VALIDATION REPORT

FOR

A-LIS VERSION 1.0

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Introduction and Scope of ALIS

Laboratory Information Systems have become a crucial component of clinical and Public Health Information management in developing countries. A country like Uganda an Electronic Laboratory Information Management System is a crucial asset to an ongoing effort to strengthening the public health Sector.

Uganda has dwelled on the use of paper based standardized tools for the last 14 years but given that this is a resource constrained country this system is not sustainable. A lot of money has been invested in printing tools for daily data capture and reporting, this has gain the health information system infrastructure a great deal of informative decision making. This is in especially the management of HIV/AIDS as a disease and the management of the effected Patients both Adults and Children.

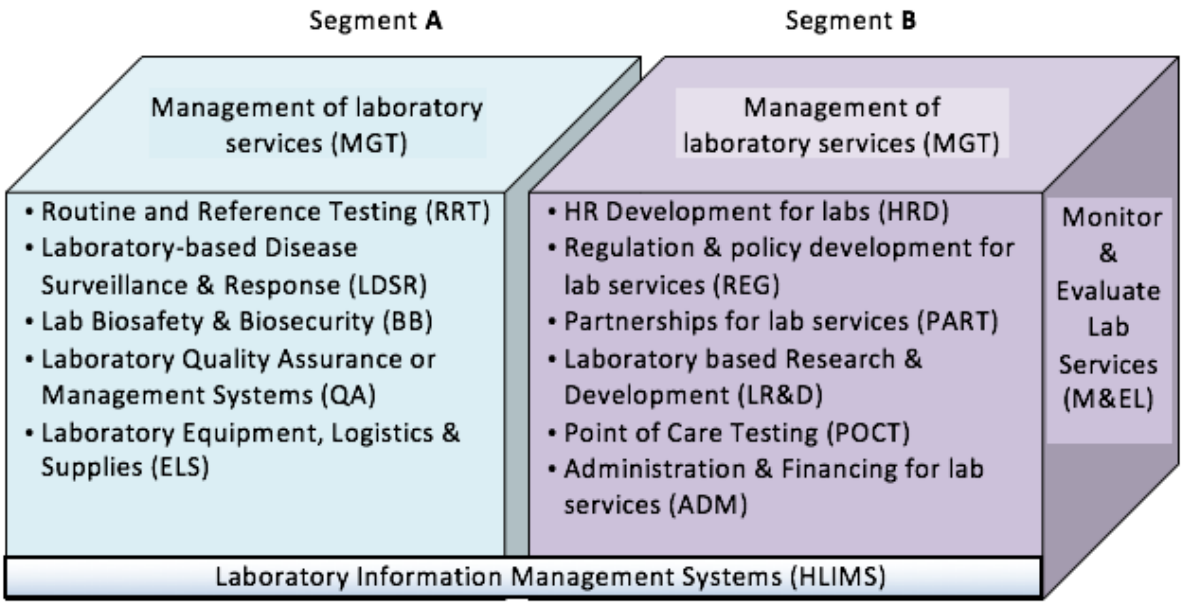
Consequently, for a better management of the countries diseases and patient, a swifter information sharing protocol or platform is suitable. Therefore, Public Health Laboratories such as the ones in Uganda, have become a target for various pilots of different Electric Laboratory Information Systems (ELIS). One such ELIS is Basic Laboratory Information Systems (CG4-BLIS), which is an open source software application developed in a joined effort to track patient specimens and *laboratory* results. Using a central repository called GitHub, developers across the world can share and update the BLIS Code. The initial scope of CG4 BLIS was to support PEPFAR objectives to support service delivery in Laboratories and to address their data collection, storage and analysis needs. BLIS focused on 2 areas;

Firstly, to manage and maintain all data about patients' specimen and test results that are generated within the laboratory;

Secondly it focused on the accuracy and reliability of clinical Laboratory test results that are critical components to a public health approach to any management of a disease(s) given the limited resources.

Uganda through the guidance of a Health Laboratory Information Management Systems Technical Working Group (HLIMS-TWG) and with a recommendation from CDC took the decision to adopt BLIS but rebranded it African Laboratory Information System (ALIS), for the purpose of customizing BLIS to fit within any African laboratory setting.

The HLIMS-TWG developed a HLIMS Master plan to guide the process of customizing ALIS. This HLIMS Master Plan was based on the 12 thematic areas under the Central Public Health Laboratories (CPHL) which were divided into 2 blocks;



Phase 1 of ALIS customization was based on Segment A in the HLIMS Master Plan.

