Kenya Laboratory Capacity Mapping Report

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HARAMBEE

MINISTRY OF HEALTH

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ACRONYMS

AES	Advanced Encryption Standard
AIDS	Acquired Immune Deficiency Syndrome
APHL	Association of Public Health Laboratories
ASF	African swine fever
AST	Antibiotic Susceptibility Testing
CDC	Centers for Disease Control and Prevention
CFT	Complement fixation test
CGHR	Center for Global Health Research
CIPDCR	Center for Infectious and Parasitic Diseases Control Research
COC	Clinical Officers Council
CRDR	Center for Respiratory Diseases Research
CVL	Central Veterinary Lab
DGHP	Division of Global Health Protection
DGHT	Division of Global HIV/AIDS and TB
DHIS2	District Health Information System 2
DVS	Directorate of Veterinary Services
ELISA	Enzyme-Linked Immunosorbent Assay
FMD	Foot and Mouth Disease
GOK	Government of Kenya
GHSA	Global Health Security Agenda
HF	Health Facility
HIV	Human Immunodeficiency Virus
ICT	Information and Communications Technology
ILRI	International Livestock Research Institute
KEMRI	Kenya Medical Research Institute
KETRI	Kenya Trypanosomiasis Research Institute
KMLTTB	Kenya Medical Laboratory Technicians and Technologists Board
KNDI	Kenya Nutritionists and Dieticians Institute
KNH	Kenyatta National Hospital
LCS	Laboratory Capacity Score
LIS	Laboratory Information System
MFL	Master Facility List
MOH	Ministry of Health
MTRH	Moi Teaching and Referral Hospital
NCK	Nursing Council of Kenya
NFL	Non-Facility Labs
NLS	National Laboratory Services
NMRL	National Microbiology Reference Laboratory
NPHL	National Public Health Laboratory
NRL	National Reference Laboratory
NTRL	National TB Reference Laboratory
PCR	Polymerase Chain Reaction

ACRONYMS (cont'd)

PGH	Provincial General Hospital
PHOTC	Public Health Officers and Technicians Council
PPB	Pharmacy and Poisons Board
PII	Personally Identifiable Information
PPR	Peste Des Petits Ruminants
RCT	Rapid Cholera Test
RPB	Radiation Protection Board
RVF	Rift Valley fever
RVIL	Regional Veterinary Investigation Labs
SAT	Salmonella Antigen Testing
SLIPTA	Stepwise Laboratory Improvement Process towards Accreditation
SOPs	Standard Operating Procedures
TWG	Technical Working Group
UHPLC-MS/MS	Ultra Performance Liquid Chromatography- Tandem Mass Spectrometer
UTI	Urinary Tract Infection
VIL	Veterinary Investigation Labs
WHO AFRO	World Health Organization Regional Office for Africa
WHO	World Health Organization
WRP	Walter Reed Programme
ZDU	Zoonotic Disease Unit

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EXECUTIVE SUMMARY

"Compliance to the International Health Regulations is central to responding to severe and sustained outbreaks such as Ebola and pandemic influenza. Health systems must be properly resourced; with staff, equipment, availability of medical countermeasures, community engagement, understanding culture, communication, research and long term financing paramount to proper response."

Dr. Margaret Chan, Director General, WHO
speaking at the conference "Lessons Learned for Public Health from the Ebola Outbreak in West Africa–
How to Improve Preparedness and Response in the EU for Future Outbreaks"
Mondorf les Bains, 12-14 October 2015

During a conference on the Ebola outbreak in West Africa, Dr. Margaret Chan (Director General of WHO in 2015) emphasized the need for health systems to be properly resourced with staff and equipment, and availability of medical countermeasures. She also reiterated the need to comply with the International Health Regulations (IHR) as the most appropriate way to invest in preparedness.

The Kenya National Public Health Laboratory (NPHL), with an aim to meet the laboratory requirements of IHR, collaborated with the US Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) to conduct a situation analysis of Kenya's national laboratory system in 47 counties, and develop metrics to inform decision making for the national laboratory system.

NPHL is responsible for strengthening Kenya's national public laboratory system and infrastructure. The laboratory capacity mapping initiative is critical for timely and accurate data on capabilities of laboratories in the national network and the ability of the laboratories in the network to prevent avoidable epidemics, detect threats early and respond to health risks,

The report highlights the following areas as needing attention: workforce capacity, testing of key priority diseases, referral networks for strengthening priority diseases, safety/biosafety, quality, and zoonotic testing and surveillance. The laboratory workforce requires attention as only 8% of all facilities sampled met the staffing criteria mandated by Kenya's 2006 policy guidelines. While some laboratories demonstrated ability to test for key priority diseases such as cholera, typhoid, malaria and Human Immunodeficiency Virus (HIV), diseases such as pneumonia or African swine fever (ASF) lacked sufficient testing capability. Food safety will also require attention as only one lab can test for *Staphylococcus aureus* and *Escherichia coli*. While lower tier laboratories were able to refer samples of critical disease to high tier labs, the communication between labs was not always two ways. In order to test effectively, laboratory equipment must be functional and appropriately maintained. While most equipment were functioning, only 18% had service contracts, leading to questions about long term viability. Laboratories had a poor laboratory capacity score for policy management, equipment management, data management, quality and biosafety/biosecurity, and zoonotic testing and surveillance, but scored well for commodity management.

Current human resources policies need to be reviewed to respond to a changing health environment. Greater investment in workforce is needed by the Government of Kenya including investing in staff capacity through supportive supervision, mentorship and continuous medical education and on-the-job training. To strengthen testing capacity, MOH can form bilateral partnerships with institutions with interest and expertise in specific pathogens, and collaborate with external governments with interest in specific pathogens. To improve testing of priority trade sensitive diseases, the relevant ministry can seek sustainable funding mechanisms to ensure continuous funding for testing and surveillance as well as set up short term mechanisms to establish testing for these diseases in select facilities. A robust communication strategy is needed to ensure two-way exchange between tiers, while optimizing sample collection and referral to ensure efficiency, both of which are key to strengthening the overall laboratory system. To improve laboratory capacity scores, the Ministry of Health (MOH) needs to establish and implement strategies to measure progress for the national quality standards on policy management, quality management, data management, equipment management, commodity/inventory management, safety/biosafety/security and zoonotic testing and surveillance.

1.
INTRODUCTION

"Laboratories play an essential part in both the detection and prevention of diseases. In order to deal effectively with the detection, treatment and prevention of threats to the health of the public, it is essential that accurate, reliable and responsive health laboratory systems are in place. This starts with doing the right test, at the right place, at the right time and achieving the right result."

Mr. G. Fine, Executive Vice President, CLSI
Joint WHO–CDC Conference on Health Laboratory Quality Systems
Lyon, France, April 2008

BACKGROUND

Public health laboratories (PHLs) play an important role in protecting societies, communities and individual health. PHLs perform public health reference tests and provide data and information to monitor community health conditions, inform population-based interventions, and provide timely and trusted test results to healthcare providers to aid accurate diagnosis and appropriate treatment. Additionally, PHLs provide surveillance for high consequence pathogens to detect disease threats and guide a timely and effective health response to limit the adverse consequences. PHLs lead the laboratory response to emerging threats with the capability to provide high numbers of tests and timely data analysis to inform the MOH with evidence-based information regarding disease or pathogen trends, incidences and prevalence for informed decision making.

The Kenya PHL is the National Public Health Laboratory (NPHL), a Division within the Department of Preventive and Promotive Health in the MOH charged with the role of Kenya's national reference laboratory. NPHL is the national referral center for all public health laboratory programs and diagnostic services. It is responsible for meeting the laboratory requirements of the International Health Regulations as described in the Laboratory Capacity Requirements for the International Health Regulations (WHO/AFRO, 2013): providing reference testing services and assuring the capabilities and quality of laboratory diagnostic testing services as mandated by the MOH for the national laboratory system; and providing laboratory results and information to the MOH.

In order to meet its core public health laboratory functions effectively, NPHL collaborated with the CDC to undertake a situational analysis of the Kenya national laboratory system, review options for on-going capacity mapping of the laboratory system and develop appropriate metrics that can inform and guide evidence-based decision making for the national laboratory system. The NPHL partnered with the CDC Kenya Division of Global HIV/AIDS and TB (CDC/DGHT), Division of Global Health Protection (CDC/DGHP) and APHL to initiate a laboratory capacity mapping assessment project beginning in April 2015.

RATIONALE

Kenya NPHL developed a comprehensive five-year national laboratory strategic plan and an implementation plan (NPHL SP 2016-2020). These accomplishments provide NPHL with the reliable roadmap to continue its notable progress in strengthening laboratory services for Kenya.

One of the three strategic priorities for NPHL services is to "manage the national regional and sentinel public health laboratories for disease surveillance and response with a reliable specimen transport system and a real-time communication network to report specimen test status and test results; communicate nationally with all public health, veterinary and other key stakeholder laboratories and externally with WHO, international reference laboratories and other international partners in the disease surveillance networks. The comprehensive network will detect threats early and respond rapidly and effectively to health risks to guide national health treatment and prevention interventions and programs and reduce the effects of epidemics."

NPHL has made notable progress in the strengthening of its national laboratory systems and the national laboratory infrastructure,

but much work remains to be done. NPHL's initiative to develop a mechanism to gather accurate and timely data of the capabilities and capacities of laboratories in the national network will provide the foundation to implement effective and efficient strategic initiatives to make further headway on strengthening priority services.

A laboratory capacity mapping was planned to facilitate the capture of a laboratory's capabilities and to identify the level of maturity in key areas such as the types of testing performed, strength of quality assurance, safety/biosafety, equipment and data management, among others. The data was to be generated in the form of maturity model-based scores focused description by capability area. In general, the data generated was intended to provide:

- An overview of the overall public health laboratory capacity across the nation, as well as a breakdown by county and by region by analyzing total scores of all capability areas.
- An overview of overall laboratory capacity within a level or tier of laboratories.
- An indication of the laboratory's level of maturity for specific capability - at a national, county, or regional level as well as within a level of laboratories.

OBJECTIVES

The mapping exercise had several primary and secondary objectives. The primary objectives of the study were:

- To assess the testing capabilities of laboratories as measured against the standard expected for each laboratory tier
- To assess the ability of laboratories to refer specimens for tests not within their testing capacity and receive results including the turnaround time for these results
- To assess the ability of laboratories to manage data and report on priority diseases including use of data/information systems
- To assess the training and experience of laboratory staff and identify gaps
- To assess the ability of laboratories to be part of a sentinel surveillance system
- To assess the quality control and quality assurance measures in place
- To assess the availability and proper management of supplies, logistics, guidelines
- To assess the capacity of referral laboratories to provide confirmation testing and feedback as well as feed forward results
- To provide national norms or scores for individual laboratories at every level on each of the above thematic areas and on an overall basis to facilitate comparisons between peer facilities and identify laboratories with common needs
- To summarize capacities of laboratories and facilities at the individual, county, and national levels.

The secondary objectives of the study were:

- To identify means to build a national laboratory information system and database for near real-time test result reporting and transport/tracking of specimens.
- To provide data to assist with strengthening the national laboratory network testing services.
- To assess the ability of laboratories to detect and report on early warning signals.
- To develop a robust web-based system aligned to the DHIS platform for periodic laboratory status updates.

SCOPE OF STUDY

The Kenya laboratory capacity mapping project activity was implemented in three phases.

Phase 1 (Pilot phase) involved data collection from select samples of laboratories in 3 counties to inform on effectiveness of methodologies and tools used, including Survey protocol, DHIS2 tools and database and Mobile device internet connectivity. The phase 1 data collection also provided an assessment of logistics and resource requirements for data collection, which provided feedback for phase 2.

Phase 2 included data collection, which was done in 40 counties in two rounds i.e. 20 counties in 2016 and 20 in 2017. During Phase 2, survey questions were refined (specific objectives), the scope of survey required (all laboratories or a sample, frequency, metrics, options for data collection) was assessed, and improvements were made to the questionnaire and the tool used for data capture, analysis and presentation.

In Phase 3, data was collected in seven counties, and additional information on equipment and turnaround time was solicited from all facilities.

The population of interest included laboratories throughout Kenya that provide a public health service, and perform some level of patient-based services, research laboratories and/or veterinary testing as well as government chemist laboratories. The patient-based laboratories ranged from Level 2 to Level 6 facilities.

The following staff from the sampled laboratories were included:

- Laboratory staff who perform testing and support daily laboratory activities
- Laboratory supervisors and managers who oversee the testing, result approvals and the training of staff
- Laboratory/hospital leadership who had a role in the support and sign off on laboratory activities and processes.

2. METHODOLOGY

"Public health laboratories are critically important to the health of their communities and the entire nation. We must do all we can to ensure that the public health laboratory system maintains its capacity to address today's health threats and those of the future."

Thomas R. Frieden, MD, MPH
Director, US Centers for Disease Control and Prevention, 2012

STUDY DESIGN

The laboratory mapping study used a mixed methods approach: cross-sectional and retrospective approach, based upon direct on-site observation, record/document reviews, and responses to questionnaires. Data for observations and questionnaires were collected on the day of site visit.

The laboratory capacity mapping study used a mixed methods approach: cross-sectional and retrospective approach, based upon direct on-site observation, record/document reviews, and responses to questionnaires. Data for observations and questionnaires were collected on the day of site visit.

Laboratory capacity mapping involved gathering details on all major areas of competency and capability necessary to meet the obligations and responsibilities of a laboratory in the national laboratory system. These areas include:

- Policy Management
- Equipment Management
- Commodity/Inventory Management
- Data Management
- Quality Management
- Safety/Biosafety/Security Management
- Testing Profile/Referral Management.

The specific capabilities addressed under each major area of interest were derived from relevant standards, guidelines and policy regulations as well as input by the Technical Working Group (TWG) and leadership from the MOH and NPHL.

Data was collected from 1820/4168 facilities as shown in Table 1.

Table 1: Sampling and Sample Size Distribution

FACILITY LEVEL	ESTIMATED NATIONAL TOTAL (N)	FACILITIES SAMPLED (N)	% SAMPLED
2	2685	478	18%
3	989	870	88%
4	423	401	95%
5	11	11	100%
6	9*	9	100%
NFLs	51	51	100%
TOTAL	**4168**	**1820**	**44%**

**KNH was split into six independent laboratories.*

DATA MANAGEMENT

Data Collection Tools

The following documents or literature were referenced in the development of the Laboratory Mapping Tool:

- The World Health Organization's Guide for the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) in the African Region
- The Global Health Security Agenda (GSHA) Scorecard
- The Laboratory Capacity Requirements for IHR and their implementation in the WHO African Region
- ISO 15189 Standards
- Food and Agriculture Organization of the United Nations – FAO Laboratory Mapping Tool
- EMPRES Transboundary Animal Diseases Bulletin: Profiling Laboratory Capacity in the context of emerging pandemic threats: The FAO Laboratory Mapping Tool
- APHL Informatics Self-Assessment Tool.

Data Collection and Entry

Data collection for the Laboratory Capacity Mapping study was conducted by members of the TWG and laboratory personnel identified from the counties. The members were divided into two-person teams and each team was assigned specific counties/region. Each team conducted the survey of the laboratories in their assigned counties over a 5-10 day period. Data was collected using a structured questionnaire that was available in hard copy/paper form and on handheld tablet devices. Each team was supplied with one handheld tablet. One team member recorded data on a hard copy questionnaire while another member entered data on a handheld tablet. Data collected on the tablet was electronically transferred to a server at MOH. Hard copy questionnaires were used to verify and validate the electronic data. Each laboratory provided responses to the questionnaire that were recorded by the TWG team while on site.

Data collection was delayed in seven counties that were deemed to have high security risk concerns, as logistics were worked out to have the assessment entirely conducted by county staff assigned by their respective county administration. The data from the seven counties was merged into the main database in April 2018; this report covers all the 47 counties in Kenya.

DHIS2 (www.dhis2.org) was used to capture data on the handheld devices. The handheld tablets were configured with DHIS2 tracker module, an application that was used for gathering laboratory capacity, assigning scores based on capacity and generating reports. Capacity mapping information was collected either offline on the handheld, or transmitted seamlessly to a central database hosted at NPHL using available internet connectivity.

Data Analysis

Data was collected by facility level. Amongst other considerations, analysis was conducted by facility level as the basic unit of measurement reference.

Site information and responses obtained were exported from DHIS2 database and analysis done using STATA. A data manager on site reviewed the data entry and data security. Data analysis output were presented in tables and charts depicting frequencies and percentages. Graphical presentation in charts was done using DHIS2 data visualizer tool. Further analyses were performed using SAS, Excel, and ArcGIS.

Using the Medical Laboratory Services of Kenya National Policy Guideline 2006, staff level analysis was conducted to identify current staffing capacities as well as gaps.

To compute laboratory capability score (LCS) analysis was performed for each major capability area to identify gaps and/or weaknesses by level of laboratory, by county and at national level. Using mean squared scores for each indicator and overall sum of indicators for each capability domain within the questionnaire, a LCS was generated at facility, county and national level. The

main LCS domains were: Policy Management, Equipment Management, Commodity/Inventory Management, Data Management, Quality Management, Safety/Biosafety/Security and Zoonotic Disease Surveillance.

Data Quality Assurance

To reduce bias that may have arisen by county staff conducting the survey within the county where they are employed, TWG members at NPHL reviewed responses and validated these against existing knowledge of county laboratory capacity. The data was also monitored by the MOH ICT team as it was keyed into the system.

All site data in DHIS2 were subjected to consistency and validation checks as they were relayed to the central database managed at the NPHL ICT department. Further checks were done during the data cleaning activity by comparing data collected on the handheld with data collected on the hardcopy questionnaire. Verification was conducted and duplicates deleted. In addition to the hardcopy check, respondents were called to resolve inconsistencies as hard copy is not always gold standard.

To ensure further quality control and integrity of the analyzed data, the following were observed:

- Only designated staff had access to the data
- Analysis was conducted in conjunction with Kenya MOH, NPHL, CDC and APHL
- All analyzed data was reviewed by multiple project participants to manage any bias.

ETHICAL CONSIDERATIONS

The laboratory capacity mapping effort did not involve the collection of samples, specimen or collection of patients' personal identifiable data. Any information containing personally identifiable information (PII), such as laboratory managers contact information, was encrypted using a package that meets Advanced Encryption Standard (AES) criteria if not anonymized (as is aggregated data).

Participation was voluntary and respondents were informed of their rights to terminate interviews if they felt a need to do so. Prior to this, participants signed informed consent.

All data transfers were approved by appropriate officials. Backup files transmitted to any partners for ongoing system development was anonymized and/or encrypted for PII.

3. FINDINGS AND DISCUSSION

"Countries need to have access to safe and accurate laboratory services to facilitate the early detection, tracking and monitoring of infectious agents and to support alert and response activities under the International Health Regulations (2005)"

Dr. Corinne Capuano
WHO Representative for Brunei Darussalam, Malaysia and Singapore
October 2011

BASIC INFORMATION

Data was collected from 47 Kenya counties with a total of 1820 facilities and an estimated staff capacity of 5403. A vast majority of the facilities were affiliated to respective county governments-only 3% were linked to the national government. Twenty-six percent of the sampled facilities were Level 2, 48% Level 3, 22% Level 4, 0.6% Level 5, 0.3% Level 6 and 3% non-facility laboratories (NFLs - Government Chemist labs, Veterinary labs, National Public Health Laboratory reference labs and Research labs). Fifty-nine percent (59%) of all staff were GOK employees while the remainder were non-GOK.

Table 2: Number of Facilities Sampled by Level

FACILITY LEVEL	N SAMPLED/ TOTAL N BY EACH LEVEL	N SAMPLED AT LEVEL/ N SAMPLED ALL LEVELS
2	478/2685 (18%)	478/1820 (26%)
3	870/989 (88%)	870/1820 (48%)
4	401/423 (95%)	401/1820 (22%)
5	11/11 (100%)	11/1820 (0.6%)
6	9/9 (100%)	9/1820 (0.3%)
NFLs	51/51 (100%)	51/1820 (3%)
Total	**1820/ 4168 (44%)**	**1820/1820 (100%)**

LABORATORY WORKFORCE

In Kenya's blueprint of long-term economic development, Vision 2030 targets to reduce health workforce shortages by 60% to achieve quality health care service delivery. In Kenya, all health workers should receive training from approved institutions and are later licensed to practice by their respective regulatory agency: Nursing Council of Kenya (NCK), Medical Practitioners and Dentist Board (MPDB), Clinical Officers Council (COC), Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), Pharmacy and Poisons Board (PPB), Public Health Officers and Technicians Council (PHOTC), Radiation Protection Board (RPB) and Kenya Nutritionists and Dieticians Institute (KNDI). Whilst the Medical Laboratory Services of Kenya, Policy Guidelines 2006 provide minimum laboratory staffing recommendations at each level of health facility, workload is recognized as a determining factor in actual staffing. The Medical Laboratory Services of Kenya National Policy Guideline 2006 stipulates that Level 2 and 3 should have a minimum of two lab staff, Level 4 should have 24 and Level 5 a minimum of 38 lab staff.

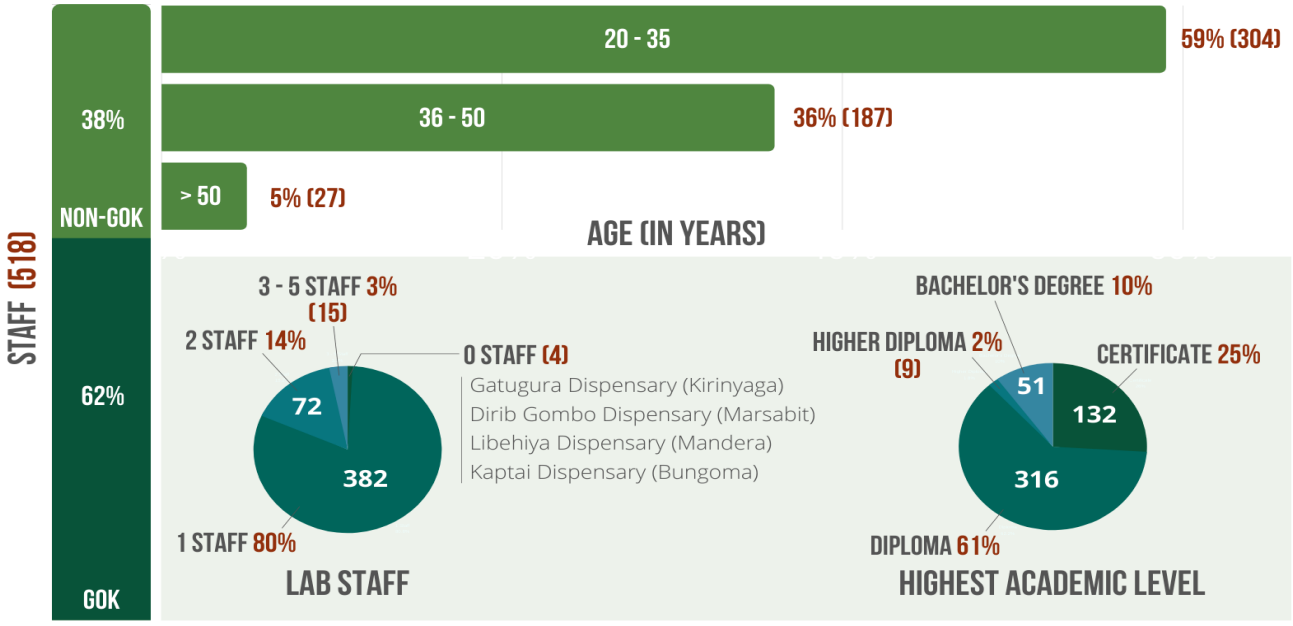
However, according to the Kenya Health Strategic and Investment Plan 2014-2018, "Human Resources For Health Norms and Standards Guidelines For The Health Sector,"[1] the recommended laboratory human resources for health are two for Level 2, 10 for Level 3, 40 for Level 4 and 50 for Level 5 and any other referral hospital (based on need and population served).

Level 2

From the 478 Level 2 laboratories sampled, there were 518 staff (62% were GOK and 38% were non-GOK). The age distribution was: 304 (59%) 20-35 years old, 187 (36%) between 36-50 years old, and 27 (5%) over 50 years old. The distribution of highest academic level for staff within the labs was: 132 (25%) Certificate, 316 (61%) Diploma, 9 (2%) Higher Diploma and 51 (10%) Bachelor's degree.

At the time of the assessment, four facilities—Gatugura Dispensary (Kirinyaga), Dirib Gombo Dispensary (Marsabit), Libehiya Dispensary (Mandera) and Kaptai Dispensary (Bungoma)—did not have any laboratory staff. Facilities with only one staff member numbered 382 (80%), 72 (14%) facilities had the recommended staffing levels of two lab staff and 15 (3%) facilities had between 3-5 lab staff.

Figure 1: Workforce Characteristics of Level 2 Laboratories



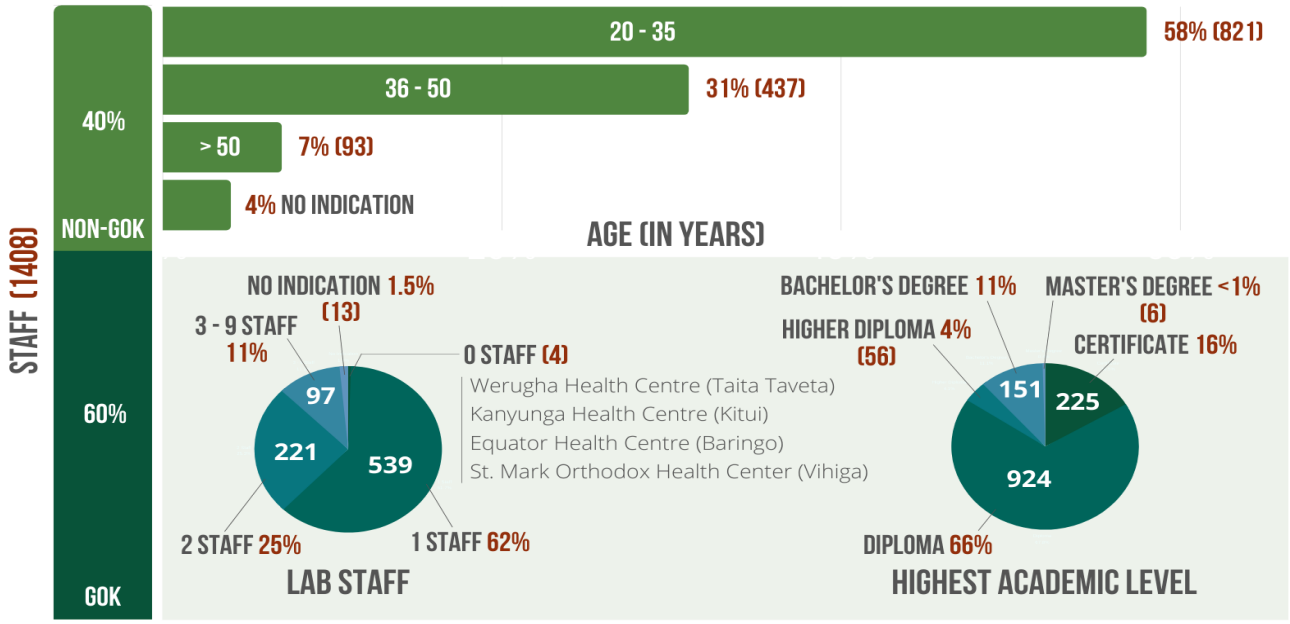
Level 3

Out of the 870 facilities sampled, there were 1408 staff (60% were GOK and 40% non-GOK). The age distribution was: 817 (58%) 20-35 years old, 437 (31%) 36-50 years old and 99 (7%) over 50 years old. The remainder (4%) did not indicate their ages. The distribution of highest academic level for staff within the labs was: 225 (16%) Certificate, 924 (66%) Diplomas, 56 (4%) Higher Diploma, 151 (11%) Bachelor's degree and 6 (<1%) had a Master's degree.

