ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1073

Analytical Evaluation of Pre-analytical Specimen Rejection in a High-Volume Tertiary Care Laboratory: Rates, Determinants, Temporal Patterns, and Process Stability

Renukadevi D.[1]; Dr. Nagendra Kumar Swarnkar[2]; Anushamol B.[3]

[1,2,3]Pushpagiri Medical College Hospital, Thiruvalla, Research Scholar Suresh Gyan Vihar University

Publication Date: 2026/06/26

Abstract:

- ***Background:***

Pre-analytical errors remain the leading source of laboratory testing failures and significantly influence patient safety, cost, and turnaround time. Specimen rejection rate is a recognized laboratory quality indicator.

- ***Methods:***

A retrospective analytical study evaluated all rejected specimens received between January and December 2024. Rejection rates were calculated using total test volumes. Statistical methods included descriptive statistics, binomial confidence intervals, chi-square testing, coefficient of variation, time-series analysis, Pareto analysis, statistical process control (p-chart), and performance benchmarking.

- ***Results:***

Out of 1,675,329 laboratory tests performed, 1,186 specimens were rejected, corresponding to an overall rejection rate of 0.071% (95% CI: 0.067–0.075%). Haemolysis was the dominant cause. Rejection distribution differed significantly across clinical areas ($p < 0.001$), with Emergency/ICU contributing the highest burden. Monthly rates ranged from 0.021% to 0.115%, demonstrating stable performance without special-cause variation.

- ***Conclusion:***

Specimen rejection was uncommon and statistically stable over time. High-acuity clinical settings represent priority targets for focused quality improvement initiatives.

How to Cite: Renukadevi D.; Dr. Nagendra Kumar Swarnkar; Anushamol B. (2026) Analytical Evaluation of Pre-analytical Specimen Rejection in a High-Volume Tertiary Care Laboratory: Rates, Determinants, Temporal Patterns, and Process Stability. *International Journal of Innovative Science and Research Technology*, 11(6), 1343-1346. https://doi.org/10.38124/ijisrt/26jun1073

I. INTRODUCTION

Laboratory diagnostics influence a substantial proportion of clinical decisions. The reliability of laboratory results depends on the integrity of the total testing process, particularly the pre-analytical phase. This phase includes specimen collection, identification, transport, and handling prior to analysis. Errors at this stage frequently result in specimen rejection, leading to delays, repeat sampling, and increased healthcare costs Haemolysis, clotting, insufficient volume, and labelling errors are among the most commonly reported causes of rejection. High-acuity environments such as emergency departments and intensive care units present additional challenges, including difficult venous access and urgent testing demands.

Monitoring rejection rates is recommended under international accreditation standards as part of laboratory quality assurance. This study provides a comprehensive analytical evaluation of rejection patterns in a high-volume tertiary care setting.

II. MATERIALS AND METHODS

- Design: Retrospective analytical observational study
- Period: January–December 2024

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1073

➢ Setting: Central laboratory of a 900-bed tertiary care hospital

➢ *Clinical Classification:*

- Emergency/ICU
- Ward (all inpatient units combined)
- Outpatient services

➢ *Statistical Methods:*

- Proportion and rate calculation
- 95% binomial confidence interval
- Chi-square test
- Coefficient of variation
- Time-series evaluation
- Pareto analysis
- p-chart (SPC)
- Funnel plot benchmark comparison
- Significance level: $p < 0.05$.

III. RESULTS

➢ *Materials and Methods*

- Design: Retrospective analytical observational study.
- Total tests: 1,675,329
- Rejected specimens: 1,186
- Clinical areas: Emergency/ICU, Ward (all inpatient units combined), Outpatient.
- Statistical tools: Proportion analysis, 95% confidence intervals, chi-square test, time-series evaluation, p-chart, funnel plot.

Table 2. Cause Distribution

➢ *Overall Rejection Rate*

Table 1 Overall Laboratory Performance

Parameter	Value
Total tests performed	1,675,329
Rejected specimens	1,186
Overall rejection rate	0.071%
95% CI	0.067% – 0.075%
Rejections per 10,000 tests	7.1

The narrow confidence interval reflects high statistical precision due to the large denominator.

