1. **PURPOSE**

1.1. To describe procedure for LIS Validation & Verification in the Laboratory

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 In-Charge
4.3. IT Support In-Charge

5. **PROCEDURE**

5.1. Validation Frequency

5.1.1. At the time of Initial Installation / any major software changes / updates
5.1.3. After any changes by the User, Vendor or Laboratory
5.1.4. After any data file restoration

Verification Frequency

5.1. Every 6 months
5.1.3. After any changes by the User, Vendor or Laboratory
5.1.4. After any data file restoration/ software changes / updates

6. **VERIFICATION PROCESS**

6. 1 All functions of Laboratory Information Systems from accession to reporting are verified after installation

6.2 The verification process involves:

6.2.1. Input patient data and save demographics and clinical information
6.2.2. retrieve the same data
6.2.3. capture screen print
6.2.4. compare with data on paper form or in a paperless system
6.2.5. sign and file with date

6.3. Verification is conducted every 6 months review during which the above process is repeated for a minimum of 10 different types of samples / tests

6.4. The Interface between hardware (analyzer) and LIS is verified to ensure that the interface transmits data in the intended manner and that there is no misfiling of results in the database or in-appropriate formatting of the report

6.5. Rule based systems for automated selection and reporting of results, shall be verified

6.6. If there is major change in any of the components of the information system, the effect on the entire workflow for a selected sample shall be demonstrated to have no deleterious effect.

6.7. To ensure Security and confidentiality – the laboratory ensures that there is a role based authenticated access into the information system and there shall be procedures to inactivate users who are no longer authorized to access these systems.

6.8. There is a facility to demonstrate an audit trail to link the activity undertaken by a user with relation to patient data or software change

6.9. Redundancy (Back-up), manual procedures for down times and disaster recovery systems is defined in the Redundancy/Contingency SOP

7. Random Data verification process:

7.1. The instrument print-outs are used for verification of data with approved result reports that contain patient/test identification details

7. 2. The related LIS report is printed for each piece of raw data selected

Compare the raw data (instrument or manual report) with the printed LIS reports. Verify the following areas for accuracy:

7.2.1. Patient Identification (as per requisition form)

7.2.2. Specimen collection date and time

7.2.3. Name of test

7.2.4. Test result

7.2.5. Units

7.2.6. Reference Range/Interpretation

7.3. If there is any data is discrepancy, an incident form is documented and relevant corrective and preventive actions

7.4. The Laboratory Director and Quality Manager is informed of the discrepancy in the LIS Data Validation Process

7.5. If the LIS Data Verification Fails - Do not report unacceptable patient results on the LIS.

7.6. If the LIS Data Verification results are acceptable, document the successful completion of the verification process

8. **RECORDS**

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

S. No	Record	Responsibility	Retention Period
1	LIS Verification Form	In-charge	1 Year
2	LIS Validation Form	In-charge	1 Year
3	LIS Error /Incident & CAPA Report	In-charge	1 Year
4	LIS Data sheets	In-charge	1 Year
5	Equipment Print Out Data	In-charge	1 Year
6	LIS Verification Register	In-charge	1 Year
7	LIS Validation Register	In-charge	1 Year