Only 221 (25%) of Level 3 facilities sampled met the two lab staff threshold by the Medical Laboratory Services of Kenya National Policy Guideline 2006. At the time of the assessment Werugha Health Centre (Taita Taveta), Kanyunga Health Centre (Kitui), Equator Health Centre (Baringo) and St. Mark Orthodox Health Center (Vihiga) did not have any lab technical based staff. Facilities with only one staff member numbered 539 (62%), 97 (11%) had between 3-9 staff manning their laboratories while the remainder 13 (1.5%) had not indicated the number of staff at their laboratories.

1 MOH 2014. http://www.health.go.ke/wp-content/uploads/2015/09/16th%20october%20WHO%20Norms%20and%20Standarnds%20%20Book.pdf

Figure 2: Workforce Characteristics of Level 3 Laboratories



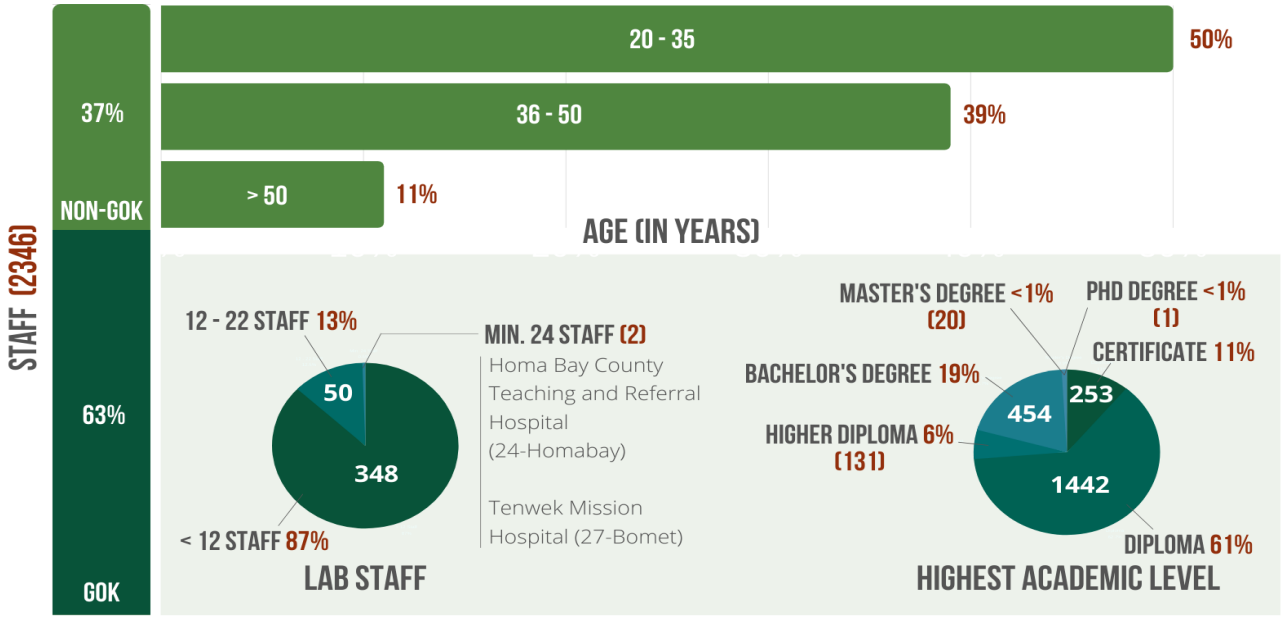
Level 4

A total of 2346 staff were spread across the 401 sampled Level 4 facilities (63% were GOK and 37% were non-GOK staff). Out of these staff, 253 (11%) were Certificate holders, 1442 (61%) were Diploma holders, 131 (6%) had attained Higher Diploma, 454 (19%) were Bachelor's degree holders, 20 (<1%) held a Master's degree and 1 (<1%) had a PhD.

From the 401 sampled, 348 (87%) facilities had less than 12 lab staff and 50 (13%) had between 12-22 lab staff. Only 2 facilities, Homa Bay County Teaching and Referral Hospital (24-Homabay), and Tenwek Mission Hospital (27-Bomet) met the threshold of minimum of 24 lab staff for Level 4 facility.

Half (50%) of the Level 4 staff were aged between 20-35 years old, 39% were between 36-50 years old and 11% were above 50 years old.

Figure 3: Workforce Characteristics of Level 4 Laboratories



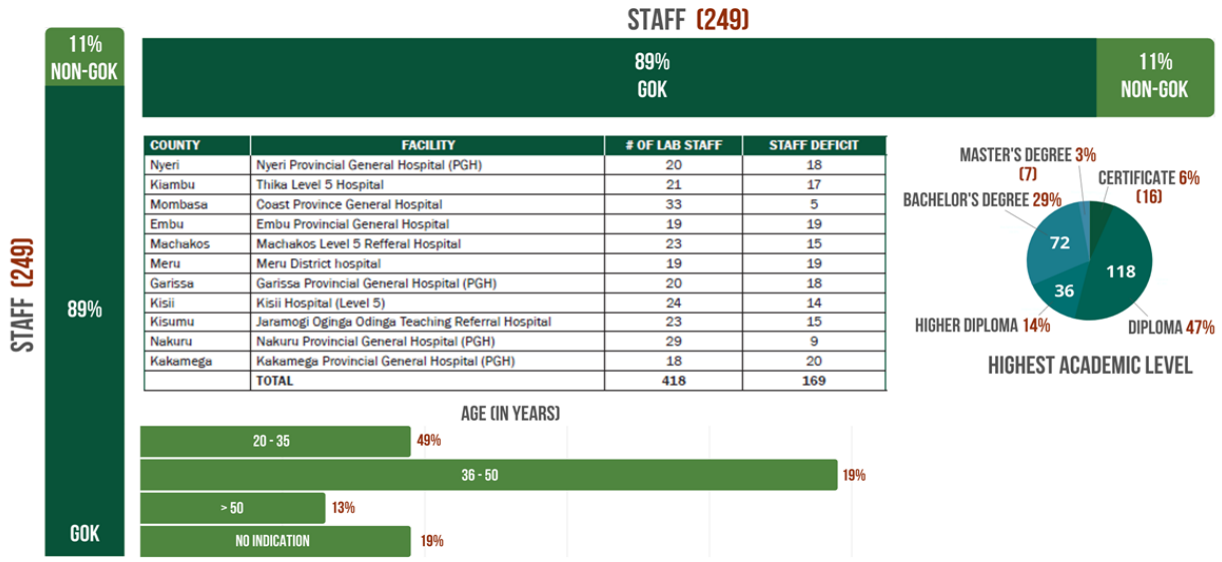
Level 5

Eleven Level 5 facilities were sampled with a total of 249 staff (89% were GOK and 11% non-GOK). Out of these staff, 16 (6%) were Certificate holders, 118 (47%) were Diploma holders, 36 (14%) had attained Higher Diploma, 72 (29%) were Bachelor's degree holders, 7 (3%) held a Master's degree and no staff had a PhD.

The age distribution was: 19% were aged 20-35 years old, almost half (121 or 49%) were aged 36-50 years old, 33 (13%) were 50 or more years old, the remainder (19%) did not provide their ages.

None of the Level 5 facilities met the minimum threshold of 38 lab staff. Coast PGH with 33 staff was the closest to meet the threshold of 38 while Embu, Meru and Kakamega PGHs had 19, 19, and 18 lab staff deficit, respectively.

Figure 4: Workforce Characteristics of Level 5 Laboratories



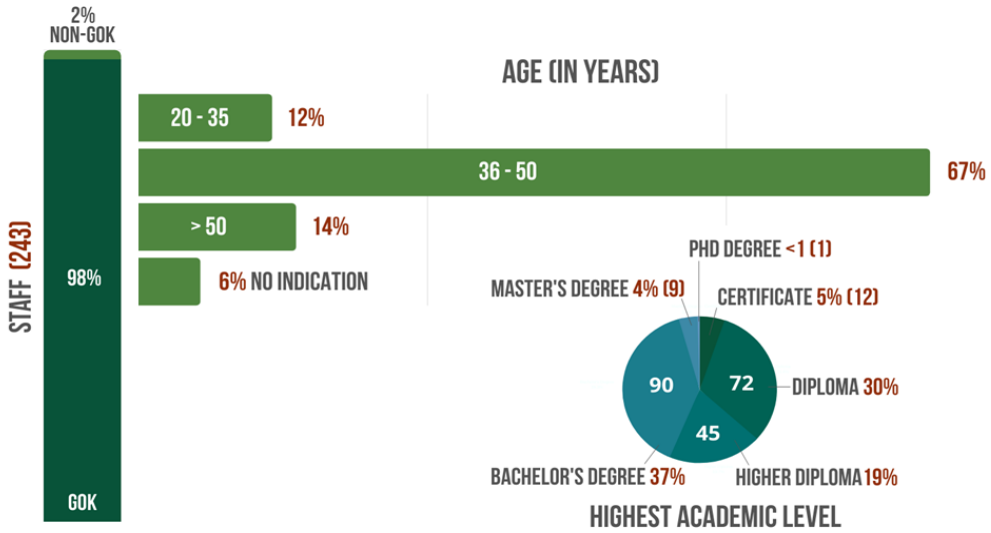
COUNTY	FACILITY	# OF LAB STAFF	STAFF DEFICIT
Nyeri	Nyeri Provincial General Hospital (PGH)	20	18
Kiambu	Thika Level 5 Hospital	21	17
Mombasa	Coast Province General Hospital	33	5
Embu	Embu Provincial General Hospital	19	19
Machakos	Machakos Level 5 Refferal Hospital	23	15
Meru	Meru District hospital	19	19
Garissa	Garissa Provincial General Hospital (PGH)	20	18
Kisii	Kisii Hospital (Level 5)	24	14
Kisumu	Jaramogi Oginga Odinga Teaching Referral Hospital	23	15
Nakuru	Nakuru Provincial General Hospital (PGH)	29	9
Kakamega	Kakamega Provincial General Hospital (PGH)	18	20
	TOTAL	418	169

Level 6

Four Level 6 facilities comprising nine distinct laboratories affiliated with hospitals—KNH, Moi Teaching and Referral Hospital, Mathare Hospital and Spinal Injury—were sampled with a total of 243 staff (98% were GOK and 2% non-GOK). Out of these staff, 12 (5%) were Certificate holders, 72 (30%) were Diploma holders, 45 (19%) had attained Higher Diploma, 90 (37%) were Bachelor's degree holders, 9 (4%) held a Master's degree and 1 (<1%) staff had a PhD.

The age distribution was: 12% of the staff were aged 20-35 years old, 161 (67%) were aged 36-50 years old, 35 (14%) were 50 or more years old, the remainder 15 (6%) did not provide their ages.

Figure 5: Workforce Characteristics of Level 6 Laboratories



Non-Facility Laboratories

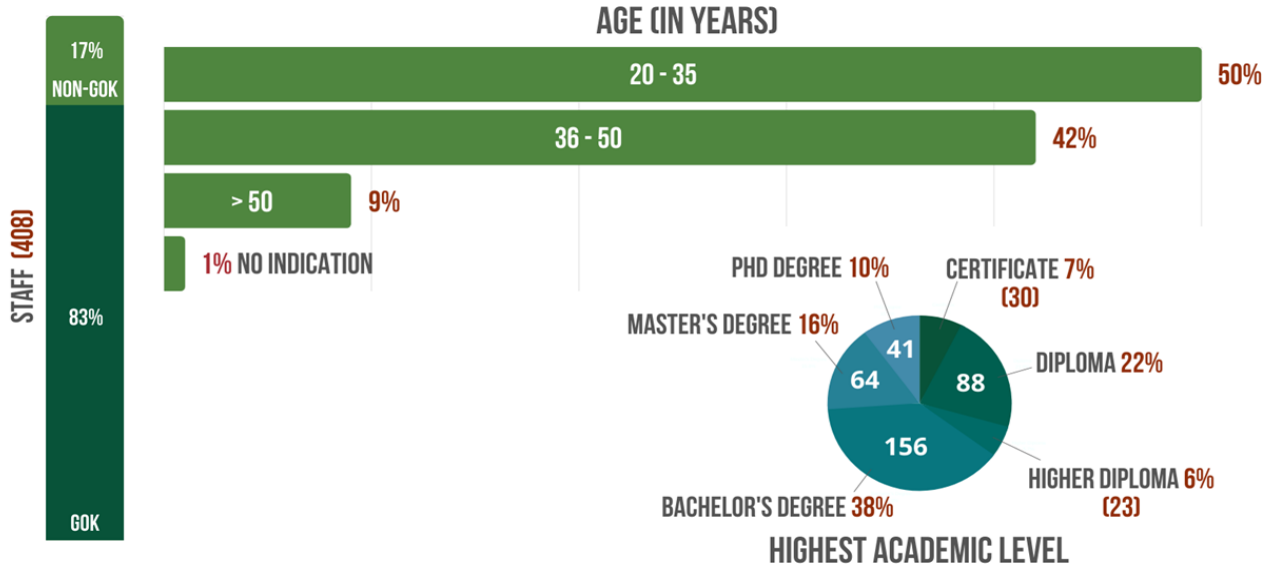
A total of 51 non-facility laboratories (NFLs) associated with KEMRI, Government Chemists, Veterinary and NPHL were sampled with the distribution of demographic and other characteristics described below.

Research Laboratories

In this mapping assessment, 27 KEMRI labs were sampled with a total laboratory workforce of 408 staff (17% were GOK while 83% were non-GOK). Thirty (7%) were Certificate holders, 88 (22%) were Diploma holders, 23 (6%) had attained Higher Diploma, 156 (38%) were Bachelor's degree holders, 64 (16%) held a Master's degree and 41 (10%) staff had a PhD.

Half (50%) of the staff were aged 20-35 years old, 170 (42%) were aged 36-50 years old, 37 (9%) were 50 or more years old; only 5 (1%) did not provide their ages.

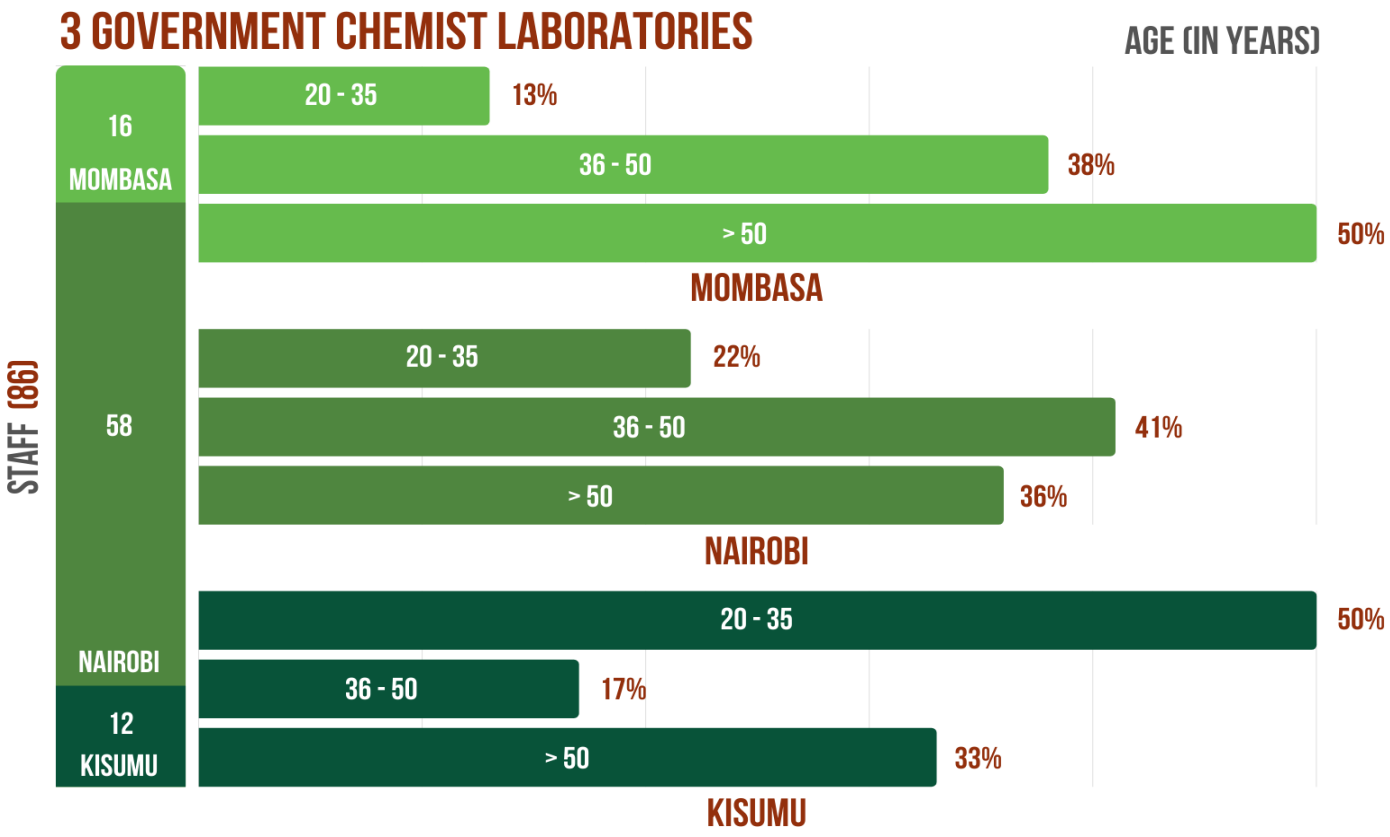
Figure 6: Workforce Characteristics of Research Laboratories

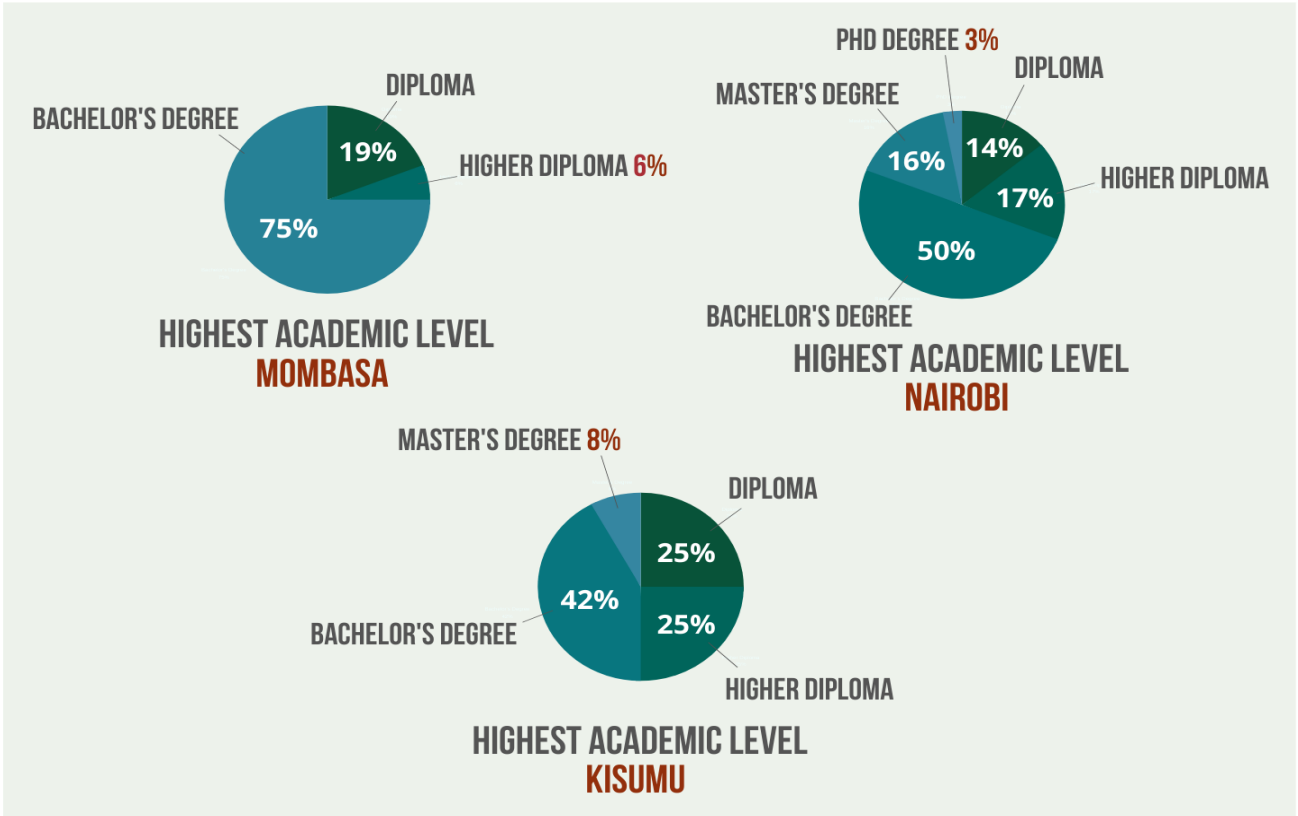


Government Chemist Laboratories

All the Government Chemists (Nairobi, Mombasa and Kisumu) with a total of 86 staff participated in the laboratory capacity mapping exercise; all were GOK employees. Half (50%) and 75% of the staff in Nairobi and Mombasa, respectively, had a Bachelor's degree, no staff in Mombasa held a Master's degree at the time of the assessment and only two staff (3%) had a PhD. While half of the staff in Kisumu are between 20-35 years old, half of the staff in Mombasa were above 50 years old..

Figure 7: Workforce Characteristics of Government Chemist Laboratories

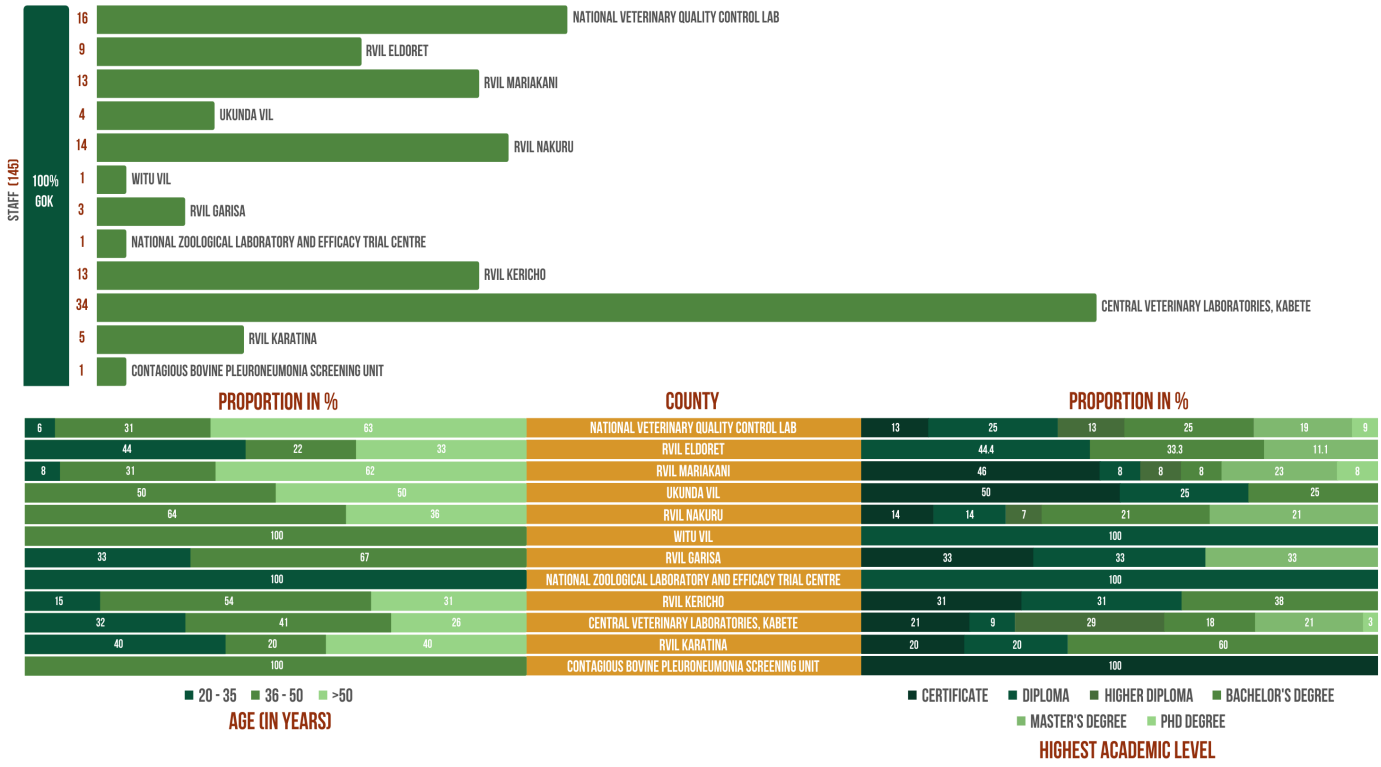




Veterinary Laboratories

Twelve veterinary laboratories with a total of 145 staff and who all were GOK staff, were mapped. National Veterinary Quality Control Lab, RVIL Mariakani, RVIL Eldoret and Ukunda VIL had 63%, 62%, 57% and 50% of their lab staff above 50 years old, respectively. Witu VIL, National Zoological Laboratory and Efficacy Trial Centre and Contagious Bovine Pleuroneumonia Screening Unit all reported having 1 staff only. National Veterinary Quality Control Lab (6%) and RVIL Mariakani (8%) were the only labs that reported having staff with a PhD. At the time of this exercise, there was no workforce guideline in place indicating minimum number of technical staff.

Figure 8: Workforce Characteristics of Veterinary Laboratories

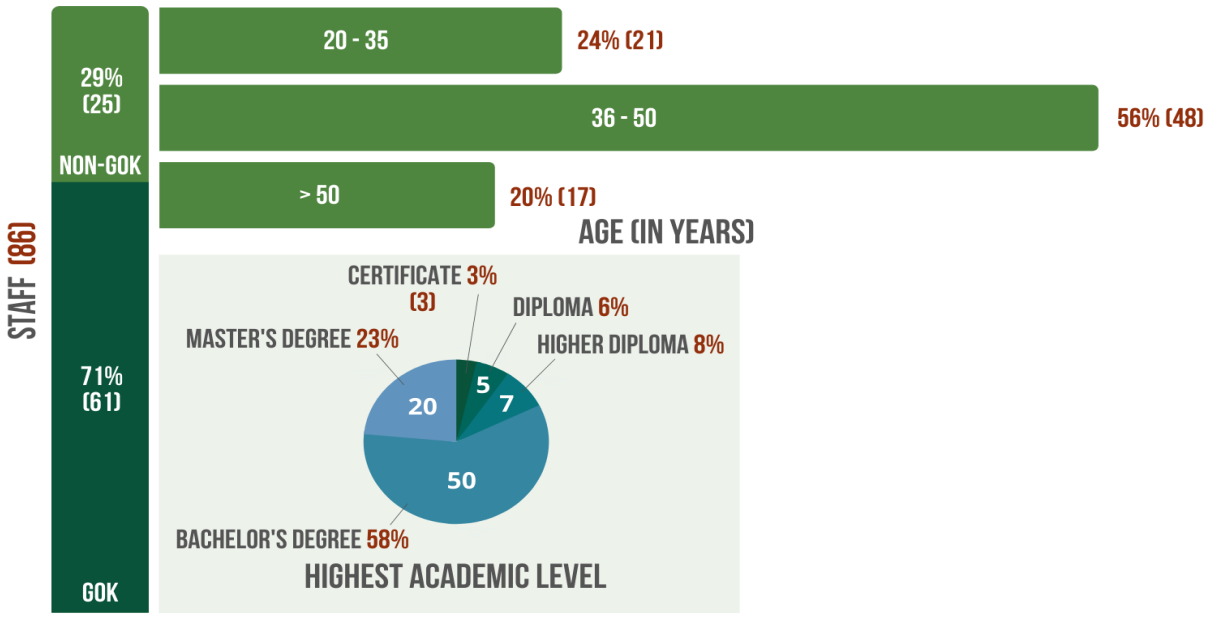


National Public Health Laboratory

Seven reference labs within NPHL with a workforce of 86 staff were mapped. Sixty-one (71%) were GoK employees while 25 (29%) were partners supported. Three (3%) were certificate holders, five (6%) were Diploma holders, seven (8%) were Higher National Diploma holders, 50 (58%) were BSC holders and 20 (23%) held Master's degrees.

