Requirements for the development of the national Integrated Laboratory Information System

Table of Contents

1. General Laboratory Requirements

1. Comply with ISO 15189:2022, ISO 17025, ISO 9001:2015, ISO 15190:2020, ISO 17043, ISO 7101, CLSI document
2. Compliance with the Rwanda-adapted API assessment toolkit
3. Comply with the following regulations and standards: CAP, JCAHO, FDA, FACT, AABB and HIPAA
4. Follow and conform to the Laboratory handbook, SOPS, manuals and other laboratory forms
5. Refer to laboratory legacy systems

2. Patient registration

Req ID	Requirement	Description	Priority (M/D)
1	Add patient	Ability to add patients with demographics details, address details, insurance details, and unique patient identifier (UPID) from the health information exchange (HIE). Ability also to register a new patient without national ID i.e children, foreigners, unknown	M
3	View patient details	Ability to display patient details such demographics, permanent and residence address, contacts, using different identification as captured during registration.	M
4	View patient lab history	Ability to display patient lab history in conformity with role-based mechanisms and data protection.	M
5	Edit patient details	Ability to modify or update patient details	M
6	Patient deactivation	Ability to deactivate a patient in case of duplication	M

* *M: Mandatory ; D: Desired*

3. Lab order management

Req ID	Requirement	Description	Priority (M/D)
1	Search patient	Search patient by patient details such as National ID, Patient ID, Names, phone number	M
2	Display patient details	Ability to display patient details such demographics, permanent and residence address, contacts, etc..	M
4	Display available tests	Ability to display available tests. Tests are displayed by lab service(department) and its ID, test ID, test name and the list of subtests and their Ids and the price	M
5	Select lab test	Ability for the clinician to select nature of specimen (routine, urgent etc..) and tests	M
6	Save lab test order	Save the ordered lab tests and the order changes the status to requested. The lab order information will follow the existing SOP	M
7	Edit lab test order	Ability to edit lab order while it is still in requested status	M

8	View lab requests and specific lab order details	Ability to view lab orders by department, by requester, patient, date range, status, TAT status, lab order ID etc...	M
9	Cancel lab test order	The ability to cancel lab order or specific lab tests within the lab order while it is still in the requested status. Cancel should provide the ability to select reasons and comments for cancelation	M
10	Create lab test	Create lab exams by minimally specifying lab department, Lab department ID, test name, test ID, test description and subtests and ID for each subtest and test statuses, price, critical values, normal ranges, TAT, etc.. according to lab handbook.	M
11	Modify lab test status	Ability to modify lab test status (available, not available, deactivated, inactive), lab test status change should reflect date of change, reason and comments for change and role-based	M

4. Sample registration/collection

Req ID	Requirement	Description	Priority (M/D)
1	Search patient	Search patient by patient details such as National ID, Patient ID, Names, phone number	M
2	View lab request	Ability to display lab request details (patient details, requester details such as Names, department, Phone Number; request time), payment details, urgency	M
4	Display available tests	Ability to display available tests. Tests are displayed by lab service(department) and its ID, test ID, test name and the list of subtests and their Ids and the price together with container type code	M
5	Generate sample ID code	Generate sample Identification including patient ID, Barcode/QR code and patient name	M
6	Print sample ID	Ability to print sample identification with barcode/QR code	M
7	Create sample manifest	Ability to create sample manifest with a list of samples and their details together with sample barcode and manifest barcode	M
8	View sample manifest details	Ability to display manifest details	M

5. Sample packaging and shipment

Req ID	Requirement	description	Priority (M/D)
1	Sample tracking at source	At the source site for Bulk samples: Ability to record identification details of the transporter, shipment details, picking time, destination, and expected delivery time and step by step tracking of the sample	M

2	Packaging condition	Ability to record packaging details such as temperature and triple packaging.	
3	Change of route	Ability to record the change of route in transit, including reasons for rerouting.	M
4	Incident report	Ability to create an incident report in case of damaged or lost samples	M