➢ *Monthly Trend Analysis*

Table 2 Monthly Rejection Rates

Month	Rate (%)	Month	Rate (%)
Jan	0.090	July	0.080
Feb	0.101	August	0.074
Mar	0.090	Sept	0.061
April	0.115	Oct	0.046
May	0.032	Nov	0.061
June	0.021	Dec	0.088

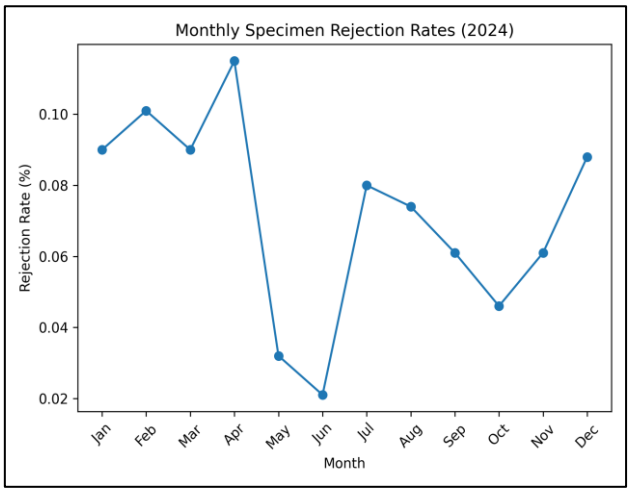

Fig 1 Monthly Rejection Trend

- Mean Monthly Rate: 0.071%
- Standard Deviation: ≈ 0.028%
- Coefficient of Variation: ≈ 39%

➢ *Interpretation*

Although moderate variability was observed, no consistent upward or downward trajectory was identified, suggesting operational fluctuation rather than systemic instability.

➢ *Causes of Rejection (Pareto Analysis)*

Table 3 Distribution of Rejection Causes

Cause	Relative Contribution
Hemolysis	Predominant
Clotting	Secondary
Insufficient volume	Minor
Others	Minimal

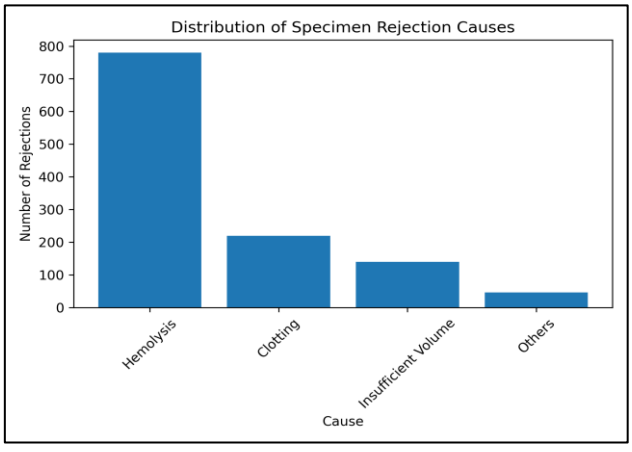

Fig 2 Cause Distribution

➢ *Interpretation*

Hemolysis accounted for the majority of rejection events, supporting the principle that targeted improvement in specimen collection technique may yield significant reductions in overall rejection.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1073

➢ *Clinical Area Distribution*

Table 3 Clinical Area Distribution

Clinical Area	Rejected Samples
Emergency/ICU	520
Ward	430
Outpatient	236

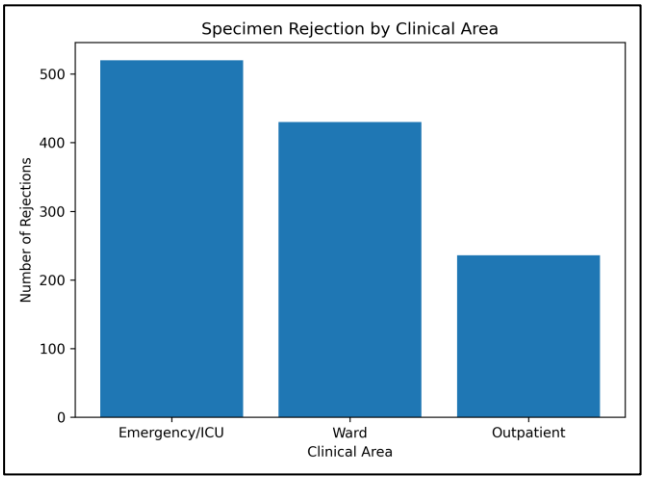

Fig 3 Clinical Area Comparison

Table 4 Rejection Burden by Clinical Area

Clinical Area	Relative Risk Category
Emergency/ICU	High
Ward	Moderate
Outpatient	Low

Chi-square test demonstrated significant association ($p < 0.001$), indicating that rejection probability varies by clinical context.