The age distribution was: 24% were aged 20-35, 56% aged 36-50 and 20% were above 50 years.

Figure 9: Workforce Characteristics of NPHL



Summary

A summary of the workforce data shows that 1820 facilities with a total of 5403 staff were sampled. Only 8% (n=1820) of all facilities sampled met the staffing criteria as stipulated by the 2006 Policy Guideline with none of the Level 5 facilities meeting the minimum staffing threshold. Further, 59% (almost six in every 10 sampled individuals) were GOK employees. However, worth noting is that all staff of the veterinary and government chemist laboratories were government employees. Nine percentage (9%) of all staff sampled were above 50 years of age hence nearing retirement. Thirteen (13%) of all respondents were Certificate holders, 55% Diploma holders, 18% Bachelor's degree holders, 4% Masters' degree holders and <1% PhD holders (only four respondents).

PRIORITY COMMUNICABLE DISEASES AND METHODS

Cholera

Only seven of the 47 counties did not report testing for cholera - Lamu, Isiolo, Nyandarua, Uasin Gishu, Nandi, West Pokot and Elgeyo- Marakwet. Egerton University (Nakuru), which is a Level 3, performed cholera culture tests. Only 13% of Level 4 had cholera culture tests while only one Level 6 facility (KNH - Microbiology Lab) and seven non-facility labs did cholera culture tests (Wellcome Trust Kilifi, DLSP Enteric Lab – CGHR KEMRI, CIPDCR, CRDR-TB Lab, NMRL, CMR-Kwale and CGHR-Influenza Lab). Molecular testing was only done by one Level 6 and three NFLs. The National Microbiology Reference Lab (NMRL) conducted cholera testing using AST method. Table 3 highlights which facility and level carried out cholera-related tests. Only 68% of Level 4 facilities indicated provision for culture testing for cholera testing.

Table 3: Cholera Tests

Facility Level	Cholera- Culture for isolation	Cholera-Serotyping	Cholera AST	Cholera Molecular	Cholera- Rapid testing
Level 2 (n = 478)	None	None	None	None	13 (3%)
Level 3 (n=870)	Egerton University	None	None	None	36 (4%)
Level 4 (n=399)	52 (13%)	23 (6%)	34 (9%)	None	49 (12%)
Level 5 (n=11)	All 11 Level 5 facilities	Embu PGH Meru District hospital Nakuru PGH Kakamega PGH	Thika Lev 5 Embu PGH Machakos Lev 5 Garissa PGH Kisii Lev 5 JOOTRH Nakuru PGH Kakamega PGH	None	Embu PGH Machakos Referral Hosp Meru District hospital Garissa PGH Kakamega PGH
Level 6 (n=9)	KNH-Microbiology Lab	KNH-Microbiology Lab	KNH-Microbiology Lab	KNH-Microbiology Lab	KNH-Microbiology Lab
NFLs (n=51)	CRDR-TB Lab, NMRL CMR-Kwale CGHR-Influenza Lab CRDR-TB Lab NMRL CMR-Kwale CGHR-Influenza Lab	CRDR-TB Lab NMRL CMR-Kwale CGHR-Influenza Lab	National Microbiology Reference Lab (NMRL)	CRDR-TB Lab NMRL CGHR-Influenza Lab	None

Only 3% and 4% of Level 2 and 3 facilities respectively provide cholera rapid testing.

Typhoid Fever

All but one (Lamu) of the 47 counties reported laboratory typhoid fever testing. Table 4 highlights which facility and level carried out typhoid-related tests: *Salmonella* antigen and serologic testing was the most commonly used methods. All Level 5 facilities conducted culture for isolation and identification and antibiotic susceptibility testing.

Table 4: Typhoid Tests

Facility Level	Culture for isolation and identification	Serological test	Antibiotic Susceptibility testing (AST)	Molecular	Salmonella antigen testing
Level 2 (n=477)	None	46 (10%)	None	None	230 (48%)
Level 3 (n=869)	Mnyenzeni HC Kairuri HC Kutulo HC (Wajir East) Egerton University Nkararo HC St Antony HC Sipili Maternity and Nursing Home (Ol-Moran) St Angela Melici HC Shinyalu HC Bidii HC	118 (14%)	None	None	467 (54%)
Level 4 (n=399)	68 (17%)	70 (17.5%)	53(13.3%)	None	241 (60%)
Level 5 (n=11)	All 11 Facilities	Thika Hospital Meru District Hospital Garissa PGH	Nyeri PGH Thika Hospital Coast PGH Embu PGH Machakos Referral Hospital Garissa PGH Kisii Hospital Jaramogi Oginga Odinga TRH Nakuru PGH Kakamega PGH	None	Machakos Referral Hospital Garissa PGH Kakamega PGH
Level 6 (n=6)	KNH - Microbiology Lab Moi Teaching Referral Hospital	KNH - Microbiology Lab Moi Teaching Referral Hospital	KNH - Microbiology Lab National Spinal Injury Hospital	None	KNH - Microbiology Lab Mathari Hospital

Facility Level	Culture for isolation and identification	Serological test	Antibiotic Susceptibility testing (AST)	Molecular	Salmonella antigen testing
NFLs (n=51)	Wellcome Trust Kilifi DLSP Zoonosis Lab - CGHR KEMRI CMR Parasitology Lab KEMRI WRP - Kondele KEMRI WRP - Kericho CIPDCR CRDR-TB Lab KEMRI WRP - Kombewa	Wellcome Trust Kilifi DLSP Zoonosis Lab - CGHR KEMRI CMR Parasitology Lab	Wellcome Trust Kilifi DLSP Zoonosis Lab - CGHR KEMRI Kisumu Government Chemist KEMRI WRP - Kericho CIPDCR CRDR-TB Lab KEMRI WRP - Kombewa NMRL CMR-Kwale CGHR-Influenza Lab	DLSP Zoonosis Lab CGHR KEMRI KEMRI WRP – Kondele CRDR-TB Lab	Centre for Clinical Research CGHR-Entomology Lab CIPDCR CRDR-TB Lab KEMRI WRP - Kombewa

Malaria

Ninety percent of all facilities mapped in all the 47 counties reported testing for malaria. Table 5 highlights which facility and level carried out malaria-related tests: smear microscopy was common across all levels while only NFL used molecular method for malaria testing. KEMRI CGHR Malaria Lab, KNH Immunology lab, KEMRI WRP Kondele lab, KEMRI WRP-Kisian Lab, CBRD Lab, CGHR Entomology Lab and KEMRI Welcome Trust Kilifi Lab conducted molecular testing while no other Level 5 or 6 facilities conducted molecular tests.

Table 5: Malaria Tests

FACILITY LEVEL	SMEAR MICROSCOPY N (%)	MALARIA RDT N (%)	MOLECULAR N (%)
Level 2 (n=477)	437 (92%)	381 (80%)	None
Level 3 (n=869)	802 (92%)	696 (80%)	None
Level 4 (n=399)	377(95%)	209(52%)	None
Level 5 (n=11)	Nyeri PGH Thika Level 5 Hosp Embu PGH Machakos Level 5 Referral Hosp Meru District Hosp Garissa PGH Kisii Hosp (Level 5) Jaramogi Oginga Odinga TRH Nakuru PGH Kakamega PGH	Machakos Level 5 Referral Hosp Nakuru PGH	None

FACILITY LEVEL	SMEAR MICROSCOPY N (%)	MALARIA RDT N (%)	MOLECULAR N (%)
Level 6 (n=8)	KNH Microbiology Lab Mathari Hosp National Spinal Injury Hosp Moi Teaching Referral Hosp	Mathari Hosp	None
NFLs (n=51)	Wellcome Trust Kilifi CGHROtherLabs CGHRNTD Labs CRCMalaria Laboratory KEMRI WRP Kisian KEMRI WRP Kondele KEMRI WRP Kericho Centre for Clinical Research CIPDCR KEMRI WRP Kombewa CGHRMalaria Lab CMRKwale CRCHIV Research Lab CBRD Lab	Wellcome Trust Kilifi CGHR-OtherLabs CGHR NTD Labs CRC Malaria Laboratory KEMRI WRP – Kisian Mtwapa HIV/STI Clinic KEMRI WRP-Kondele Centre for Clinical Research CIPDCR KEMRI WRP Kombewa CMR-Kwale CBRD Lab	Wellcome Trust Kilifi WRP Entomology, Kisian KEMRI WRP Kisian KEMRI WRP Kondele CGHR Entomology Lab CGHR Malaria Lab CBRD Lab

Tuberculosis

Table 6 highlights which facility and level carried out tuberculosis-related tests: ZN microscopy was the most common test method across all the facility levels. All the AST tests were done by NFL facilities only (WRP Kericho, CRDR-TB lab, CGHR TB lab and NTRL [TB reference lab]).

Table 6: Tuberculosis Tests

FACILITY LEVEL	ZN MICROSCOPY N (%)	TB FLUORESCENCE MICROSCOPY N (%)	GENEXPERT N (%)	TB CULTURE N (%)	AST N (%)
Level 2 (n=477)	342 (72%)	18 (4%)	15 (3%)	•	None
Level 3 (n=869)	696 (80%)	76 (9%)	26 (3%)	•	None
Level 4 (n=399)	274 (69%)	177 (44%)	111 (28%)	•	None

FACILITY LEVEL	ZN MICROSCOPY N (%)	TB FLUORESCENCE MICROSCOPY N (%)	GENEXPERT N (%)	TB CULTURE N (%)	AST N (%)
Level 5 (n=11)	Machakos Level 5 Referral Hosp Garissa PGH Kisii Hosp (Level 5) Kakamega PGH	Nyeri PGH Thika Level 5 Hosp Embu PGH Machakos Level 5 Referral Hosp Meru District Hosp Kisii Hosp (Level 5) Jaramogi Oginga Odinga TRH Nakuru PGH Kakamega PGH	Nyeri PGH Thika Level 5 Hosp Embu PGH Machakos Level 5 Referral Hosp Meru District Hosp Garissa PGH Kisii Hosp (Level 5) Jaramogi Oginga Odinga TRH Nakuru PGH Kakamega PGH	None	None
Level 6 (n=8)	KNH Microbiology Lab KNH Histopathology Mathari Hosp Moi Teaching Referral Hosp	KNH Microbiology Lab Mathari Hosp	KNH Comprehensive Care Center Lab KNH Microbiology Lab Mathari Hosp Moi Teaching Referral Hosp	None	None
NFLs (n=51)	KEMRI WRP Kericho RVIL Nakuru Centre for Clinical Research CRDRTB Lab CGHRTB Lab National TB Reference Lab	KEMRI WRP Kericho CRDRTB Lab CGHRTB Lab National TB Reference Lab	KEMRI WRP Kericho CRDRTB Lab KEMRI WRP Kombewa CGHRTB Lab National TB Reference Lab	KEMRI WRP Kericho CRDR TB Lab CGHR TB Lab National TB Reference Lab	KEMRI WRP Kericho CRDR TB Lab CGHR TB Lab National TB Reference Lab

Pneumonia (bacterial)

Testing for pneumonia was reported in 64 laboratory facilities in 31 of the 47 counties assessed. The 16 counties that were not testing for pneumonia were Kwale, Lamu, Tana River, Marsabit, Isiolo, Nyandarua, Samburu, Elgeyo Marakwet, West Pokot, Nandi, Baringo, Laikipia, Narok, Vihiga, Homabay and Kisii.

Table 7 highlights which facility and level carried out pneumonia-related tests: Level 4 and 5 accounted for most of the pneumonia tests with the bulk of the tests done using culture of isolation and identification, serotyping and antibiotic sensitivity testing. Forty-four (11%) facilities used culture for isolation and identification while 41 (10%) used antibiotic sensitivity testing. Seven of the 44 facilities did culture of isolation and not AST (Longisa District Hospital, Makueni District Hospital, Coptic Hospital, Nanyuki District Hospital, Tawfic Muslim Hospital, Wajir County referral Hospital and Murang'a Dist Hospital) while 3 facilities conducted AST and not culture of isolation (Nyakach Sub-County Hospital, Kajiado County Referral Hospital and Bondo County Referral Hospital).

Table 7: Pneumonia Tests

FACILITY LEVEL	CULTURE OF ISOLATION AND IDENTIFICATION	SEROTYPING	ANTIBIOTIC SENSITIVITY TESTING	MOLECULAR
Level 2 (n=477)	None	None	None	None
Level 3 (n=869)	None	None	None	None
Level 4 (n=399)	44 (11%)	Kijabe (AIC) Hosp Kikuyu (PCEA) Hosp Nyahururu District Hosp Malindi District Hosp Wajir County Referral Hosp Kitale County Referral Hosp Magadi Hosp Nyuki Cottage Hosp Busia County Referral Hosp	41 (10%)	None
Level 5 (n=11)	Nyeri PGH Thika Level 5 Hosp Embu PGH Machakos Level 5 Referral Hosp Meru District Hosp Jaramogi Oginga Odinga TRH Nakuru PGH Kakamega PGH	Thika Level 5 Hosp Nakuru PGH Kakamega PGH	Thika Level 5 Hosp Embu PGH Machakos Level 5 Referral Hosp Garissa PGH Jaramogi Oginga Odinga TRH Nakuru PGH Kakamega PGH	None
Level 6 (n=8)	KNH Microbiology Lab Moi Teaching Referral Hosp	KNH Microbiology Lab Mathari Hosp Moi Teaching Referral Hosp	KNH Microbiology Lab Moi Teaching Referral Hosp	None
NFLs (n=51)	Wellcome Trust Kilifi DLSP Zoonosis Lab CGHR KEMRI KEMRI WRP Kericho RVIL Nakuru CRDRTB Lab KEMRI WRP Kombewa NMRL CGHR Influenza Lab	Wellcome Trust Kilifi DLSP Zoonosis Lab CGHR KEMRI CRDRTB Lab KEMRI WRP Kombewa NMRL CGHR Influenza Lab	Wellcome Trust Kilifi DLSP Zoonosis Lab CGHR KEMRI KEMRI WRP Kericho CIPDCR CRDRTB Lab KEMRI WRP Kombewa NMRL	KEMRI WRP Kondele CRDRTB Lab NMRL CGHR Influenza Lab

Measles

KEMRI WRP (Kondele) did PCR and ELISA measles tests. Even though it was not sampled for the mapping exercise, the WHO reference laboratory at KEMRI Nairobi also conducts measles test.

Dysentery (shigellosis)

Table 8 highlights which facility and level carried out dysentery-related tests: the most common tests for dysentery testing were culture of isolation and identification and antibiotic sensitivity testing. No other laboratory apart from four of the NFL facilities (DLSP Zoonosis Lab - CGHR KEMRI, CRDR-TB Lab, NMRL and CGHR-Influenza Lab) conducted molecular testing for dysentery. The results show that only three Level 6 facilities carried out dysentery testing.

Table 8: Dysentery (shigellosis) Tests

FACILITY LEVEL	CULTURE OF ISOLATION AND IDENTIFICATION	SEROTYPING	ANTIBIOTIC SENSITIVITY TESTING	MOLECULAR
Level 2 (n=477)	None	None	None	None
Level 3 (n=869)	Acef E HC Egerton University St Antony HC Lusheya HC Sipili Maternity and Nursing Home (Ol-Moran) St Angela Melici HC	None	Acef E HC Koru Mission HC Sipili Maternity and Nursing Home (Ol-Moran)	None
Level 4 (n=399)	66 (17%)	Kijabe (AIC) Hosp Kikuyu (PCEA) Hosp Malindi District Hosp Kitui District Hosp Wajir County Referral Hosp Fatima Maternity Hosp Kajiado District Hosp Kitale County Referral Hosp Magadi Hosp Nyuki Cottage Hosp Busia County Referral Hosp Butere District Hosp Likuyani Sub-District Hosp Lumakanda Sub County Hosp	56 (14%)	None

FACILITY LEVEL	CULTURE OF ISOLATION AND IDENTIFICATION	SEROTYPING	ANTIBIOTIC SENSITIVITY TESTING	MOLECULAR
Level 5 (n=11)	Nyeri PGH Thika Level 5 Hosp Embu PGH Machakos Level 5 Referral Hosp Kisii Hosp (Level 5) Jaramogi Oginga Odinga TRH Nakuru PGH Kakamega PGH	Thika Level 5 Hosp Machakos Level 5 Referral Hosp Meru District Hosp Kisii Hosp (Level 5) Jaramogi Oginga Odinga TRH Nakuru PGH Kakamega PGH	Nyeri PGH Coast Province General Hosp Embu PGH Machakos Level 5 Referral Hosp Meru District Hosp Garissa PGH Kisii Hosp (Level 5) Jaramogi Oginga Odinga TRH Nakuru PGH Kakamega PGH	None
Level 6 (n=8)	KNH - Microbiology Lab National Spinal Injury Hosp Moi Teaching Referral Hosp	KNH - Microbiology Lab	KNH - Microbiology Lab Moi Teaching Referral Hosp	None
NFLs (n=51)	Wellcome Trust Kilifi DLSP Zoonosis Lab - CGHR KEMRI KEMRI WRP - Kericho CIPDCR CRDR-TB Lab KEMRI WRP - Kombewa NMRL CMR-Kwale CGHR-Influenza Lab	Wellcome Trust Kilifi DLSP Zoonosis Lab - CGHR KEMRI CRDR-TB Lab KEMRI WRP - Kombewa NMRL CMR-Kwale CGHR-Influenza Lab	Wellcome Trust Kilifi DLSP Zoonosis Lab - CGHR KEMRI KEMRI WRP - Kericho CIPDCR CRDR-TB Lab KEMRI WRP - Kombewa NMRL CMR-Kwale CGHR-Influenza Lab	DLSP Zoonosis Lab - CGHR KEMRI CRDR-TB Lab NMRL CGHR-Influenza Lab

Poliomyelitis

None of the sampled facilities reported conducting any poliomyelitis tests even though the WHO polio reference laboratory at KEMRI Nairobi conducts polio testing.

Meningococcal Meningitis (bacterial)

Thirty-six out of the 47 counties reported meningococcal meningitis testing—Kwale, Tana River, Lamu, Mandera, Isiolo, West Pokot, Elgeyo Marakwet, Narok, Vihiga, Busia and Baringo counties facilities did not report testing for meningitis. Table 9 highlights which facility and level carried out meningococcal meningitis (bacterial)-related tests: Level 4 and 5 facilities accounted for 79% of all meningitis tests. Only two Level 2 reported using rapid testing while only 1 Level 6 facility reported using AST for Meningococcal meningitis determination. Only one Level 4 (Kericho District Hosp) and one NFL (CRDR TB lab) carried out meningococcal meningitis testing using molecular method.

Table 9: Meningococcal Meningitis (bacterial) Tests

FACILITY LEVEL	CULTURE OF ISOLATION AND IDENTIFICATION	SEROTYPING	ANTIBIOTIC SENSITIVITY TESTING	MOLECULAR	RAPID TESTING
Level 2 (n=477)	None	None	None	None	GK Prisons Dispensary - Kakamega Central Emusanda Dispensary
Level 3 (n=869)	Acef E HC	None	Acef E HC	None	Athi River HC Embakasi HC Karen HC Kibera South (Msf Belgium) HC Ngara HC (City Council of irobi) Riruta HC Kitengela Medical Services Elwesero Dispensary (Model HC) Khwisero HC Kilingili HC Lusheya HC Makunga Rhdc Shamakhubu HC Shikusa HC EDARP Komarock HC
Level 4 (n=399)	27 (7%)	Charity Medical Centre Kiambu County Referal Hosp Kikuyu (PCEA) Hosp Nyahururu District Hosp Tigoni District Hosp Malindi District Hosp Matata Nursing Hosp Kajiado District Hosp Kitale County Referral Hosp Londiani District Hosp Magadi Hosp nyuki Cottage Hosp Butere District Hosp	51 (13%)	Kericho District Hosp	36 (9%)

FACILITY LEVEL	CULTURE OF ISOLATION AND IDENTIFICATION	SEROTYPING	ANTIBIOTIC SENSITIVITY TESTING	MOLECULAR	RAPID TESTING
Level 5 (n=11)	Nyeri PGH Coast Province General Hosp Embu PGH Machakos Level 5 Referral Hosp Meru District Hosp Garissa PGH Kisii Hosp (Level 5) Nakuru PGH	Thika Level 5 Hosp Garissa PGH Kisii Hosp (Level 5) Nakuru PGH Kakamega PGH	Nyeri PGH Thika Level 5 Hosp Embu PGH Machakos Level 5 Referral Hosp Meru District Hosp Garissa PGH Kisii Hosp (Level 5) Jaramogi Oginga Odinga TRH Nakuru PGH	None	Kakamega PGH
Level 6 (n=8)	None	KNH - Microbiology Lab	KNH - Microbiology Lab Moi Teaching Referral Hosp	None	KNH - Microbiology Lab
NFLs (n=51)	NMRL	Wellcome Trust Kilifi CRDR-TB Lab KEMRI WRP - Kombewa NMRL	Wellcome Trust Kilifi CIPDCR CRDR-TB Lab KEMRI WRP - Kombewa NMRL	CRDR-TB Lab	CRDR-TB Lab

Yellow Fever

ELISA tests were done by the National Virology Reference Lab, IDRL-CIPDCR KEMRI-Alupe and KEMRI WRP-Kondele and PCR was performed by two facilities as shown in Table 10 below.

Table 10: Yellow Fever Tests

FACILITY LEVEL	PCR	ELISA
Level 2 (n=477)	None	None
Level 3 (n=869)	None	None
Level 4 (n=399)	None	None
Level 5 (n=11)	None	None
Level 6 (n=8)	None	None
NFLs (n=51)	IDRL-CIPDCR KEMRI, Alupe KEMRI WRP - Kondele	IDRL-CIPDCR KEMRI, Alupe KEMRI WRP – Kondele National Virology Reference Lab

Influenza

A total of six facilities (NFLs) reported conducting influenza tests. Table 11 shows the distribution of the tests with molecular method the most common way of determining influenza.

Table 11: Influenza Tests

FACILITY LEVEL	SUBTYPING	RAPID TESTING	MOLECULAR
Level 2 (n=477)	None	None	None
Level 3 (n=869)	None	None	None
Level 4 (n=399)	None	None	None
Level 5 (n=11)	None	None	None
Level 6 (n=8)	None	None	None
NFLs (n=51)	DLSP Zoonosis Lab CGHR KEMRI CRDR-TB Lab CGHR-Influenza Lab National Influenza Centre (NIC)	CRDR-TB Lab National Influenza Centre (NIC)	DLSP Zoonosis Lab CGHR KEMRI CRDR-TB Lab CGHR-Influenza Lab National Influenza Centre (NIC)

HIV/AIDS

A total of 1759 (97%) of the total laboratory facilities assessed were mapped to offer HIV/AIDS testing services in all the 47 counties. Table 12 shows the distribution of HIV/AIDS testing methods across the facility levels. The most common testing method was rapid tests, especially among Level 2, 3, 4 and 5 facilities. A total of eight facilities used PCR for HIV/AIDS testing: AMPATH Eldoret, CVR-HIV lab, CGHR-HIV Lab, National HIV Reference Laboratory, KEMRI WRP–Kericho, CRDR-TB Lab and CGHR-Kisian. Only three facilities used Western Blot for HIV/AIDS testing: Coast PGH, KEMRI WRP–Kericho and CRDR-TB Lab).

Table 12: HIV/AIDS Tests

FACILITY LEVEL NO. (%)	RAPID TEST	ELISA	PCR	WESTERN BLOT
Level 2 (n=477)	455 (95%)	None	None	None
Level 3 (n=869)	844 (97%)	Coptic Nursing Home	None	None
Level 4 (n=399)	380 (95%)	17(4%)	None	None

FACILITY LEVEL NO. (%)	RAPID TEST	ELISA	PCR	WESTERN BLOT
Level 5 (n=11)	Nyeri PGH Thika Level 5 Hosp Embu PGH Machakos Level 5 Referral Hosp Meru District Hosp Garissa PGH Kisii Hosp (Level 5) Jaramogi Oginga Odinga TRH Nakuru PGH Kakamega PGH	Kakamega PGH	None	Coast Province General Hosp
Level 6 (n=8)	Moi Teaching Referral Hosp	KNH - Immunology Lab Moi Teaching Referral Hosp	KNH CCC Lab	None
NFLs (n=51)	Wellcome Trust Kilifi Mtwapa HIV/STI Clinic CGHR-HIV Lab KEMRI WRP - Kericho CIS-Project Lumumba Lab CMR - KEMRI Kisumu Centre for Clinical Research CIPDCR CRDR-TB Lab KEMRI WRP - Kombewa CRC-HIV Research Lab CGHR-Kisian	Wellcome Trust Kilifi Mtwapa HIV/STI Clinic CVR-HIV lab CGHR-HIV Lab National HIV Reference Laboratory KEMRI WRP - Kericho CIS-Project Lumumba Lab CMR - KEMRI Kisumu Centre for Clinical Research CRDR-TB Lab KEMRI WRP - Kombewa CGHR-Kisian	AMPATH Eldoret Mtwapa HIV/STI Clinic CVR-HIV lab CGHR-HIV Lab National HIV Reference Laboratory KEMRI WRP - Kericho CRDR-TB Lab CGHR-Kisian	KEMRI WRP - Kericho CRDR-TB Lab

PRIORITY TRADE SENSITIVE DISEASES AND METHODS

Eleven laboratories under the Division of Veterinary Services (DVS) were mapped for disease types and testing methods for eight priority trade sensitive diseases. However, none of the eleven laboratories tested for Ovarian rinderpest commonly known as Des Petits Ruminants (PPR) and the African swine fever (ASF). Further, the National Zoological Laboratory and Efficacy Trial Centre did not specify method(s) used in testing of Rift Valley fever (RVF). Table 13 presents list of diseases mapped at the various veterinary laboratories by testing method. Although grouped as part of the national laboratory networks in this mapping assessment, the DVS laboratories, like other national level labs are not necessarily county specific.

Table 13: Priority Trade Sensitive Diseases and Methods

DISEASE	FACILITY	TESTING METHOD
Foot & Mouth	National Veterinary Quality Control Lab	ELISA PCR Serum neutralization test Virus neutralization test
Contagious Bovine	RVIL Karatina	CFT
	Central Veterinary Laboratories, Kabete	ELISA CFT PCR
Contagious Caprine	RVIL Karatina	CFT
	Central Veterinary Laboratories, Kabete	CFT PCR
Rift Valley Fever	Central Veterinary Laboratories, Kabete	CFT PCR Serum neutralization test
	National Zoological Laboratory and Efficacy Trial Centre	Not stated
Newcastle Disease	Central Veterinary Laboratories, Kabete	ELISA PCR Haemoglutination inhibition test
	RVIL Nakuru	Haemoglutination inhibition test
	Kitale Satellite Lab	Haemoglutination inhibition test
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	Central Veterinary Laboratories, Kabete	ELISA PCR

PRIORITY FOOD SAFETY TESTS (CONTAMINANTS)

Food safety testing is done by the three Government Chemists in Nairobi, Kisumu and Mombasa and the Food Safety and Nutrition Laboratory. During the mapping exercise, the laboratories were assessed on testing of six priority food safety contaminants: Aflatoxins, *Clostridium perfringens*, *Staphylococcus aureus*, *Campylobacter* species, *Salmonella* species and *Escherichia coli*.

Aflatoxin

Aflatoxins are poisonous cancer-causing chemicals that are produced by certain molds which grow in soil, decaying vegetation, hay and agricultural crops such as maize, peanuts, cottonseed, and tree nuts. Aflatoxin can be tested using the following methods: ELISA, Thin Layer Chromatography, High Performance Liquid Chromatography, Liquid Chromatography Mass Spectrophotometry, Microarray system and UHPLC-MS/MS.

Government Chemist Nairobi tested for aflatoxin using ELISA, Thin Layer Chromatography and High Performance Liquid Chromatography, Food Safety and Nutrition Laboratory tested using ELISA and High Performance Liquid Chromatography while Government Chemist Mombasa used ELISA test only. Government Chemist Kisumu did not carry out aflatoxin testing.