6. Sample reception and internal dispatch

Req ID	Requirement	description	Priority (M/D)
1	Search shipment manifest	Search for shipment manifest by manifest code or barcode or QR code	M
2	Display and view shipment manifest	display details of a specific sample by label ID, barcode or QR code and View the contents of the manifest (list the attributes of the manifest)	M
3	Receive manifest in bulk mode	Receive manifest in bulk mode	M
4	View sample details	Ability to view all the details of the sample (including details/attribute of the sample)	M
5	Receive samples	Receive samples one by one. (include reception details such as temperature, date, status, etc...)	M
6	Validation rules	Ability to apply validation rules to avoid duplication of samples received	M
7	Sample rejection	Ability to reject samples within a manifest that does not pass rejection criteria (including rejection criteria list here) by providing reasons (among predefined reasons) for rejection and comments	M
8	View of rejected samples	Ability to view rejected samples and rejection details	M
9	Get new samples	Ability to request and send a new sample to replace the rejected one.	M
10	Sample reception reports	Ability to generate sample reception reports: - Detailed Daily report (Received samples, Dispatched samples to different lab sections/units, Samples not dispatched) - Generate a reception report based on date ranges.	M
11	View manifest and samples	Ability to view manifest and samples by various filters and status (date range, received, unreceived, rejected...include all states)	M
12	Rejection criteria	The rejection criteria list must be configurable	M
13	Internal sample dispatch	Ability to track sample received and dispatched into the service, including details and status of sample at reception and details of the sample as received by the service, the details of both the receptionist and receiver in the service, and prevent sample dispatch if not yet received.	
14	Conditions for sample reception	Ability for the system to prevent sample testing if not received by the lab service	M

	and testing in the service		

7. Services/Health facility

Req ID	Requirement	description	Priority (M/D)
1	Laboratory units	Ability to accommodate the various services/units of the National reference laboratory and health facility laboratories. The list includes but is not limited to: - Bacteriology - AMR Surveillance - Parasitology - Biochemistry - Hematology - Serology - Histopathology - Cytology - Medical genetics - Molecular biology - Toxicology - Mycobacteriology - Immunology - Genomics - Entomology - Mycology	M
2	Facility and laboratory set up	Ability to set up and configure facility and laboratory	M
3	Lab unit specificities	Ability to accommodate specificities of each laboratory unit according to the manuals, handbook, SOPs and process flow.	M
4	Service configuration and set up	The system should allow administrators to configure and set up new tests and services.	M
5	Lab test set up	Ability to set up lab test type with services, steps, turnaround time on each step, flag critical results, reference ranges, units, results type, reportable and non-reportable results etc, and ability to suggest other required tests depending on the results of the previous step, notifications to the lab test requester by SMS and emails; possibility to add comments to the results.	M
6	Sample tracking	The system should be able to track (i.e status) the specimen location throughout the preanalytic, analytic, and postanalytic phases.	M
7	Worksheet generation	Ability to generate sample batch list (worksheet)	M

8	Configure details of Pre-analytical, analytical and post-analytical Phases	Ability to record all the details of each step in the pre-analytical, analytical and post analytical phases for each laboratory unit with reference to the laboratory handbook and SOPs.	M
9	Lab results	Ability to record and validate results based on laboratory testing process steps.	M
10	Flagging critical results	Ability to flag critical results and communicate based on roles and responsibilities.	M
11	Automated reading of results	Ability to read results from lab instrument either through the instrument interface or directly from the machine	M
12	Manual results inputs	The system should allow the manual input of results and display of results of previous encounters.	M
13	Edit lab results	Ability to edit lab results before validation with audit trail capability while keeping previous results	M
14	Results ranges	Ability to accommodate and differentiate results in normal ranges, out of ranges and critical ranges	M
15	Turn Around Time	Ability to create and track turnaround time of each step in the lab processing	M
16	Raw values	Ability to provide both raw values results and interpreted results including numeric, numeric and text with text interpretations, json, csv, and other attachment results.	M
17	Notifications	Ability to send notifications such as SMS, Email or alerts at predefined steps, intended receiver, urgency and criticality.	M
18	Print results	Ability to print test results in user friendly format/template to PDF, HTML,JPEG etc..	M
19	Results interpretation	Ability to accommodate interpretation of results using AI technologies	D

