
MINISTRY OF HEALTH

**STATE DEPARTMENT FOR MEDICAL SERVICES**
**ADDENDUM 1**

## SPECIFICATIONS FOR A LABORATORY MANAGEMENT INFORMATION SYSTEM (LMIS

### System Overview

The system should have the following:

1. Personnel roles and rights management capability. ii. Highly innovative configuration management tools
2. Ability for interpretation of raised events dependent on defined result limits. Out of limit values should be clearly visible or user notified at the point of result entry.
3. Sample registration, storage, tracking and archiving capability v. Sample management capability
4. Deployable on both LAN and Web.
5. Instrument calibration and maintenance management capability.
6. Capability to manage both internal and external quality assurance programs of the laboratory
7. Laboratory workflows management capability.
8. The system should have laboratory resource management capability
9. Able to support integration solutions to external systems
10. Able to support integration/interfacing to lab instruments for automatic result uploading and support manual result entry where samples are analyzed manually.
11. Able to manage samples from submission through testing, result entry and checking, result validation and approval to final reporting and data archiving.
12. The system should be barcode compatible, both for printing and reading barcodes, so that samples can be logged and tracked throughout the LIMS.
13. The system should allow for Review, Approval, and Release of results .
14. The system should allow for electronic signatures.
15. Allow for the creation of client reports and other laboratory reports.
16. The system should have support generation of reports especially lab summary, management, turnaround time, inventory, instrument reports and any other on demand reports based on the data captured in the system, provide up- to-date information about samples, schedules, instruments, reports.
17. Generate dashboard statistics, graphs and charts reports

18. Ability to extract all details relating to a sample from related databases
19. Test menu configuration with the capability for formula inclusion for auto calculation on relevant tests and allow for addition and modification of tests.
20. Unique sample numbers
21. Sample Repository with sample retrieval mechanism for structured storage and archival.
22. Inventory management capabilities Inclusive of main store and sectional stores configuration
23. The system should be able to provide alerts on the status of the inventory items
    a. including expiry dates, stock levels etc
24. Ability to schedule automated operations including but not limited to batch operations and processes, emailing, SMS notifications, system schedules and data sharing.
25. Ability to generate barcodes for laboratory items in the stores.
26. Scalable and deployable to various sections within laboratories.
27. It should provide for results approval screens to ensure results verified by appropriately qualified personnel before they are released
28. It should provide a secure log in for individuals or groups of individuals with system access defined by log in-credentials
29. The system should provide for an audit trail of all changes to the system and information it contains
30. The system should allow for a dual Desktop/Browser interface
31. An automated result calculation with components when raw data is fed into the system.
32. The system should support additional required information fields, screen layouts, and templates
33. It should provide for Quality Controls and Quality Assurance

**Technical Requirements**

i. Application should be designed to run on a Windows-based environment on PC's running Windows and a dual Windows/Browser interface so that it can use the most appropriate interface for the current task
ii. HL7 and ASTM interface
iii. Extensible: The system should have the ability to define new fields to capture for certain types of data
iv. Flexible form generation including user-configurable field layout, text descriptors.
v. Fully configurable so that the system is built to customers design and requirements leading to fast familiarization and acceptance of the system.
vi. System designed for change when required so that a longer operational life and lower life-time cost of ownership
vii. One-time Configuration Tools where any changes made to the system configuration are immediately reflected in both the desktop and browser versions as soon as the changes are installed on the live system
viii. Ability for interpretation of raised events dependent on defined result limits. Out of limit values should be clearly visible or user notified at the point of result entry.

ix. Patient management system with ability to link sample management to patient data

**Database**

i. The type of database employed by the application needs to be a modern, relational database, widely supported by current technology.
ii. Ability to automatically re-establish database connections in the event of minimal network interruption.
iii. Ability for advanced users to develop custom queries from the front-end

**Sample registration**

Samples received are to be registered with a unique sample number and sent to respective laboratory section for testing. The LIMS should have the ability to allow for:

a) Easy Quick Registration of samples
b) Add as many Sample types/Batches per registration
c) Adding/removing tests

**Bar code labelling**

The system should provide barcode label generation in code 39, 128 and QR. There should be configuration to specify event to generate a label

**Data Back-up**

System data backup and recovery processes should have minimal impact on system availability.

**Customization**

Ability to add new, modify and delete roles to the security model by laboratory's LIMS system administrator. The system should allow users to customize and maintain (add, modify, delete) forms, screens and system components used for test order entry, result entry and result reporting.

**Analysis**

System provides authorized users ability to extract data in a form that is used by a variety of commonly available analysis tools e.g. excel.

**Batch Input**

The system to handle batch imports or data loads from XML, CSV or other standard data formats.

**Test and Specification Management**

The system should support tests with relevant attributes and switches that can be maintained based on test category and sections that will handle tests. Tests can have one or multiple parameters. The system must support parameters that are:

- numeric,

- character/text,
- calculated,
- List etc.

