UGANDA EMR ENHANCEMENT

Clinical Laboratory Module

Software Requirements Specification (SRS)

Project: *UGANDA_EMR_CLINICAL_LABORATORY_MODULE*
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Revision History

Date	Version	Description	Author
04/06/2024	0.1	First draft	Komusoft

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Software Requirement Specification

1. Introduction

1.1. Overview

1.2. Background

1.3. Problem Statement

1.4. Purpose

- To design and develop a comprehensive clinical laboratory module in Uganda EMR supporting test order placement, sample accessioning, and diagnostic test results within a health facility.

2. Software Requirements

2.1. Scope

- Build a system that will provide full visibility of clinical laboratory workflow in real-time.
- The system will enable timely ordering and resulting of patient diagnostics requests.
- The module will cater for the entry of test results either using a direct manual approach or through an instrument-to-system interface where appropriate to a particular health facility setting.
- The system will offer a dedicated configuration page where various parameters including a test menu list, test categories, test panels, result outcomes, etc. will be available to enable end-user customization to match health facility requirements.
- Provisions will be made for future integrations with other systems through the exposure of applicable API (Application Programming Interface) both .to the national level and with other relevant key stakeholders.
- The module will provide primary users (clinicians, laboratory technologists, and others like M&E, finance, date clerks, etc.) with appropriate rights to adequately utilize the module.
- Appropriate report outputs will be provided to cater for daily test registers, monthly test performance summary reports among others.
- Users will be able to receive early warning indicators in form of notifications e.g. incoming/pending test requests, alerts for processes past turnaround time, etc.

2.2. Product perspective

2.2.1. System Interfaces

- System customizations will be based on an already existing UgandaEMR implementation, thus riding on the already established clinical workflows. Specifically, the existing laboratory module will be extended to accommodate all the requisite features.

2.2.2. User Interfaces

The application GUI (Graphic User Interface) will provide menus, toolbars, buttons, panes, containers, and grids allowing ease to use and control through a keyboard and a mouse ensuring minimum learning curve. The user interface for the new module will utilize the UgandaEMR/OpenMRS API to allow various view layer technologies to be incorporated to enhance system scalability.

2.2.3. Hardware Interfaces

Not applicable at this stage. No external hardware interface is required. At the least, these will match the UgandaEMR specifications.

2.2.4. Interoperability Requirements

The new module should be built to allow for future interoperability with complementary systems including but not limited to;

- Uganda electronic Health Management Information System (e-HIMS)
- National Test Catalogue (UNHLS)

2.3. Product functions

- The product should support various aspects of the laboratory workflow (test order entry, sample accessioning, results entry, results approval) by the different diagnostic service points such as the main laboratory, ART Lab, MCH Lab, TB Lab etc. The different service points shall be configurable.
- On top of supporting test orders placement by clinicians, the module will manage, and document all the major laboratory functions as mentioned above to enable the clinician obtain the final diagnostic result for further patient management in real-time.
- The clinical laboratory module shall generate various reports concerning all applicable laboratory workflow activities.
- Data validation checks to improve the quality of data captured and reported.

- Timestamping of key processes completion to enable Early warning mechanism (e.g. alerts functionality) to monitor turnaround time, incoming requests, and completed test orders, among others.
- The module shall integrate with the national test menu catalog for a standardized list of tests.
- The module shall exchange a minimum dataset of laboratory diagnostic data as required by UNHLS

2.4. User characteristics

- Medical Doctors
- Clinical Officers
- Laboratory technologists/technicians
- Health Information Assistants
- Nurse and Midwives
- Other support staff (Data Clerks, M&E Officers, Facility Administrators etc.)

2.5. Limitations

- Hardware and/or maintenance limitations
- Interoperability with non-standardized platforms
- Running a centralized application poses a single-point-of-failure scenario
- Wide Area Network (WAN) connectivity service
- Software version updates

2.6. Assumptions and dependencies

- The application will require a standardized test catalog which will serve as the basis for the auto generated diagnostic menu.
- The current national test catalog (by UNHLS) is available.

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2.7. Definitions, Acronyms and abbreviations

- eHMIS - Uganda electronic Health Management Information System
- ID - Identifier
- GUI - Graphical User Interface
- HIE – Health Information Exchange
- HIS - Health Information System

- HTML - Hypertext Markup Language
- NMS - National Medical Stores
- SRS - Software Requirements Specification
- UNHLS – Uganda National Health Laboratories services

3. Business Requirements for the Uganda EMR

3.1. Implement a system that will track all applicable clinical laboratory workflow activities necessary to support a health facility in public/government setting including but not limited to (test order placement, sample accessioning, test results and machine interfacing) to support seamless and uninterrupted service delivery.

3.2. To improve or extend the existing laboratory module to provide real-time information and reports required for monitoring of laboratory diagnostic service and associated activities in a health facility setting.

