



MINISTRY OF HEALTH

**STATE DEPARTMENT FOR MEDICAL SERVICES
ADDENDUM 1**

Background and Informational Materials

A. BACKGROUND

0.1 NPHI Laboratory Information System

Laboratory data serves as the backbone of effective disease surveillance. By providing accurate and timely diagnostic results, laboratory data enables the early detection of infectious diseases, monitoring of outbreaks, and evaluation of public health interventions. This data is critical for identifying patterns of disease transmission, antimicrobial resistance trends, and potential public health emergencies. Furthermore, robust laboratory systems contribute to evidence-based decision-making and policy formulation, ensuring that health responses are both effective and targeted.

The Ministry of Health Kenya, with support from various development partners, has implemented Labware LIMS in 38 public health facilities, including 12 national and regional reference laboratories to anchor data driven responses to public health threats. One of the major challenges in utilizing this data has been slow uptake of data aggregation due to connectivity, infrastructure and lack of Interoperability and Standardization.

0.2 Objectives

- Optimize LIMS for quality data generation for Surveillance and Sample Referral through. This included: Updating LIMS instances for conformance to standards already developed by NPHL (LOINC and FHIR/REST API)
- Update of Labware LIMS deployments at Regional Reference Laboratories to support increasing demand for data

- Surveillance data for One Health approach to include Animal Health Regional Laboratories for surveillance
- Biorepository module development and customization: This will integrate with the sample referral system to form a complete chain of custody for specimens at reference laboratory

0.3 Expected Outcomes

- All National and Regional Reference laboratories utilizing standard nomenclature for unified reporting to KHIS and other systems.
- Dashboard with hierarchy of up-to-date testing data statistics from the national and regional testing laboratories
- Custom and standard reports for IDSR and WHO priority diseases
- FHIR REST API to support remote login integration from other client facing systems from referring facilities

B. INFORMATIONAL MATERIALS

0.3 The Legal, Regulatory, and Normative Context for the Information System

1. Primary Legislative Framework

The Digital Health Act (2023): This is the most critical pillar. It mandates the establishment of a Comprehensive Integrated Digital Health Information System. For the NPHI, this means the LIS cannot exist in a silo; it must be interoperable with the national health data exchange.

The Kenya National Public Health Institute (KNPHI) Order (2022): Established under Legal Notice No. 14, this gives the NPHI the legal mandate to coordinate "Disease Surveillance, Zoonotic Disease Management, and Laboratory Capacity." The LIS is the technical vehicle for this legal mandate.

The Health Act (2017): Provides the overarching structure for health service delivery. It requires all health providers (including national labs) to maintain accurate health records and "Health Information Management Systems."

2. Data Governance & Privacy (The "Guardian" Norms)

Because lab results are "sensitive personal data," the LIS must strictly adhere to:

Data Protection Act (2019): Administered by the ODPC (Office of the Data Protection Commissioner).

Data Minimization: Collecting only what is necessary for public health action.

Localization: Sensitive health data must generally be stored on servers located within Kenya unless specific exceptions apply.

3. Standards and Technical Norms

The LIS is shaped by "normative standards" that ensure data can be shared across the East African region and globally:

Kenya Health Data Governance Framework: Defines who "owns" lab data and how it can be shared between the NPHI and County Governments.

Interoperability Standards: Adoption of HL7 FHIR (Fast Healthcare Interoperability Resources) and LOINC (Logical Observation Identifiers Names and Codes) is now a formal requirement for any national-level health system in Kenya to ensure the LIS can "talk" to hospital systems.

ISO 15189:2022: While a technical laboratory standard, the LIS must be built to support the data integrity and traceability requirements necessary for the NPHI labs to maintain their international accreditation.

4. International Health Regulations (IHR 2005)

As a signatory to the WHO's IHR, Kenya is legally obligated to maintain "core capacities" for surveillance and response.

Timely Reporting: The LIS must be designed to facilitate the immediate notification of "notifiable diseases" to the WHO.

One Health Integration: Norms are shifting to require that the LIS eventually links with animal health and environmental data, reflecting the NPHI's role in the One Health strategic plan.

0.4 Existing Information Systems / Information Technologies Relevant to the Information System

Labware LIMS is the primary laboratory information system utilized in the scoped reference laboratories. This is implemented in the hospital networks and hosted locally within the health facilities .

The subsequent hospitals also utilize other health information systems for patient management billing and operation, all of which should communicate with the laboratory information system through the setout standards i.e. FHIR and LOINC (Kenya National Health Terminology Services)

Ministry of Health Kenya also mandates reporting to the Kenya Health Information System (KHIS) . The Laboratory information system report their data to the KHIS platform , however this needs standardization relevant to priority disease testing .