8. Pathogen monitoring

Req ID	**Requirement**	**description**	**Priority (M/D)**
1	Traveler Registration & Consent	Provide a user-friendly interface for travelers to register and give consent for pathogen testing.	M
2	Capture Travel Details	Collect traveler origin, transit countries, and demographics crucial for strain mapping.	M
3	Unique Sample Identification	Generate a unique ID for each individual sample across the system.	M
4	Sample Pooling Algorithms	Implement automated pooling (e.g., double pooling) to optimize testing resources and efficiency.	M
5	Worksheet generation	Ability to generate sample worksheet	M

6	Integration with PCR platforms	Receive test outputs directly from PCR machines without manual entry.	M
7	Wastewater Sample Management	Register, track, and process wastewater samples from aircraft/points of entry,/Hospitals	M
8	Multi-Pathogen Support	Support data structures and workflows for pathogens beyond COVID-19.	M
9	Automated Reporting	Generate automated test and sequencing reports (individual and pooled).	M
10	Real-Time Dashboard	Provide a live dashboard tracking sample status, test results, and alerts.	M
11	Pooling Strategy Configuration	Enable adjustments to pooling strategies (number of samples per pool, double pooling, etc.)	M
12	API Endpoints for External Integrations	Provide REST/JSON/HL7/ FHIR APIs for integration with other public health or transit systems.	M
13	Automated Alerts for Positive Results	Send alerts (e.g., email, SMS, in-app) immediately upon detection of a positive sample.	M
14	Strain Distribution Reports	Ability to link strain/variant with metadata	M
15	Sample Rejection Logging	Track and record reasons for sample rejection (insufficient volume, contamination, etc.).	M
16	Sample tracking	Maintain full documentation of sample transfers, from collection to sequencing.	M
17	Multilingual Interface	Provide at least English and French support on the user interface platform.	M
18	Configurable Sample Types	Accommodate various sample types: nasal swab, saliva, blood, environmental samples, etc.	M
19	Time-Stamped Notifications	Include precise timestamps in system-generated messages and alerts.	M
20	Daily Statistical Summaries	Automatically generate daily reports on tested samples, positivity rates, and variants updates.	M
21	Real-Time Positivity Monitoring	Display immediate positivity trends (by flight, by region) as samples are processed.	M
22	Historical Trend Analysis	Enable storage and comparison of testing data over time to identify patterns or surges.	M
23	Secure Third-Party Lab Collaboration	Share data with external partner labs under restricted permissions and review processes.	M

9. Quality assurance

Req ID	Requirement	description	Priority (M/D)
1	Deviation/Non-Conformities Management	• The system must allow for the recording, tracking of deviations, non-conformities, corrective and preventive actions. • The module must be integrated with the LIS workflow, ensuring deviations are linked to test results, sample processing, equipment, and personnel. • Ability to log a new deviation or non-conformity • Attachment of supporting documents, images, or reports. • Ability to create and assign corrective and preventive actions linked to a deviation. • Verification and closure of corrective and preventive action after effectiveness review. • Generate corrective and preventive actions reports	M
2	Complaint Management	• The system must allow logging and tracking complaints from clients. • Ability to log a new complaint to designated personnel or department based on oot cause analysis (RCA) if the complaint involves non- the complaint (Open, In Progress, Resolved, Closed). d approval before closing a complaint. • Maintain a complete audit log of complaint records, actions taken, and resolutions. • Generate complaint trend analysis reports for quality improvement	M
3	Document Management	• Create a new document in Microsoft Office • Upload and download the document • Allow approval of the document • Open and edit the document • Tabs to view current quality documents in use per document category • Make a document obsolete • Document manager (document file, version, revision, changed on and changed by)	M

10. Biobank

Req ID	Requirement	description	Priority (M/D)
1	Sample Management	Allows biobank to efficiently store and track various types of samples along with associated metadata. It enables tracking of samples' locations, traceability, and	M

		the Ability to link samples from the same patient; the ability to record an incident report related to any damaged samples.	
2	Quality Control	Ability to record the quality control results of stored samples at regular intervals; ability to flag samples stored beyond the expected period (Av 5 Years).	M
3	Access Control and Security	Ensure that sensitive data is protected through access control mechanisms and security measures. Allow different levels of user access based on roles and permissions, ensuring data privacy and confidentiality.	M
4	Data Query and Reporting	Offer powerful search, query capabilities to explore samples and associated data. Allow users to generate customizable reports, export data for analysis, and visualize results, speeding up data-driven research and discovery.	M
5	Dashboard	Provide a live dashboard of stored samples and their types based on role access.	
6	Performance and Scalability	Depending on the size and expected growth of the biobank, the system should be able to handle large volumes of data.	M