A-LIS development life cycle

Before a decision to develop A-LIS, a gap analysis was performed through meetings, brainstorming and interviews. A high level risk assessment was performed and because the system is used for processing and maintaining patients and samples data, a decision to validate the database system was also made. The iterative and incremental development model was adopted for the development of A-LIS. Development of each module went through the requirements, design, implementation and testing phases while each subsequent release of the module added function to the previous release. The process continued till the complete system was ready as per the requirements below which were identified during the gap analysis;

- Managing large volumes of data
- Multi User access to data without compromising performance
- Reduction of turnaround time from sample reception to results dispatch
- Generation of patients' history records (profiles)
- Generation of periodic reports

Purpose of validation

Validation provides documented evidence that A-LIS is suitable for its intended use by ensuring that it generates, collates, stores, reports and archives patient, sample and testing information and reports.

A-LIS validation process ensures that;

i. Validation is documented, including that for day to day functioning of the system, and readily available to authorized users and decision makers at the Ministry
ii. The database is protected from unauthorized access;
iii. The database is safeguarded against tampering or loss;
iv. The database is operated in an environment that complies with Lab specifications
v. Maintenance is done in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;
vi. Services are maintained in the event of failure or downtime.

1. Scope of validation

The validation covers all hardware, software and networks that support the implementation of A-LIS at a facility.

2. Installation requirements

Installation of A-LIS on a server computer requires specific software and hardware specifications as shown below;

Server requirements

Specification	**Requirement**
Web Server	Apache2 or Nginx
Database Management System	MySQL v5.5 or greater
Program Language Interpreter	PHP5.3 or greater
Operating System	Windows 7/8/Server, Ubuntu Server
CPU speed	1.4 GHz or faster
Memory	At least 2 GB and should be increased as database size increases to ensure optimal performance
Hard Disk	Minimum 10GB free space

Network	Local Area Network Connection (Ethernet or Wireless), Ethernet recommended

Client Requirements

- The Client must be connected to the Local Area Network on which the server is hosted
- Installation of A-LIS on a client computer requires a web browser. Recommended web browsers are Mozilla Firefox, Google Chrome and Opera. Internet Explorer is not recommended.

Testing and Validation activities

System testing and validation was done through hardware installation and verification of the computer functionality at CPHL, followed by module testing, integration testing, and finally, system testing. While performing the tests, test data was used to ascertain whether modules, interfaces and the whole system were suitable for their intended use.

- Individual modules of the system were tested to ensure they are fully functional units before integrating them. This was done by examining each unit; each script was checked to ensure that it functions as required and that it performed exactly as intended.
- The success of each individual unit gave a go ahead to carry out integration testing. Different system modules were put together to make a complete system and integration testing ensured modules were compatible to be integrated to form a complete working system.
- The complete system was then tested as a whole entity using test data to assess if the system met users' needs and requirements.

The testing and validation exercise showed that the system performed in conformance to the then defined user needs and requirements. Below is a summary of the validated system features.

#	ALIS features	PASSED? (YES/NO)	Comment and proposed changes by target user (Optional)
1	Login Page	YES	

2	Home page of ALIS (after logging in)	YES	
3	Help menu/options/ Frequently asked questions	NO	The page/section does not exist
4	Categorization or layout or structuring of main menu and sub menus	YES	
5	Other comments		

1. ALIS Functionality and Behaviour

#		**Support for Routine & Reference Testing (RRT) activities**	**PASSED? (YES/NO)**	**Comment and proposed changes by target user (Optional)**
1	Pre-analytic management tasks			
a)	Manage Patient Data			
	i)	Register patient	YES	
	ii)	Retrieve/view data on existing patient	YES	
	iii)	Edit/update patient data	YES	
	Other comments on managing patient data			
b)	Request lab tests and view lab test result report(s)			
	i)	Request for lab tests	YES	
	ii)	View, download, print patient lab history report	YES	
	iii)	View an approved lab report	YES	
	Other comments on requesting for lab tests			
c)	Assign patient ULIN, register sample, accept/reject samples			
	i)	Assign patient a ULIN	YES	The system automatically generated ULIN and assigned it to the patient
	ii)	Register a sample (sample ID)	YES	
	iii)	Accept or reject sample	YES	

	iv)	Update status of a specific lab request at a facility lab	YES	
	v)	Refer sample (note that sample and results tracking will be in upcoming modules)	NO	True this feature is Non-functional. Recommendation, let the link be deactivated until the feature is functional
	Other comments on patient ULIN and sample ID			
2	Analytic management tasks			
a)	Manage lab requests			
	i)	View pending lab test requests per category of test type	YES	
	ii)	Generate lab test result report	YES	
	iii)	Update status of a specific lab request at a facility lab	YES	
	Other comments on managing information on processing requested tests			
3	Post-analytic management tasks			
	a)	Prepare lab test result report	YES	
	b)	Generate/create draft lab test result report	YES	
	c)	View draft lab test result report	YES	
	d)	Verify/approve draft lab test result report	YES	The page doesn't redirect to the index page
	e)	Comment on (or amend) draft lab test result report	YES	
	f)	Update status of a specific lab request at a facility lab	YES	
	Other comments on managing the lab test result report			