Clostridium perforigens

These are bacteria that produce toxins harmful to humans. *Clostridium perfringens* and its toxins are found everywhere in the environment but human infection most likely come from eating food with the bacteria in it. *Clostridium perfringens* can be tested using the following methods: culture for isolation and identification, serotyping and PCR.

None of the four laboratories were testing for *Clostridium perfringens* at the time of the mapping assessment.

Staphylococcus aureus

This is a gram-positive bacterium that is frequently found in the nose, respiratory tract, and on the skin. It is often positive for catalase and nitrate reduction and is a facultative anaerobe that can grow without the need for oxygen. *Staphylococcus aureus* can be tested using the following methods: culture for isolation and identification, serotyping and PCR.

Only Government Chemist Mombasa was testing for *Staphylococcus aureus* using culture for isolation and identification method.

Campylobacter species

Campylobacter is a leading cause of bacterial diarrhea. Most *Campylobacter* species can cause disease and can infect humans and other animals. Currently, there are 17 species and six subspecies. Most people who become ill with campylobacteriosis get diarrhea, cramping, abdominal pain, and fever within two to five days after exposure to the organism. *Campylobacter* species can be tested using the following methods: culture for isolation and identification, serotyping and PCR.

None of the four laboratories were testing for *Campylobacter* species at the time of the mapping assessment.

Salmonella species

Salmonella is a bacterial strain or organism closely related to the *Escherichia* genus and cause illnesses such as typhoid fever, paratyphoid fever, and foodborne illness. *Salmonella* infections are zoonotic and can be transferred between humans and non-human animals. *Salmonella* species can be tested using the following methods: culture for isolation and identification, serotyping and PCR.

Only Government Chemist Mombasa was testing for *Salmonella* species using culture for isolation and identification method.

Escherichia coli

Escherichia coli is a coliform bacterium of the genus *Escherichia* that is commonly found in the lower intestine of warm-blooded organisms (endotherms). Most *E. coli* strains are harmless, but some serotypes can cause serious food poisoning. *E. coli* is one of the most frequent causes of many common bacterial infections, including cholecystitis, bacteremia, cholangitis, urinary tract infection (UTI), and traveler's diarrhea, and other clinical infections such as neonatal meningitis and pneumonia. *E. coli* can be tested using the following methods: culture for isolation and identification, serotyping and PCR.

Only Government Chemist Mombasa was testing for *E. coli* using culture for isolation and identification method.

PRIORITY ZOONOTIC DISEASES AND METHODS

Eighteen zoonotic diseases were mapped during the assessment.

Avian Influenza

Avian influenza can be tested using rapid test, ELISA and PCR. Avian Influenza pathogens were tested using rapid test method at RVIL Eldoret, RVIL Mariakani, RVIL Kericho, Central Veterinary Laboratories, Kabete, RVIL Karatina, RVIL Nakuru and KEMRI DLSP Lab in Kisumu. ELISA tests were done at RVIL Mariakani and Central Veterinary Laboratories, Kabete. PCR tests for Avian Influenza

pathogen were reported at Central Veterinary Laboratories, Kabete, KEMRI DLSP Lab and National Influenza Center.

Leishmaniasis

Leishmaniasis tests can be done using: rapid tests, microscopic smear, inoculation, aldehyde test, ELISA, PCR and direct fluorescence. Microscopic smear test for Leishmaniasis were provided at RVIL Nakuru whilst ELISA tests were provided at Central Veterinary Laboratories-Kabete.

Brucellosis

Brucellosis can be tested using Rapid test, ELISA and PCR. Rapid tests for detecting Brucellosis pathogens were done at Ukunda VIL, Kitale Satellite Lab, RVIL Nakuru, RVIL Garisa, Isiolo County Lab, RVIL Karatina, Contagious Bovine Pleuroneumonia Screening Unit and RVIL Kericho. ELISA tests for detecting Brucellosis pathogens were done RVIL Nakuru and Central Veterinary Laboratories, Kabete. PCR Brucellosis test was only provided at Central Veterinary Laboratories, Kabete.

Leptospirosis

Leptospirosis can be tested using micro agglutination, ELISA and ImmunoComb Technique. Leptospirosis tests using ELISA method and ImmunoComb Technique were provided at Central Veterinary Laboratories, Kabete, RVIL Eldoret and RVIL Nakuru. No laboratory provided Micro Agglutination test for Leptospirosis pathogens.

Anthrax

Anthrax can be tested using culture, ELISA, staining and molecular methods. Only RVIL Kericho reported conducting anthrax tests using the culture approach. Central Veterinary Laboratories-Kabete and Contagious Bovine Pleuroneumonia Screening Unit reported using ELISA for anthrax detection. RVIL Eldoret, RVIL Mariakani, Kitale Satellite Lab, RVIL Nakuru and RVIL Garisa used staining tests for detection of anthrax pathogens. No laboratory provided molecular testing for anthrax.

Plague

Even though plague can be tested using microscopy, fluorescent antibody technique and PCR, no veterinary laboratories provided tests for plague pathogens.

Rabies

Rabies can be tested using: PCR, indirect fluorescence, cellular staining, immuno-chromatography, staining for negri bodies and other (mice inoculation). RVIL Mariakani, RVIL Kericho and DLSP zoonosis lab used indirect fluorescence to test for rabies. Cellular staining test for rabies detection was done at RVIL Nakuru and RVIL Kericho. RVIL Nakuru, RVIL Karatina, Central Veterinary Laboratories, Kabete and RVIL Kericho used Immuno-chromatography to test for rabies pathogens. Staining for negri bodies test for rabies detection was used at RVIL Nakuru, RVIL Mariakani and RVIL Karatina.

Table 14: Rabies Test Methods by Laboratory

LAB	MICE INOCULATION	INDIRECT FLUORESCENCE	CELLAR STAINING	IMMUNO-CHROMATOGRAPHY	STAINING FOR NEGRI BODIES
National Veterinary Quality Control Lab					
RVIL Eldoret					
RVIL Mariakani		●			●
Ukunda VIL					
Kitale Satellite Lab					
RVIL Nakuru			●	●	●

LAB	MICE INOCULATION	INDIRECT FLUORESCENCE	CELLAR STAINING	IMMUNO-CHROMATOGRAPHY	STAINING FOR NEGRI BODIES
Witu VIL					
RVIL Garisa					
DLSP Zoonosis Lab		●			
National Zoological Laboratory and Efficacy Trial Centre					
RVIL Kericho		●	●	●	
Central Veterinary Laboratories, Kabete				●	
RVIL Karatina				●	●
Contagious Bovine Pleuroneumonia Screening Unit					

West Nile virus

Even though the West Nile virus can be tested using serological and molecular biology methods, none of the sampled laboratories provided tests for West Nile virus detection.

Bovine tuberculosis

Bovine tuberculosis can be tested using culture, acid fast staining, ELISA, immune-chromatography and PCR. Acid fast tests for bovine tuberculosis detections were used by RVIL, Mariakani, RVIL Nakuru, RVIL Kericho, Central Veterinary Laboratories, Kabete and RVIL Karatina. PCR tests for detection of bovine tuberculosis pathogens was only provided at Central Veterinary Laboratories-Kabete. No facility used culture, serological and immune-chromatography methods to test for bovine tuberculosis.

Tularemia

No veterinary facilities provided tests for tularemia pathogens.

Toxoplasmosis

No veterinary laboratory provided tests for toxoplasmosis pathogens.

Salmonellosis

The table below indicates facilities with capacity to test Salmonellosis and the methods used.

Table 15: Salmonellosis Test Methods

TEST METHODS	FACILITIES
Culture	RVIL Eldoret, RVIL Mariakani RVIL Nakuru RVIL Kericho Central Veterinary Laboratories-Kabete RVIL Karatina
Serotyping	RVIL Mariakani Ukunda RVIL
AST	RVIL Eldoret RVIL Mariakani RVIL Karatina RVIL Kericho Central Veterinary Laboratories-Kabete RVIL Nakuru
PCR	None

Helminths

Helminths tests can be done using direct microscopy, floatation and ELISA methods. Direct microscopy tests for helminths detection were done at RVIL Eldoret, RVIL Mariakani, Ukunda VIL, Kitale Satellite Lab, RVIL Nakuru, Witu VIL, Central Veterinary Laboratories, Kabete, RVIL Karatina and Contagious Bovine Pleuroneumonia Screening Unit. Floatation tests for helminths detection were done at RVIL Eldoret, RVIL Mariakani, Ukunda VIL, Kitale Satellite Lab, RVIL Nakuru, Witu VIL, RVIL Garisa, RVIL Kericho, Central Veterinary Laboratories, Kabete and RVIL Karatina. No laboratory provided ELISA test for helminths pathogen detection.

Table 16: Helminths Tests

LAB	DIRECT MICROSCOPY	FLOATATION	ELISA
National Veterinary Quality Control Lab			
RVIL Eldoret	●	●	
RVIL Mariakani	●	●	
Ukunda VIL	●	●	
Kitale Satellite Lab	●	●	
RVIL Nakuru	●	●	
Witu VIL	●	●	
RVIL Garisa		●	
Isiolo County Lab			
National Zoological Laboratory and Efficacy Trial Centre			
RVIL Kericho		●	
Central Veterinary Laboratories, Kabete	●	●	
RVIL Karatina	●	●	
Contagious Bovine Pleuroneumonia Screening Unit	●		

Fungal Diseases

Fungal diseases can be detected using direct microscopy, Indian ink, rapid test, microscopic smear, culture, ELISA, PCR, and direct agglutination. Direct microscopic method for fungal disease detection was used at RVIL Eldoret, RVIL Mariakani, Kitale Satellite Lab, RVIL Nakuru, RVIL Garisa, RVIL Kericho and RVIL Karatina. Indian ink test method was only used at RVIL Nakuru. Rapid test for fungal diseases was only used at RVIL Eldoret. Microscopic smear test services for fungal diseases were provided at RVIL Eldoret, RVIL Mariakani, RVIL Ukunda and RVIL Nakuru. Culture test services for fungal disease detection were offered at RVIL Eldoret, RVIL Mariakani, RVIL Nakuru, RVIL Kericho, Central Veterinary Laboratories-Kabete and RVIL Karatina. No veterinary laboratory offered ELISA, PCR, Direct Agglutination and for fungal diseases pathogen detection.

Table 17: Fungal Diseases

LAB	DIRECT MICROSCOPY	INDIAN INK	RAPID	MICROSCOPIC SMEAR	CULTURE	ELISA	PCR	DIRECT AGGLUTINATION
National Veterinary Quality Control Lab								
RVIL Eldoret	●		●	●	●			
RVIL Mariakani	●			●	●			
Ukunda VIL				●				
Kitale Satellite Lab	●							
RVIL Nakuru	●	●		●	●			
Witu VIL								
RVIL Garisa	●							
Isiolo County Lab								
National Zoological Laboratory and Efficacy Trial Centre								
RVIL Kericho	●				●			
Central Veterinary Laboratories, Kabete					●			
RVIL Karatina	●				●			
Contagious Bovine Pleuroneumonia Screening Unit								

Schistosomiasis

Schistosomiasis can be tested using direct microscopy, ELISA and molecular methods. RVIL Garisa and RVIL Kericho used microscopy testing for schistosomiasis pathogen detection. No veterinary laboratory provided ELISA and molecular tests for schistosomiasis pathogen detection.

Trypanosomiasis

Trypanosomiasis can be detected using the following methods: microscopic smear, ELISA, PCR and indirect-fluorescent technique. Microscopic smear test was the most commonly used method for trypanosomiasis pathogen detection. RVIL Eldoret, RVIL Mariakani, Ukunda VIL, Kitale Satellite Lab, RVIL Nakuru, RVIL Garisa, Isiolo County Lab, National Zoological Laboratory and Efficacy Trial Centre, RVIL Kericho Central Veterinary Laboratories-Kabete, RVIL Karatina and Contagious Bovine Pleuroneumonia Screening Unit used the microscopic smear method. PCR tests for trypanosomiasis pathogen detection were only conducted at Central Veterinary Laboratories-Kabete. No laboratory used ELISA and indirect-fluorescent technique tests for trypanosomiasis pathogen detection.

Rickettsia

WRP Entomology lab Kisian and KEMRI WRP in Kondele Kisumu reported to be testing for Rickettsia using Realtime PCR method.

Viral Hemorrhagic Fever

The viral hemorrhagic fever pathogen detection tests were reported to be done at the National Virology Reference Lab at NPHL, CGHR-Influenza Lab, WRP ENTOMOLOGY, Kisian, IDRL-CIPDCR KEMRI, ALUPE and KEMRI WRP – Kondele using realtime PCR method. ELISA method was also used at National Virology Reference Lab.

Table 18: Laboratories Testing for VHF

LABORATORY	DISEASE	METHOD
National Virology ref lab	Dengue	PCR, ELISA
	Rift Valley Fever	PCR
KEMRI WRP Kondele		PCR
WRP Entomology		PCR
IDRL-CIPDCR Alupe		PCR
CCGHR-Influenza Kisian		PCR

ESPECIALLY DANGEROUS PATHOGENS (EDPs)

Several laboratories, especially at the national level, reported that they had capacity to test especially dangerous pathogens (EPDs). Among the EPDs tested at the lab facilities include anthrax, brucellosis, hemorrhagic fever, Rift Valley fever, African swine fever, Rickettsia, Rinderpest and Foot and Mouth Disease.

Only RVIL Kericho reported conducting anthrax tests using the culture approach. Central Veterinary Laboratories-Kabete and Contagious Bovine Pleuroneumonia Screening Unit reported using serological tests for anthrax detection. RVIL Eldoret, RVIL Mariakani, Kitale Satellite Lab, RVIL Nakuru and RVIL Garisa used staining tests for detection of anthrax pathogens. No laboratory provided molecular testing for anthrax pathogens.

Brucellosis testing using rapid ELISA and PCR were reported. Rapid tests for detecting Brucellosis pathogens were done at Ukunda VIL, Kitale Satellite Lab, RVIL Nakuru, RVIL Garisa, Isiolo County Lab, RVIL Karatina, Contagious Bovine Pleuroneumonia Screening Unit and RVIL Kericho. ELISA tests for detecting Brucellosis pathogens were done at RVIL Nakuru and Central Veterinary Laboratories, Kabete. PCR Brucellosis testing was only provided at Central Veterinary Laboratories, Kabete.

- Foot and mouth testing using ELISA, PCR, serum and virus were conducted at the National Veterinary Quality Control Lab.
- Rift valley fever test services were provided at Central Veterinary Laboratories-Kabete.
- The viral hemorrhagic fever pathogen detection tests were reported to be done at the influenza laboratory at NPHL, National virology lab, WRP entomology lab and IDRL CIPDCR Alupe.
- No laboratory offered tests for rickettsia pathogen detection.
- No laboratory offered tests for ovarian rinderpest pathogens.

- No laboratory offered tests for ASF pathogens even though this test is being done at International Livestock research institute (ILRI).

EQUIPMENT INVENTORY

The laboratory capacity mapping exercise covered the different types of lab equipment in facilities, functionality status of the equipment, service contract and maintenance.

Types of Laboratory Equipment

Over 14,000 lab equipment items of about 30 common different types were documented during the mapping exercise. The types of lab equipment ranged from more specialized ones such as microtomes, tissue processors and blood culture machines to most common equipment like microscopes, glucometers and refrigerators as shown in Appendix Table A2. During the data collection process, data on some aspects of some equipment items was missed. For this reason, total number of equipment varies across tables and figures.

Most of the laboratory equipment across the 1,820 facilities were in functional status during the time of this assessment, however 5.1% were non-functional. In terms of maintenance, 83.7% of all lab equipment with a planned preventive maintenance schedule were reported to have undergone maintenance within a year.

Laboratory Equipment Models and Manufacturers

Biosafety Cabinets

There were 21 documented manufacturers of biosafety cabinets over 300 facilities countrywide. Faster manufacturers had a total of 32 machines with four different models (the most common models were Sterilegard II-10 machines and SG403A-9 machines). Germfree manufacturers had a total of 40 machines distributed in four different models (the most common model was VCE-36). Walker Safety Company had 19 machines with four different models (all of them Class Gen Series). Labex had 42 machines with five different models (BBS 700 II-17 machines, BS 8-10 machines and BSC-110011A 2x-8 machines). Other manufacturers were included Bibase, Gelaire, Thermo Scientific, Lab Care, ESCO, Hitachi, LabCONCO and BioBase. Out of the 313 machines, 224 (72%) had updated certification.

GeneXpert

Cepheid was the only reported manufacturer for GeneXpert machines with the Cepheid and GXVRZ models being used. Both had valid service contracts.

Hematology Analyzer

There were 110 documented manufacturers of hematology analyzers over 470 different laboratories countrywide. Medonic manufacturers had a total of 73 machines across 20 different models (the most common models were M-Series-27 machines, M32M-10 machines and M20M-5 machines). Nikon Kohden manufacturers had a total of 64 machines distributed in 14 different models (the most common models were Celtic MEK 6400-with 22 machines, Celltac-with 16 machines). MINDRAY 280P had 60 machines across 24 different models (the most common model was BC 2800 with 23 machines). Sysmex Corporation had 30 machines distributed countrywide with over 18 different models (XP300-7 and KX21N-5 were the most common). Other manufacturers were Human (30 machines), Beckman Coulter (21 machines), Boule Medical Labs (18 machines), 23 models did not have any listed manufacturers. Out of the 473 machines, 236 (50%) had valid service contracts.

CD4 Analyzer

Seven different manufacturers were reported to have supplied 273 machines. Pima (Alere technologies) and Facscount from BD had 87 and 80 machines respectively distributed in different facilities. Other models were FacsPresto (26) and Facscalibur (BD) (11). Partec manufacturers also had 52 machines distributed with the Cyflow Counter model having 46 machines. 109 (40%) of all CD4 analyzers had valid service contracts.

Blood Culture

There were seven manufacturers who had supplied 21 blood culture machines. Becton Dickinson had 15 machines (Bactec 9050-9 machines, FX40-4 and NB2552-2 machines). Biometrix UX, Vitek, Eurolyser, MED, Renjer and DURGA all had one machine each.

Fifteen (71%) had valid service contracts in place.

Chemistry Analyzer

There are 58 manufacturers with 89 models of chemistry analyzers in the market and a total of 512 machines distributed all over the country. Fujifilm manufacturers had 69 machines (with the NX500i model comprising of 62-90%). Biosystems had 68 machines with the BTS330 (39) as their most common model. Human manufacturers had 54 machines across 6 different models andthere were 19 and 18 Humalyzer 2000 and 3000 series machines respectively. Other manufacturers were Mindray 38 machines, Roche 33 and LandWind with 20 machines.

There were 206 (40%) valid service contracts for all the reported chemistry analyzers.

Laboratory Equipment Service Contract Status

Of the functional 12,625 pieces of laboratory equipment across the country for which the availability of a service contract is known, 20.2% of equipment had service contracts.

Table 19: Service Contract Status for Laboratory Equipment in the Country

Equipment	Number of Equipment by Contract Status					
	No contract			Has contract		
	Functional	Non-functional	Total	Functional	Non-functional	Total
Chemistry Analyzer	212	31	243	201	5	206
Electrolyte Analyzer	27	8	35	28	0	28
Microscope	1,731	130	1,861	224	3	227
Centrifuge	1,084	46	1,130	187	4	191
Glucometer	1,454	25	1,479	21	0	21
HB Meter	1,135	63	1,189	42	0	42
Hematology Analyzer	178	34	212	229	7	336
Water Bath	240	16	256	60	1	61
Incubator	230	23	253	111	4	115
Autoclave	105	17	122	51	5	56
CD4 Analyzer	136	12	148	99	10	109
Biosafety Cabinets	98	8	106	219	5	224
Oven	128	14	142	32	1	33
Mechanical Pipette	460	15	475	69	1	70
Shakers	230	7	237	28	0	28
GeneXpert	0	0	0	125	0	125
Molecular Equipment	56	7	63	198	1	199
Analytical Weighing Balance	373	11	384	52	1	53
PH Meter	115	4	119	12	0	12
Blood Culture Machine	1	2	3	13	0	13
Serology Equipment	11	4	15	2	0	2
Microtome	6	0	6	6	0	6
Tissue Processor	21	1	22	3	0	3
Vortex	61	4	65	53	0	53
Immuno Analyzer	27	1	28	45	2	47
Hoods	83	23	106	35	0	35
Rotator	199	3	202	23	1	24

Equipment	Number of Equipment by Contract Status					
	No contract			Has contract		
	Functional	Non-functional	Total	Functional	Non-functional	Total
Refrigerator	1,084	43	1,127	228	3	231
Freezer	75	1	76	134	1	135
Other	227	22	249	63	3	66
Total	**9,787**	**575**	**10,362**	**2,478**	**58**	**2,534**

PRIORITY ANALYTICAL TESTS

Priority analytical test mapping was done for the three Government Chemists. In summary, Kisumu Government Chemist conducted four tests: Immunoassay for narcotics, DNA profiling for species identification using genetic analyzer, conventional PCR and real time PCR. Mombasa and Nairobi Government Chemists carried out 20 and 36 tests respectively as shown in Table 23. None of the three facilities reported carrying out tests for vitamins in foods and amino acids in foods. All the three labs conducted DNA profiling for species identification. The Nairobi Government Chemist is the only one that reported conducting testing for cannabis, pesticide poisoning and antibiotic residue in food.

Table 20: Priority Analytical Tests

TEST	METHOD	KSM	MBS	NBI	TEST	METHOD	KSM	MBS	NBI
Methanol	GC		●	●	Portable Water	AAS		●	●
	GC-HS			●		UV			●
	GC- MS		●	●		Bacteriological		●	
Arrow Poison	UV		●	●	Effluent	BOD		●	●
	GC-MS		●	●		COD reactor		●	
	TLC		●	●	Amino acids in food	LC-MS/MS			
Alcohol Content	GC		●	●		UPHLC-MS/MS			
	GC-MS		●	●	Heavy Metal	AAS		●	●
	GC-HS			●		ICP-AES			
Nicotine	UV		●	●	Antibiotic Residue In Food	GCMS			●
	GC			●		UV			●
	HPLC			●		TLC			
	LCMS					LCMS/MS			
	MS				Pesticides Residue In Food	GCMS		●	●
Narcotics	Immuno Assay	●		●		UV			●
	GCMS			●		TLC			●
	TLC					LCMS/MS			
	Marquis				DNA Profiling For Species Identification	Genetic Analyser	●	●	●
Pesticides Poisoning	GCMS			●		PCR	●	●	●
	UV			●		Real time PCR	●	●	●
	TLC			●	DNA Paternity	Genetic Analyser		●	●
	LCMS					PCR		●	●
	MS					Real time PCR		●	●

TEST	METHOD	KSM	MBS	NBI	TEST	METHOD	KSM	MBS	NBI
Vitamins in food	ELISA				Arson	UVSPEC			●
	Serotyping				Cannabis	UV			●
	Rapid testing					GC			●
	PCR					HPLC			●

Note: Apart from the Govt. Chemists Labs, FSNRL was found to be testing for vitamins in food, alcohol, methanol, portable water and heavy metals.

WORKLOAD AND REFERRALS

Referral Pattern-Level 2

The most referred tests from Level 2 facilities to either sub-county or county facilities were for cholera, typhoid, TB GeneXpert and HIV CD4. TB PCR tests in 40 counties were referred to the National TB Reference Laboratory (NTRL) either directly (60%) or indirectly through their respective county mechanisms.

Out of the 32 counties that referred HIV viral load specimens, Level 2 facilities in 10 counties reported that they sent specimens for HIV viral load tests through their county referral hospitals. The main testing sites for viral load were Ampath Eldoret, KEMRI WRP Kericho, KEMRI Alupe, KEMRI CGHR Kisian, KEMRI P3 Lab Nairobi, Coast PGH and NHRL. Level 2 facilities in 29 counties reported that they also referred viral load samples for PCR testing.

All Level 2 facilities indicated that they did not refer malaria samples for testing.

A total of 214 (45%) Level 2 facilities referred schistosomiasis, 145 (30%) facilities referred brucellosis and 24 (5%) facilities referred trypanosomiasis samples to other labs.

Referral Pattern-Level 3

Level 3 facilities generally referred their samples to Level 4, 5, 6 and NFLs.

Out of the 413 cholera referrals, 298 (72%) were to Level 4, 5 and 6 facilities while the remainder were to NFLs. Nineteen facilities referred Yellow Fever samples to Level 4, 5, 6 and NFL laboratories. Facilities referring HIV viral load samples for testing either to Level 4, 5, 6 or NFLs totaled 284 (32%).

Referral Pattern-Level 4

Cholera

Level 4 laboratories are mainly in the sub-county referral facilities. A total of 41 counties reported referring cholera samples. Among these, 28 reported referring to their respective County referral and Level 5 labs, 12 to the National Microbiology Reference Laboratory (NMRL), nine to other Counties, while 14 indicated referring to other agencies' labs.

Kilifi and Murang'a referred samples to Coast PGH and NMRL respectively yet they were also reported elsewhere as referral sites. They were either a referral node where samples would be dropped off for onward transmission or they occasionally experienced difficulties with processing cholera samples.

Table 21: Referral Laboratories and Respective Referring Counties

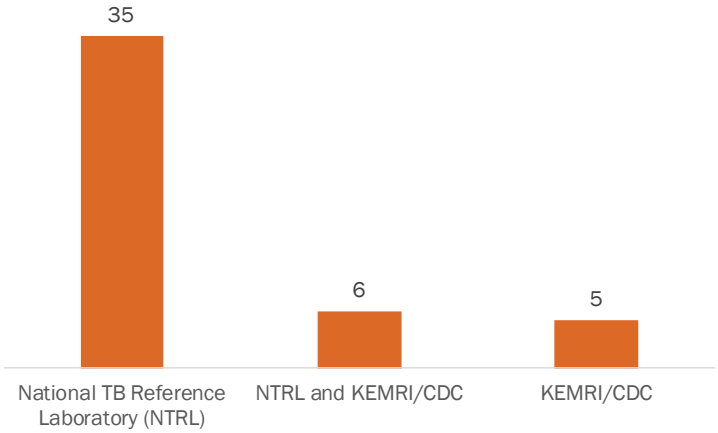
REFERRAL LABS	NO. COUNTIES	REFERRING COUNTIES
NMRL	12	Baringo, Bomet, Isiolo, Kiambu, Kirinyaga, Makueni, Marsabit, Murang'a, Nairobi, Narok, Tharaka-Nithi, Turkana

REFERRAL LABS	NO. COUNTIES	REFERRING COUNTIES				
Other County	9	Kakamega (Kitale DH lab), Eldoret (MTRH) Kilifi (CPGH lab), Kirinyaga (Murang'a CRH lab), Lamu (Malindi Hospital lab), Narok (Kisii Level V lab), Tana River (Malindi SDH lab), Tharaka Nithi (Embu CRH lab) WestPokot (Kitale SDH lab)				
Other labs	14	KEMRI/CDC-Nrb	KEMRI/CDC Ksm	IRC	Alupe	WRP
		Kajiado, Mandera, Meru, Mombasa, Nairobi, Tharaka-Nithi, Turkana	Bungoma, Kisumu, Nyamira, Vihiga	Garissa	Busia	Kericho

Tuberculosis

Two referral laboratories for TB culture were reported; the National TB Reference Laboratory (NTRL) and the KEMRI/CDC laboratory, Kisumu-Kisian. Six counties indicated referring their samples to both NTRL and KEMRI/CDC laboratory (Figure 9).

