1. PURPOSE

1.1. To ensure sample integrity check is conducted on all samples to determine the acceptance / rejection for further sample analysis

2. SCOPE

2.1. This procedure is applicable to the sample processing facility in the laboratory

3. REFERENCES

3.1. Quality Manual
3.2. Sample Collection Manual
3.3. ISO 15189:2012 Standard
3.4. NABL 112

4. RESPONSIBILITY

4.1. Quality Manager
4.2. Sample Collection Facility - Staff
4.3. Laboratory Director

5. PROCEDURE

5.1. Sample reception and processing area is one of the most important elements of the analytical process
5.2. The integrity check of samples is conducted at the Sample reception and processing area of the laboratory
5.3. Samples collected at the sample collection area are processed as per instructions in the sample collection manual and transported under proper cold chain conditions (2-8 Deg C) to the sample reception and processing area
5.4. The technician trained in checking for sample integrity conducts integrity check of the sample received at the sample reception and processing area
5.5. The acceptance / rejection criteria are used to assess the integrity of the collected samples for further processing
5.6. Whenever samples are stored for re- testing in the laboratory. Sample Integrity check is repeated by the technician handling the processing area
5.7. Only after successful completion of sample integrity check the sample is introduced for further processing
5.8. If the stored sample is does not pass the integrity check the said sample is processed for discard and a new sample is request is made to the patient for retesting of the sample
5.9. The following criteria are used to assess the integrity of samples
  5.9.1. Sample identity details on the request form
  5.9.2. Sample collection procedure
  5.9.3. Sample Labelling
  5.9.4. Sample Containers
  5.9.5. Sample Volume
  5.9.6. Appropriate Transport / Storage Conditions
  5.9.7. Hemolyzed/Clotted/Lipemic/Contaminated samples
  5.9.8. Delayed Sample Transport

5.9.9. Package conditions

5.10. Tested Sample Storage, Integrity check and Disposal process

5.10.1. The tested sample retention period (from the time of release of test results) in the laboratory is given in the Table below

S. No	Department	Sample Retention Period	Storage Temperature	Storage Location
1	Clinical Biochemistry	24 hours	2-8 Deg	2-8 Deg Refrigerator

5.10.2. All the samples are retained and stored in the Refrigerator and the samples are discarded after 48 Hours from release of test results and the details are recorded in the Tested Sample Discard Record

5.10.3. Integrity studies for different parameters are carried out on the retained samples for a specific retention period as mentioned in the table above. This is done by analyzing and comparing the values obtained on the specimens tested on receipt at the laboratory and at the end of the storage period (48 Hours)

5.10.4. All other biohazardous and non-biohazardous materials are segregated and disposed in the respective color-coded bags as per 'Treatment of Bio Medical waste' procedure

5.11. The following are the actions to be taken when a sample fails the integrity check in the laboratory

5.11.1. Inform the concerned Authority/Doctor/Patient concerned

5.11.2. Request for another sample to be collected

5.11.3. Record the rejected specimen in the sample rejection form and register

5.11.4. Retain the rejected specimen till discard instructions from concerned lab authority are provided

5.11.5. Once a sample is marked as a rejected sample it is planned for discard as per approvals. Document the rejection and discard details in the rejection & discard registers

6. RECORDS

6.1. The following records are maintained in the sample collection area in the format mentioned below, for the period defined

S. No	Record	Responsibility	Review after
1	Sample Collection Records	In-Charge	1 Year
2	Test Requisition Records	In-Charge	1 Year

S. No	Record	Responsibility	Review after
3	Sample Storage – Temperature Monitoring Record	In-Charge	1 Year
4	Sample Transport – Temperature Monitoring Record	In-Charge	1 Year
5	Sample Repeat / Retesting Records	In-Charge	1 Year
6	Sample Rejection Register	In-Charge	1 Year
7	Tested Sample Discard Register	In-Charge	1 Year