11. Proficiency testing

Req ID	**Requirement**	**description**	**Priority (M/D)**
1	General Requirements	• The e-PT should support the integration of proficiency testing workflows. • The system must comply with relevant regulatory standards and guidelines for proficiency testing. • The interface should be user-friendly and intuitive for laboratory personnel. • Record and track international PT for NRL and lab network	M
2	Participant Management	• Ability to add new PT participants with details, including Laboratory name, contact info, region, etc. • Ability to update/edit participant information. • Ability to deactivate or archive participants without deleting history.	M
3	PT Administrator	• Ability to add PT Manager details (name, contact, assigned schemes etc..). • Ability to update or deactivate PT Managers. • Ability to assign PT Managers to specific schemes or surveys. • Ability to configure PT participants • Ability to add or update PT participants	M

4	Test Kit Management	• Ability to add test kit details: name, lot number, manufacturer, expiry date etc……. • Ability to add the Internal control status and the analyzer name • Ability to edit or deactivate test kits. • Ability to generate a Test Kits Report including usage and distribution history.	M
5	PT Survey and Scheme Management	• Ability to create and configure PT surveys: Survey name, code, start/end dates, assigned schemes. • Ability to assign schemes to specific analytes (e.g., Complete Blood Count, Liver Function Test). • Ability to define and manage acceptable value ranges or evaluation criteria per parameter. • Ability to configure scoring models per discipline: Qualitative and quantitative methods with target values and acceptable ranges. • Ability to track and manage multiple testing schemes. • Ability to support reference values from peer group means, expert-defined ranges, or method-specific targets.	M
6	Enrollment and Assignment	• Ability to enroll participants into surveys/schemes. • Ability to assign participants specific test kits and panels. • Ability to track enrollment history per participant and survey.	M
7	Shipment Management	• Ability to add shipment details: Courier name, tracking number, dispatch date, destination, package contents etc..... • Ability to enroll shipment to selected participants. • Ability to edit/update shipment records. • Ability to track and mark shipment status (in transit, delivered, etc.). • Ability to upload and attach shipping documents. • Ability to generate Shipment Reports and Shipment Responses Reports.	M
8	Response Monitoring and Reminders	• Ability to monitor response submission status. • View response timelines and history for each participant. • Ability to send automatic and manual reminders to non-responding laboratories. • View submission deadlines and delays.	M
9	Data Entry and Submission	• Participants can submit results securely via web interface.	M

		• Admin users can enter responses on behalf of participants. • Validation checks on data inputs to ensure completeness and correctness.	
10	Scoring and Evaluation	• Ability to evaluate participant responses against reference values and scoring rules. • Ability to automatically calculate scores and assign performance ratings. • Ability to generate and store Participant Performance Reports and detailed evaluation results. • Ability to score manually with audit trail history	M
11	Reporting and Analytics	• Ability to generate the following reports: o Shipment Reports o Shipment Response Reports o Participant Performance Reports o Participant Trend Reports (performance over time) o Corrective Action Reports o Test Kits Report o Annual Performance Reports by participant, facility type, scheme, or region • Reports should be exportable in PDF, Excel, and CSV formats. • Ability to generate charts and dashboards for performance monitoring and trends. • Ability to apply filters (by date, region, lab type, test type, etc.) for custom reports.	M
12	Data Import and Export	• The e-PT should facilitate importing PT sample data from external sources (e.g., PT providers) in various formats (e.g., CSV, XML). • The system should enable the export of test results and data to external PT providers or regulatory bodies in standard formats.	M
13	Result Entry and Analysis	• The e-PT should provide a secure interface for entering PT results manually or automatically • The system should support the calculation of statistical metrics such as mean, standard deviation, and Z-scores. • Users should be able to compare individual laboratory performance against peer group data.	M
14	Reporting and Feedback	• The e-PT should generate comprehensive reports on PT results, including graphical representations of performance trends. • Reports should be customizable to meet specific laboratory and regulatory requirements.	M