Figure 10: Referral Laboratories for TB Culture

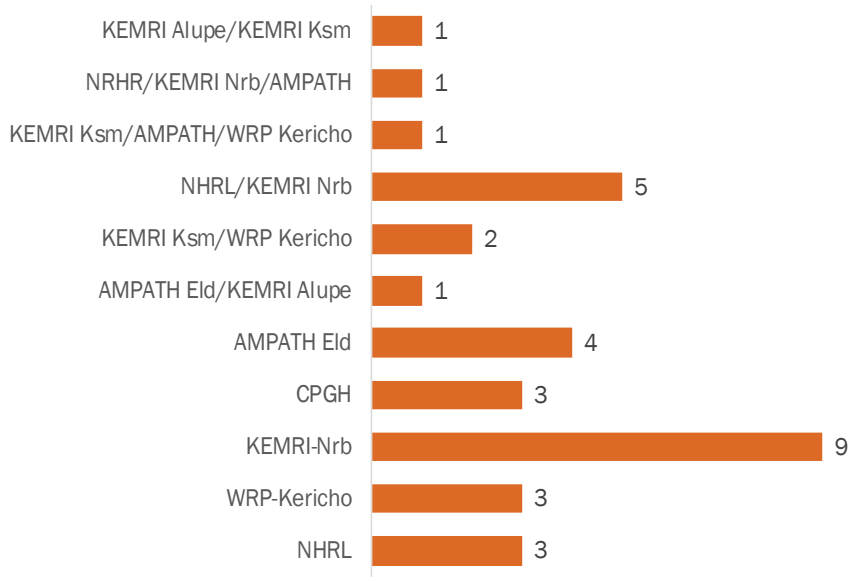


Referral for GeneXpert was mostly available within the counties except for two counties (Elgeyo Marakwet and Kilifi) which reported referring to MTRH and CPGH respectively.

HIV Viral Load and EID

Among the 33 counties that responded that they refer HIV viral load and EID sample testing 11 reported referring to multiple testing laboratories (Figure 10).

Figure 11: HIV Viral Load and EID Referral Testing Labs



Referral Pattern-Level 5

Cholera

Embu PGH, Thika Level 5 and Meru District indicated referring cholera samples to NMRL while JOOTRH referred to KEMRI CGHR.

TB Culture

Embu PGH, Garissa PGH, Kakamega PGH, Thika Level 5, Kisii Level 5, Coast PGH, Nakuru PGH indicated referring to NTRL and JOOTRH to KEMRI CGHR.

Other Referrals

All Level 5 facilities apart from Garissa PGH, Kakamega PGH and JOOTRH indicated referring measles samples to KEMRI CVR. Poliomyelitis samples were reportedly referred to KEMRI CVR.

Only Kakamega PGH and Machakos Level 5 reported referring Yellow Fever to KEMRI CVR.

Table 22: Level 5 Facility Referrals

LEVEL	LABORATORIES	DISEASE	REFERRALS	TESTS	REFERRALS	TESTS
National	CVL	ASF	ILRI	PCR		
National	CVL	CBPP	KALRO MUGUGA			
National	CVL	Trypanosomiasis	KETRI			
Regional	RVILs	RVF	CVL			
Regional	RVILs	CCPP	CVL			
Regional	RVILs	CVL	FMD -EMBAKASI		PIRBRIGHT, UK	Gene characterization

LEVEL	LABORATORIES	DISEASE	REFERRALS	TESTS	REFERRALS	TESTS
Regional	RVILs	PPR	CVL		IETA LAB - SIEBERSDOF	
Regional	RVILs(Garissa)	ASF	CVL			
Regional	RVILs(Garissa)	Viral hemorrhagic fevers (in camels)	CVL UON			

Thika Level 5 reported sending Anthrax samples to KEMRI CMR and Rabies to KEMRI CVR.

Garissa PGH reported referring RVF and VHF samples to KEMRI CVR.

Referral Pattern-Level 6

Facilities in Level 6 constitute National Reference, Research and Government Chemist labs and did not refer any samples.

Veterinary Labs

These comprise of CVL, National FMD lab, National Quality lab, RVIL and satellite veterinary labs.

RVILs reported sending all their referral samples to the CVL.

CVL reported referring trypanosomiasis tests to the Kenya Trypanosomiasis Research Institute (KETRI), Viral hemorrhagic fever tests to KEMRI and African Swine Fever (ASF) PCR tests to the International Laboratory Research Institute (ILRI), Kabete.

Referral Network Maps

The referrals maps show consistent referral pathways for cholera, CD4, EID, typhoid and polio. While most of the referrals are generally from lower level facilities to higher level ones (i.e. from Level 2 to 3 to 4 to 5 to 6 and NFLs), there are no defined ground routes that the samples use. There are reported cases of samples moving to more than one or two facilities before reaching their destination lab. Most referral pathways were established and maintained by implementing partner activities and affiliations. These partner networks do not necessarily follow the nearest or shortest route pathways hence leading to cross-funding inefficiencies (but do not necessarily compromise the quality). In many cases, even though not in competition with each other, partners do not share their referral infrastructure.

Figure 12: Referral Networks for Cholera

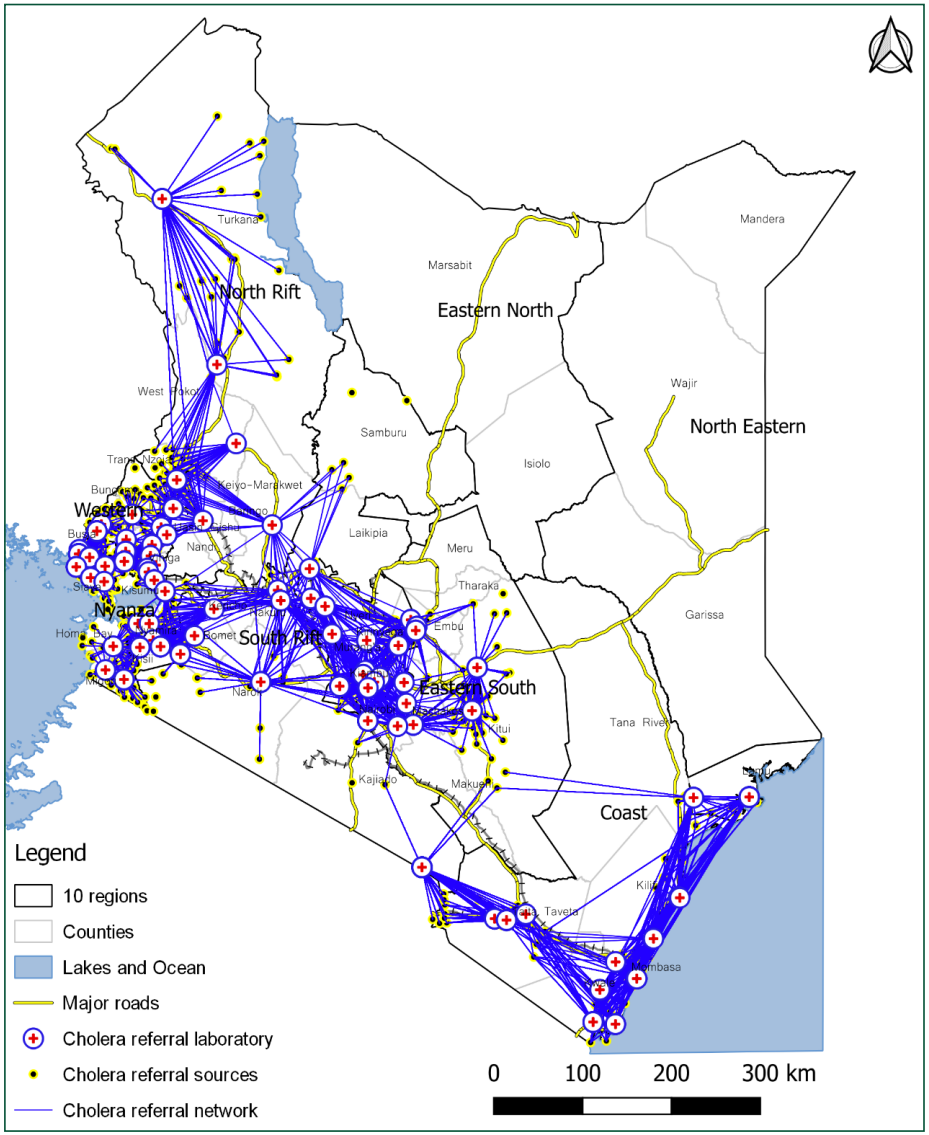


Figure 13: Referral Networks for CD4

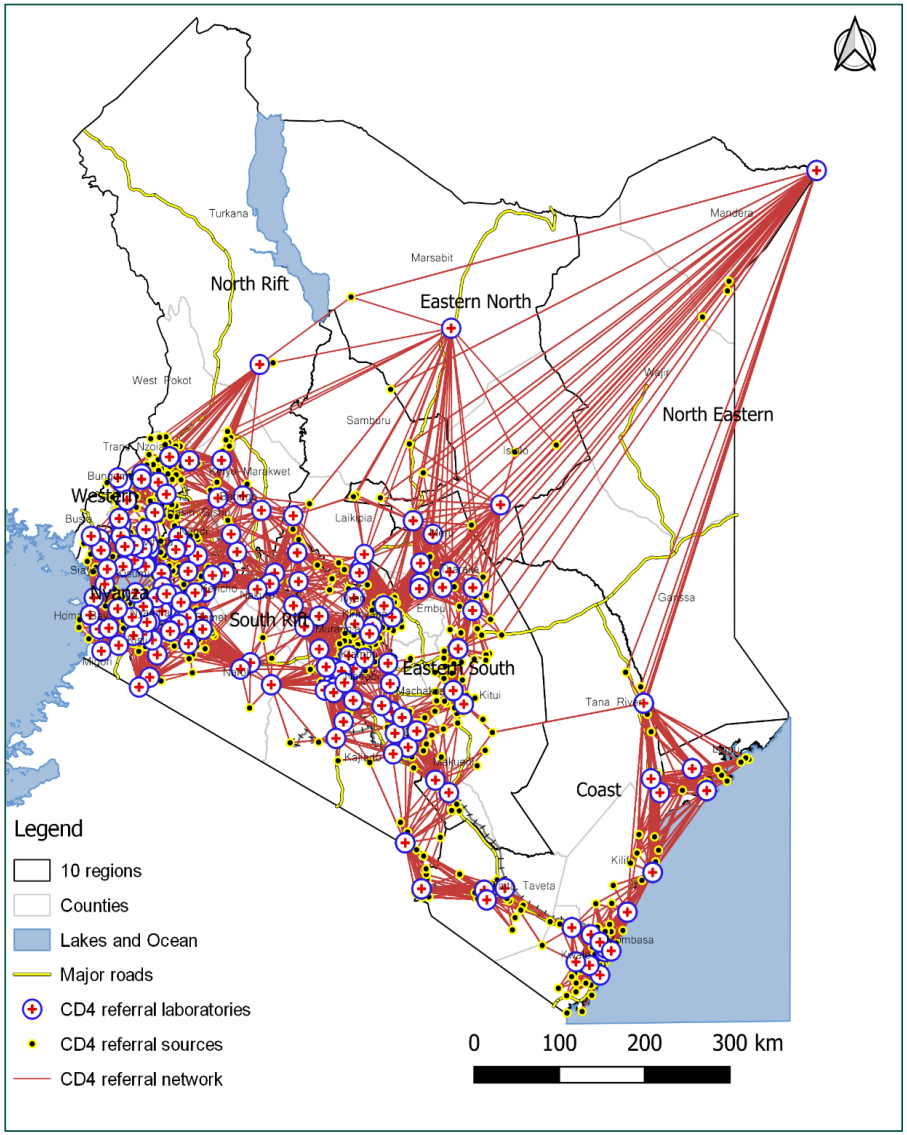


Figure 14: Referral Networks for EID

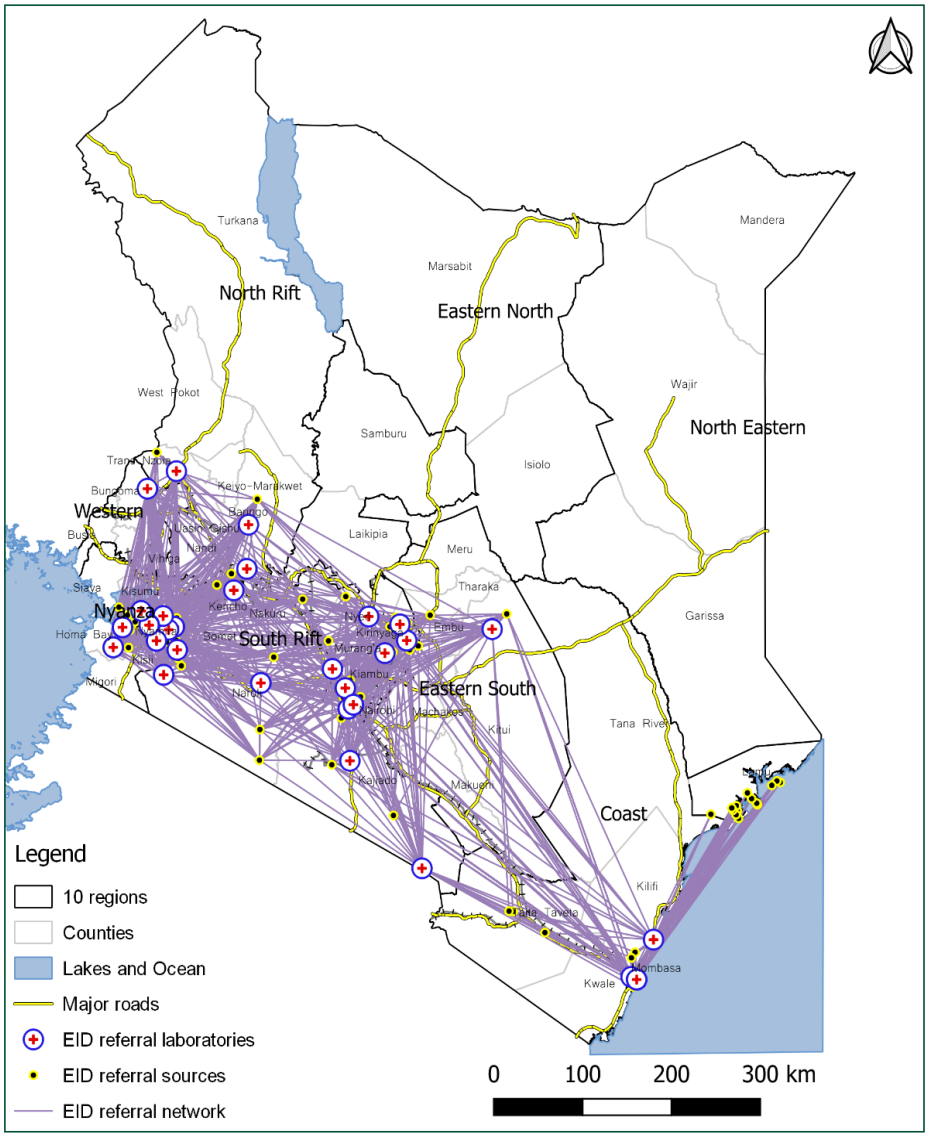


Figure 15: Referral Networks for Typhoid

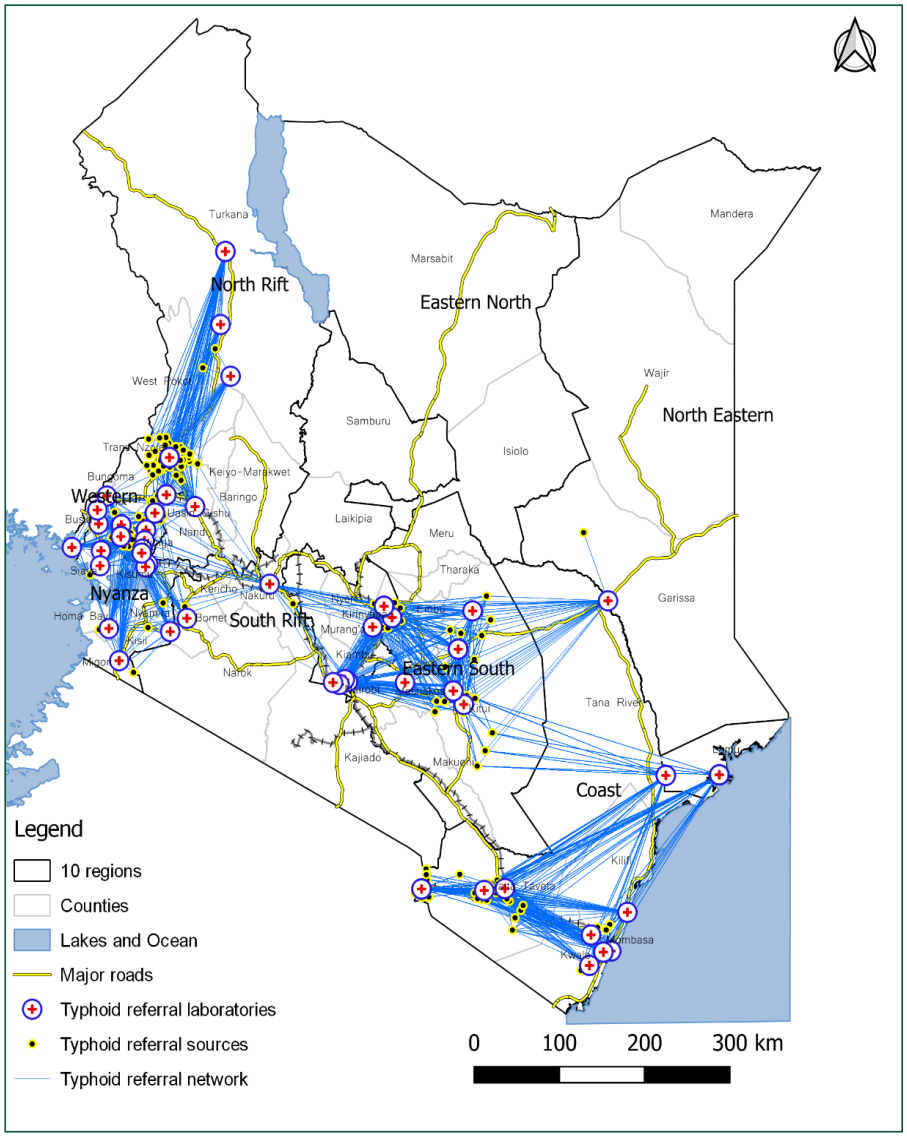
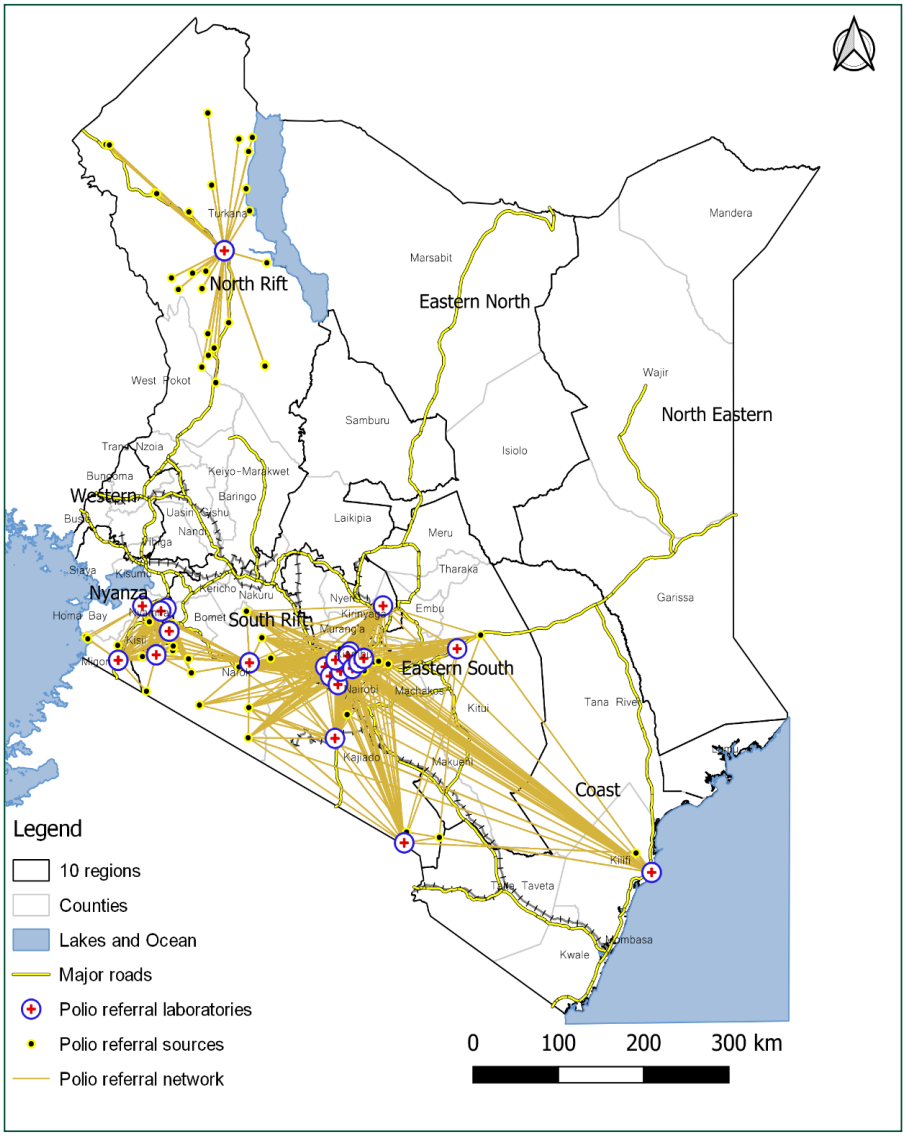


Figure 16: Referral Networks for Polio



LABORATORY CAPACITY SCORES

In this section, laboratories were scored against a set of pre-determined standards for policy management, equipment management, commodity/inventory management, data management, quality management, safety/biosafety/security and zoonotic surveillance. Each section had a set of questions that had rating options based on the performance of the laboratories against each question/ indicator. A rating score of 1 to 4 (apart 1-3 for commodity management) were given against each indicator for every laboratory capacity score dimension. A score of less than 1 (<1) means lack of the indicator or systems to support it completely hence requiring urgent intervention/response; 1-2.5 means presence of indicator but lack of systems or processes to support it hence requires strategies for improvement and actual improvement; >2.5-3.5 means presence of indicators plus systems to support it but maybe lacking measures for sustainability hence need for establishing long term interventions to ensure sustainability and; >3.5-4 means there are indicators, systems and process in place and sustainable mechanisms to ensure continued success.

Policy Management

Under policy management, the laboratories were assessed and scored against three questions/indicators: whether a budget was assigned for laboratory activities/services; whether the laboratory participated in health management team meetings and strategic planning initiatives and; whether the laboratory complied with the National Laboratory Services Policy Guidelines. A rating of 1 to 4 was scored against each lab based on the status of indicator under question (where 1 was the lowest score and indicated that

the lab did not have a budget, was not part of any health management team meetings or did not comply with the NLS Policy Guidelines) and 4 was the highest score and was an indicator that the lab had a budget with all accountability checks like expenditure tracking in place, was an active member of health meetings and strategic planning process and complied with all NLS Policy Guidelines—see annex 1 - questionnaire.

The overall mean score for all the labs sampled for the three policy management indicators was 2.28.

The mean score for budget allocation for lab activities/ services was 2.03 (Level 2 had a mean score of 1.78, Level 3 had a mean score of 1.92, Level 4 had a mean score of 2.57, Level 5 had a mean score of 3.91, Level 6 had a mean score of 4.00 and non-facility labs had a mean score of 3.35). The counties with the highest scores on this indicator were Kiambu (3.23), Laikipia (3.39), Taita Taveta (3.48) and Nakuru (3.66), while Wajir (1.18), Kitui (1.17), Murang'a (1.02) and Lamu (1.00) counties scored lowest.

The mean score for lab participation in health management meetings and strategic planning was 2.81 (Level 2 had a mean score of 2.55, Level 3 had a mean score of 2.77, Level 4 had a mean score of 3.39, Level 5 had a mean score of 4.00, Level 6 had a mean score of 4.00 and non-facility labs had a mean score of 3.49, with RVIL Mariakani, Kisumu Government Chemist, Nairobi Government Chemist, Witu VIL, CMR-Kwaleand Central Veterinary Laboratories, Kabetelabs scoring 1). The best performing counties were Kiambu (3.68), Laikipia (3.74), Taita Taveta (3.75) and Makueni (3.81) while Isiolo (1.71), Murang'a (1.47), Kitui (1.44) and Lamu (1.13) counties registered the lowest scores.

The mean score for compliance to National Laboratory Services Policy Guidelines was 2.01 (Level 2 had a mean score of 1.77, Level 3 had a mean score of 1.94, Level 4 had a mean score of 2.62, Level 5 had a mean score of 3.91 [all had 4 except for Garissa Level 5 which had a score rating of 3], Level 6 had a mean score of 3.50). Even though it was not a requirement for NFLs to adopt national laboratory service policy guidelines as they do not belong to the MOH, data was collected on the indicator and non-facility labs had a mean score of 2.94, with DLSP Zoonosis Lab - CGHR KEMRI, CGHR-NTD Labs, RVIL Eldoret, RVIL Mariakani, Kisumu Government Chemist, Nairobi Government Chemist, Food Safety and Nutrition Laboratory, Witu VIL, CIPDCR, KEMRI WRP-Kombewa, CGHR-Influenza Lab, Mombasa Government Chemist, National Spinal Injury Hospital and Contagious Bovine Pleuroneumonia Screening Unit all scored 1. Nakuru (2.84), Makueni (2.94), Taita Taveta (3.18) and Elgeyo Marakwet (3.36) were ranked as the top counties while Baringo (1.17), Tana River (1.14), Lamu (1.13) and Marsabit (1.05) were the least ranked counties.

Policy management: The overall mean score for all laboratories in policy management was 2.28 out of 4 and the best performing indicator/dimension was whether the laboratory participated in health management team meetings and strategic planning initiatives (2.9) while the indicators whether a budget was assigned for laboratory activities/services and whether the laboratory complied with the National Laboratory Services Policy Guidelines both scored a 2.1.

Laboratory equipment: The overall mean score for all laboratories in equipment management was 1.01 out of 4 and the best performing indicator/dimension under equipment management was presence of equipment management logs (2.74) while the indicators with the lowest score were routine calibration and availability of service contracts (0.27).

Commodity management: The overall mean score for all laboratories in commodity management was 1.91 out of 3.The best performing indicator/dimension under commodity/ inventory management was lab reagents/kits being within the manufacturer's expiry dares (2.73) while the indicator with the lowest score was laboratories maintaining a stock of emergency sample collection and transport supplies (1.74).

Data management: The overall mean score for all the labs sampled was 1.63 out 4 and the best performing indicator/ dimension under data management was use of standard data collection tools (3.18) while the indicator with the lowest score was laboratories having a LIS modification protocol (0.81).

Quality management: The overall mean score for all the labs in quality management indicators was 1.76 out of 4 and the best performing indicator/dimension under quality management was laboratories having SOPs (2.97) while the indicator with the lowest score was laboratories having training policies (2.28).

Safety/biosafety/security: The overall mean score for all the laboratories was 1.31 out of 4 and the best performing indicator/ dimension under safety/biosafety/security was laboratories having safety equipment (2.87) while the indicator with the lowest score was reporting system (0.77).

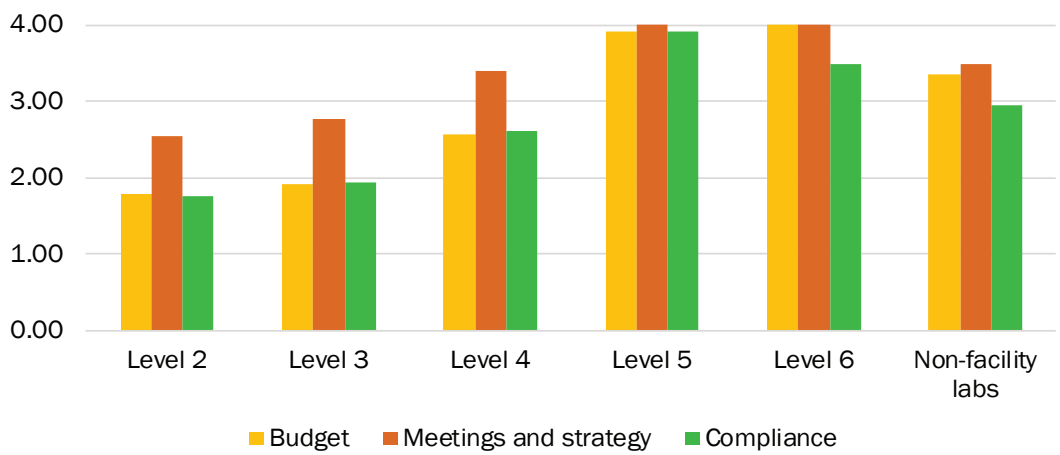
Zoonotic: The overall mean score for all the laboratories in zoonotic was 1.19 out of 3 and the best performing indicator/ dimension under zoonotic was outbreak preparedness (1.37) and the indicator with the lowest score was displayed poster on zoonotic diseases (0.91).

