilities, sample reception, and specimen quality can clarify how these functions contribute to patient safety. Improved specimen quality supports diagnostic reliability, but reductions in rejection or labeling errors do not independently establish improved diagnostic accuracy or patient outcomes. This review therefore aims to critically examine the role of clinical laboratories in patient safety, focusing on sample reception practices, specimen quality problems, their implications for reliable and timely diagnostic testing, and strategies for improvement.

LITERATURE REVIEW

The literature increasingly describes laboratory safety as a responsibility spanning the entire testing process. Mrazek et al. (2020) examined errors from test selection to clinical interpretation and emphasized that laboratory professionals contribute through consultation, specimen assessment, analytical quality assurance, and result communication. Their review challenges an instrument-centered understanding of quality by demonstrating vulnerabilities at clinical interfaces. However, the evidence summarized across settings uses different definitions and surveillance methods, limiting direct comparisons of error frequency. Sample reception represents a practical checkpoint within this wider safety system. World Health Organization (WHO, 2011) guidance recommends checking identification, specimen quantity and condition, request completeness, and suitability for the examination. It also emphasizes documentation and communication when specimens are unsuitable. These recommendations establish a procedural foundation, but guidance alone does not demonstrate effectiveness in practice. Its contribution depends on implementation, staff competency, adherence, and evaluation of whether problems are detected and appropriately resolved.

Empirical research illustrates the consequences of specimen defects. Cao et al. (2016) retrospectively examined 837,862 clinical chemistry specimens and identified 2,178 rejections. Contamination, inappropriate containers, insufficient quantity, and labeling errors were prominent causes. Recollection increased turnaround time by an average of 108 minutes. The study links specimen rejection to measurable service disruption, supporting attention to collection and reception processes. Nevertheless, its single-center design and particular patient population restrict generalizability, and the reported delays should not be interpreted as direct measurements of diagnostic harm. Identification technology provides another important strand of evidence. Brown et al. (2011) reported that mislabeled specimens decreased from 103 to eight annually after implementation of barcode-based patient identification and bedside printing. This finding supports connecting patient verification with labeling at collection, rather than relying exclusively on checks after laboratory arrival. However, a before-and-after comparison cannot fully separate the technology's contribution from accompanying training, workflow changes, or other changes over time. Annual event counts also require specimen-volume information for meaningful rate comparisons. Broader evidence supports the identification benefits of barcoding. Snyder et al. (2012) synthesized 17 observational studies, including ten examining patient specimens and seven examining point-of-care testing; all favored barcoding. Their synthesis strengthens the argument that electronically linked identification systems can reduce identification errors across settings. Nevertheless, the outcomes primarily concern identification performance. Fewer identification errors should not automatically be translated into quantified improvements in diagnostic accuracy, morbidity, or mortality without studies measuring those endpoints. The age of this evidence also warrants examination of newer implementations. Continuous monitoring complements procedural and technological safeguards. Plebani et al. (2017) described quality indicators covering the total testing process, offering a structured approach to identifying vulnerabilities and evaluating improvement. For reception-related practice, relevant measures include identification discrepancies, unsuitable specimens, and delays. Meaningful interpretation requires consistent definitions and denominators. A low rejection rate may indicate better collection, but it could also reflect less effective detection or more permissive acceptance. Conversely, improved detection may initially increase recorded rejection without representing deterioration in specimen collection. These possibilities highlight the importance of interpreting performance measures in their operational context. Taken together, these sources support a coordinated approach combining standardized reception procedures, reliable identification, staff development, clinical communication, and quality monitoring. They also reveal an important distinction between detecting defective specimens and demonstrating better patient outcomes. Future research should connect reception interventions with recollection burden, time to actionable results, treatment delays, and documented diagnostic consequences. Multicenter studies using comparable indicators would help determine which improvements are transferable across laboratory disciplines and healthcare settings. This synthesis positions reception as one component of laboratory responsibility, integrated with analytical quality and appropriate clinical use of results.