		• The system should provide feedback mechanisms to inform laboratories of their performance and suggest areas for improvement	
15	Security and Access Control	• The e-PT system should ensure data security and integrity through role-based access control (e.g., Admin, PT Manager, Lab User). • Only authorized personnel should be able to view, enter, or modify PT data. • The system must implement secure user authentication, including password protection. • A comprehensive audit trail should be maintained to log all data modifications and user actions related to PT activities.	M
16	Performance and Scalability	• The e-PT should handle large volumes of PT data efficiently without compromising performance. • The system should be scalable to accommodate future growth in PT program participation.	M
17	Backup and Recovery	• The e-PT should have robust backup and recovery mechanisms to prevent data loss. • The system should support regular backups of PT data and provide quick recovery options in case of system failures.	M
18	System Administration	• Configurable lists (e.g., lab types, test kits, regions). • System backup and restore functionality. • Configurable survey templates for repeat use.	M

12. HTS (HIV testing service)

Req ID	Requirement	description	Priority (M/D)
1	Site information	Ability to capture site related information including but not limited to health facility information, algorithm, testers, reporting period.	M
2	Test details	Ability to capture test details including but not limited to start date, end date, test kits, lot number and its expiration.	M
3	Test Kits Results details	Ability to capture the number of Reactive, Non-Reactive and invalid results from entry points	M
4	Final Results details	Ability to capture number of positive, negative and Indeterminate results from entry points	M
5	Aggregated reports	Ability to generate aggregated reports and analytics. Refer to legacy HTS tool.	M
6	Aggregation Results	Ability to evaluate algorithm performance	M

13. Audits and certification/ODK

Req ID	Requirement	description	Priority (M/D)
1	ODK checklist	System shall allow to capture ODK checklist. Refer to ODK checklist	M
2	Analysis and reporting	Ability to analyze ODK checklist and produce reports and dashboards.	M

14. Quality control/Retesting

Req ID	Requirement	description	Priority (M/D)
1	Record retesting sample details	Ability to record sample details for retesting	M
2	Record first controller results	Ability to record sample testing results by first controller	M
3	Record second controller results	Ability to record sample testing results for the second controller	M
4	Generate a quality control/retesting report	Ability to generate testing and quality control/retesting reports	M
5	View the report at sites	Preview and print retesting reports at sites.	M

15. Internal quality control/Statistical Quality Control (SQC)

Req ID	Requirement	Description	Priority (M/D)
1	QC Data Entry and Management	• Support manual entry or instrument interfacing of QC data. • Display lot number and expiration date during QC entry. • Ability to activate QC lot	M
2	Auto Verification & Validation	• Suspend patient testing when QC fails • Check QC against lab-defined criteria, including SD.	M
3	QC Rule & Limits Configuration	• Support multiple Westgard rules • Support lab-defined acceptable ranges • Allow technologists to mark QC as reviewed and take corrective actions.	M
4	QC Trending, Review & Analysis	• Display Levey-Jennings graphs • Provide monthly and user-defined QC • Provide QC performance reports	M
5	Alerts, Flags & Notifications	• Flag QC results falling out of the expected ranges • Ability to document corrective action	M

		• Track who performed and who reviewed each corrective action.	
6	Standards and Reagents Management	• Ability to record standard and reagent preparation • Ability to track storage and expiration • Ability to monitor Quality control • The LIS shall allow users to create and configure new standards and reagents with relevant metadata (e.g., name, batch number, concentration, preparation date, expiry date, storage conditions). • The LIS shall support the assignment of unique identification numbers for each standard and reagent. • The LIS shall provide predefined templates for commonly used reagents and standards, customizable as per laboratory protocols. • The LIS shall support stepwise documentation of reagent preparation procedures. • The LIS shall enable barcode generation and printing for labeling prepared reagents. • The LIS shall track reagent inventory levels and notify users when stock is low. • The LIS shall enforce expiration date tracking and prevent the use of expired reagents and prevent saving batch when standard and reagent is not used • The LIS shall track reagent usage across different tests and procedures. • The LIS shall allow the linking of reagents to Quality Control (QC) results and generate reports on reagent performance. • The LIS shall support data export in formats such as CSV	M

16. Instrument management

Req ID	Requirement	description	Priority (M/D)
1	Register new laboratory instrument	The system should allow users to register new laboratory instruments with details such as: o Instrument Name o Model Number o Serial Number o Manufacturer o Date of Installation o Assigned Laboratory/Department o Assigned Users o Maintenance Schedule	M