0.5 Available Training Facilities to Support the Implementation of the Information System

Training facilities are available at 3 sites :

- National Public Health Laboratories Nairobi
- Kenyatta National Hospital Nairobi
- Machakos Regional Reference Laboratory

0.6 Technical Requirements-Specifications

0.6.1 Software Specifications

Web LIMS: A web version (running on a browser) of the exact same LIMS , for remote access for remote Login and access by other non-Windows PC devices

Mobile LIMS: IOS and Android LIMS companions with full workflow connectivity to the main LIMS system at KNPHI reference laboratories. These will be used by the Mobile laboratories when referring specimens to the main laboratories

Terminology Compliance (LOINC): LOINC (Logical Observation Identifiers Names and Codes) is the global standard for identifying medical laboratory observations. The update should include mapping of all test menus in the facilities to LOINC standard as well as the results outcomes .

Interoperability Framework (HL7 FHIR): FHIR (Fast Healthcare Interoperability Resources) provides the structural framework for exchanging the data identified by LOINC.

Resource	Usage in Laboratory Context
DiagnosticReport	The primary container for the overall lab result, including conclusions.
Observation	Individual result components (e.g., glucose level, hemoglobin). Uses LOINC in the code element.
Specimen	Details about the sample (source, collection time, additive).
ServiceRequest	The laboratory order that initiated the testing.
Patient	Demographic details of the subject.
Practitioner	The clinician who ordered the test or the pathologist who verified it.

Quality Assurance : Support for ISO 15189:2022 (Medical laboratories — Requirements for quality and competence)

- Data Integrity: Systems must ensure that results are not altered during transmission from instruments to the LIS or from the LIS to the clinician
- Continuity Planning: New requirements in the 2022 version include mandatory downtime plans and continuity/emergency preparedness for the information system
- Release of Results: The LIS must track who authorized a result and manage the "pre-analytical, analytical, and post-analytical" phases of data flow

Data migration tool: For migrating data from previous versions of LIMS to the current version and identifying broken foreign key links and views.

Documentation: Provide detailed documentation with illustrations where necessary for the following :

- System Deployment
- System Administration
- User Manual

Reporting : Update of standardized Reports using LOINC standard as defined by :

- MoH 706 – Monthly laboratory workload and outcome summary report (excel)
- MoH 643 – Commodities Report
- AMR One health dashboard

Notification : Update LIMS to support configurable SMS and Email gateway notification for specimen and testing status via Oracom and Zepto gateways .

Security: Update security logins to the LIMS system to support two factor authentication and password reset for system users. This ensures users can recover their account in the event of a forgotten password.

Equipment interfacing: New and previous equipment not yet interfaced with LIMS for result transmission. These include (but not limited to)

- Hematology Analyzers – Full hemogram
- Biochemistry analyzers for Liver Function Test panel

- Blood and Stool cultures
- RNA and PCR analyzers at the facilities

0.6.2 Hardware Specifications

Item	Specifications	Quantity
Network Switch	Network switch : Layer 3 ,32 x 1GbE RJ45 ,16 X 2.5GbE RJ45 , 4 x 10G SFP+ , Switching Capacity 220 Gbps , 1.3" touchscreen	6
Network Switch	Compact, 5 X 2.5G PoE , 5W (AC/DC input) , 6.4W (PoE input) ,Switching Capacity 25 Gbps	6
Network Firewall	Network Firewall gateway, Application-Aware Layer 7 Firewall ,2.3 Gbps IDS/IPS Throughput, 6 X 2.5 GbE RJ45 WAN/LAN ,Quad-core ARM® Cortex®-A53 at 1.5 GHz, 3 GB, USB type C powered, Minimum 1 year IDS IPS subscription	6
Wifi Access Point	WiFi AP : 4 spatial streams , 2.5 GbE uplink, MIMO , Mobile app configuration, 2 x 2 (DL/UL MU-MIMO), 802.11be (WiFi 7) 7.3 Mbps to 4.3 Gbps (MCS0 - MCS13 NSS1/2, EHT 20/40/80/160/240). 2.5G PoE+ Adapter Surge, peak pulse, and overcurrent protection	8
UPS	UPS , 286Wh LiFePO4 battery, IP54 protection, 3 UK outlets 600W total (Surge 1200W) ,<10 ms UPS , AC Input 200~240V, 6A, 50/60Hz, 360W, 0-100% in 60 min , USB-C Output 1 port, 5/9/12/15=3A max, 20V=5A max, 100W max , mobile app management(ios and android)	12
UPS	UPS : 1024Wh ,Chemistry LFP ,10 ms UPS switchover , Outlet 4 x 1800W (Surge 3600W) , AC charging 1500W (1.5 Hr), 2 X 100w USB C , IP54 protection,mobile app management(ios and android) , Expandable modular battery capacity, 5 year warranty	6
UPS	UPS : 2500Wh ,Chemistry LFP ,15 ms UPS switchover , Outlet 4 x 1800W (Surge 3600W) , AC charging 1500W (1.5 Hr), 2 X 100w USB C , IP54 protection,mobile app management(ios and android) , Expandable modular battery capacity, 5 year warranty	2
Desktop Computer	Desktop - Tower PC, Intel Core i 5-12400, 8GB DDR4 3200,256GB SSD, Wifi 6e, 20 inch FHD Monitor - USB Keyboard ,Mouse, Windows 11	20
Label Printer	Label Printer - thermal transfer ,300dpi, USB + Modular Connectivity Slot ,Link-OS ZPL II; EPL 2; XML; ZBI; PDF Direct ,512MB Flash 256MB SDRAM	6
Barcode Scanner	Handheld Barcode scanner - 1D Laser, Single Scan Line , USB , Windows 11 compatible	12
Server	Server : 1U rack, Intel Xeon E-2436 2.9 GHz 6c/12t,Intel X550-T2,32GB(2X16) RAM, 2 X 480GB SATA 6G Mixed Use SFF , 4x 1GbE	4

