# A Study in Pre-Analytics in A Laboratory Diagnostics Setup: Enhancing Quality and Efficiency

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# Introduction

- Laboratory Diagnostic Setup.
- For laymen, it generally means to get tests done or the reports.
- But that is either the first or the last point of a laboratory process.
- A laboratory process starts with the patient and ends with the patient.
- This entire process is called the Total Testing Process.

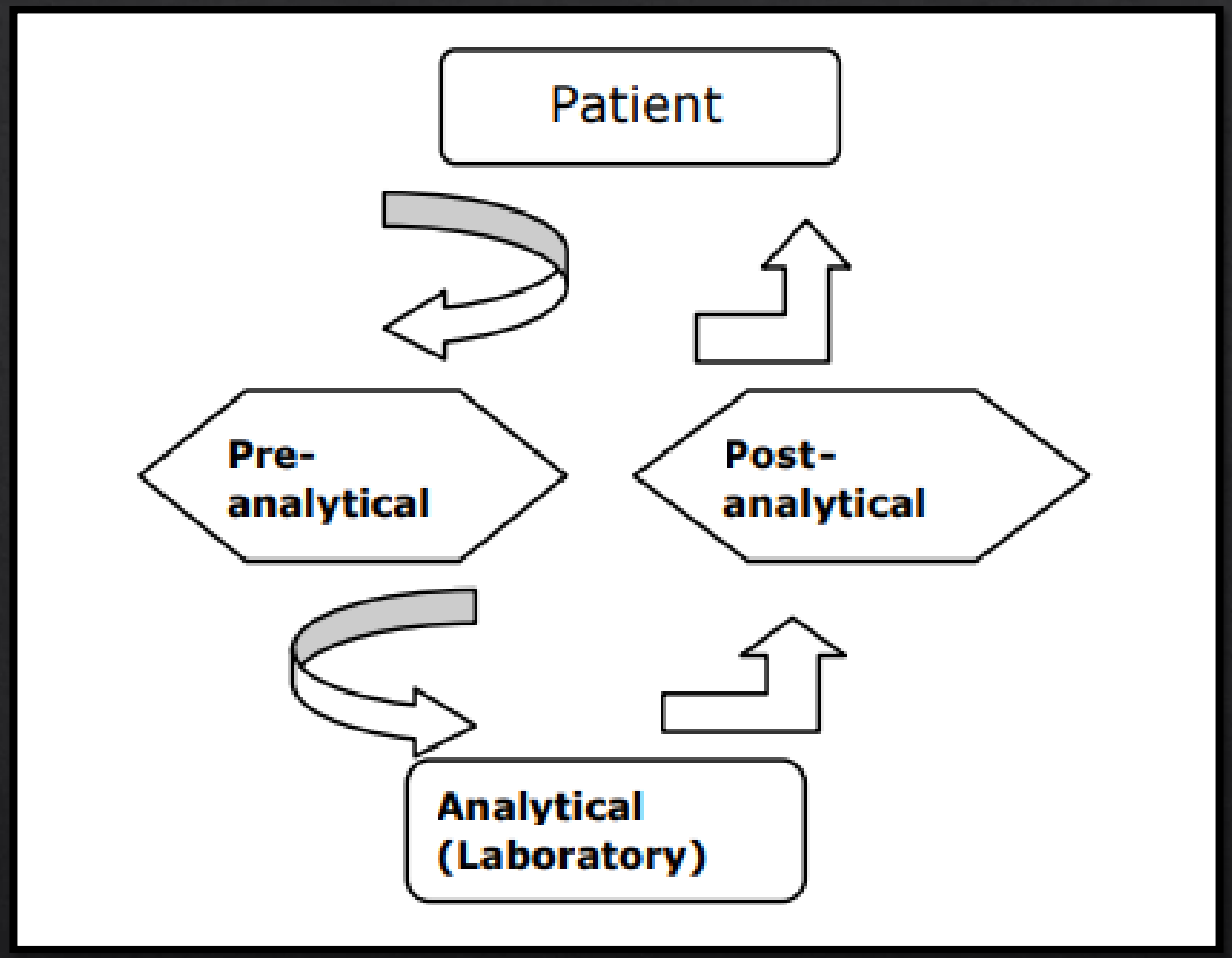



Fig: Total Testing Process

An overview:

- Pre-analytical processes: Activities occurring before the analysis of a sample, including sample collection, handling, transportation, and preparation.
- Analytical processes: The actual analysis of the sample using various techniques and instruments to obtain quantitative or qualitative information.
- Post-analytical processes: Activities after the analysis, involving data management, result interpretation, reporting, and quality control.