#	Support for Equipment Logistics & Stores (ELS) activities		PASSED? (YES/NO)	Comments
1.	Laboratory equipment inventory and maintenance management tasks			
	a)	Register equipment	YES	
	b)	Manage service schedule of equipment	YES	
	c)	Report equipment breakdown	YES	
	d)	Report equipment restoration details	YES	
	e)	Generate periodic equipment performance report	NO	
2.	Laboratory commodities management tasks			
	a)	Update inventory of lab commodities	YES	
	b)	Issue requested lab commodities	YES	
	c)	Record findings from conducted physical counts		
	d)	Generate stock status report	YES	

#	Support for Biosafety & Biosecurity Incident Management activities	PASSED? (YES/NO)	Comment by target user
a)	Register biosafety or biosecurity incident	YES	
b)	View biosafety or biosecurity incident	YES	
c)	Update biosafety or biosecurity incident	YES	
d)	Clinical intervention, Incident analysis and Emergency Incidence Response entry	YES	
e)	Assess reported biosafety or biosecurity incident	YES	

f)	Follow-up reported biosafety or biosecurity incident	NO	Feature/page does not exist in the system
g)	Generate biosafety and biosecurity incident report	YES	

#	**Support for Management and reporting activities**	**PASSED? (YES/NO)**	**Comment by target user**
a)	Key statistics from RRT functions	YES	
b)	Key statistics from BB functions	YES	
c)	Key statistics from ELS functions	YES	
d)	Special reports		
	Instant HMIS 033A report	YES	
	Biosafety and biosecurity incident report	YES	
	Stock status report	YES	
e)	Periodic reports to support the filling or generating of the monthly HMIS 105 (section 7 – laboratory)	YES	
f)	Periodic reports to support the filling or generating of the weekly HMIS 033B report	NO	There is data but 033B report is not among the listed reports generated
g)	Periodic reports to support the filling or generating of the quarterly & annual lab report	YES	
i)	Other comments on reports		

System Control Features

#	**System Control Section**	**PASSED? (YES/NO)**	**Comment by target user**
a)	Registration of users	YES	
b)	Changing of passwords	YES	
c)	Assignment of access rights to users with respect to job description	YES	
d)	Authentication of users	YES	

e)	Track user activities (user log)	YES	
f)	Configure or update major system menus such as drop down menus	YES	
g)	Data back up	YES	The system automatically backs up to another server
h)	System and data restoration/recovery	YES	
i)	Data archival from facility level to national level	NO	

Conclusion

A-LIS has been found to be effective and functional in handling patient samples and management of data respectively and is deemed fit for use by all facilities. However, specification and abilities of the A-LIS may change from time to time after consultation with the stakeholders and verification by the users will be performed before newer versions are adopted.

