**Example of LIS Validation SOP**

**Purpose, Scope and Responsibility**

The purpose of Laboratory Information System (LIS) validation is to ensure that the LIS reported data accurately reflects the raw data reports for all laboratory tests for patient ID, specimen collection, test, test results, units, reference range, LIS calculated results, critical and amended results.

This procedure applies to all laboratory staff performing data entry, review or inquiry on the LIS and should be performed by individuals knowledgeable of laboratory data and terminology.

The laboratory staff are responsible for training and compliance with this SOP. The Laboratory Manager and/or designee are responsible for annual review and/or revision of this SOP.

**Safety Precautions**

The LIS is located in a hazardous environment. Each system will be designated as “clean’ or ‘contaminated’ and labeled accordingly:

* + 1. *Clean Area Only – Do not contaminate* or
		2. *Contaminated – Wear gloves when using this system*

Use standard safety precautions according to the safety SOP in all areas of the laboratory.

**Quality Control**

If QC data is interfaced or manually entered in the LIS and used for tracking and review, validate the QC reports using the methods listed below.

**Frequency**

LIS validation will be performed as follows:

* + 1. Initially
		2. After system changes by the user, vendor or laboratory

After any data file restoration

**Procedure**

1. Randomly select normal raw data for each protocol analyte/method combination.

Automated Tests (Instruments) – Use instrument print-outs. If an instrument interface is utilized, use raw data that was interfaced to the LIS.

Manual Tests – Use approved result reports that contain patient/test identification.

1. Print the corresponding LIS report for each piece of raw data selected.
2. Compare the raw data (instrument or manual report) with the printed LIS reports. Verify the following areas for accuracy:

Patient Identification (as required by protocol)

Specimen collection date and time

Name of test

Test result

Units

Reference Range

1. If any data is unacceptable, complete an error report (see example at end of document) and notify the lab designee immediately. Do not report unacceptable patient results on the LIS.
2. If acceptable, document the validation according to “approval” section below.

Critical Result Validation

1. Randomly select high and low critical results for each protocol test and method combination. If critical patient results are not available, create test data:
	1. Create a ‘test patient’ in the LIS for all of the applicable tests (more than one test patient may be needed to capture each test/method combination).

Interfaced Instruments

* Select or prepare samples that will provide critical results. Internal or external quality control material can be used.
* Label the sample as needed to ensure result interface from the analyzer to the LIS.

Non-Interfaced Tests

* Prepare manual raw data reports using the test patient. Randomly select results that fall within the critical range for the chosen test and method.
* Manually enter the test patient results into the test patient field in the LIS and obtain the appropriate LIS result report.

1. Review all critical LIS reports for specific identification as a critical value.
2. If any data is unacceptable, complete an error report and notify the lab designee immediately. Do not use the LIS until this problem is resolved.
3. If acceptable, document the validation according to “approval” section below.

Amended (Revised) Result Validation

1. Create a ‘test patient’ in the LIS for ***one test*** only. Amended result validation is ***not*** required for all protocol analyte and method combinations.
2. Enter and finalize a random test result in the test patient file in the LIS.
3. Amend the test result in the LIS two times in order to present multiple corrections of a single result.
4. Print the LIS report and review it for the following:
* Original data and revised data are present and clearly identifiable in the revised report.
* Multiple sequential corrections of a single result are in sequential order on the report.
1. If any data is unacceptable, complete an error report and notify the lab designee immediately. Do not use the LIS until this problem is resolved.
2. If acceptable, document the validation according to section “approval” below

Validation Documentation and Approval

1. Documentation - Compile copies of the raw data and LIS reports into a binder and complete the LIS Validation and Approval Report (see related documents). Document the following:

Normal results

Critical results

Calculation verification (refer to “calculation” section below)

Amended reports

1. Approval - Document approval on the LIS Validation and Approval Report (see related documents) before using the LIS to report patient results.
2. Retain the data in accordance with study record retention guidelines or indefinitely.

**Calculations**

Validate all LIS calculated results initially, annually and after any system change that impacts calculation for each protocol analyte and method. If calculations vary based on patient parameters (for example, sex) verify calculations for each variation. Perform calculations using normal, missing and ridiculous data to ensure that erroneous results are not released.

The following protocol analyte results are calculated and reported by the LIS. [This is an example only. Provide details for all analytes calculated by your LIS]

1. Creatinine Clearance (CC)
	1. Calculation:



* 1. Male Example:
* Patient Sex: Male
* Age = 40
* Weight = 80 kg
* Serum Creatinine = 100 mls
* CC =
	1. Female Example:
* Patient Sex: Female
* Age = 60
* Weight = 50 kg
* Serum Creatinine = 100 mls
* CC =
	1. Acceptable Criteria: ± 0.5
1. If any calculations are unacceptable, complete an error report and notify the lab designee immediately. Do use the LIS to calculate this test until the problem is resolved.
2. Document the verification on the LIS Validation and Approval Report (see related documents).

**Expected Values**

1. All qualitative and quantitative automated or manually entered data must be identical.
2. Calculated data must fall within the acceptable criteria as noted in “calculations” section above.
3. Any discrepancies must be resolved before utilizing the LIS to report any patient results.

**Method Limitations**

The LIS computer system may malfunction due to unforeseen hardware or software errors. Any discrepant data must be documented by the identifying technologist on the LIS error report and reported immediately to the laboratory designee.

**Related Documents**

LIS Validation and Approval Report

**References**

1. College of American Pathologists (CAP) 2023. Commission on Laboratory Accreditation, Laboratory Accreditation Program; Laboratory General Checklist, Revised 8/24/2023.
2. Code of Federal Regulations. CFR 21 Part 11. Rev 2/27/2024.
3. DAIDS Good Clinical Laboratory Practice Guidelines. Rev 08/16/2021
4. CLSI. *Managing and Validating Laboratory Information Systems*; Approved Guideline. CLSI document AUTO08-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2006.

**LIS Error Report**

|  |  |
| --- | --- |
| Tech Preparing Report:Date: |  |
| Applicable Test and Instrument: |  |
| Description of the Problem: |  |
| Documentation Available and Attached: |  |
| Clinical Staff Notified: |  |
| Laboratory Supervisor Notified: |  |
| Corrective Action: |  |
| QA Committee Review:Date: |  |
| QA/QC Coordinator Review:Date: |  |
| Supervisor Review:Date: |  |