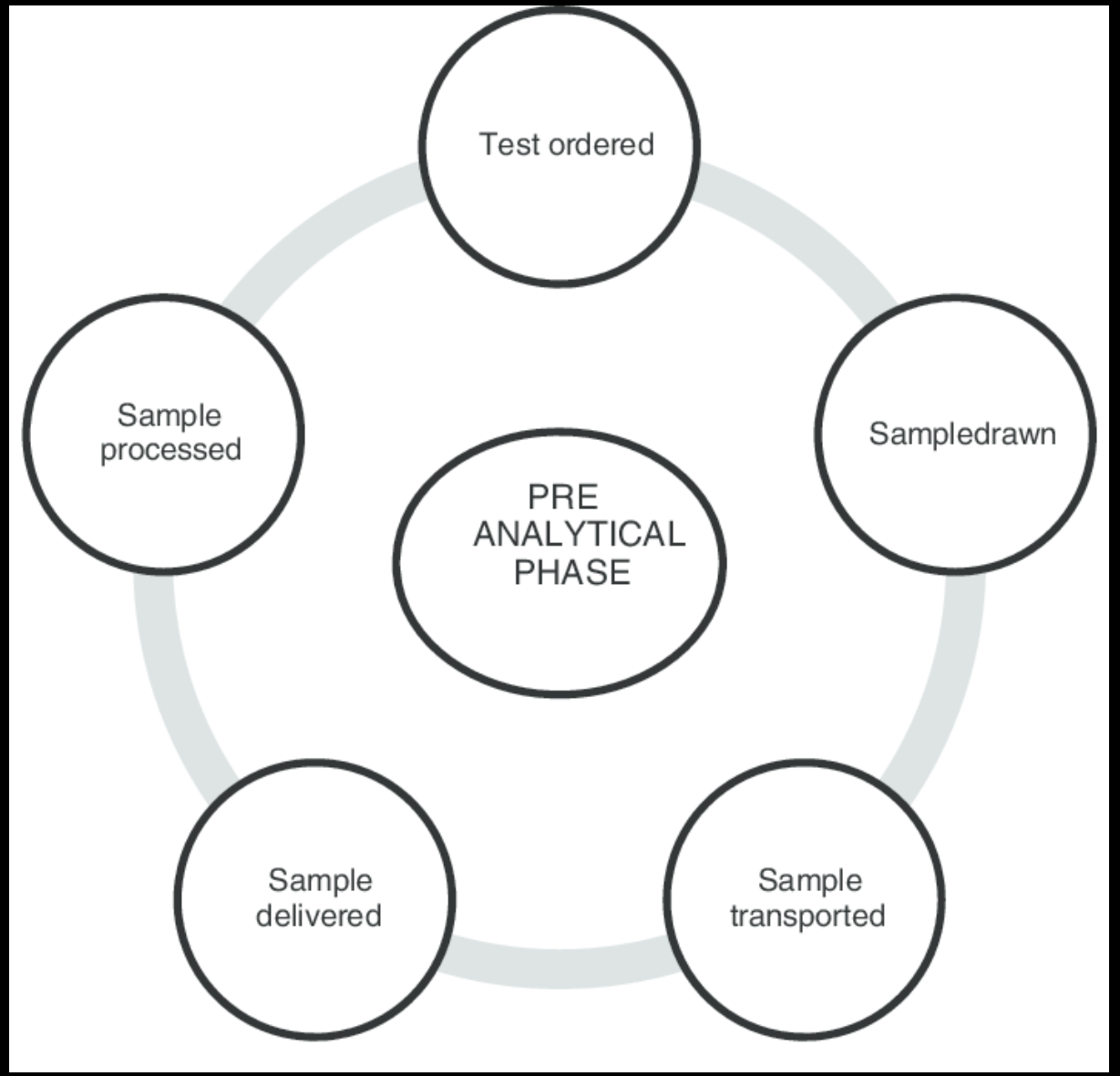



Fig: Pre-Analytical Phase

# Objectives

The objective of the given pre-analytics study is

1. To present a comprehensive review of current standards and procedures of a diagnostic laboratory setup.

2. Identifying the gaps in the pre-analytics aspect in a new diagnostic setup.

3. Review risk mitigation procedures for pre-analytics.

# Summary of Literature Review

- The pre-analytical phase is responsible for around 60-70% of laboratory errors, making it the most error-prone phase.
- Investing in pre-analytics can have positive impacts on public health challenges and advancements in tumour processing.
- Quality indicators should encompass all aspects of the pre-analytical phase, including test requesting and sample storage.
- Up to 61% of laboratory problems are associated with the pre-analytical phase, with errors in test request forms, sample collection, and sample processing.

- Quality control measures should be implemented throughout the diagnostic process to ensure high-quality services and protect patient interests.
- Integration between automation and information management is crucial for improving control and coordination in laboratory operations.
- Regular appraisals, audits, and a comprehensive approach to quality assurance are necessary for delivering high-quality services.

# Methodology

- The study employed a combination of descriptive analysis, retrospective study, and observational study.
- Data was extracted from the internal system of the laboratories, specifically the Laboratory Information Management System (LIMS).
- The aim was to comprehensively examine and analyse various aspects related to the research topic.
- The LIMS system provided quantitative data on elements such as accessioning delays, test turnaround time (TAT), and sample requirements.
- The gathered data was stored in a secure database and analyzed using Excel.

- The LIMS system was regularly cross-checked with physical registers to ensure proper functioning and confidentiality was maintained to protect patient data.
- A mixed method approach was used to collate important facts and data points for a comprehensive review.
- The combination of descriptive analysis, observational study, and LIMS study helped provide a comprehensive understanding of the research topic.
- Extensive literature review was conducted to identify key factors and precisely define variables related to pre-analytics.