		○ Lifespan	
2	Categorize instruments	Ability to categorize instruments by type, location, and status (active, under maintenance, decommissioned).	M
3	Unique identification for instrument	Maintain a unique identification number for each instrument.	M
4	Update status	Real-time instrument status updates (Available, In Use, Maintenance, Out of Service).	M
5	Calibration and maintenance notifications	Notify users about instruments that are due for calibration or maintenance**.**	M
6	Preventive maintenance	Schedule and track preventive maintenance (PM) and calibration activities.	M
7	Automatic reminders	Generate automatic reminders and alerts for due maintenance and calibration.	M
8	Record maintenance actions	Record maintenance actions, including: ○ Date of Service ○ Technician/Engineer Name ○ Service Details ○ Issues Identified & Resolved ○ Next Maintenance Due Date ○ Capture downtime events and duration ○ Track root causes of failures.	M
9	Restricts use of instruments	Restrict use of instruments that are not calibrated or are overdue for maintenance.	M
10	Retrieve QC data	Ensure LIS can retrieve QC data from connected analyzers.	M
11	Flagging of instrument errors and QC failures	Enable real-time flagging of instrument errors and quality control failures.	M
12	Concurrent instrument connections	Support concurrent instrument connections and data processing**.** Allow batch processing for high-throughput instruments.	M
13	Reporting	Generate reports for: ○ Instrument maintenance ○ Calibration history ○ Instrument downtime & utilization ○ Quality control deviations • Users shall be able to generate customized reports based on instrument type, date range, or compliance status. • Reports shall be exportable in PDF, Excel, and CSV formats**.**	M
15	Dashboards	• Provide interactive dashboards for real-time instrument monitoring.	M

		• Provide a **centralized dashboard** for instrument monitoring. • Allow **color-coded instrument statuses** (Green: Available, Yellow: Maintenance Due,	
16	Interoperability with Other systems	• Ability to integrate MEMMS (Medical Equipment Management and Maintenance System) with LIS	M

17. Inventory/Stock management

Req ID	Requirement	description	**Priority (M/D)**
1	Inventory/Stock management	• Receive items • Receive request • Disburse items • Registering new items • Generate real time inventory reports • Alert when stock is about to expire • Alert when the stock is about to finish • Differentiate Donation from purchases • Record the value of the equipment	M

18. Research and development management

Req ID	**Requirement**	**description**	**Priority (M/D)**
1	The R&D module will support	• Registration and tracking of research projects • Sample and data management for research • Collaboration and data sharing • Research data analysis and visualization • Compliance with ethical and regulatory guidelines • Integration with external databases and systems (e.g., DHIS2, GenBank) • Research Project Management: Allow users to create, register, and track research projects, including project title, objectives, principal investigators, funding sources, and collaborators. • Study Protocol Management: Enable storage and version control of research protocols, approvals, and amendments. • Sample Management: Track research samples, including collection, storage, and usage, with metadata like sample type, condition, and expiration.	M

		• Data Collection and Entry: Provide structured forms for entering research data, linking to study participants, and enabling bulk data import • Integration with Laboratory Tests: Allow research studies to request tests directly from the LIS and receive results. • Data Analysis and Visualization: support export to analytical software and provide real-time dashboards • Collaboration & Access Control: Provide multi-user roles, permissions, and collaboration tools for shared research projects. • Ethics & Regulatory Compliance: Ensure adherence to regulatory requirements by enforcing required approvals before data access. • Audit Trail & Version Control: Maintain a detailed log of data modifications, approvals, and study changes. • Data Export & Reporting: Enable customized data export in formats like CSV and Excel for external use • The system should support multiple research projects and large datasets without performance degradation. • Provide an intuitive, web-based interface with user-friendly navigation and accessibility features • Ensure encrypted data storage and role-based access control • The system should support concurrent users with minimal latency for data retrieval and analysis • Ensure research projects obtain necessary ethical approvals before data collection. • Allow data archiving based on predefined regulatory policies. • Enable data sharing with public health and surveillance systems. • Enable export and direct analysis of research data. • Researcher Create, manage, and analyze research projects. • Principal Investigator (PI) Approve study protocols, monitor research progress, and ensure compliance. • Laboratory Technician Process and manage research samples and test results. • Data Manager Ensure quality and integrity of research data.	