Regarding existence of a specific budget for lab activities and services, the following facility proportion represents laboratory levels that had a rating of 4: 16%-Level 2 & 3, 35%-Level 4, 91%-Level 5 and 75%-Level 6 laboratories. A rating of 1 was distributed thus: 58%-Level 2, 51%-Level 3, 31%-Level 4 and 14%-Level 6 (no Level 5 lab had a rating of 1).

With regards to the lab participation in health management meetings and strategic planning, the following is the distribution of labs with a rating of 4: 45%-Level 2, 52%-Level 3, 73%-Level 4, 100%-Level 5 and 81%-Level 6 laboratories whilst the distribution of a rating of 1 was thus: 40%-Level 2, 31%-Level 3, 13%-Level 4 and 7%-Level 6 laboratories (no Level 5 lab had a rating of 1).

The indicator compliance to National Laboratory Services Policy Guidelines, had a score rating of 4 distributed thus: 10%-Level 2, 11%-Level 3, 27%-Level 4, 91%-Level 5 and 59%-Level 6 laboratories whilst the distribution of a rating of 1 was: 53%-Level 2, 43%-Level 3, 22%-Level 4 and 19%-Level 6 laboratories (no Level 5 lab had a rating of 1).

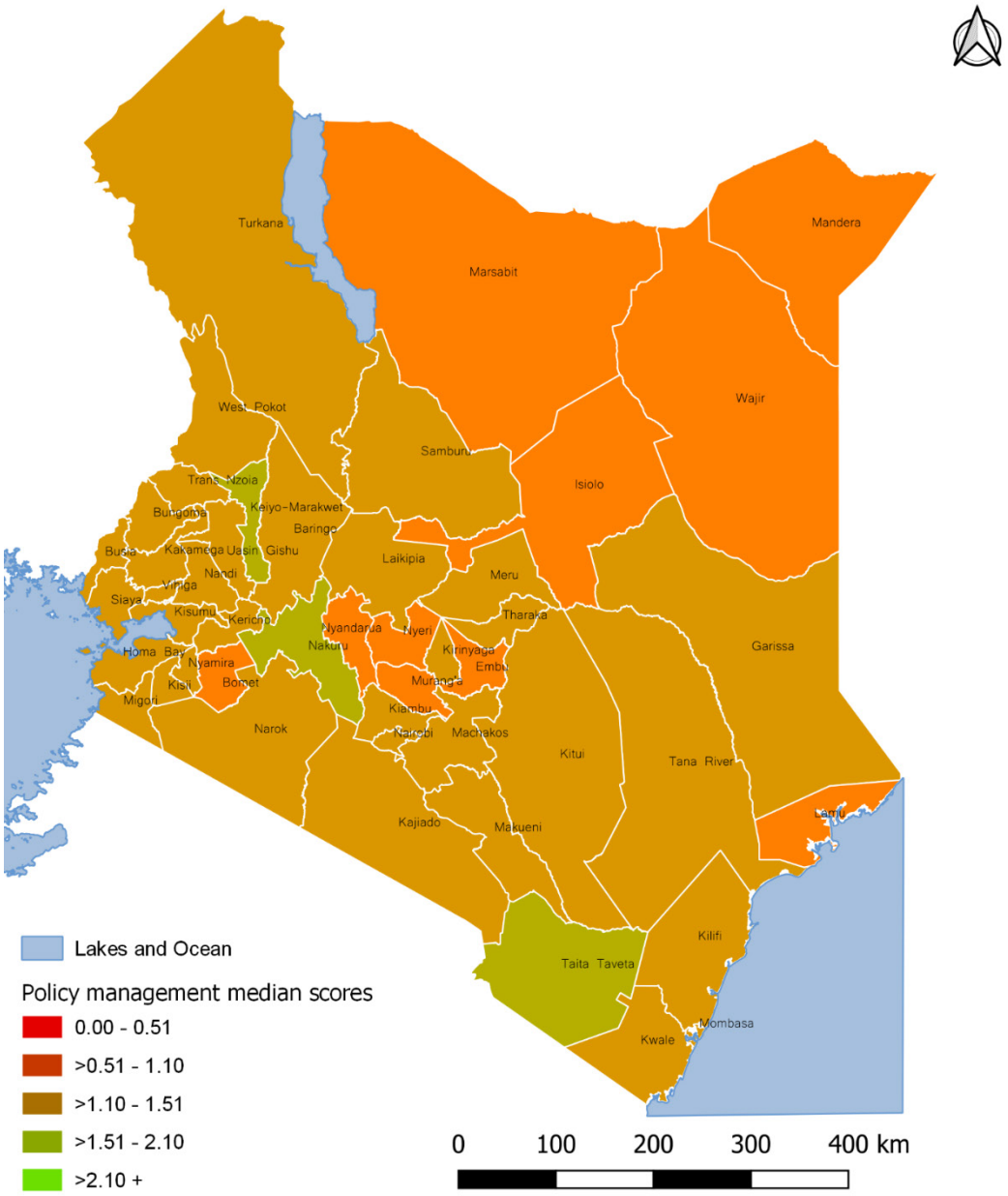
Figure 17: Laboratory Capacity Score - Policy Management



Overall County Policy Management Laboratory Capacity Scores

Overall, the counties with the lowest scores on policy management (average score of the 3 indicators) were: Marsabit (1.44), Isiolo (1.38), Murang'a (1.33) and Lamu (1.09) while the best performing counties were Makueni (3.11), Nakuru (3.22), Elgey-Marakwet (3.35) and Taita Taveta (3.47). Figure 10 corroborates this as Marsabit, Mandera, Wajir, Isiolo, Lamu, Embu, Murang'a, Bomet, Nyeri and Nyandarua Counties have a deep amber/brown color indicating that their overall policy management capacity scores ranged between >0.51-1.10 for all the lab capacity score dimensions. Taita Taveta, Nakuru and Trans Nzoia have a green shade implying that they had an overall score of >1.51-2.10 for policy management dimensions of lab capacity. All the remaining 34 counties recorded overall capacity scores of between >1.10-1.51. Mombasa County had a mean score of 2.56.

Figure 18: Policy Management Median Scores



Equipment Management

In this section, the laboratories were assessed and scored against seven questions/indicators: whether the labs produced equipment maintenance logs; whether the lab had established a preventive maintenance schedule for analytical equipment; whether the lab had systematic processes for verification of instrumentation; whether the lab had back up or secondary equipment; whether the lab had a service contract for instruments; whether the lab had an adequate number of personnel and whether the instruments are routinely calibrated. A rating of 1 to 4 was scored against each lab based on the status of indicator under question (where 1 was the lowest score and 4 was the highest score).

The overall mean score for all the labs sampled for the seven equipment management indicators was 1.01.

The mean score for equipment maintenance logs was 1.82 (Level 2 had a mean score of 1.49, Level 3 had a mean score of 1.78, Level 4 had a mean score of 2.57, Level 5 had a mean score of 3.73 and Level 6 had a mean score of 3.75 and non-facility labs had a mean score of 3.12). The counties with the highest scores in this indicator were Homabay (3.04), Nairobi (2.82), Kisumu

(2.82) and Kakamega (2.81), while the least performing counties were Wajir (1.06), Lamu (1.07), Tana River (1.09) and Isiolo (1.10).

The mean score for lab preventive maintenance schedule was 1.38 (Level 2 had a mean score of 1.01, Level 3 had a mean score of 1.22, Level 4 had a mean score of 2.14, Level 5 had a mean score of 3.09 and Level 6 had a mean score of 3.75 and non-facility labs had a mean score of 3.00). Best performing counties in this indicator was Elgeyo-Marakwet (2.4), Nairobi (2.32), Homa Bay (2.10) and Kisumu (1.98) whilst Turkana (0.71), Tharaka-Nithi (0.72), Kilifi (0.79) and Embu (0.85) were the lowest performing in score for this indicator.

The mean score for systematic verification was 1.11; (Level 2 had a mean score of 0.90 (based on the basic equipment at Level 2, systemic verification is not a requirement), Level 3 had a mean score of 0.96, Level 4 had a mean score of 1.62, Level 5 had a mean score of 2.36, Level 6 had a mean score of 3.38 and non-facility labs had a mean score of 2.84). The counties with the highest score in this indicator were Kisumu (2.13), Kericho (2.10), Nairobi (1.88) and Homabay (1.71) while Embu (0.30), Baringo (0.39), Kajiado (0.44) and Mombasa (0.57) were the lowest scoring counties.

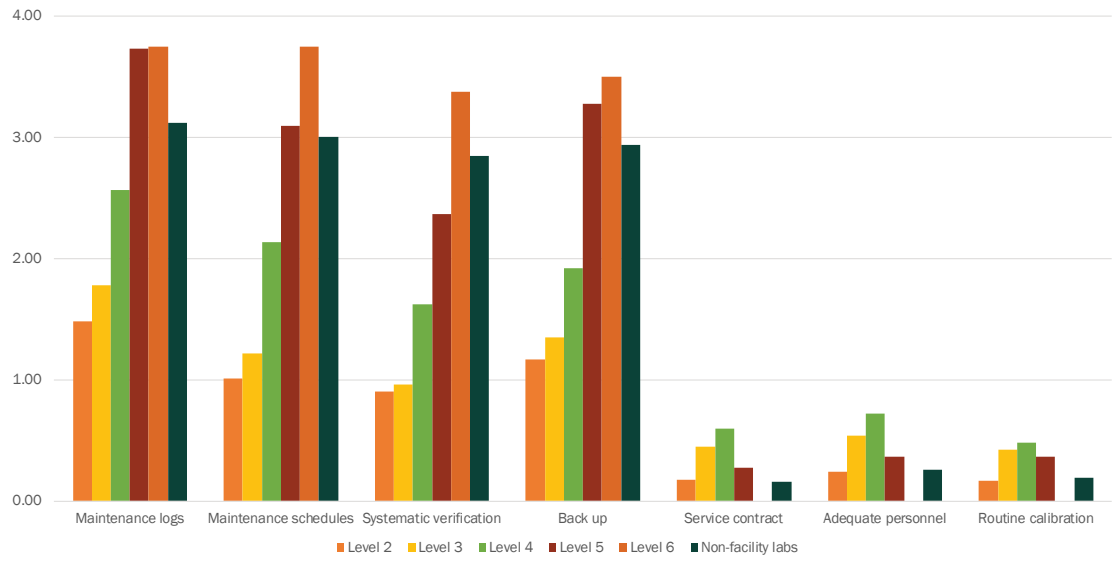
The mean score for laboratories having a backup or secondary equipment was 1.45 (Level 2 had a mean score of 1.17, Level 3 had a mean score of 1.35, Level 4 had a mean score of 1.92, Level 5 had a mean score of 3.27, Level 6 had a mean score of 3.50 and non-facility labs had a mean score of 2.94). Mombasa (2.38), West Pokot (2.25), Kericho (2.18), and Kisumu (2.16) are counties with highest score in this indicator while Turkana (0.74), Murang'a (0.91), Baringo (0.94) and Isiolo (0.95) are the lowest performing counties.

The mean score for laboratories having service contracts was 0.41, even though Level 2 had a mean score of 0.17 the kind of basic equipment at these facilities does not require service contract, Level 3 had a mean score of 0.45, Level 4 had a mean score of 0.59, Level 5 had a mean score of 0.27. The best performing counties in this indicator were West Pokot (1.38), Mandera (1.32), Elgeyo-Marakwet (1.26) and Garissa (1.24) while Samburu, Laikipia, Kwale and Isiolo were the least with a score of 0.00.

The mean score for adequate number of personnel was 0.51 (Level 2 had a mean score of 0.24, Level 3 had a mean score of 0.54, Level 4 had a mean score of 0.72, Level 5 had a mean score of 0.36). The counties with the highest score in this indicator were Mandera (2.00), Garissa (1.83), Nakuru (1.72) and West Pokot (1.50) whilst Samburu, Laikipia, Kwale and Isiolo were the lowest performing with a score of 0.00.

The mean score for routine calibration was 0.38 (Level 2 had a mean score of 0.16 even though the basic equipment available at this level does not require routine calibration, Level 3 had a mean score of 0.43, Level 4 had a mean score of 0.48, Level 5 had a mean score of 0.36. Garissa (1.97), Mandera (1.33), West Pokot (1.13), and Lamu (1.07) had the highest score in this indicator while Samburu, Laikipia, Kwale and Isiolo were the lowest performing with a score of 0.00).

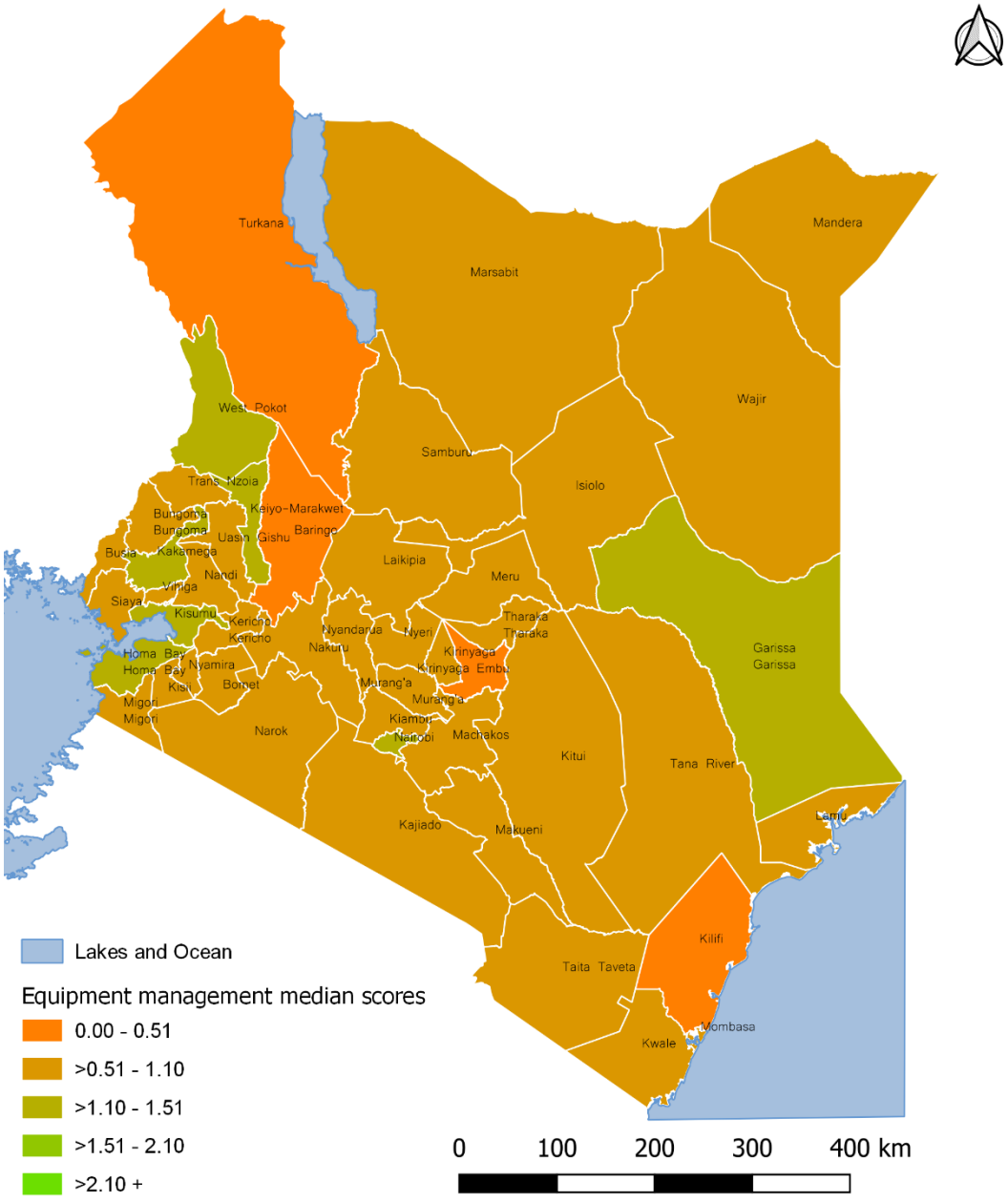
Figure 19: Laboratory Capacity Score - Equipment Management



Overall County Equipment Management Laboratory Scores

Overall, the counties with highest score in equipment management were Nairobi (1.64), Garissa (1.58), West Pokot (1.54) and Elgeyo-Marakwet (1.48) while the lowest performing counties were Turkana (0.57), Isiolo (0.59), Baringo (0.62) and Tharaka-Nithi (0.68). Mombasa County had a mean score of (1.03).

Figure 20: Equipment Management Median Scores



Commodity/Inventory Management

Under commodity/inventory management, the laboratories were assessed and scored against four questions/indicators: whether the lab had a system to routinely monitor stock; whether lab reagents /kits are within manufacturers' expiration dates; whether labs have adequate designated storage areas and whether the lab maintains a stock of emergency sample collection and transport supplies. A rating of 1 to 3 was scored against each lab based on the status of indicator under question (where 1 was the lowest score and 3 was the highest score).

The overall mean score for all the labs sampled for the four commodity/inventory management indicators was 1.91.

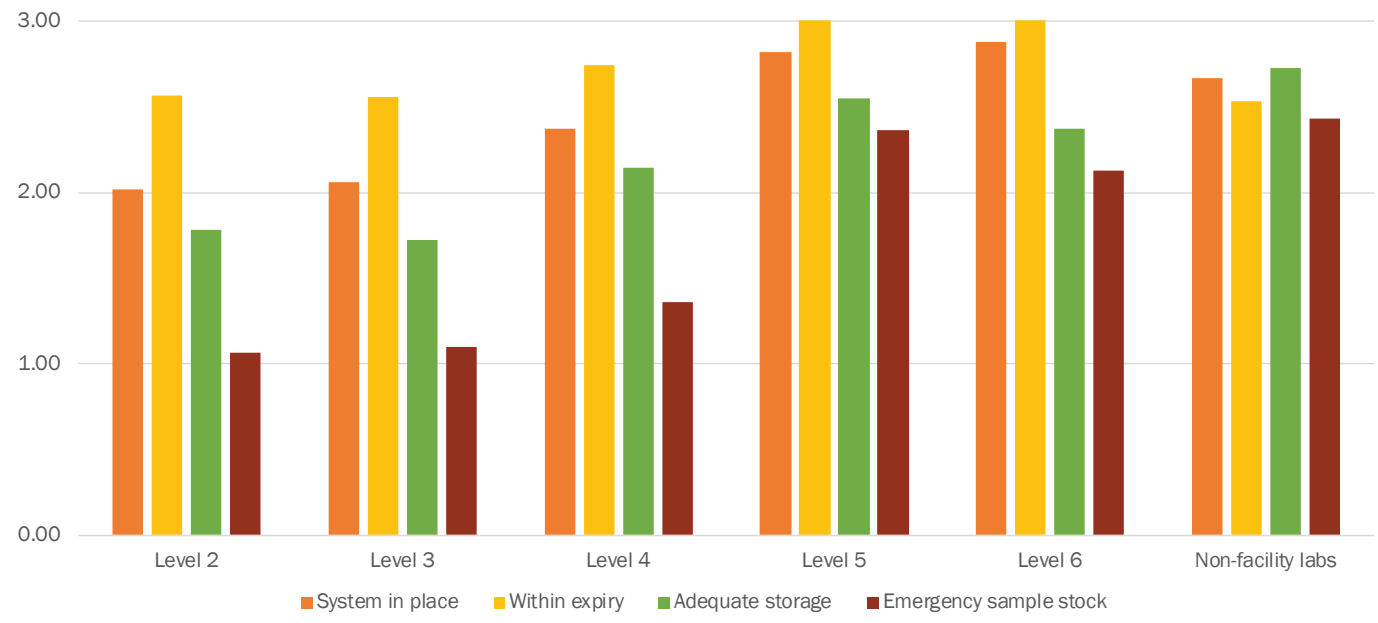
The mean score for system to routinely monitor stock was 2.07 (Level 2 had a mean score of 2.02, Level 3 had a mean score of 2.06, Level 4 had a mean score of 2.37, Level 5 had a mean score of 2.82, Level 6 had a mean score of 2.88 and non-facility labs had a mean score of 2.67). The best performing counties in this indicator was Migori (2.82), Kajiado (2.69), Nairobi (2.66) and Homa Bay (2.66) while the least performing counties were Wajir (1.29), Isiolo (1.33), Baringo (1.37) and Bomet (1.43)).

The mean score for lab reagents/kits are within the manufacture expiry dates was 2.57 (Level 2 had a mean score of 2.57, Level 3 had a mean score of 2.56, Level 4 had a mean score of 2.74, Level 5 had a mean score of 3.00, Level 6 had a mean score of 3.00 and non-facility labs had a mean score of 2.53). The counties with highest score in this indicator were Tana River, Nandi and Mombasa at 3.00 and Machakos at 2.98 while the least performing counties were Lamu (1.47), Wajir (1.88), Nyandarua (2.00) and Busia (2.08).

The mean score for lab having adequate designated storage areas was 1.82 (Level 2 had a mean score of 1.78, Level 3 had a mean score of 1.72, Level 4 had a mean score of 2.14, Level 5 had a mean score of 2.55, Level 6 had a mean score of 2.38 and non-facility labs had a mean score of 2.73). Bungoma (2.59), Laikipia (2.52), Kirinyaga (2.44) and Kajiado (2.44) were the best performing counties in this indicator whilst Lamu (1.07), Baringo (1.17), Isiolo (1.19) and Wajir (1.24) were the least performing counties in this indicator.

The mean score for laboratories maintaining a stock of emergency sample collection and transport supplies was 1.17 (Level 2 had a mean score of 1.06, Level 3 had a mean score of 1.10, Level 4 had a mean score of 1.36, Level 5 had a mean score of 2.36, Level 6 had a mean score of 2.13 and non-facility labs had a mean score of 2.43). The counties with highest score in this indicator were Kericho (2.05), Nairobi (1.63), Samburu (1.62) and Kisumu (1.57) while the counties with least scores were Kajiado (0.44), Bomet (0.73), Tana River (0.91) and Garissa (0.93).

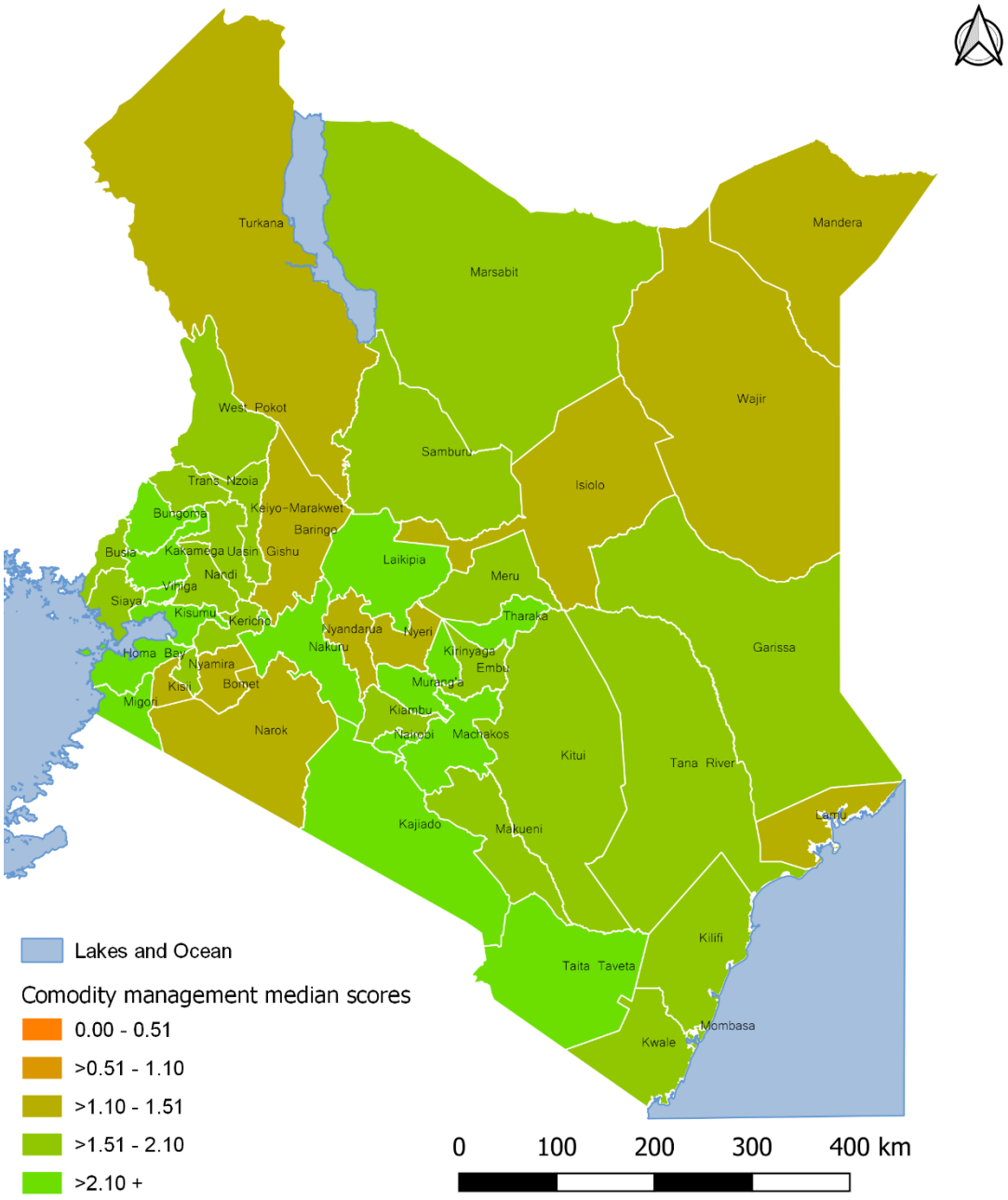
Figure 21: Laboratory Capacity Score - Commodity/Inventory Management



Overall Commodity/Inventory Management Laboratory Capacity Scores

Overall, the counties with the lowest scores in commodity management were Lamu (1.32), Wajir (1.37), Baringo (1.43) and Isiolo (1.50) while the counties with highest scores in commodity management were Nairobi (2.31), Kirinyaga (2.26), Migori (2.24) and Machakos (2.23). Mombasa County had a mean score of 1.99.

Figure 22: Commodity Management Median Scores



Data Management

In the data management section, the laboratories were assessed and scored against eleven questions/indicators: whether the lab use an electronic laboratory information system (LIS); whether lab has a backup for LIS data; whether lab LIS is integrated into Hospital Information management system; whether lab has documented protocols; whether lab has LIS modification protocol; whether lab has the capacity to archive data; whether lab has reliable, dedicated internet connectivity; whether lab uses

standardized data collection tools; whether lab uses standardized report format/tools; whether lab surveillance data is submitted to DSRU and whether lab submit report indicators to DHIS-2. A rating of 1 to 4 was scored against each lab based on the status of indicator under question (where 1 was the lowest score and 4 was the highest score). Facilities from all the 47 counties reporting use of an electronic information system of any form (either the electronic medical records system (EMR), health information management systems (HIMS) or laboratory information systems (LIS) totaled 215.

The overall mean score for all the labs sampled for the eleven data management indicators was 1.63.

The mean score for use of electronic information system was 1.24 (Level 2 had a mean score of 1.01, Level 3 had a mean score of 1.14, Level 4 had a mean score of 1.45, Level 5 had a mean score of 2.63, Level 6 had a mean score of 1.67 and non-facility labs had a mean score of 2.03). The counties with the highest score in this indicator were Baringo 2.34, Garissa 2.04, Bungoma 1.98 and Turkana 1.77 while the counties with the lowest score were Mandera 0.09, Kakamega 0.87, Siaya 0.97 and Makueni 0.80.