Appendices

Appendix 1: Patient Report

CENTRAL PUBLIC HEALTH LABORATORIES
P.O. BOX 7272, KAMPALA
UGANDA.
PHONE: +256 414-230265

LABORATORY REPORT

Patient Report - 23-05-2017

Patient name	John Paul	**Gender**	Male
Patient ID	222	**Age**	1 years

Lab Reception

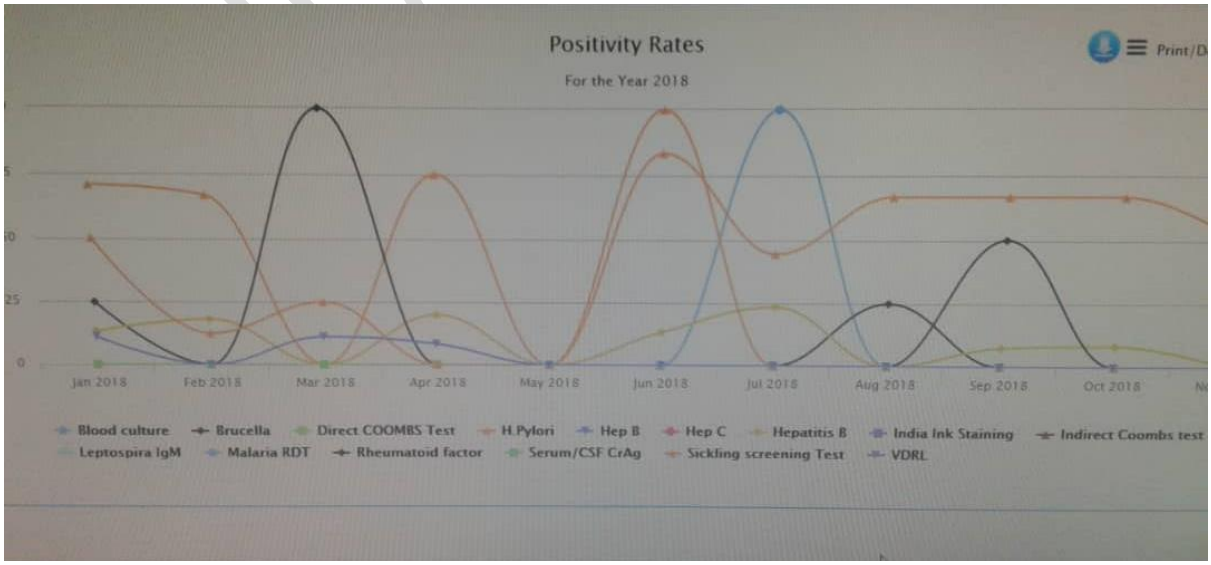
Specimen Type	Tests	Date Ordered	Lab Sections	Status	Collected By/Rejected by	Date Checked
CSF	Appearance	2017-05-23 11:45:09	MICROBIOLOGY	Accepted	A-LIS Admin	2017-05-23 11:44:00

Results

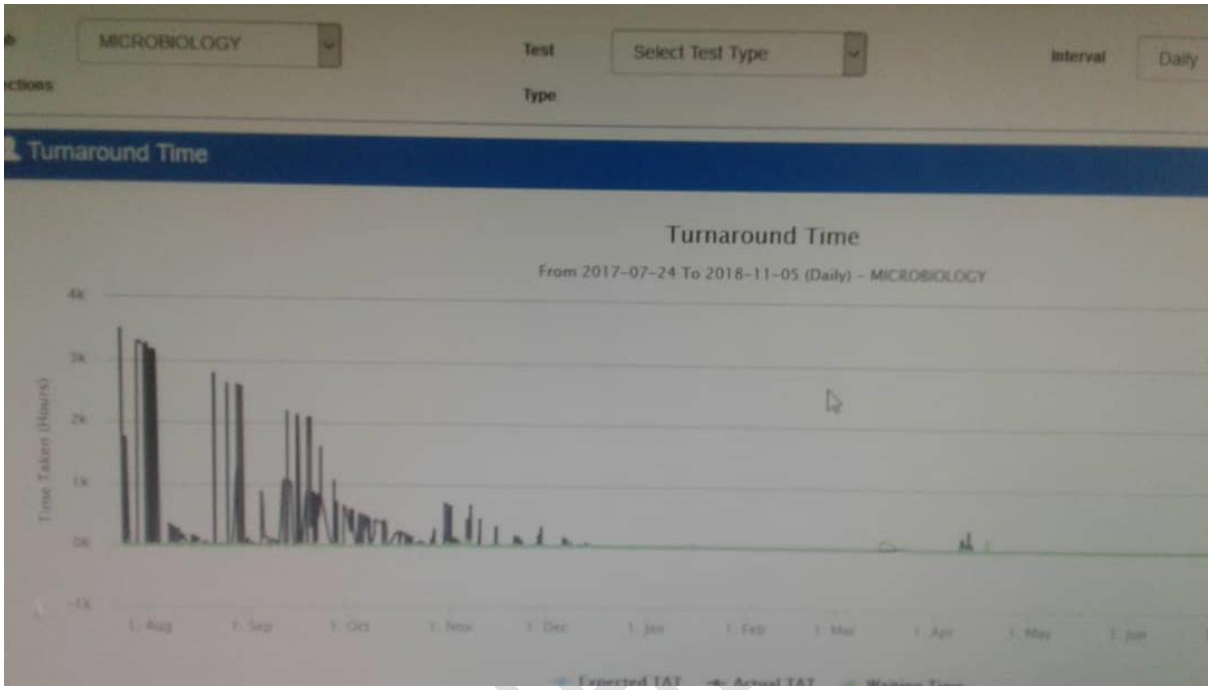
Test Type	Test:Result	Remarks	Performed By	Results Entry Date	Date Tested
Appearance		xx	A-LIS Admin		2017-05-23 11:45:45

Name:	**Name:** .....
Organization	**Organization** .....
Requesting Clinician	**Laboratory Manager**

Appendix 2: Prevalence rate



Appendix 3: Turnaround Time



Reviewed by:

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