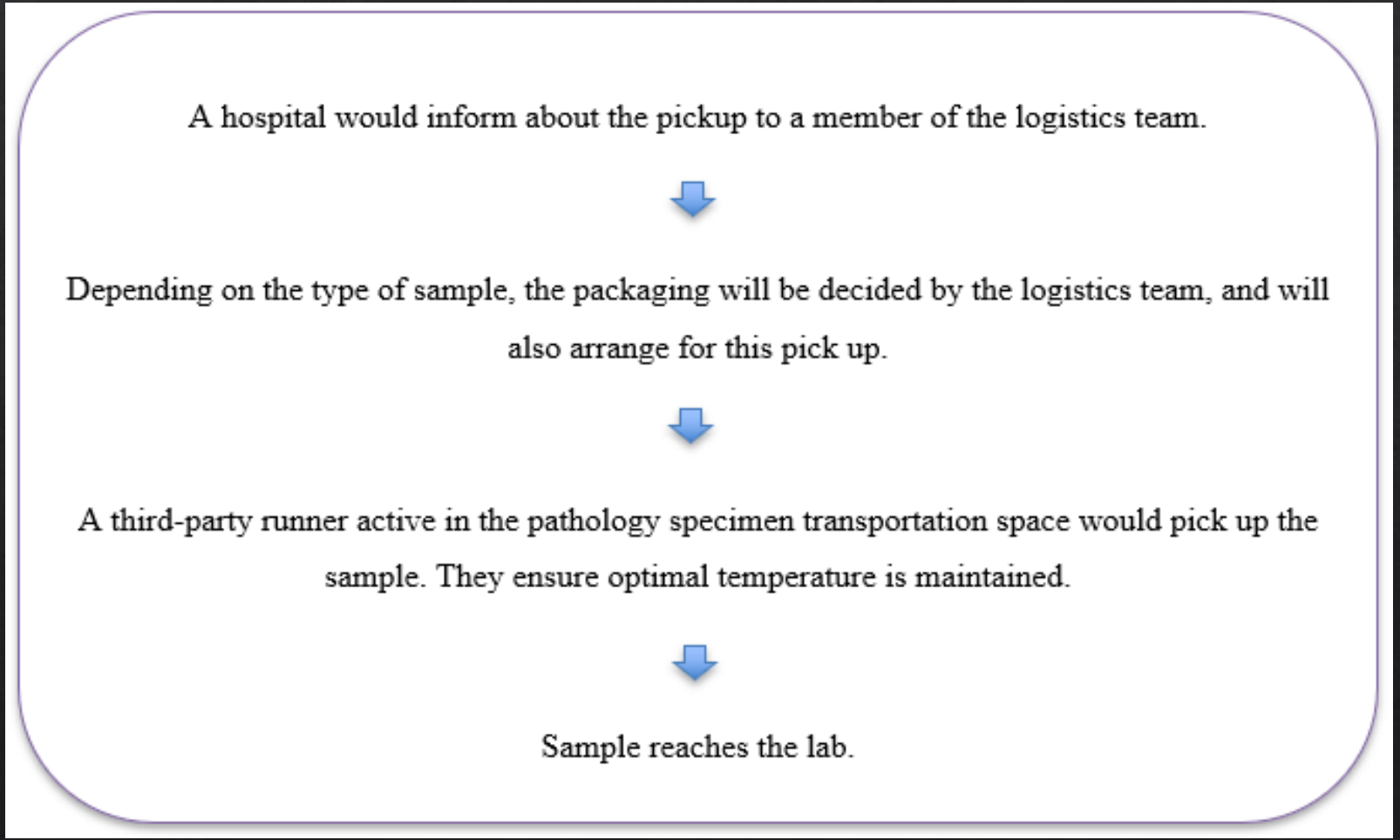
# Results

- The review identified significant issues in process flows and personnel training within the laboratory setup.
- Problems were found in the management of samples, including lack of standardization in collection, handling, and transportation methods across different labs.
- Insufficient training and knowledge among lab personnel contributed to difficulties in maintaining sample quality and condition.
- The study revealed issues in the coordination and task assignment among lab staff during the pre-analytical phase, leading to confusion and inefficiency.
- Better communication and teamwork between lab workers and healthcare professionals involved in sample collection were emphasized to minimize delays, misunderstandings, and errors in sample identification and documentation.

- These are the few gaps that were detected during the corresponding study. However, these few gaps created the most part of the reason for the pre-analytic errors. That said, some solutions that could be implemented are:
- Firstly, the development and implementation of standardized protocols for sample collection, handling, and transportation are crucial to maintain sample integrity and consistency across laboratory units.
- Training programs should be established to educate laboratory personnel on these standardized procedures and emphasize the importance of proper sample handling techniques.

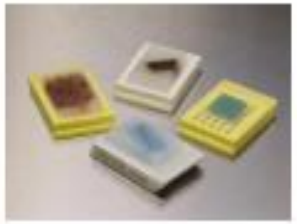
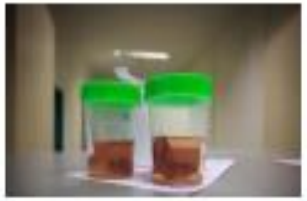
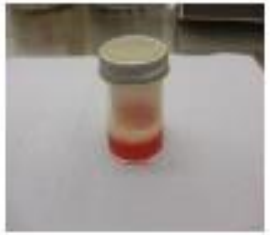
The following process flow was established:

1. Sample Collection
2. Sample Transportation

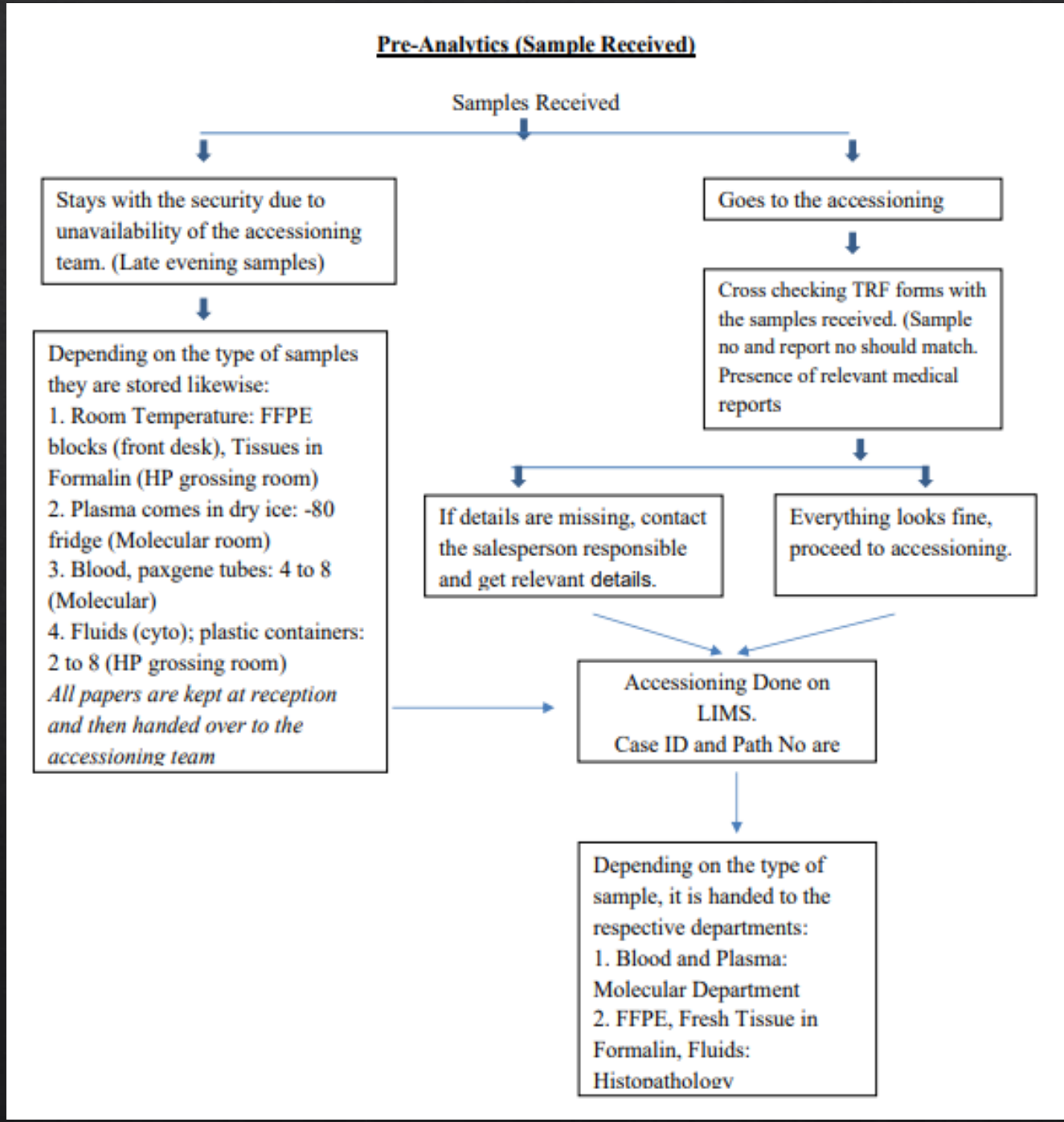



Sample Transportation Process

# 3. Sample Storage

| Sr no | Type of Sample | Temperature of Storage | Location | Reference Image |
|---|---|---|---|---|
| 1 | FFPE blocks, Slides | Room Temperature | Front desk |  |
| 2 | Tissues in Formalin | Room Temperature | HP grossing room |  |
| 3 | Separated Plasma (comes in dry ice) | -80 Fridge | Molecular |  |
| 4 | Blood (PaxGene tubes, comes with a light blue cap) | 4 to 8 degrees | Molecular |  |
| 5 | Fluids (usually comes in plastic containers) | 4 to 8 degrees | HP grossing room |  |

# 4. Sample Processing



# Errors in Pre-Analytics

- The observation was carried out for the month of April.
- Total 269 samples were received in the two departments of the organization of Molecular and Histopathology.
- Out of these 84 samples were cancelled due to the pre-analytic errors.

| | Specimen Type | | | |
|---|---|---|---|---|
| **Lab Department** | Block | Blood | Tissue | Grand Total |
| **Histopathology** | 22 | | 22 | 44 |
| **Molecular** | 12 | 28 | | 40 |
| **Grand Total** | 34 | 28 | 22 | 84 |