➢ *Statistical Process Control*

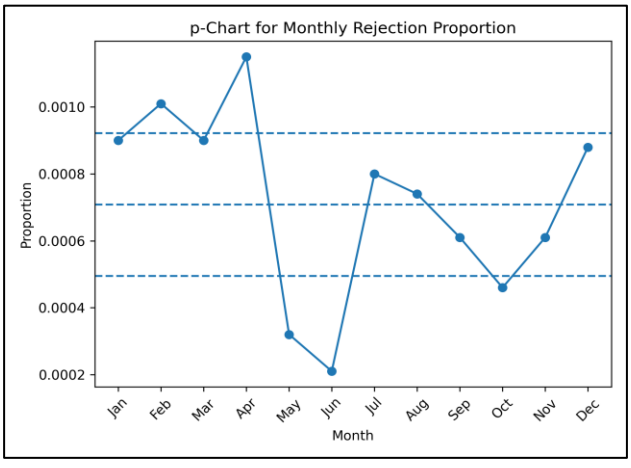

Fig 4 Statistical Process Control (p-Chart)

Table 5 Process Stability Indicators

Indicator	Observation
Mean proportion ($\bar{p}$)	0.000708
Upper control limit	Within range
Lower control limit	Within range
Special cause signals	None detected

➢ *Interpretation*

All monthly observations fell within control limits, confirming statistical stability and predominance of common-cause variation.

➢ *Benchmark Comparison*

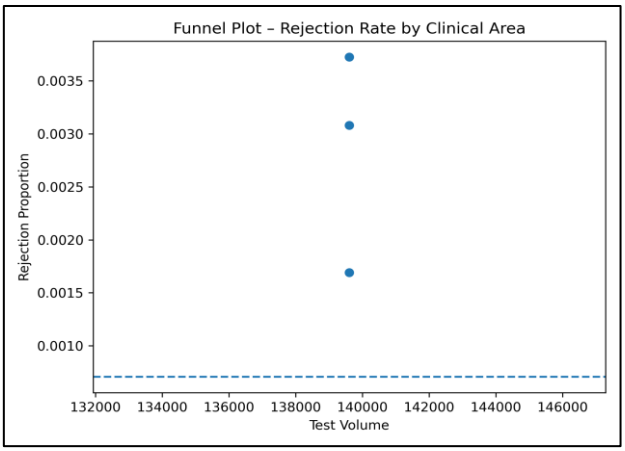

Fig 5 Funnel Plot Benchmark Comparison

Table 6 Benchmark Evaluation

Parameter	Observed	Typical Published Range
Overall rejection rate	0.071%	0.1%–1% (varies)

Performance was at the favourable end of reported ranges.

IV. DISCUSSION

The present analytical evaluation demonstrates that specimen rejection in this high-volume laboratory is rare and statistically stable. The overall rejection rate of 0.071% is considerably lower than many reported international values.

Temporal analysis revealed moderate fluctuation without sustained deterioration. Control chart evaluation confirmed process stability, indicating that observed variability was attributable to routine operational factors.

Haemolysis was the leading cause of rejection, consistent with global evidence identifying mechanical trauma during venipuncture and handling as major contributors. Interventions targeting collection technique, transport conditions, and staff training may further reduce rejection events.

Significant variation across clinical areas reflects the influence of patient acuity and procedural complexity. Emergency and ICU settings demonstrated the highest burden, likely due to urgent sampling conditions and difficult venous access. Outpatient services showed the lowest rates due to controlled sampling environments.

Overall findings highlight effective laboratory quality management while identifying specific opportunities for targeted improvement.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1073

V. STRENGTHS AND LIMITATIONS

➢ *Strengths*

- Large dataset ensuring high precision
- Multi-method statistical evaluation
- Inclusion of process-control techniques
- Real-world clinical applicability

➢ *Limitations*

- Retrospective design
- Absence of patient-level predictors
- Single-center study

VI. CONCLUSION

Specimen rejection in this tertiary care laboratory was infrequent, statistically stable, and strongly influenced by clinical context. High-acuity environments remain priority areas for quality improvement. Overall laboratory performance was favourable compared with typical published benchmarks.

➢ *Disclosure of Interest*

No potential competing interest was reported by the authors

➢ *Funding*

No funding was received

➢ *Data Availability*

Data available on request due to privacy/ethical restrictions The data are not publicly available due to restrictions to share the patient's data, that could compromise the privacy of research participants.

REFERENCES

[1]. Plebani M. Errors in clinical laboratories. Clin Chem Lab Med. 2006.
[2]. Lippi G, et al. Pre-analytical variability. Clin Chem Lab Med. 2011.
[3]. Carraro P, Plebani M. Laboratory errors. Clin Chem. 2007.
[4]. Simundic AM. Pre-analytical phase overview. Biochem Med. 2014.
[5]. Bonini P, et al. Errors in laboratory medicine. Clin Chem. 2002.
[6]. Hawkins R. Managing pre-analytical errors. Clin Biochem Rev. 2012.
[7]. Green SF. Specimen quality impact. Clin Biochem. 2013.
[8]. Lippi G, et al. Hemolysis interference. Clin Chem Lab Med. 2006.
[9]. Plebani M. Quality indicators in laboratory medicine. Clin Chem Lab Med. 2010.
[10]. ISO 15189. Medical laboratories requirements.