SYNOPSIS FOR DISSERTATION REPORT

TITLE:
Assessing the major pre-analytical rejection reasons of samples coming in laboratory at Medanta - The Medicity Hospital, Gurugram, India.

INTRODUCTION:
At Medanta the Medicity, a quaternary care hospital in Gurugram, thousands of diagnostic samples are processed daily. Its Laboratory caters a large volume of tests as well as people due to which sample rejections are also significant. Major reasons such as blood haemolysis, insufficient sample, blood clotting, or contamination contribute to these rejections. These not only delay clinical care but also increase the workload, cost, and potential for medical errors. This study aims to review the main reasons of sample rejection over the past one year, and to propose improvements that align with the operational environment of a high-volume hospital like Medanta.

LITERATURE REVIEW:

Year	Article Name	Author(s)	Sample Size	Study Location	Key Findings / Solutions
2012	Preanalytical Errors in Clinical Laboratory Testing at a Glance.	J.A. Hammerling	Review article	USA	Discusses common pre-analytical errors and stresses education, SOPs, and automation to reduce errors. [1]
2011	Preanalytical Quality Improvement: From Dream to Reality	Lippi G. et al.	Review article	Global	Emphasizes standardization, staff training, adoption of checklists, and system-level interventions to improve lab accuracy. [2]
2012	Reducing Preanalytical Sample Errors through Educational & Technological interventions.	Lippi G. et al.	Not specified	Italy	Shows significant reduction in errors through combined staff education and barcode-based technology use. The study highlights that effective error reduction requires both well-informed personnel and supportive

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					technological infrastructure. [3]
2009	The Detection and Prevention of Errors in Laboratory Medicine	Plebani M.	Review article	Italy	Explores the full lab error spectrum, giving particular attention to the vulnerabilities of the pre-analytical phase and recommends a quality culture across lab phases encouraging proactive error reporting and root cause analysis [4]
2023	Frequency & Types of Pre- analytical Errors in a clinical Laboratory of a Specialized Healthcare Hospital	Ali A. et al.	254,267 samples	Pakistan	Haemolysis and clotting were key causes of pre-analytic rejections; recommends continuous monitoring and retraining. [5]
2019	An Audit of Preanalytical Errors as a Quality measure in central Clinical Laboratory of a Rural Tertiary care Hospital in Eastern Uttar Pradesh	Dhananjay K. et al.	Not specified	India	Most common errors were underfilled and clotted samples; suggests the necessity of routine error audits & regular training to ensure adherence to proper blood collection protocols. [6]
2020	Challenges in pre-analytical phase of laboratory medicine: Rate of Blood Sample Nonconformity in a Tertiary Care Hospital.	Alavi N. et al.	113,817 samples	India	Highlights labelling, clotted, and haemolysed samples as significant causes of sample rejection; implemented continuous audit and staff sensitization. These efforts aimed to increase awareness of proper sample handling practices

Year	Article Name	Author(s)	Sample Size	Study Location	Key Findings / Solutions
					and reduce the recurrence of preventable errors. [7]
2020	A study on identifying the pre-analytical phase errors leading to biochemistry and haematology sample rejection by using FMEA & Pareto's Principle	Singh P. et al.	Not specified	India	Applied FMEA & Pareto charts to prioritize and identify errors; found labelling and collection issues were top concerns. [8]
2023	Study of Pre-Analytical Errors in Clinical biochemistry laboratory in – Dhiraj General Hospital, Piparia.	Patel C. et al.	15,189 samples	India	Found 3.75% error rate, mostly haemolysis; emphasized hands-on training and monitoring. Additionally, they highlighted the importance of establishing a real-time internal monitoring system to promptly detect and address errors as they occur. [9]
2024	Evaluation of issues pertaining to the pre-analytical phase within the Biochemistry laboratory of the National Hospital of Sri Lanka: A case study.	Chathurika HLS, Nanayakkara R, Priyanka HL.	Not specified	National Hospital of Sri Lanka (NHSL), Colombo	The study identified sample collection and transportation errors as key issues in the pre-analytical phase. Using a nominal group technique, researchers prioritized these problems, and a problem tree analysis helped trace root causes. The proposed solutions included staff training, improved transportation systems, and standardized procedures to enhance

Year	Article Name	Author(s)	Sample Size	Study Location	Key Findings / Solutions
					efficiency and diagnostic accuracy. [10]

RESEARCH QUESTION:

What are the predominant pre-analytical reasons for sample rejection coming in laboratory at Medanta the Medicity Hospital over the last one year (from April 2024 to March 2025), and how can these be minimised?

OBJECTIVES:

- To identify and categorize the major pre-analytical reasons of sample rejection coming in laboratory from hospital over the last year.
- To examine monthly trends in rejection data over the past one year.
- To analyse the number of sample rejection across different departments of laboratory.
- To compare rejection reasons across patient categories—In-Patient Department (IPD) and Out-Patient Department (OPD).

MATERIAL AND METHODS:
Study Design: Retrospective Observational study.
Setting: Medanta the Medicity hospital, Gurugram, India.

Study Population: All patient samples received from different departments submitted to the central laboratory from April 2024 to March 2025.

- **Inclusion Criteria:** All rejected blood, urine, and other body fluid samples submitted to lab from 1st April 2024 to 31st March 2025.
- **Exclusion Criteria:** The samples rejected due to analytical and post-analytical factors and Samples with incomplete rejection documentation in LMIS.

Study Tools: Rejection logs from Laboratory Management Information System (LMIS).

Duration of Study: 3 months (from 17th March 2025 – 17th June 2025)

SAMPLE SIZE:
Estimated 2.24M total samples over the year, with expected rejection rate of approximately 0.23%.

Sampling Technique:
Total enumeration of every rejected sample meeting inclusion criterion.

Data Collection Procedure:

Rejection logs from LMIS will be extracted. Each rejected sample will be analysed based on the type of rejection reasons that are predominant and which department is receiving and sending more rejected samples, reason for rejection, and their month wise trend.

Operational Definitions:

- ***Pre-analytical error*:** An error occurring from sample collection to delivery in the lab, before testing begins.
- **Sample rejection:** Refusal of laboratory to accept a clinical sample due to improper collection, labelling, preservation, or transport.

DATA ANALYSIS PLAN:

Data will be compiled and analysed using Microsoft Excel.

ETHICAL CONSIDERATIONS:

All data will be anonymized and obtained from existing hospital records with administrative approval. Patient confidentiality will be maintained strictly.

IMPLICATIONS OF RESEARCH:

This study will help identify key operational and training gaps in sample handling. The interventional or improvement strategies can increase lab efficiency, cost effectiveness, turnaround time, and ultimately patient outcomes, especially in critical care settings. The findings may also be used for policy revisions, SOP improvements, and periodic training programs for nursing and phlebotomy staff.

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