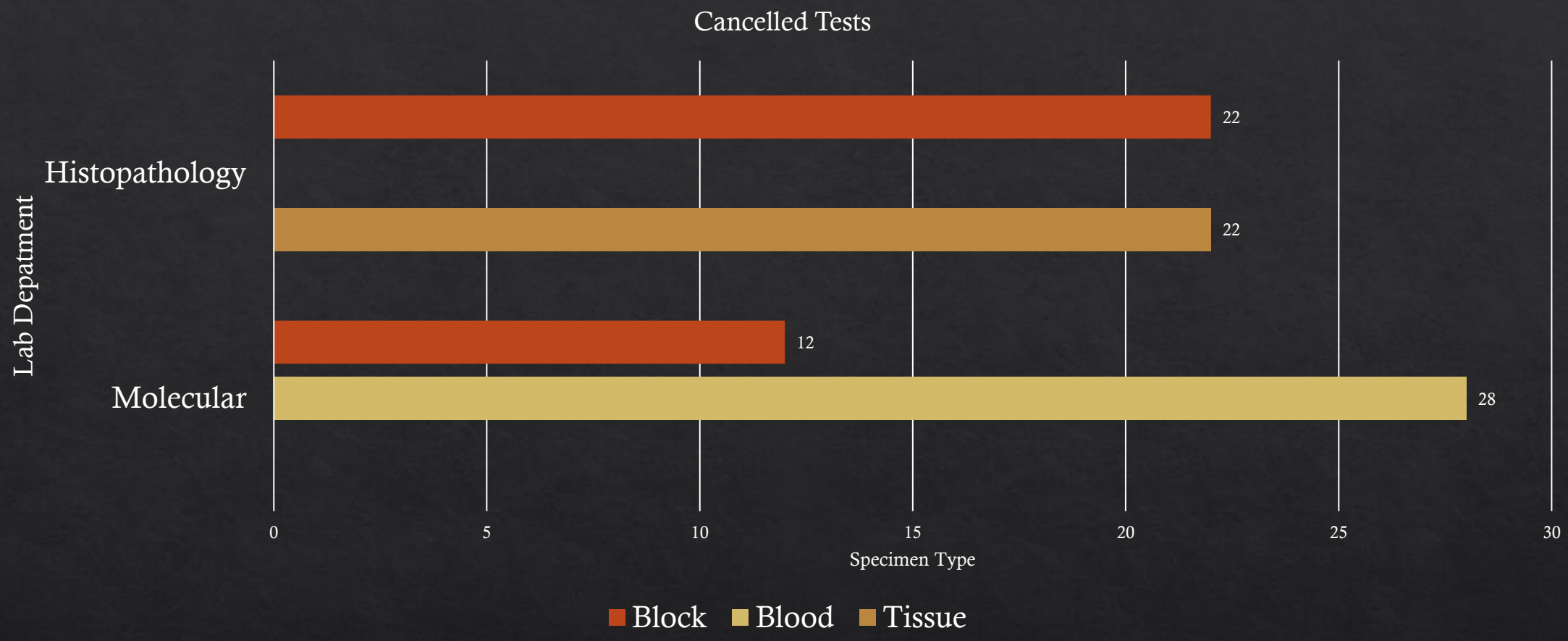



Fig: Department wise Cancelled Tests

# Reasons for Sample Rejection

| Reason Rejected | Quantity |
|---|---|
| **Unlabeled samples:** | 32 |
| **Inadequate volume (blood)** | 18 |
| **Inadequate content (FFPE)** | 13 |
| **Inappropriate samples** | 4 |
| **Discrepancy in TRF** | 15 |
| **Other** | 1 |