The mean score for backup of LIS data was 0.59 (Level 2 had a mean score of 0.39, Level 3 had a mean score of 0.47, Level 4 had a mean score of 0.81 Level 5 had a mean score of 2.19, Level 6 had a mean score of 1.00 and non-facility labs had a mean score of 1.83). The best performing counties in this indicator were Turkana (1.71), Garissa (1.18), Baringo (1.17) and Kisii (1.04) while the least performing counties were Bomet (0.02), West Pokot (0.06), Elgeyo-Marakwet (0.07) and Kitui (0.08).

The mean score for LIS integration was 0.48 (Level 2 had a mean score of 0.25, Level 3 had a mean score of 0.40, Level 4 had a mean score of 0.77, Level 5 had a mean score of 2.0, Level 6 had a mean score of 1.66 and non-facility labs had a mean score of 0.74). The counties with the highest scores in this indicator were Baringo (1.83), Garissa (1.60), and Turkana (1.31) while the counties with the lowest scores in this indicator were Elgeyo-Marakwet (0.00), Nyamira (0.00), Makueni (0.02) and Mandera (0.04).

Only 82 facilities had documented protocols that define how to contact IT support.

The mean score for laboratories IT support protocol was 0.52 (Level 2 had a mean score of 0.31, Level 3 had a mean score of 0.40, Level 4 had a mean score of 0.75, Level 5 had a mean score of 1.87, Level 6 had a mean score of 0.67 and non-facility labs had a mean score of 1.74). The counties with the highest score in this indicator were Turkana (1.78), Garissa (1.39), Kericho (1.1) and Kisii (1.04) while the counties with the lowest scores were Nyamira (0.0), Mandera (0.05), Bomet (0.05) and Nyeri (0.07).

The mean score for laboratories having a LIS modification protocol was 0.36 (Level 2 had a mean score of 0.18, Level 3 had a mean score of 0.27, Level 4 had a mean score of 0.52, Level 5 had a mean score of 1.63, Level 6 had a mean score of 0.67 and non-facility labs had a mean score of 1.53). The best performing counties in this indicator were Turkana (1.46), Kericho (1.00), Kisii (1.00) and Kericho (1.00) while the least performing counties were Makueni (0.00), Nyamira (0.02), Nyeri (0.03) and Elgeyo Marakwet (0.04).

The mean score for data archiving was 1.90 (Level 2 had a mean score of 1.67, Level 3 had a mean score of 1.80, Level 4 had a mean score of 2.20, Level 5 had a mean score of 3.40, Level 6 had a mean score of 3.00 and non-facility labs had a mean score of 3.0). The counties with the highest scores in this indicator were Migori (3.90), Narok (3.62), West Pokot (3.25) and Tharaka Nithi (2.94) while the counties with the lowest scores were Mandera (0.04), Embu (0.61), Marsabit (0.95) and Isiolo (1.00).

Seventy-eight percent of the facilities visited had no internet connectivity. Only 10 % of the facilities had reliable and dedicated internet connectivity. The mean score for internet connectivity was 1.37 (Level 2 had a mean score of 1.17, Level 3 had a mean score of 1.14, Level 4 had a mean score of 1.75, Level 5 had a mean score of 3.56, Level 6 had a mean score of 1.67 and non-facility labs had a mean score of 3.08). The best performing counties in this indicator were Kisumu (2.05), Kiambu (1.96), Mombasa (1.90) and Machakos (1.83) while the least performing counties were Kitui (0.98), and Elgeyo Marakwet, Lamu, Mandera, Tana River, and Kisii at 1.00.

The mean score for laboratories using standard data collection tools was 3.28 (Level 2 had a mean score of 3.36, Level 3 had a mean score of 3.30, Level 4 had a mean score of 3.32, Level 5 had a mean score of 3.78, Level 6 had a mean score of 3.00 and non-facility labs had a mean score of 2.33). The best performing counties were Kajiado (4.00), Nyamira (3.98), Migori (3.92) and Makueni (3.91) while the least performing counties were Lamu (1.28), Kisii (1.35), Isiolo (1.52) and Narok (2.41).

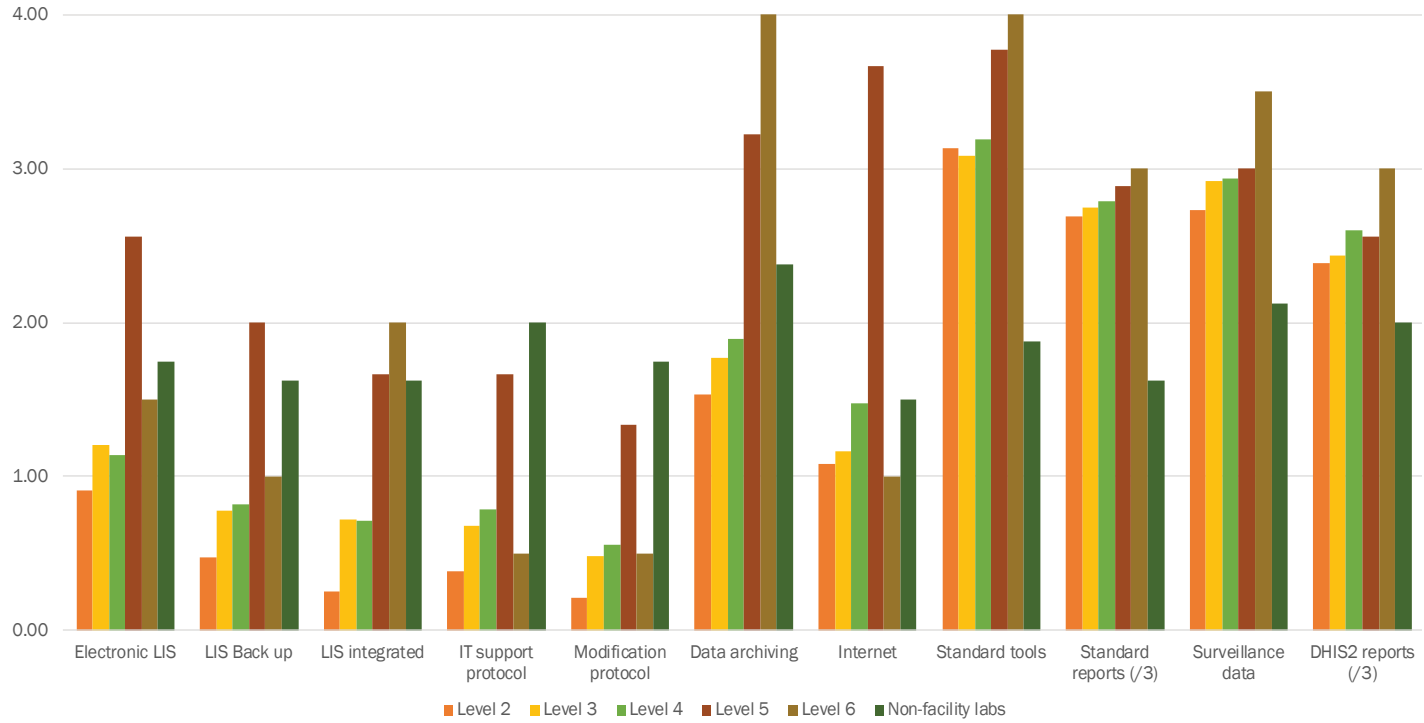
The mean score for laboratories using standard reporting tools was 2.73 (Level 2 had a mean score of 2.80, Level 3 had a mean score of 2.74, Level 4 had a mean score of 2.77, Level 5 had a mean score of 2.69, Level 6 had a mean score of 2.33 and non-

facility labs had a mean score of 1.84). The counties with the highest score in this indicator were Tana River, Migori, Nyamira and Kisii with a score of 3.00 whilst the counties with the lowest scores were Lamu (1.42), Narok (2.30), Nyandarua (2.32) and Nairobi (2.32).

The mean score for surveillance data was 2.98 (Level 2 had a mean score of 2.97, Level 3 had a mean score of 3.10, Level 4 had a mean score of 2.97, Level 5 had a mean score of 3.18, Level 6 had a mean score of 3.00 and non-facility labs had a mean score of 1.76). The counties with the highest score were Elgeyo Marakwet (4.00), Tharaka-Nithi (3.94), Turkana (3.91) and Nyamira (3.89) while counties with the lowest scores in this indicator were Lamu (1.29), Nyandarua (1.58), Marsabit (1.71) and Bomet (1.73).

The mean score for laboratories submitting reports to DHIS-2 was 2.48 (Level 2 had a mean score of 2.44, Level 3 had a mean score of 2.50, Level 4 had a mean score of 2.63, Level 5 had a mean score of 2.63, Level 6 had a mean score of 3.00 and non-facility labs had a mean score of 1.19). The counties with the highest scores in this indicator were Elgeiyo-Marakwet, Embu, Kajiado, Kirinyaga, Nandi, Nyeri, Tana River and Kisii at 3.00 while the counties with the lowest scores were Bomet (0.98), Marsabit (1.14), Migori (1.25) and Lamu (1.28).

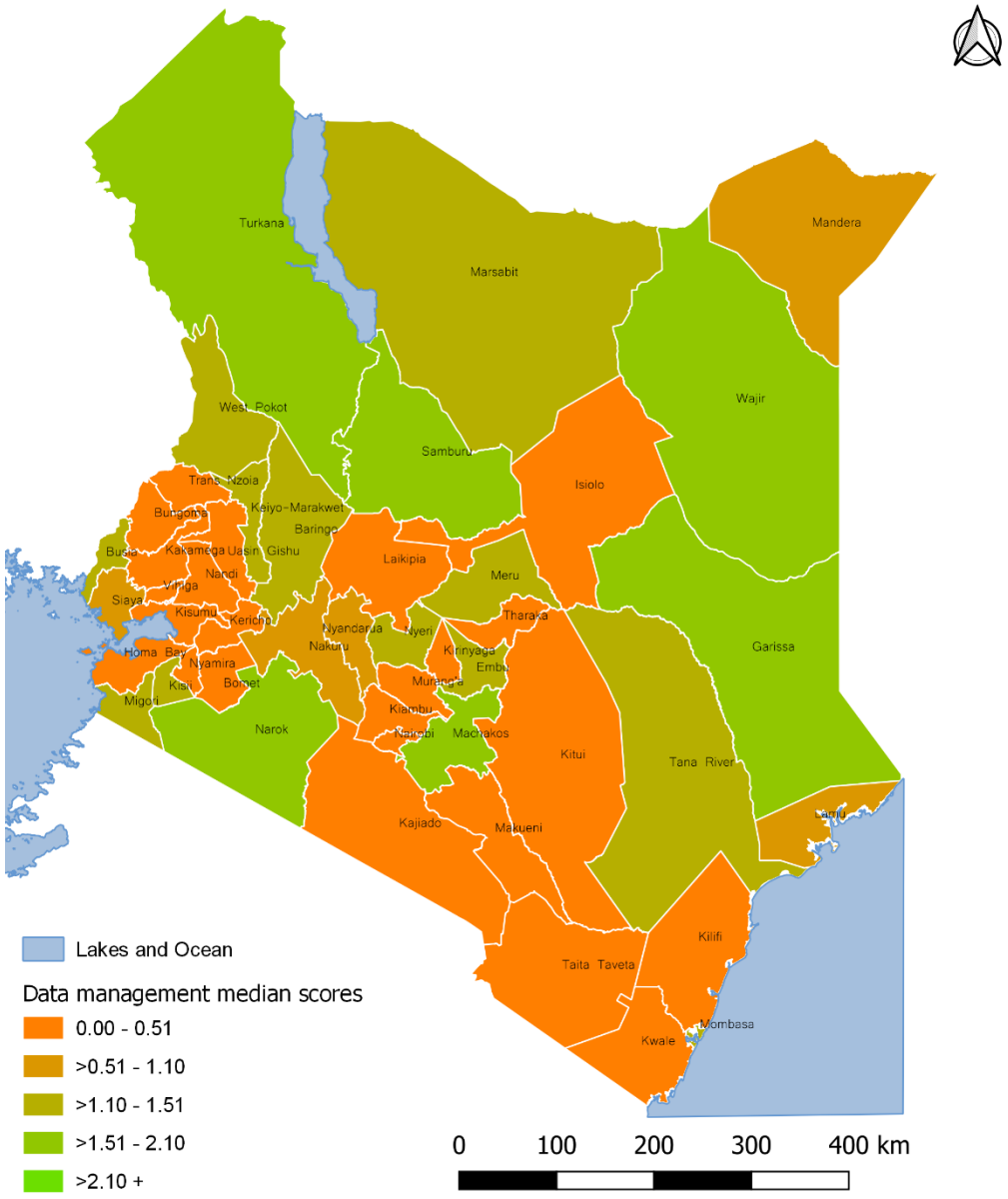
Figure 23: Laboratory Capacity Scores - Data Management



Overall County Data Management Laboratory Capacity Scores

Overall, the counties with the lowest scores in data management were Lamu (1.14), Marsabit (1.47), Nyandarua (1.59), Isiolo (1.71) and Wajir (1.75) while the counties with highest score were Nairobi (2.78) and Embu (2.76).

Figure 24: Data Management Median Scores



Quality Management

In the quality management section, the laboratories were assessed and scored against eight questions/indicators: whether the laboratory has a comprehensive quality manual; whether laboratory has a designated quality assurance officer; whether the laboratory has external QA programs; whether laboratory had SOPs; whether laboratory has training policies; whether laboratories have a temperature monitoring system; whether laboratories run internal quality control and whether the laboratories maintain documentation on a referred samples. A rating of 1 to 4 was scored against each lab based on the status of indicator under question (where 1 was the lowest score and 4 was the highest score).

The overall mean score for all the labs sampled for the eight quality management indicators was 1.76.

The mean score for quality manual of was 1.35 (Level 2 had a mean score of 1.11, Level 3 had a mean score of 1.16, Level 4 had a mean score of 1.97, Level 5 had a mean score of 3.73 and Level 6 had a mean score of 3.50 and non-facility labs had a mean

score of 3.12). The counties with the highest scores for this indicator were Nairobi 2.44, Kisumu 2.16, Kericho 2.07 and Kirinyaga 2.05 while the counties with the lowest scores were Baringo 0.43, Embu 0.73, Elgeyo Marakwet 0.96 and Lamu 1.00.

The mean score for quality assurance officer was 1.79 (Level 2 had a mean score of 1.50, Level 3 had a mean score of 1.59, Level 4 had a mean score of 2.56, Level 5 had a mean score of 4.00 and Level 6 had a mean score of 4.00 and non-facility labs had a mean score of 3.29). The best performing counties in this indicator were Nairobi 2.88, Bungoma 2.76, Kirinyaga 2.73 and Kisumu 2.66 while the lowest performing counties were Lamu 1.00, Trans Nzoia 1.11, Baringo 1.11 and Marsabit 1.14.

The mean score for external QA program was 1.98 (Level 2 had a mean score of 1.84, Level 3 had a mean score of 1.99, Level 4 had a mean score of 2.26, Level 5 had a mean score of 2.91, Level 6 had a mean score of 3.50 and non-facility labs had a mean score of 2.55). The counties with the highest scores in this indicator were Kakamega 2.81, Kirinyaga 2.61, Kitui 2.42 and Migori 2.42 while the counties with the lowest scores were Lamu 1.13, Marsabit 1.19, Wajir 1.29 and Mandera 1.41.

The mean score for laboratories having SOPs was 2.16 (Level 2 had a mean score of 1.86, Level 3 had a mean score of 2.20, Level 4 had a mean score of 2.79, Level 5 had a mean score of 3.64, Level 6 had a mean score of 3.88 and non-facility labs had a mean score of 3.45). The best performing counties in this indicator were Homabay 3.38, Kirinyaga 3.27, Makueni 3.23 and Nairobi 3.21 while the least performing counties were Wajir 1.06, Lamu 1.07, Mandera 1.14 and Marsabit 1.24.

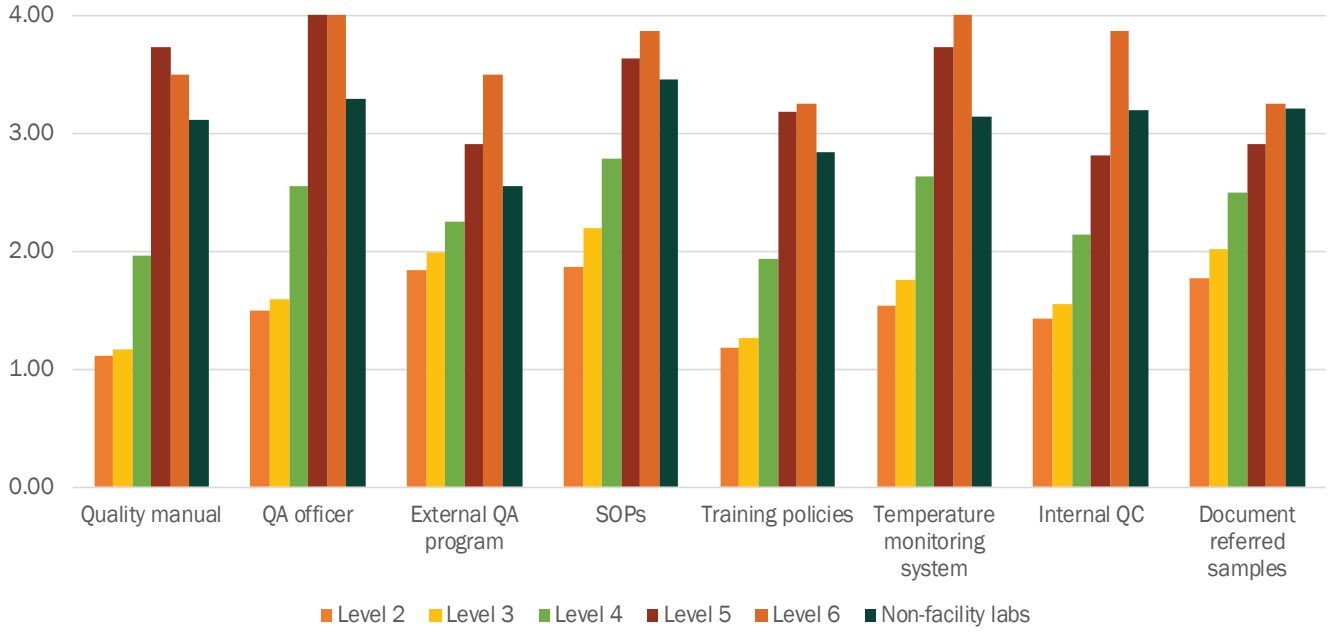
The mean score for laboratories having training policies was 1.41 (Level 2 had a mean score of 1.18, Level 3 had a mean score of 1.27, Level 4 had a mean score of 1.94, Level 5 had a mean score of 3.18, Level 6 had a mean score of 3.25 and non-facility labs had a mean score of 2.84). The counties with the highest scores in this indicator were Migori 2.89, Homa Bay 2.34, Nairobi 2.20 and Kisumu 2.10 while the counties with the lowest scores were Elgeyo Marakwet 0.96, Lamu, Tana River and Laikipia at 1.00.

The mean score for temperature monitoring system was 1.84. Even though most of the basic equipment at Level 2 does not require this indicator, Level 2 had a mean score of 1.54, Level 3 had a mean score of 1.75, Level 4 had a mean score of 2.63, Level 5 had a mean score of 3.73, Level 6 had a mean score of 4.00 and non-facility labs had a mean score of 3.14). The best performing counties in this indicator were Nairobi 2.99, Kirinyaga 2.76, Homa Bay 2.74 and Kajiado 2.69 while the least performing counties were Lamu 1.00, Mandera 1.00, Tana River 1.05 and Wajir 1.06.

The mean score for internal quality control was 1.61 (Level 2 had a mean score of 1.43, Level 3 had a mean score of 1.54, Level 4 had a mean score of 2.14, Level 5 had a mean score of 2.82, Level 6 had a mean score of 3.88 and non-facility labs had a mean score of 3.20). The counties with the highest scores in this indicator were Migori 2.87, Nairobi 2.85, Kericho 2.71 and Kakamega 2.50 while those with the lowest scores were Mandera 1.00, Tana River 1.00, Isiolo 1.00 and Lamu 1.07.

The mean score for documentation of referred samples was 1.96 (Level 2 had a mean score of 1.78, Level 3 had a mean score of 2.01, Level 4 had a mean score of 2.49, Level 5 had a mean score of 2.91, Level 6 had a mean score of 3.25 and non-facility labs had a mean score of 3.22). The best performing counties in this indicator were Taita-Taveta 3.60, Kakamega 3.48, Homa Bay 3.30 and Kwale 3.00.

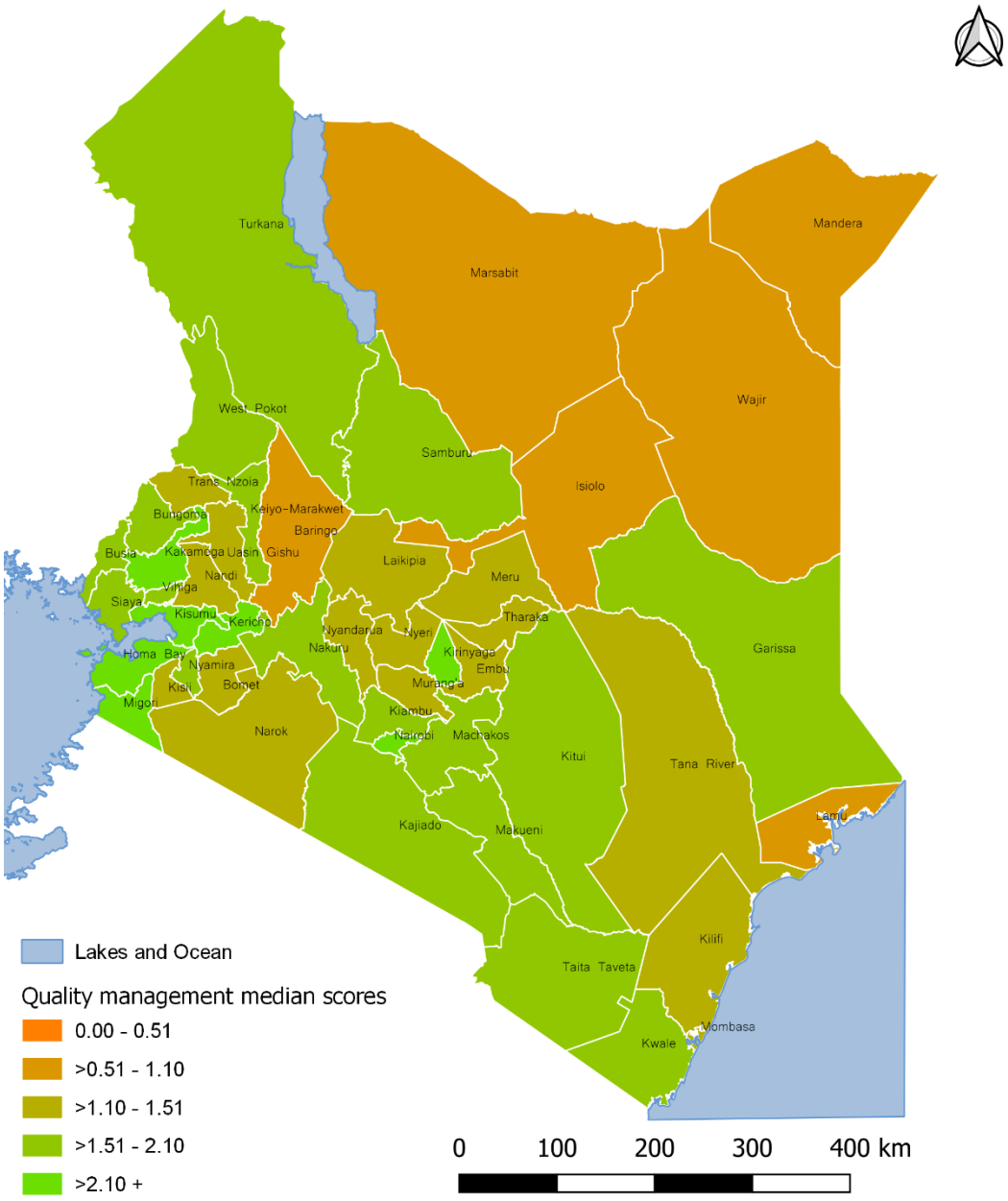
Figure 25: Laboratory Capacity Score - Quality Management



Overall County Quality Management Laboratory Capacity Scores

Overall, the counties that had the lowest scores in quality management were Lamu (1.04), Marsabit (1.11), Mandera (1.13) and Wajir (1.13) while the counties with the highest scores in quality management were Nairobi (2.67), Kisumu (2.50), Kirinyaga (2.48) and Migori (2.43). Mombasa County had a mean score of 1.62.

Figure 26: Quality Management Median Scores



Safety/Biosafety/Security

For safety/biosafety/security, the laboratories were assessed and scored against fifteen questions/indicators: whether the laboratory has a separate space for specimen collection, testing and processing; whether the laboratories have a laboratory safety manual; whether laboratory has a certified biosafety cabinet; whether the laboratory has a chemical hygiene plan; whether the lab MSDS for all chemicals are up to date; whether laboratory has a trained safety officer; whether the laboratory has a trained biosafety officer; whether the laboratory has safety equipment; whether the laboratory has personal protective equipment (PPE); whether the laboratory has a functioning autoclave and incinerator; whether the laboratory employees are trained on packaging, labelling and shipping infectious substances; whether laboratory stores infectious substances in controlled manner; whether the laboratory has a control list; whether the lab has a reporting system and whether highly infectious pathogens are handled in BSL-3. A rating of 1 to 4 was scored against each lab based on the status of the indicator under question (where 1 was the lowest score and 4 was the highest score).

The overall mean score for all the labs sampled for the fifteen safety/biosafety/security indicators was 1.31.

The mean score for specimen space was 1.64 (Level 2 had a mean score of 1.37, Level 3 had a mean score of 1.44, Level 4 had a mean score of 2.41, Level 5 had a mean score of 3.91, Level 6 had a mean score of 3.88 and non-facility labs had a mean score of 3.49). The counties with the highest scores in this indicator were Kakamega (2.69), Kisumu (2.66), Kajiado (2.59) and Kericho (2.56) while the counties with the lowest scores were Vihiga (1.03), Lamu (1.07), Mandera (1.09) and Kirinyaga (1.15).

The mean score for safety manual was 1.53 (Level 2 had a mean score of 1.23, Level 3 had a mean score of 1.42, Level 4 had a mean score of 2.24, Level 5 had a mean score of 3.82, Level 6 had a mean score of 3.50 and non-facility labs had a mean score of 2.90). The best performing counties in this indicator were Kisumu (2.75), Nairobi (2.55), Makueni (2.51) and Kericho (2.27) whilst the least performing counties were Wajir (0.82), Elgeyo-Marakwet (0.96), Lamu (1.00) and Tana River (1.00).

The mean score for biosafety cabinet was 1.10 (it is not a requirement for Level 2 facilities to have biosafety cabinets, Level 3 had a mean score of 0.88, Level 4 had a mean score of 1.78, Level 5 had a mean score of 3.45, Level 6 had a mean score of 3.14 and non-facility labs had a mean score of 3.16). The counties with the highest score in this indicator were Nairobi (2.33), Kisumu (2.30), Kericho (1.95) and Homa Bay (1.65) while the counties with the lowest scores were Tana River (0.27), Lamu (0.33), Kitui (0.47) and Garissa (0.52).

The mean score for hygiene plan was 1.32. It is not a requirement to have hygiene plan for Level 2. Level 3 had a mean score of 1.23, Level 4 had a mean score of 1,82, Level 5 had a mean score of 2.64, Level 6 had a mean score of 3.00 and non-facility labs had a mean score of 2.94. The counties with the highest scores in this indicator were Nairobi (2.35), Kisumu (2.28), Homa Bay (1.98) and Migori (1.84) while the counties with the lowest scores were Baringo (0.94), Tana River (0.95), Elgeyo-Marakwet (0.96) and Mandera, Marsabit and Isiolo at 1.00.