METHODS

This manuscript uses a preliminary critical narrative approach to examine the role of clinical laboratories in patient safety, focusing on sample reception, specimen quality, and diagnostic reliability. It draws on selected published research and authoritative guidance rather than a completed systematic database search. Targeted web searches identified relevant publications through PubMed-indexed records, publisher websites, and official World Health Organization and International Organization for Standardization resources. Searches addressed clinical laboratory safety, specimen rejection, sample reception, preanalytical errors, patient identification, and barcode-based labeling. Bibliographic details and numerical findings were checked against accessible abstracts, publication records, and available article text. No comprehensive Scopus search or reproducible database screening process was completed. Sources were selected for their relevance to laboratory responsibilities, specimen suitability, identification safeguards, and consequences for testing and care. The quantitative synthesis describes four primary studies addressing specimen rejection or identification interventions. One systematic review provides supporting context. Additional reviews and guidance inform the discussion of laboratory processes and quality management. Earlier publications were retained because they directly addressed the interventions discussed; no fixed publication-year restriction was applied.

Extracted information included authorship, publication year, setting, study design, specimen numbers, outcome definitions, rejection reasons, error frequencies, and reported intervention findings. Specimen counts were distinguished from unique patients and literature-search records. Primary studies appearing within the supporting systematic review were not counted again as additional independent evidence. Findings were organized thematically around laboratory responsibilities, reception safeguards, specimen defects, rejection management, timeliness, electronic identification, and quality monitoring. Methodological limitations were discussed descriptively, including single-center designs, uncontrolled

comparisons, differing denominators, and limited measurement of clinical outcomes. No formal risk-of-bias scoring or meta-analysis was performed. Search yields, exclusion counts, and a final included-study total are not reported because a complete screening record is unavailable. Conclusions distinguish observed process improvements from demonstrated changes in diagnostic accuracy or patient outcomes.

RESULTS AND FINDINGS

This section synthesizes findings from four selected primary studies, one supporting systematic review, and relevant guidance. It remains a preliminary narrative synthesis because the proposed database search and screening have not been completed. Search totals and a final included-study count are therefore unavailable.

The primary studies examined specimen rejection, labeling errors, and electronic identification interventions. Their outcomes included rejected specimens, identification discrepancies, processing errors, and delays associated with recollection. Three studies evaluated changes following identification and labeling interventions, while one examined the causes and consequences of specimen rejection.

They demonstrate the laboratory's contribution to recording specimen defects, monitoring identification errors, and evaluating changes in collection-to-laboratory workflows. However, these studies do not independently quantify the laboratory's overall effect on patient outcomes. Authoritative guidance identified sample reception as a checkpoint for verifying specimen suitability before testing. WHO guidance specifies assessment of labeling, quantity, condition, suitability for the requested examination, and completeness of request information. It also calls for specimen registration and documented management of unsuitable samples (WHO, 2011). These are recommended practices rather than effect estimates from intervention research. WHO's implementation guidance additionally links reception procedures with traceability, urgent-specimen processing, and documentation of collection and receipt information. These activities provide a procedural basis for tracking specimens and investigating discrepancies. Nevertheless, the selected primary studies mainly examined wider collection and identification systems; they did not isolate the independent effect of reception checks. Cao et al. (2016) reported several reasons for specimen rejection, covering contamination, collection-container problems, insufficient quantity, labeling discrepancies, hemolysis, and clotting. Contamination accounted for the largest proportion of rejected specimens in that clinical chemistry setting.

Table 1. Characteristics and principal findings of the selected primary studies

Study	Design and focus	Specimen numbers or outcome unit	Principal findings
Cao et al. (2016)	Retrospective examination of clinical chemistry specimen rejection	837,862 specimens received; 2,178 rejected	Rejection rate was 0.26%. Recollection increased turnaround time by an average of 108 minutes.
Hill et al. (2010)	Before-and-after evaluation of electronic ordering and barcode identification/labeling	Before: 724,465 specimens; 3,007 errors. After: 334,039 specimens; 379 errors	Processing errors decreased from 0.42% to 0.11%, representing a reported 74% relative reduction.
Morrison et al. (2010)	Before-and-after evaluation of positive patient identification during inpatient phlebotomy	Labeling errors per 10,000 specimens	Errors decreased from 5.45 to 3.20 per 10,000 specimens, p = .0013.
Brown et al. (2011)	Evaluation of barcode identification and bedside printing	Annual labeling-error counts	Errors decreased from 103 to 8 annually, p < .001.