		• Regulatory Officer Monitor compliance with ethical and legal requirements. • System Administrator Manage user accounts, security, and system configurations.	

19. Integration and interoperability

Req ID	Requirement	description	Priority (M/D)
1	Integration with external systems	Ability to integrate with Electronic Medical Records Systems, surveillance systems and point of care systems and health information exchange, SMS, Payment systems, Medical Equipment Management and Maintenance System (MEMMS), HIE, blood bank etc…	M
2	Instrument interfacing	Ability to interface with laboratory analyzers directly or indirectly using internationally recognized standards such as but not limited to RS-232/USB/TCP/IP port, ASTM or Hl7, Connection between analyzer and interface device	M
3	API provision	Ability to provide API and its documentation on predefined features and information	D

20. System architecture

Req ID	Requirement	description	Priority (M/D)
1	Platform independence	Ability to be hardware and software platform independent	M
2	Scalability	Ability to be upwardly scalable in the event of increased usage of the system such as in case there is an increased number of facilities and users	M
3	flexibility	Ability to be flexible to accommodate the change requirement to an already existing function to meet business/ regulatory needs	M
4	Web based	Ability to be a centralized web-based system	M
	Mobile app	Ability to support mobile app capabilities	
5	Offline mode	System should allow people to work in an offline mode at a local facility and be able to synchronize with central system at predefined schedule.	M
6	System technology stack	The system development should use a programming languages, frameworks and databases that are popular and common in Rwanda to allow ease maintenance and knowledge transfer.	M
7	User friendliness	Ability to have a logical Graphical User Interface that is user friendly and responsive. The menus' structure	M

		shall be logical given content and workflow. The screens shall be consistent with regard to layout, wording, and use of color.	
8	Languages	Ability to accommodate multiple languages such English and French	M
9	Application Backup	Ability to backup and restore the application, its parameters and settings.	M
10	Storage backup	Ability to backup and restore the database, its parameters and settings.	M
11	Disaster recovery	Ability to provide disaster recovery capability. Ability to initiate failover/switchover to secondary site in the event of critical system failure at primary site	M
12	Performance and response time	The System shall exhibit high performance capability and shortest response time in seconds	M

21. Security requirements and System administration

Req ID	**Requirement**	**description**	**Priority (M/D)**
1	Security	1.The new system must comply with Government of Rwanda's Information Security Policy and data confidentiality and privacy law. 2. The system should also support the need to restrict user access to groups of data elements. Individual users need to be aligned with a specific health facility with users only having the ability to view or assess warehouses or inventories in their assigned location. 3. Ensure optimum uptime 24x7 availability, performance, and security of the infrastructure and assets of the system.	M
2	Confidentiality	The system shall perform the following: 1. Provide access for authorized users 2. Provide ability to authorized users to view confidential data. 3. Anonymized data that is exported and from the system 4. Log out the user after specified time of inactivity 5. Provide encrypted communication between components 6. Ability to store passwords in a strong encrypted form	M
3	Authentication	The system should perform the following 1. Notify the user to change their password the first time they log in	M

		2. Adhere to complex password requirements 3. Provide mechanism to allow the user to securely change their password 4. Notify the user of password change to their account 5. Allow the user to reset their password in a secure manner 6. Lock the user out after a specified number of wrong password attempts 7. Notify the user if their account is locked due to wrong password attempts 8. Provide role-based access to the system 9. Ability to support a workflow approval process that is flexible to assign multiple approvers based on the service	
4	Audit trail and logs	The system should perform the following: 1. Ability to capture all system and user-initiated actions/events in an audit trail. 2. Ability to capture alterations including the before and after status, e.g. interest rate changes, date of change and indicate the personnel 3. Ability to prevent any amendment/deletion of events/activities captured in the audit trail 4. Log system logins and logouts 5. Record all authentication violations 6. Log all activities performed by the user 7. Log access to views of individual client records 8. Log access to data summaries, reports, analysis, and visualization features 9. Log exchange of data with other systems 10. Generate analysis of the usage of different system features and reports 11. Log all data and system errors	M
5	User management	The system should perform the following: 1. Ability to create a role profile 2. Ability to assign rights and permissions to a role/profile 3. Ability to let administrator update/delete role profile and rights and permission associated with the created role/profile 4. Ability to create and edit a user with user details such as demographics, address, identification etc…	M