	embedded NIC, remote mgt console /KVM	
Network Storage Server	Intel N150 ,16GB LPDDR5 4800Mhz, 2 X 2TB HDD ,M.2 2280 PCIe 3.0 X 3 , 2.5G intel i226-v, HDMI, USB - C	8
TV	TV - 55inch 4K LED ,Google Tv OS , Ethernet ,Brightness: ~300 nits	6
Internet	Safaricom 5G Router with ethernet , 1 year , 250mbps	7

0.7 Implementation

0.7.1 Implementation Sites LIMS Software

NPHI Referral Laboratories Nairobi (9 Laboratories) Kisian TB Referral Laboratory Kenyatta National Hospital Wajir Regional Referral Laboratory Machakos Regional Referral Laboratory Coast General Hospital Laboratory	Kitale Hospital Laboratory Thika Level 5 Laboratory JOTRH Laboratory Kisumu Embu County Referral Hospital Laboratory Karatina Sub-County Hospital Makueni County Referral Hospital
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0.7.2 Implementation Sites LIMS Hardware

System Inventory tables.

Item	Sites	Quantity
Network Switch	NPHI, Makueni ,Coast General ,Embu, Machakos Reference Laboratory ,	6
Network Switch	NPHI , Kisian Reference Laboratoey	6
Network Firewall	NPHI, Makueni ,Coast General ,Embu, Machakos Reference Laboratory , JOTRH Laboratory Kisumu	6
Wifi Access Point	NPHI, Makueni ,Coast General ,Embu, Machakos Reference Laboratory , JOTRH Laboratory Kisumu	8
UPS	NPHI, Makueni ,Coast General ,Embu, Machakos Reference Laboratory , JOTRH Laboratory Kisumu	12
UPS	NPHI, Makueni ,Coast General ,Embu, Machakos Reference Laboratory , JOTRH Laboratory Kisumu	6
UPS LiFePo	NPHI	2
Desktop	NPHI, Makueni ,Coast General ,Embu, Machakos Reference	20

Computer	Laboratory , JOOTRH Laboratory Kisumu	
Label Printer	NPHI, Makueni ,Coast General ,Embu, Machakos Reference Laboratory , JOOTRH Laboratory Kisumu	6
Barcode Scanner	NPHI, Makueni ,Coast General ,Embu, Machakos Reference Laboratory , JOOTRH Laboratory Kisumu	12
Server	Makueni ,Coast General ,Embu, Machakos Reference Laboratory	4
Network Storage Server	NPHI, Makueni ,Coast General ,Embu, Machakos Reference Laboratory , JOOTRH Laboratory Kisumu	8
TV	NPHI, Makueni ,Coast General ,Embu, Machakos Reference Laboratory , JOOTRH Laboratory Kisumu	6
Internet	NPHI, Makueni ,Coast General ,Embu, Machakos Reference Laboratory , JOOTRH Laboratory Kisumu	7

0.7.3 Implementation Schedule

Week	Component	Site
1-2	Pre-implementation site assessment	All
1 - 2	Software Customization (Upgrade , FHIR & LOINC , reporting to KHIS)	NPHI Referral Laboratories Nairobi (9 Laboratories) Kenyatta National Hospital
2-3	Hardware Delivery	All sites
3	Testing and validation	NPHI Referral Laboratories Nairobi (9 Laboratories) Kenyatta National Hospital
4-5	Software Customization (Upgrade , FHIR & LOINC , reporting to KHIS)	Machakos Regional Referral Laboratory Thika Level 5 Laboratory
6-7	Software Customization (Upgrade , FHIR & LOINC , reporting to KHIS)	Embu County Referral Hospital Laboratory Karatina Sub-County Hospital Makueni County Referral Hospital
8-9	Software Customization (Upgrade , FHIR & LOINC , reporting to KHIS)	Kisian TB Referral Laboratory JOTRH Laboratory Kisumu Coast General Hospital Laboratory
10-11	Software Customization (Upgrade , FHIR & LOINC , reporting to KHIS)	Wajir Regional Referral Laboratory Kitale Hospital Laboratory
12-14	Post install site evaluations , bug fixing	All sites
15	User training	Nairobi
16	User training	Machakos

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