Table 2. Leading rejection reasons reported by Cao et al. (2016)

Rejection reason	Number	Percentage of rejected specimens
Contamination	764	35.1%
Inappropriate container or tube	330	15.2%
Insufficient quantity	329	15.1%
Labeling errors	321	14.7%
Hemolysis	205	9.4%
Clotting	203	9.3%

Table 3. Main findings and limits of the available evidence

Area	Finding supported by the selected sources	Limit of interpretation
Laboratory responsibilities	Safety involves the complete testing pathway	Overall effects on patient outcomes were not quantified
Sample reception	Guidance specifies verification, registration, and traceability procedures	Independent intervention effects were not established
Specimen quality	Multiple collection and identification defects caused rejection	Frequencies are setting dependent
Timeliness	Recollection increased turnaround time in one study	Diagnostic and treatment consequences were not directly quantified
Electronic identification	Three primary studies reported fewer identification or processing errors	Combined interventions and uncontrolled comparisons limit attribution
Quality monitoring	Indicators can cover the complete testing process	Comparable definitions and denominators remain necessary

The broader literature identified laboratory responsibilities throughout the testing pathway. Mrazek et al. (2020) described vulnerabilities in test selection, collection, identification, transport, preparation, analysis, reporting, and clinical interpretation. Their review emphasized collaboration between laboratory specialists and clinicians, including support for appropriate test selection and interpretation. Consequently, the laboratory's contribution to safety extends beyond analytical performance to the quality and clinical use of laboratory information. The selected primary studies provide narrower empirical evidence within this broader role.

Percentages refer to the 2,178 rejected specimens. The listed categories are not exhaustive: This distribution demonstrates that specimen rejection involves several distinct failure types. It should not be treated as a universal ranking: the authors noted that rejection rates may differ because of healthcare settings and methods used to detect unsuitable specimens. WHO guidance recommends explicit rejection criteria, documentation of the reason for rejection, prompt notification of the authorized requester, and arrangements for recollection when appropriate.

It also recognizes circumstances in which testing of a suboptimal specimen may proceed after consultation with the requester (WHO, 2011). Thus, the guidance supports a documented decision process that considers specimen suitability and clinical circumstances. The selected evidence does not establish a universal acceptance threshold or show that one rejection policy produces better clinical outcomes than another. It instead supports distinguishing specimen defects and applying examination-specific requirements. Rejection figures therefore require interpretation alongside the laboratory's criteria and detection practices. The most direct service consequence reported in the rejection study was additional time associated with recollection. Cao et al. (2016) documented an average turnaround-time increase of 108 minutes. This finding demonstrates an operational burden but does not establish that every delayed result caused a delayed diagnosis or adverse clinical event. The broader review by Mrazek et al. (2020) described mechanisms through which specimen problems can compromise result interpretation, including contamination and analytical interference. Such mechanisms explain the relevance of specimen assessment to diagnostic reliability. However, rejection rates, identification-error rates, and turnaround time are different outcomes from diagnostic sensitivity, specificity, or documented patient harm. Hill et al. (2010) reported lower processing-error rates following a combined intervention involving electronic ordering, barcode wristband verification, and specimen labeling. Many remaining errors occurred where the electronic system could not be used. Because several components changed together, the findings cannot attribute the entire reduction to barcoding alone.

Morrison et al. (2010) also reported fewer labeling errors after introducing positive patient identification. The intervention removed a manual label-preprinting step, showing that its implementation included workflow changes. Brown et al. (2011) reported a reduction in annual labeling-error counts following barcode identification and bedside printing. These findings consistently favored the interventions, although their before-and-after designs limit causal attribution. Supporting evidence came from Snyder et al. (2012), whose systematic review included 17 observational studies: 10 concerning patient specimens and seven concerning point-of-care testing. All favored barcoding. These studies are reported as the evidence base of that published review and are not counted as 17 additional independent studies in this manuscript. Plebani et al. (2017) described quality indicators spanning the total testing process. Their work provides a framework for monitoring vulnerabilities and evaluating improvement, complementing the error and rejection measures reported in the primary studies. The evidence summarized here is strongest for improvements in identification processes and documentation of specimen-related service disruption. Direct evidence connecting reception-specific interventions with diagnostic accuracy, treatment outcomes, or mortality was not established by these selected studies.