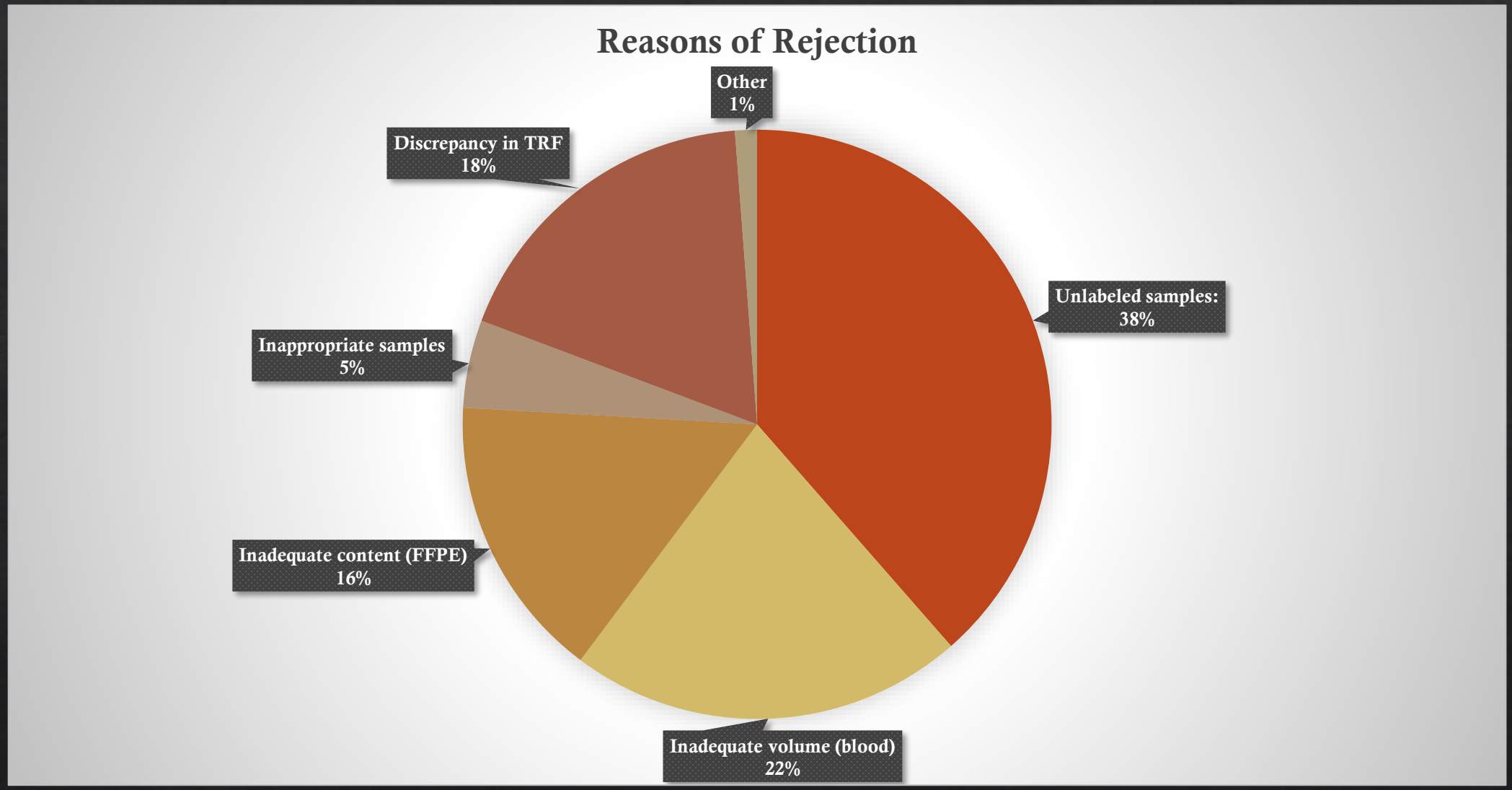



Figure : Reason of Rejection of Samples

Regarding this the following draft for Standard Operating Procedure for Sample Acceptance and Rejection was created:

***Purpose*:** This is about making sure that patient samples are received and processed correctly.
***Objective*:** This procedure explains the rules for deciding whether to accept or reject a sample.
***Responsibilities*:** The Quality Manager oversees creating policies for sample rejection and acceptance criteria. These policies need to be approved by the Laboratory Director. The laboratory staff is responsible for following the policies for sample rejection and acceptance.