**Training**

Training on the the use of the system and the technical aspects of the software configuration is a requirement and the training period and schedule provided. This should be for all the users of the system. It should include but not limited to

a) Laboratory analysts
b) System administrators

**Pre-referencing**

The system must be able to capture all the sample information at the initial registration before the samples are taken to the laboratory. The system should have the ability to search for previous patient information to link patient history. When a returning patient is found, system must be able to pre-populate demographic information with the ability to edit and save

**Priorities/Schedule**

System to allow the ability to prioritize testing of a sample. Priorities should be user definable and modifiable

**External Laboratories**

The capability for the electronic referral of samples to external laboratories and the capability for electronic receipt of reported data.

S**upervisor Verification**

The system should provide for a supervisor verification step prior to releasing laboratory results

**Sample storage and disposal inventory**

System should have a robust sample storage location manager where it lists all storage categories created. It should also have options to add, edit and delete categories. The storage template should be easy in such way that the user can understand structure of the storage area where the sample is assigned to a freezer, level of shelf, rack, plate, row, and column.

**Sample tracking**

It should be able to track the progress of analytical process and communicate the same on request. The system should support tracking of samples based on the sample status at each analytical stage.

**Report Generation**

There should be a module for generating laboratory reports. The system should be designed to quickly launch such reports from a dedicated reporting module. The reporting module should be quite powerful, based on the nature of the report the query type can be dynamically varied. Like for e.g. to create a client report for an already released sample can be done by simply typing the Sample number or by searching through the database based on dates and sample released during those dates and by batch number.

**QA/QC**

System must maintain quality control checking for results, instruments and manual input. System should produce cumulative weekly and monthly quality control reports.

**Protocols**

The system should have a built in- user management module that comprises roles and rights management. The roles and rights which allows control of each and every control within application form. The system should have necessary policy management with respect to users, passwords.Complete electronic records protection with electronic signature support.

**Instrument Interfacing**

The system should be able to support next generation interfacing solution which even end-users can interface any new instrument at any point and time without the help of the system expert. Ability to interface using ASTM is a MUST.

**Security**

The system security features should include:

a) Unique ID and password sign-in for user authentication.
b) Role-based security, providing appropriate user access to system functions and data.
c) System data backup and recovery processes should have minimal impact on system availability.
d) Access to results data shall be based on user roles and privileges.
e) System security levels to provide the ability to allow/disallow access to specific areas such as screens, windows, or logical data groupings by user role.
f) In case of a breach, proactive Alert Messages within the system to the system administrator. The Email and/or SMS alerts should inform what is happening within the system

**Audit Trail**

The system should maintain a complete audit trail of order process. This audit trail MUST be visibly accessible to an authorized LIMS user Auditing should include:

a) Status of each change that an order undergoes
b) Date and time of event change

c) ID of person who changed the order
d) Date and time of event change and initial result entry
e) Record each step that occurred in the processing of a test procedure
f) User who performed the step

**Graphical User Interface**

Easy to use graphical user interface design where workflows are designed to meet the lab business processes. The interface must be able to meet the following attributes:

a) Clear to understand for people who are not IT experts
b) Use of familiar icons to ease navigation
c) Interface should be consistent

**Hand Over and Maintenance**

The system should:

a) Have a complete user documentation and help guideline
b) Have provision of ongoing technical support for system administrators and super users. Have a system documentation after initial installation and deployment of the system. The documentation should be presented as hard copy reference materials, in CD and/or other electronic format and include the following:
    a. **Installation and administration guide:** The installation guide shall be detailed enough to provide system administrators with information necessary to install and bring the application live in a production environment. The documentation shall list all utilities and tools necessary for
    b. **T**he proper administration of the LIMS. These tools shall cover management and administration of the LIMS database, the user interface, and any auxiliary programs integrated into the delivered LIMS.
    c. **End user guide:** Laboratory User documentation should be sufficient and detailed enough to allow different levels of lab users to perform their functions without having to rely on external support.
    d. **Super User guide:** an overview of system and complete user documentation regarding Use of all applications, adding or modifying test procedures, adding or modifying testing controls, adding or modifying new data elements to the database for collection at test order entry, result data entry and for reporting, adding or modifying testing alerts and result calculations, adding or modifying reflex testing rules, adding or modifying report formats, adding or modifying a system rule, and developing electronic file formats for import or export.
c) The proposed systems must be able to integrate with other external systems. The LIMS must be able to capture and transmit data to a myriad of different applications and databases. The system must utilize standard data formats and communication protocols. HL7 capability is MANDATORY.

**Data back-up and Restoration**

a) The LIMS should have the capability to perform routine backups of the data in the system.
b) The LIMS must have the ability to do both manual and scheduled data backups. The data backups must be done to a storage media

that can be stored off-site and should also provide for the ability to do backups to remote connected devices as well.

c) The system must provide for data restore and recovery capabilities as well.

**Maintainace**

Software maintenance should include application updates and patches to the software following official installation in the laboratories. The system maintenance schedule must be specified throughout the software lifetime by the supplier.

a) Provide for Maintenance including version upgrades, Service Level Agreements(SLA’s)
b) Must provide a detailed specifications document for the proposed software
c) Must clearly state the lead time (Delivery, Installation, Training and Commissioning)
d) Provide Warranty Certificate/assurance

The closing date has been extended to 5th August,2026,11:00 Am

All other details remain the same

**PRINCIPAL SECRETARY**
**State Department Medical Services**