DISCUSSION

The evidence summarized in this review highlights the contribution of clinical laboratories to patient safety throughout the testing pathway. Although analytical quality remains essential, reliable results also depend on appropriate test selection, accurate patient identification, suitable specimens, and effective communication. Mrazek et al. (2020) emphasized these interconnected responsibilities, supporting a broader understanding of laboratory quality that includes collaboration with clinical teams. Within this framework, sample reception provides an opportunity to identify specimen problems before analysis, but its effectiveness depends on the quality of preceding collection and transport processes. The specimen rejection findings illustrate the range of problems that laboratories must detect and manage. Cao et al. (2016) identified contamination, unsuitable containers, insufficient quantity, labeling errors, hemolysis, and clotting among rejection causes. These defects require different preventive responses. For example, identification discrepancies call for stronger patient-verification procedures, whereas container and volume problems require attention to collection requirements. The findings therefore favor targeted improvement based on locally documented causes rather than a single intervention applied to every specimen-quality problem. However, the distribution observed in one clinical chemistry laboratory cannot establish priorities for all laboratory disciplines or healthcare settings. An important consideration is the relationship between rejection and patient safety. Rejecting an unsuitable specimen can prevent the release of unreliable information, but recollection can introduce additional burdens. Cao et al. (2016) documented increased turnaround time following recollection, demonstrating that specimen defects affect service delivery as well as technical quality. These delays may be clinically relevant, although the study did not quantify their effects on diagnostic decisions or patient outcomes. Laboratories should therefore assess rejection alongside the timeliness of notification, recollection, and replacement testing. WHO guidance supports prompt communication and consultation when managing unsuitable or difficult-to-replace specimens (WHO, 2011). Electronic identification systems represent a promising approach to reducing identification-related failures. Hill et al. (2010), Morrison et al. (2010), and Brown et al. (2011) consistently reported fewer errors after implementing electronic verification and labeling safeguards. Nevertheless, these interventions combined technology with workflow changes, making it difficult to isolate the contribution of individual components. Their before-and-after designs also leave uncertainty about concurrent changes in practice. The findings support integrated identification systems while indicating that implementation should include staff preparation, workflow evaluation, and monitoring of situations in which the system cannot be used.

Quality indicators can help laboratories determine whether improvements are sustained. Plebani et al. (2017) described monitoring across the total testing process, supporting evaluation beyond analytical performance. For specimen reception, interpretation requires consistent definitions, suitable denominators, and awareness of detection practices. A falling rejection rate may reflect improved collection, but it may also reflect reduced detection or altered acceptance criteria. Rejection rates should consequently be considered alongside identification discrepancies, recollection, and delays rather than used alone as evidence of safer care. This interpretation follows from the different processes that contribute to the recorded rejection outcome. The available evidence also highlights the importance of shared responsibility. Reception staff can detect many visible or documented discrepancies, but they cannot reliably identify every wrong-patient specimen or reverse damage caused before arrival. Prevention therefore requires cooperation among laboratory professionals, nurses, phlebotomists, transport personnel, and clinicians. The broader literature supports collaboration at these clinical interfaces, while WHO guidance provides procedures for communicating and managing specimen problems (Mrazek et al., 2020; WHO, 2011).

Several limitations constrain this synthesis. It draws on selected sources rather than a completed database search, and much of the intervention evidence is older and observational. Outcomes and denominators differ, preventing meaningful pooling. Moreover, improvements in labeling or processing errors do not independently demonstrate improved diagnostic sensitivity, specificity, or clinical outcomes. Future multicenter research should evaluate reception-specific interventions using comparable measures and connect process improvements with time to actionable results, repeat-collection burden, treatment delays, and documented diagnostic consequences. These outcomes would clarify how laboratory safeguards translate into measurable benefits for patients.

CONCLUSION

Clinical laboratories contribute to patient safety through reliable testing, specimen assessment, and effective communication with clinical teams. Sample reception provides an important checkpoint for identifying labeling discrepancies, unsuitable containers, insufficient

volume, and other specimen defects before analysis. The selected evidence indicates that specimen rejection can delay results and that electronic identification and labeling interventions can reduce identification-related errors. However, these process improvements do not independently establish better diagnostic accuracy or patient outcomes. Laboratories should prioritize standardized reception procedures, test-specific acceptance criteria, staff competency, traceability, and timely communication when specimens are unsuitable. Quality monitoring should consider rejection reasons, recollection, identification errors, and delays together. Because this synthesis draws on selected sources, its conclusions remain preliminary. A comprehensive literature search and multicenter research linking reception practices to diagnostic decisions, treatment delays, and documented patient harm would strengthen the evidence for practice.

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