***Specimens:***

- Histopathology Specimens (FFPE blocks, Slides, Tissues in Formalin)
- Molecular Specimens (Blood in PaxGene Tubes, Plasma, FFPE)

***Material:***

- Hand Glove
- Mask
- Lab Coat
-Closed shoes/Shoe covers

***Operating mode:***

Initial tasks when a patient sample is received:

1. Record the date and time when the sample arrived.
2. Check that the patient's identification on the TRF matches the identification on the sample.
3. Review the test request to make sure the type of sample collected is suitable for the test.
4. Enter a record of the received sample in the LIMS system in the accession room.
5. The Blood specimen in Paxgene (light blue colored cap), EDTA (Purple colored cap) should be received with Gel Packs maintaining a temperature of less than >4 degrees Celsius.

-Plasma should be received in dry ice.

-FFPE blocks (should be embedded properly in the paraffin wax), slides & Tissues in Formalin should be received at room temperature packed in proper containers.

-All the samples received should be labelled the same as the number on the histopathology reports.

- Note: The sample accessioning team should receive the samples. Samples should not be opened at the front desk.

- ***Information required on the test request form (TRF):***

- The test request form should include the following information:
  Complete patient identification (full name, age, gender, contact information)
  Clear description of the type of sample.
  Date and, if applicable, time of collection of samples.
  Tests requested.
  Diagnosis or description of the clinical investigation.
  Name and contact information of the requesting doctor & hospital.

- ***Criteria for rejecting a sample/putting a sample on hold due to Non-Compliance to the following criteria:***

- 1. Samples without labels or with incorrect labels.

- 2. Leaky containers: If the outside of the container is contaminated with the sample or the container is leaking, a new sample should be requested.

- 3. Inappropriate sample sources: Samples that don't match the required type for the test are unacceptable. For example, getting a sample for a test which we do not perform, or receiving a different sample than what is mentioned in reports.

4. Delayed transport time and sample processing: Ideally, blood samples should be less than 2 days old when received in a PaxGene tube(light blue cap) & should be less than 3 hours old when received in EDTA tube (purple colored cap). If the time between sample collection and receiving is too long for a valid test to be performed, a new sample should be requested. If a sample is received after a long delay but is not rejected, it should be documented along with the time elapsed since collection.

5. Incorrect papers along with the sample. Mismatch between the sample and the TRF.

- Actions to take when samples are rejected:
- If the unacceptable sample can be replaced, inform the requesting hospital/doctor, document the reason for rejection, and request another sample.
- Do not discard the sample until the patient's doctor confirms that another sample can be collected. If the patient has already started chemotherapy or if a repeat sample cannot be collected, this must be documented.
- If a repeat sample is not available, document the issue and proceed with the test if possible.
- If a sample is accessioned, but is rejected after investigating the tumor content, contact with the doctor/hospital is required for re-sampling.

# Discussion

- Standardization of pre-analytics procedures is crucial for consistent practices, reduced error rates, and reliable results.
- Adequate education and training programs are necessary for laboratory staff to perform pre-analytics effectively.
- Implementing strong quality control procedures is essential for accurate and trustworthy findings.
- Technological advancements, such as robotics and automation, can simplify pre-analytical procedures and improve accuracy.
- Resource constraints pose challenges for implementing best practices, necessitating sufficient funding for laboratory infrastructure and training.

- Collaboration and knowledge sharing among laboratories can enhance pre-analytics practices.
- Pre-analytics directly impact patient safety and result accuracy, emphasizing the need for improvement.
- Regulatory oversight is important in ensuring adherence to pre-analytical standards and promoting quality assurance.
- The study provides valuable insights for enhancing pre-analytics practices, focusing on standardization, training, quality control, technological advancements, resource allocation, collaboration, and regulatory oversight.

# Conclusion

- Standardizing pre-analytics procedures promotes reliability and consistency.
- Training and education are necessary to address issues in pre-analytics and improve practices.
- Technological advancements, such as automation and robotics, can enhance pre-analytics.
- Resource limitations pose challenges for implementing best practices in pre-analytics.
- Collaboration and knowledge sharing among laboratories can improve pre-analytics practices.
- Pre-analytics directly impact patient safety and test result accuracy.

- Regulatory oversight is essential for upholding and advancing pre-analytics norms.
- Prioritizing standardization, training, quality control, technological improvements, resource allocation, collaboration, and regulatory monitoring will enhance pre-analytics.
- Collaboration among laboratories, healthcare institutions, and policymakers is crucial for improving pre-analytics procedures and ensuring high-quality testing.

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