		5. Allow roles to be associated with specific geographical areas and/or health facilities 6. Allow cascading user management and assignment of roles, 7. Allow the user to change their own password 8. Allow allowed users to enable and disable another user 9. Allow admin users to request password reset 10. Ability for users to reset passwords when forgotten 11. Ability to allow a user with valid credentials to log in by providing a way 12. Ability to allow a user to log out and/or to enforce idle timeout after administrator defined time (per policy) 13. Ability to prompt the user to change the password after a specific period as per policy/instructions. 14. Ability to provide multifactor authentication 15. Notify the user to regularly change their password 16. Allocate each user to one of more roles 17. Support definitions of unlimited roles and assigned levels of access, viewing, entry, editing, and auditing	
6	General System requirements	The system should perform the following: 1. Ability to handle multi-user login. The system shall allow thousands of users to log on to the system concurrently. 2. Ability to multi-task. The system shall accept process and grant requests of all concurrent users with acceptable response times	M
7	Usability System requirement	The system should perform the following: 1. Provide informative error messages and tooltips. 2. Alert the user when navigating away from the form without saving 3. Support real time data entry validation and feedback to prevent data entry errors from being recorded 4. Simplify data recording through predefined drop-down or searchable lists, radio buttons, check boxes 5. Support multiple languages	M

		6. Use industry standard user interface practices and apply them in a consistent manner throughout the system 7. Easy to learn and intuitive to enable users to navigate between pages 8. Users are expected to be able to use the system productively with no training requiring only awareness of the availability of the system. 9. Provide access to on-line help	

22. API (American pathology informatics system standard) Conformance

Req ID	Requirement	description	Priority (M/D)
25.1	API LIS assessment toolkit	Mapping of requirements and system features to the Rwanda adapted API lab information system assessment toolkit : ADT & Registration Auditing Billing Clinician Record Collections/Specimen Procurement Communication Data Conversion Database Maintenance Foreign System Interfaces Instruments & Handheld Devices Inventory Labels & Barcodes Notifications & Warnings Orders Patient Record Regulations & Standards Management Reports Results Result Inquiry & Viewing Rules & Processing Support System Downtime User Interface Worklist & Worksheets Accession Numbers Collections/Specimen Procurement Labels & Barcodes Orders Order Entry & Format Patient Record Rules & Processing	M

		Send outs Autoverfication Provider Records Data Conversion Patient Inquiry Result Inquiry & Viewing Charting Quality Control Outreach Services Rules, Processing, & Workflow Send outs User Interface Multiple Lot Management Security Storage Processing/Tracking Statistical Reporting	

23. Reporting and analytics

Req ID	Requirement	description	Priority (M/D)
1	Generation of reports	Ability to generate a lab operations report for each functionality using various filters and ordering	M
2	Tracking of Key Performance Indicators	Ability to generate key performance indicators	M
3	Generate dashboards	Ability to generate various dashboards as per the user's needs.	M
4	Generate reports in different formats	Ability to generate and export reports in different formats, including Excel, CSV, JSON, PDF, HTML	M
5	Security and accessibility	Ability to generate and view reports based on the user's role.	M

24. Billing

Req ID	Requirement	Description	Priority (M/D)
1.	Laboratory billing process	Ability to record the costs for each Laboratory test	M
		Ability to match tests and their related costs	M
		Ability to create, view, update and print a proforma invoice	M
		Ability to update and upload payment details in the system	M
2	Generate a billing report	Ability to view and generate managerial reports related to the payments	M

25. Training Management

Req ID	Requirement	Description	Priority (M/D)

1	Personnel Training Management	• The system must allow for scheduling, tracking, and recording training reports for laboratory personnel.
		• Ability to create and manage training programs with details such as:
		  ○ Training title and description
		  ○ Training type (Onboarding, Refresher, Competency, etc.)
		  ○ Trainer details (Internal/External)
		  ○ Training schedule and duration
		  ○ Training format (Online, In-person, Workshop, e-Learning)
		  ○ Assign training to staff.
		• Maintain employee training records
		• Generate automated reminders for Training
		• Generate training reports
		• Ability to upload training attachments
			M

End