

1. PURPOSE

1.1. The laboratory has established processes to monitor the Quality Indicators on a Monthly basis

2. SCOPE

2.1. The implementation of this procedure applies to the entire lab personnel

3. RESPONSIBILITIES

3.1. Laboratory Director

3.2. Laboratory Quality Manager

3.3. Technical staff

4. DEFINITIONS AND ABBREVIATIONS

4.1. SOP - Standard Operating Procedure

5. REFERENCES

5.1. NABL 112 Document

5.2. Quality Manual

6. CALCULATION OF QUALITY INDICATORS

S. No	Quality Metric	Numerator	Denominator	Multiplier	Benchmark Value
1	% reports with TAT Delay in a month	Total reports with TAT delay in a month	Total reports generated in a month	100	Less than 2%
2	% Equipment Breakdown Time in a month	Total Equipment Breakdown Time	Total number of working hours	100	Less than 5%
3	% Needle Stick Injuries in a month	Number of Needle stick injuries	Number of Samples Collected	100	0%
4	% Samples with wrong labelling in a month	No of samples that were wrongly labelled	Total number of samples collected in a month	100	Less than 1 %
5	% Samples Transported in Wrong Temperature in a month	No of samples transported in wrong temperature	Total number of samples collected in a month	100	Less than 2 %
6	% Samples collected in wrong sample container in a month	No of samples collected in wrong container	Total number of samples collected in a month	100	Less than 1 %

Issue No: 1	Issue Date: 1.1.2024	Amend No: 00	Amend Date:	Copy No: 01
Prepared/Issued by:	Quality Manager	Approved by	Laboratory Director	

S. No	Quality Metric	Numerator	Denominator	Multiplier	Benchmark Value
7	% of Unacceptable EQAS performance in a month	No of parameters failed in EQAS	Total number of EQAS parameters	100	Less than 10 %
8	% Samples collected with wrong volume in a month	No of samples with wrong volume	Total number of samples collected in a month	100	Less than 2 %
9	% Wrong Reports generated due to Data Entry Errors in a month	No of Data entry errors	Total number of reports generated	100	Less than 1 %
10	% Wrong Reports generated due to LIS failure in a month	No of Data entry errors due to IT failure	Total number of reports generated	100	Less than 1 %
11	% of Reports release with Wrong Reports in a month	No of wrong reports released	Total number of reports dispatched	100	0%
12	% of Critical reports informed in time	No of critical reports reported in time	Total number of critical values reported	100	100%

7. RECORDS

The following records are maintained by the laboratory, in the format mentioned, for the retention period as defined below:

S. No	Record	Responsibility	Review after	Retention Period
1	Quality Indicator Records	Quality Manager	Every Month	1 Year
2	Quality Indicator Analysis Sheet	Quality Manager	Every Month	1 Year
3	RCA & CAPA Records	Quality Manager	Every Month	1 Year

Issue No: 1	Issue Date: 1.1.2024	Amend No: 00	Amend Date:	Copy No: 01
Prepared/Issued by:	Quality Manager	Approved by	Laboratory Director	