4. Functional Requirements for the Uganda EMR

4.1. Functions requirements

Functional Req. ID #	Functional Name	Functional Requirement Description
Laboratory Workflow definitions		
FR1.1	Diagnostic test menu Setup	The system shall allow for adding, updating, retiring and importing of diagnostic test and related parameters. • The minimum set of parameters to track include name, (local) code, international codes (LOINC, SNOMED etc), category, result outcome. • The system will look up and adopt any of the following applicable parameters including but not limited to (test name, …?) from the master list provided from within UgandaEMR.
	Laboratory/Diagnostic Service Point Creation or Update	The system shall allow a user to create, update or a retire a diagnostic service point which in turn will create appropriate locations in the UgandaEMR • Minimum set of parameters include name, Parent Location, Status, user remarks • The system shall automatically create and maintain the default “Main Laboratory” service point. • The system shall allow a user to delete a diagnostic service point that has not been assigned any laboratory activities
Diagnostic Test Order Placement		
FR1.2	Test Order Placement	The system must allow for placement of diagnostic test order by clinician to .one of any of the applicable diagnostic service points. • The minimum set of parameters to track will include date of order, requester, requested test, patient reference, urgency flag, accompanying remarks by clinician among others.

		• The system shall produce a test request note for each test order placed, as specified above that is available online and in printed form. • The system shall provide for an indication of whether the test requested is expected to be done from within the health facility or externally. • The system will provide for optional approval of test request where applicable.
Laboratory workflow activities		
FR1.3	Sample collection and accessioning.	The system must allow for collation of all ordered tests by patient or category to enable lab personnel handle the required tasks singularly or in a batch. • Phlebotomy records shall indicate sample type, phlebotomist, date of sample collection, sample-container .type among others. • The system shall allow for automated accessioning of the above patient samples and also auto/system-generated standardized sample identifiers that can be printed on labels for later affixation to the sample containers. • The system shall be able to print a barcode of the above labels, using a specified label printer (**This will require physical printer type to be known before hand for effective .implementation*).
	Worksheet generation	• The system will provide for generation of worksheets based on a number of criteria (e.g sample type, request type, patient). • The worksheet so generated shalloptionally be assigned to a designated laboratory personnel to aid in monitoring and followup.

FR1.4	Recording of Test Results	The system must allow for recoding of the test result according to either a predefined test outcome if applicable or a user entered free text for variable test outcomes. • The minimum set of parameter to track will include result date, responsible person (tester), test outcome, and any accompanying remarks as may be deemed by the tester. • The system shall produce a test result slip with a format similar to the MOH sanctioned form indicating quantities issued. In case of a result obtained/tested from an external lab, the above test result slip will clearly highlight the results as such. • The system will provide for optional approval of the test result by relevant persons
Clinical Side Enhancements		
FR1.5	Clinician Notification	The system shall allow for notifications of the test requestor concerning completed diagnostic test.
FR1.6	Sample repository management	The system will support specimen repository management (with respect to long term sample storage) functionality through: • Allowing check-in of samples into user defined repository structures. Baseline attributes will include sample reference, sample volume, thaw cycle, repository position reference, date of entry and recorder details, • Allow for checkout of previously checked-in samples indicating among others purpose of checkout, date of checkout, sample volume, thaw cycle and personnel details. • Allow for searching through the repository for checked/checkout samples.

Diagnostic Test Related outputs		
FR1.7	Laboratory Reports	The system shall produce the following reports in either (pdf, csv and ordinary html formats) • Daily test register • Summarized monthly and quarterly test reports • Individual Personnel Performance • Detailed/Summarized turnaround time • Dashboards to support management and operational requirements showcasing various statuses (in progress, completed, cancelled etc) • Chain of custody for sample movement • System audit trail reports • Patient specific diagnostic history These reports shall have the following parameters to inform the scope of the data reported therein. • Date range. • Test type. • Diagnostic service point.
Miscellaneous Requirements		
FR1.8	Interoperability with other systems	The system shall support a minimum set of parameters spanning all the functional areas above served via API endpoints for purposes of data/information exchange with other complementary systems. • The systems being targeted in this scope include among others:

		• ALIS • UNHLS/CPHL Viral Load and EID Dashboards • The mechanism of exchange will be via HL7/FHIR messaging protocol
FR1.9	User Permissions	The system shall use existing UgandaEMR permission schemes for enforcing user access to various activity areas where applicable. • The roles involved in the following operations will be maintained as is: Clinician, Laboratory Personnel, Laboratory Approver. • New roles will be added to cater for other operational management aspects and reporting access.
Non Functional Requirements		
TBD	TBD	This will rely on mainly UgandaEMR NFR at the time of implementation to cover areas of security, capacity, compatibility, reliability, scalability, maintainability and usability.

4.2. Logical database requirements

4.3. Design constraints

4.4. Standards compliance

4.5. Software system attributes

5. Verification

6. Supporting information

A comprehensive maintenance support plan will be implemented and handled exclusively by METS-SPH. However, Komusoft partners may be called upon for backstopping support upon mutual agreement.

7. References

UgandaEMR - https://mets-programme.gitbook.io/ugandaemr-documentation/

OpenMRS - https://openmrs.org/documentation/