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1. PURPOSE

- 1.1. To describe procedure for LIS Contingency when there is a breakdown of LIS systems

2. SCOPE

- 2.1. This procedure is applicable to all the staff members and work areas where the LIS process is used in the laboratory

3. REFERENCES

- 3.1. Relevant Process Manuals

4. RESPONSIBILITY

- 4.1. Quality Manager
4.2. Laboratory Director
4.3. IT In-Charge

5. CONTINGENCY PROCEDURE

5.1 Data backup process

Type of backup	Description	Frequency
Full backup	Complete Data backup check	Every 10 days
Differential backup	Between the intervals of complete backup	Every 5 days
Incremental backup	After every data change	Every day
Mirror backup	A parallel data structure	Every day


5.2 Backup IT systems

System/Component	Backup - Description	Responsibility
System Based Reporting	Manual Reporting	Lab Incharge
Computer Hardware	Manual Reporting	Lab Incharge
Broadband connection	Mobile Internet Connectivity	Lab Incharge

5.3 Contingency Planning Responsibility

- 5.4.1 Laboratory Director is designated as the Contingency Planning Incharge for the laboratory
5.4.2 The contingency planning Incharge makes the decision to unfold the contingency plan process
5.4.3 Provides the initial notification to activate the contingency plan

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- 5.4.4 Review and approves the contingency plan
- 5.4.5 Advises other contingency plan team members as appropriate
- 5.5.5 Issues a recovery declaration statement after the system has returned to normal operations

5.4 Contingency Planning – Coordinator

- 5.5.1 Quality Manager develops and documents the contingency plan as per instruction of the Contingency Planning Director
- 5.5.2 Ensure annual contingency planning training is conducted to the laboratory staff
- 5.5.4 Manages and monitors the overall recovery process
- 5.5.4 Leads the contingency response efforts once the plan has been activated

6. RECORDS

- 6.1. The following records are maintained for refrigerator in the format mentioned below, for the period defined

S. No	Record	Responsibility	Retention Period
1	IT breakdown register	IT Incharge	1 Year
2	LIS Breakdown register	IT Incharge	1 Year
3	LIS - Incident report	IT Incharge	1 Year
4	CAPA records	IT Incharge	1 Year
5	LIS verification record	Quality Manager	1 Year

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