The mean score for up to date MSDS was 1.44 (Level 2 had a mean score of 1.32, Level 3 had a mean score of 1.27, Level 4 had a mean score of 1.88, Level 5 had a mean score of 3.36, Level 6 had a mean score of 3.00 and non-facility labs had a mean score of 3.06). The best performing counties in this indicator were Kwale (3.81), Kisumu (2.44), Nairobi (2.39) and Samburu (2.15) while the least performing counties were Baringo (1.00), Marsabit (1.00), Tana River (1.05) and Vihiga (1.06).

The mean score for laboratories having a safety officer was 2.02 (Level 2 had a mean score of 1.66, Level 3 had a mean score of 1.96, Level 4 had a mean score of 2.66, Level 5 had a mean score of 3.27, Level 6 had a mean score of 3.50 and non-facility labs had a mean score of 3.16). The best performing counties in this indicator were Migori (3.68), Samburu (3.54), Machakos (3.22) and Kakamega (3.21) while the least performing counties were Kiambu (0.98), Lamu (1.00), Marsabit (1.05) and Isiolo (1.05).

The mean score for laboratory having a biosafety officer was 1.28 (Level 2 had a mean score of 1.10, Level 3 had a mean score of 1.20, Level 4 had a mean score of 1.62, Level 5 had a mean score of 2.36, Level 6 had a mean score of 2.88 and non-facility labs had a mean score of 2.80). The counties with the highest scores in this indicator were Kisumu (2.20), Nairobi (2.09), Kericho (1.59), Kajiado, and Kirinyaga at (1.56) while the counties with the lowest scores were Nyamira (0.98), Tana River (1.00), Mandera (1.05) and West Pokot (1.06).

The mean score for laboratories having safety equipment was 2.37 (Level 2 had a mean score of 2.24, Level 3 had a mean score of 2.32, Level 4 had a mean score of 2.64, Level 5 had a mean score of 3.45, Level 6 had a mean score of 3.25 and non-facility labs had a mean score of 3.29). The counties with the highest scores in this indicator were Kajiado (3.63), Makueni (3.45), Migori (3.32) and Kericho (3.24) whilst the counties with the lowest scores were Lamu (1.33), Vihiga (1.86), Nyamira (1.94) and Tana River (1.95).

The mean score for laboratories having PPE was 1.47 (Level 2 had a mean score of 1.27, Level 3 had a mean score of 1.33, Level 4 had a mean score of 1.94, Level 5 had a mean score of 3.18, Level 6 had a mean score of 3.50 and non-facility labs had a mean score of 3.20). The best performing counties in this indicator were Kericho (2.88), Nairobi (2.51), Makueni (2.47) and Kisumu (2.08) while the least performing counties were Wajir (1.00), Nyamira (1.04), Tana River (1.05) and Lamu (1.07).

The mean score for autoclaves and incinerators was 1.74 (it is not a requirement for Level 2 facilities to have biosafety autoclaves and incinerators, Level 3 had a mean score of 1.64, Level 4 had a mean score of 2.43, Level 5 had a mean score of 3.18, Level 6 had a mean score of 3.50 and non-facility labs had a mean score of 3.14). The counties with the highest scores in this indicator

were Migori (3.47), Machakos (3.07), Makueni (2.87) and Nairobi (2.78) while the counties with the lowest scores were Lamu (0.71), Nyamira (0.73), Kajiado (0.94) and Marsabit (0.95).

The mean score for laboratory employees trained on packaging was 1.90 (Level 2 had a mean score of 1.60, Level 3 had a mean score of 1.87, Level 4 had a mean score of 2.44, Level 5 had a mean score of 3.36, Level 6 had a mean score of 3.25 and non-facility labs had a mean score of 3.24). The best performing counties in this indicator were Migori (3.55), Samburu (3.15), Narok (3.13) and Kisumu (3.00) while the least performing counties in this indicator were Isiolo (1.00), Tana River (1.00), Murang'a (1.16) and Wajir (1.18).

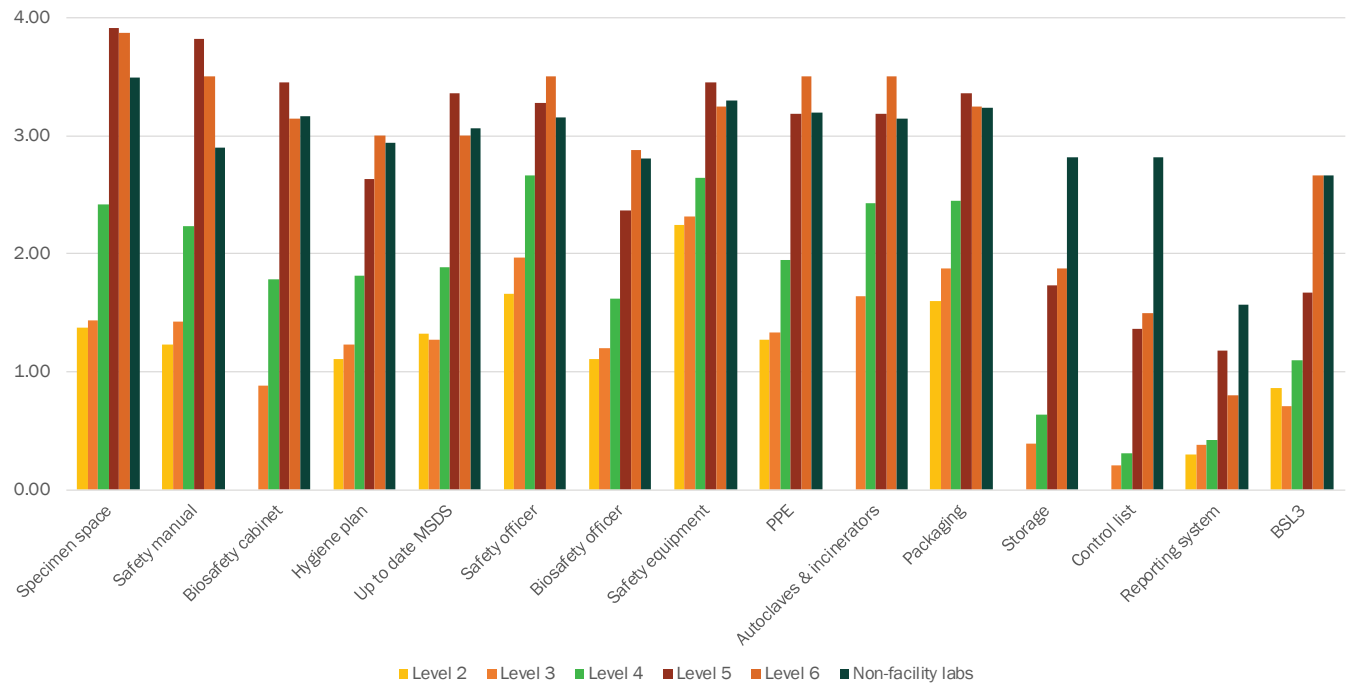
The mean score for laboratory storage of infectious substances was 0.46 (it is not a requirement for Level 2 and 3 facilities to have laboratory storage of infectious substances, Level 3 had a mean score of 0.39, Level 4 had a mean score of 0.64, Level 5 had a mean score of 1.73, Level 6 had a mean score of 1.88 and non-facility labs had a mean score of 2.82). The counties with the highest scores in this indicator were Homa Bay (1.94), Turkana (1.71), Kericho (1.34) and Nairobi (1.33) while the counties with the lowest scores were Embu, Bomet and West Pokot at 0.00 and Nyamira at 0.02.

The mean score for control list was 0.29 (it is not a requirement for Level 2, 3 and 4 facilities to have control lists), Level 5 had a mean score of 1.36, Level 6 had a mean score of 1.50 and non-facility labs had a mean score of 2.82).

The mean score for reporting system for controlled infectious substances was 0.39. However, this was specific to Level 5 and 6 facilities

BSL3 was only found in 4 facilities namely; NPHL-NTRL, KEMRI Kisumu TB lab, KEMRI Kisumu animal influenza lab and KEMRI Nairobi P3 lab.

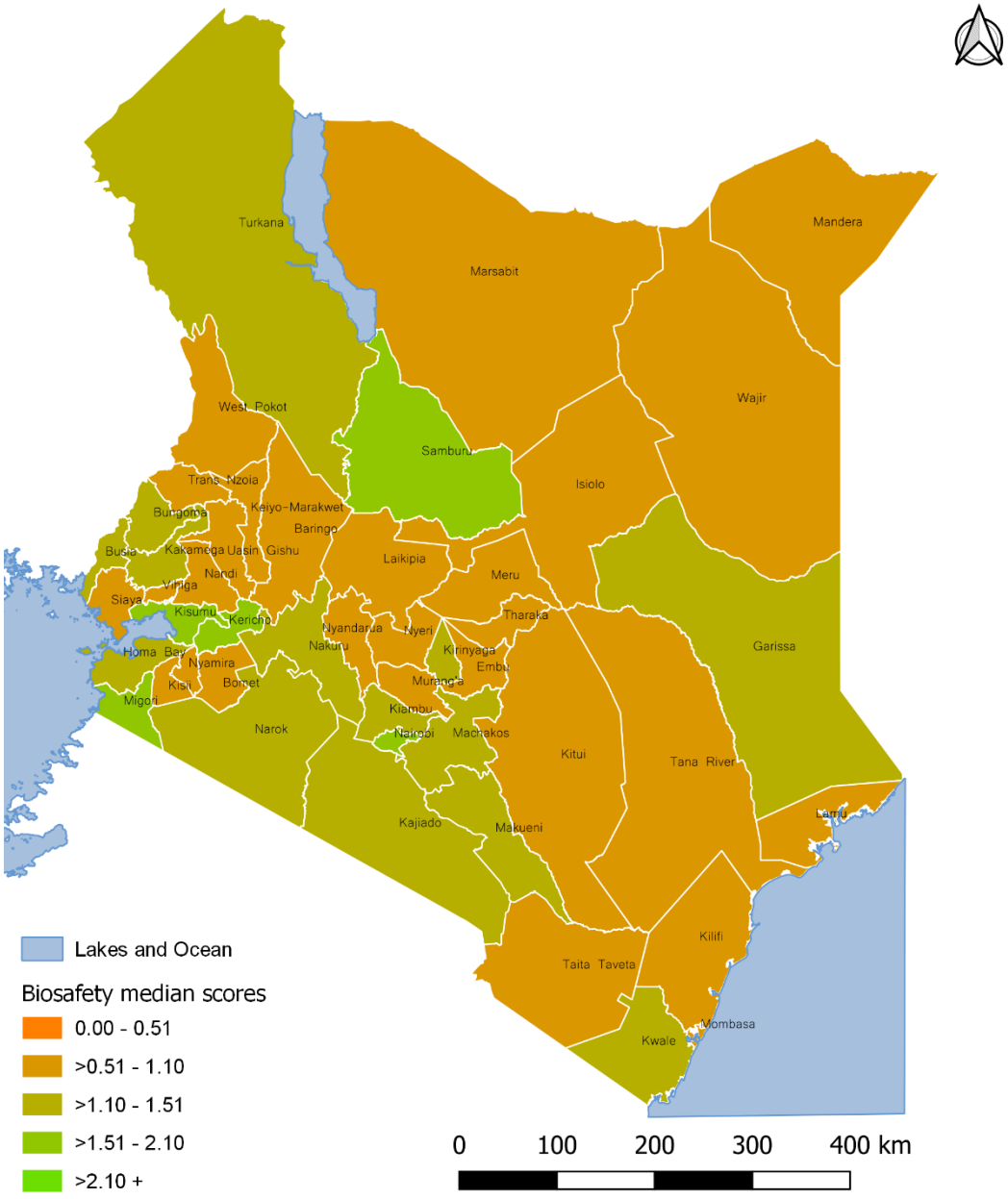
Figure 27: Laboratory Capacity Score - Safety/Biosafety/Security



Overall County Safety/Biosafety/Security Laboratory Capacity Scores

Overall, the counties with the lowest scores in safety/biosafety/security were Tana River (0.85), Lamu (0.88), Isiolo (0.95) and Mandera (0.99) while the counties with the highest scores in safety/biosafety/security were Nairobi (2.20), Kisumu (2.12), Kericho (1.94) and Migori (1.93). Mombasa County had a mean score of 1.14.

Figure 28: Biosafety Median Scores



Zoonotic Testing and Surveillance

In this section, the laboratories were assessed and scored against four questions/indicators: whether the laboratory is an active participant in the surveillance network; whether laboratory has case definition charts/poster on zoonotic diseases; whether lab communicates with ZDU and whether the laboratories routinely participate in outbreak preparedness meetings. A rating of 1 to 3 was scored against each lab based on the status of indicator under question (where 1 was the lowest score and 3 was the highest score).

The overall mean score for all the labs sampled for the four zoonotic indicators was 1.19.

The mean score for participating in the surveillance network was 1.59 (Level 2 had a mean score of 1.42, Level 3 had a mean

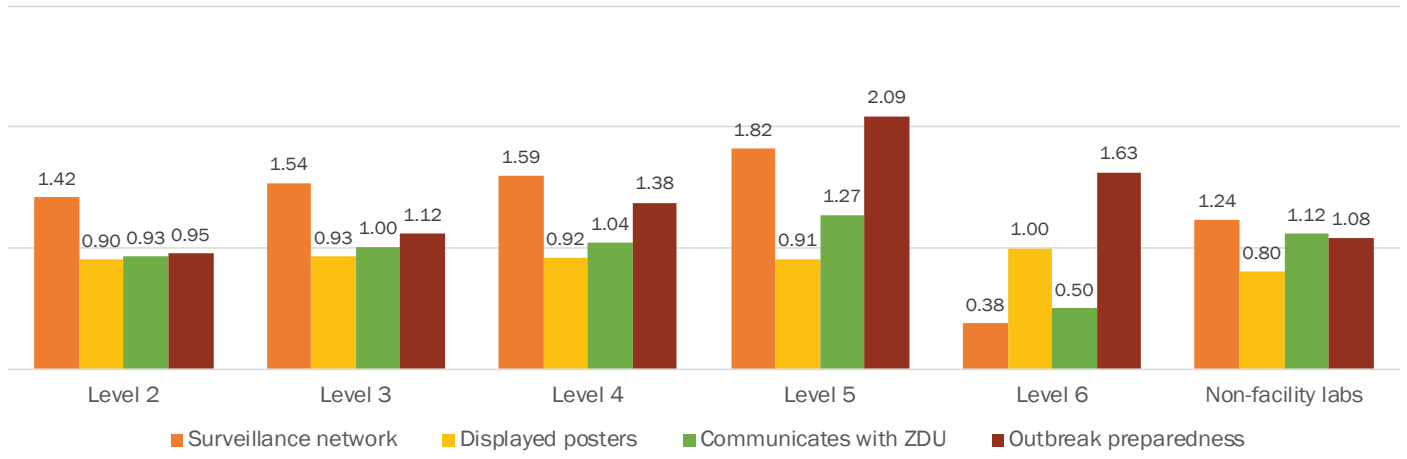
score of 1.54, Level 4 had a mean score of 1.59, Level 5 had a mean score of 1.82, Level 6 had a mean score of 0.38 and non-facility labs had a mean score of 1.24). The counties with the highest scores in this indicator were Turkana (3.00), Wajir (2.88), West Pokot (2.75) and Taita Taveta (2.68) while the counties with the lowest scores were Homabay (0.00), Kiambu (0.00), Kitui (0.00) and Bomet (0.03).

The mean score for displayed poster on zoonotic diseases was 0.97 (Level 2 had a mean score of 0.90, Level 3 had a mean score of 0.93, Level 4 had a mean score of 0.92, Level 5 had a mean score of 0.91, Level 6 had a mean score of 1.00 and non-facility labs had a mean score of 0.80). The best performing counties in this indicator were West Pokot (2.25), Garissa (1.59), Tharak-Nithi (1.50) and Turkana (1.40) while the least performing counties were Homabay (0.00), Kiambu (0.00), Kitui (0.00) and Bomet (0.03).

The mean score for lab communicating with the ZDU was 1.03 (Level 2 had a mean score of 0.93, Level 3 had a mean score of 1.00, Level 4 had a mean score of 1.04, Level 5 had a mean score of 1.27, Level 6 had a mean score of 0.50 and non-facility labs had a mean score of 1.12). The counties with the highest scores in this indicator were Kakamega (2.18), West Pokot (1.88), Garissa (1.86) and Narok (1.74) while the counties with the lowest scores were Kiambu (0.00), Kitui (0.00), Homa Bay (0.02) and Bomet (0.03).

The mean score for outbreak preparedness was 1.20 (Level 2 had a mean score of 0.95, Level 3 had a mean score of 1.12, Level 4 had a mean score of 1.38, Level 5 had a mean score of 2.09, Level 6 had a mean score of 1.63 and non-facility labs had a mean score of 1.08). The counties with the highest scores in this indicator were Garissa (2.66), Wajir (2.59), Kakamega (2.42) and Mandera (2.18) while the counties with the lowest scores were Kiambu, Kitui and Homa Bay at 0.00 and Bomet at 0.03.

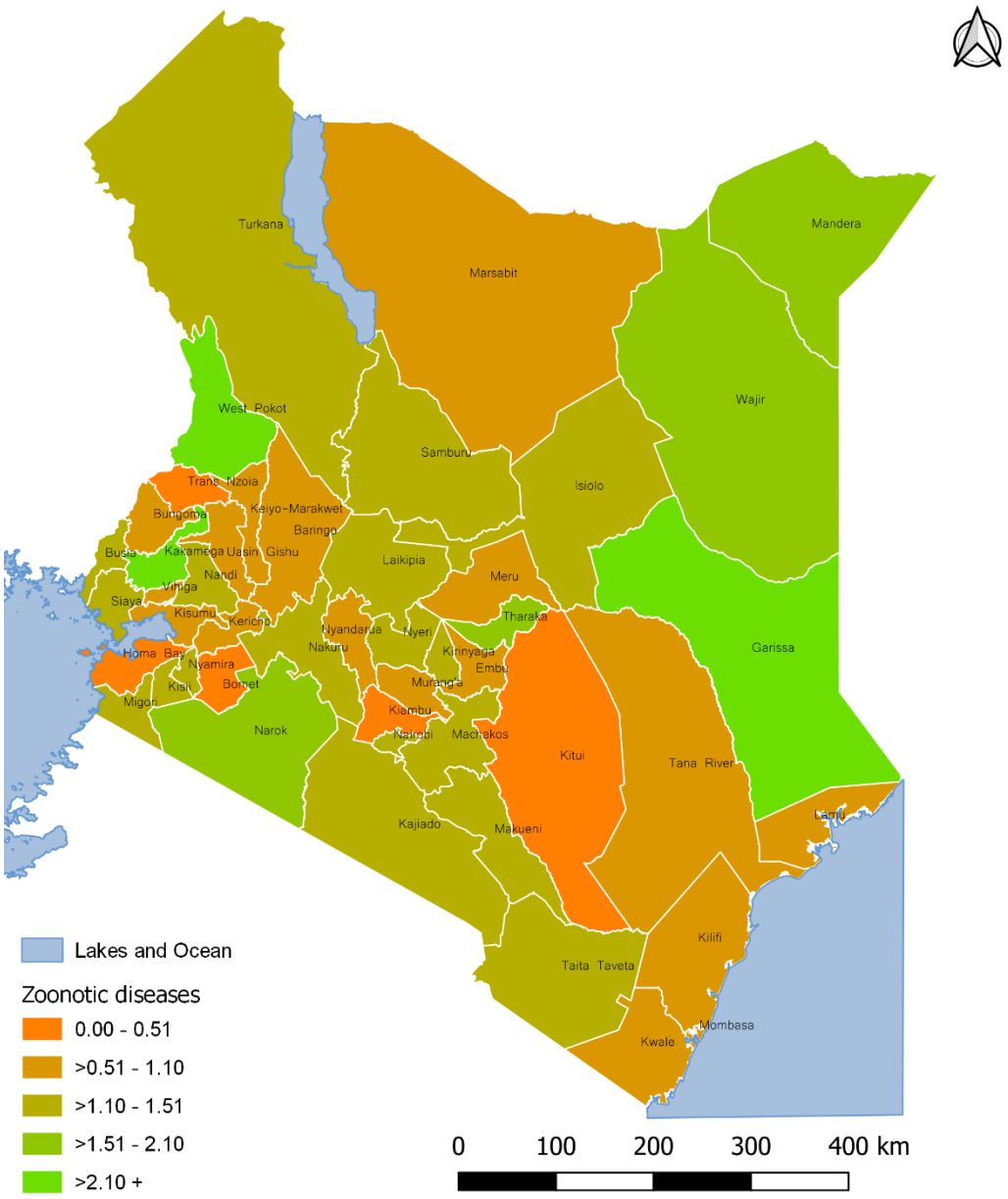
Figure 29: Laboratory Capacity Score - Zoonotic



Overall County Zoonotic Testing and Surveillance Laboratory Capacity Score

Overall, the counties with the lowest scores in zoonotic testing and surveillance were Kiambu, Kitui and Homabay with a score of 0.00 and Bomet with 0.03 score while counties with the highest scores in zoonotic testing and surveillance were Garissa (2.17), West Pokot (2.17), Kakamega (2.00) and Wajir (1.90). Mombasa County had a mean score of 1.07.

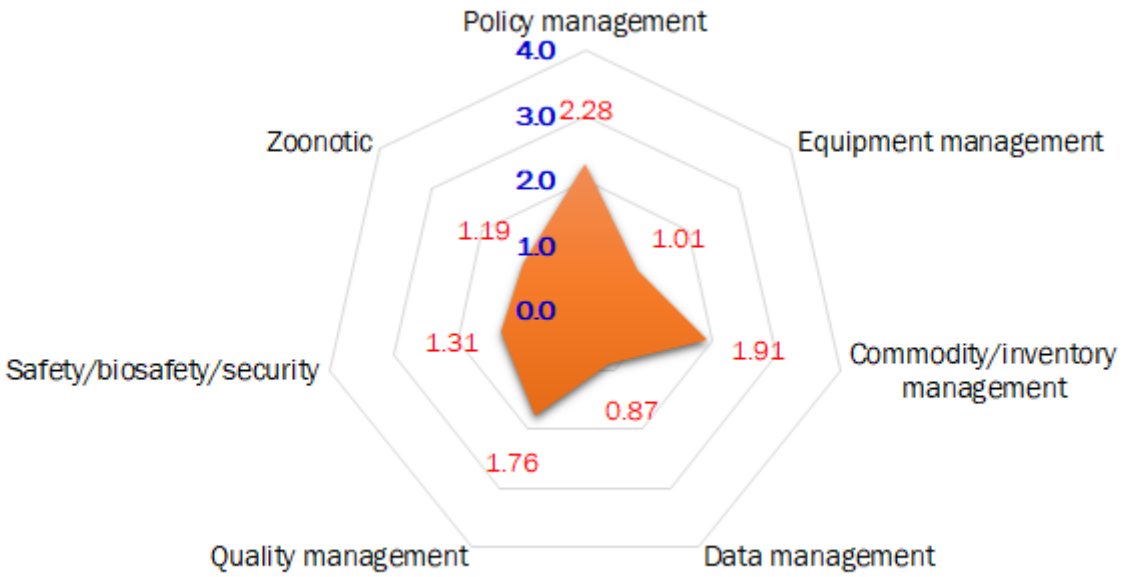
Figure 30: Zoonotic Diseases Median Scores



Overall Laboratory Capacity Dimension Scores

Figure 23 shows the overall score for all laboratories and each capacity dimension: the labs sampled scored poorly in equipment (1.01), Zoonotic surveillance and engagement (1.19) and safety/biosafety/security (1.31). Commodity/inventory (1.91) and policy management (2.28) were the highest ranked dimensions. Zoonotic surveillance, safety/biosafety/security and quality management received a score of 1.19, 1.31 and 1.76 respectively.

Figure 31: Overall Laboratory Capacity Score



4. CONCLUSIONS AND RECOMMENDATIONS

"Public health laboratories operate in a constantly changing scientific and political environment. Diminished resources, rapidly evolving technologies and struggles to hire and retain technical staff must be addressed to ensure that essential public health laboratory services are available to support local, state and national public health programs. The sustainability of public health laboratories requires enhanced operating efficiencies, sharing limited resources and greater collaboration among all public health laboratories."

Charles D. Brokopp, DrPH, MT (ASCP)
President, Association of Public Health Laboratories-2012

WORKFORCE

Health workforce is one of the health systems building blocks that WHO as a means of strengthening health systems globally.[2] In the Kenya Health Policy,[3] health workforce is one of the seven policy orientations: specifically, ensuring that there is adequate and equitable distribution of human resources for health (HRH). The Kenya Health Sector Strategic and Investment Plan (KHSSP 2014 – 2017)[4] called for prioritization of a minimum number of health workers in each facility, based on expected services to be delivered as defined in the Kenya Essential package for Health (KEPH).

PRIORITIES FOR CONSIDERATION

- Review current HRH and Medical Laboratory Services policies and guidelines
- Update policies to respond to changes in population health, health inequalities, and imbalance between demand and supply of public health laboratory services
- Mapping exercise to consider sex of staff as a key indicator to have evidence for workforce sex balance, skill mix, task delegation
- Government to make efforts to strengthen its presence in research area by investing in workforce to ultimately own research outcomes

Only 14% of Level 2, 25% of Level 3 and 0.7% of Level 4 (overall 8%) had met the optimum staffing levels as per the policy guidelines (none of the Level 5 facilities met the minimum staffing threshold respectively). This points to an acute inadequacy in both critical numbers and desired skill sets to meet the need and demand for quality laboratory services. Whilst there exists *The Kenya Health Strategic and Investment Plan, 2014–2018: Human Resources for Health Norms and Standards Guidelines for the Health Sector*[5] which has recommendations for the ideal human resources for health (HRH) for each facility level, the Medical Laboratory Services of Kenya National Policy Guideline of 2006 is still the enforced policy. This disconnect in which policy to enforce may result in wrongful staffing considerations especially for levels 3, 4, 5 and 6. There is need to implement the recommendations of the 2014 Investment Plan to reflect new realities like population growth over time as well as respond to more global health staffing standards for population to health care worker ratios.

There is also greater need to review current policies to be more respondent to changing health environment occasioned by changes in population health needs, rising health inequalities, the impact of globalization, economic development and the imbalance between the demand and supply of public health laboratory services. For instance, the recently concluded Kenya Population

2 WHO-Monitoring the Building Blocks of Health Systems https://www.who.int/healthinfo/systems/WHO_MBHSS_2010_full_web.pdf
3 Kenya Health Policy: https://www.afidep.org/?wpfb_dl=80
4 KHSSP 2014-2017: http://e-cavi.com/wp-content/uploads/2014/11/kenya-health-sector-strategic-investiment-plan-2013-to-2017.pdf
5 The Kenya Health Strategic and Investment Plan, 2014–2018: http://www.health.go.ke/wp-content/uploads/2016/03/KHSSP-BOOK.pdf

Census 2019 should be used to provide critical data/information on population dynamics/densities, disease/pathogen hotspots, and workforce distribution among others. Such a review will help to align public health laboratory services strategic priorities and policy formulation and implementation in a more systemized and respondent manner.

Even though the current policies recommend the optimal staffing numbers for each facility level, they do not explicitly outline how this can be achieved hence making implementation difficult. This study therefore proposes the development and enforcement of guidelines and SOPs that would strengthen the policy, regulatory and fiscal environments to match health workforce supply and demand by actively stewarding, managing and deploying the health workforce to equitably meet population needs across urban, rural and remote areas. Such guidelines would also help to monitor the status of the implementation of the policies through assigning responsibilities and accountability to specific individuals charged with disseminating the guidelines.

The current study did not collect data disaggregated by sex. It is not possible to therefore estimate the proportion of males and females and their distribution by facility levels, geographic locations, education levels, age among other demographic indicators. In future mapping exercises, sex should be considered as a key indicator in order to support evidence-based guidance on workforce sex balance, skill mix and task delegation, competencies and sociocultural needs. Sex data can also be useful in designing and implementing regional and/or country-specific workforce management, performance and monitoring systems to sustain high-quality laboratory services.

The results of the mapping study show that 1 in every 10 employees sampled was nearing or had already attained retirement age. This is a critical age when staff may opt for early retirement. To ensure uninterrupted continuity and quality of services, there is need to institute mechanisms that ensure smooth transition, not only of positions but also, of responsibilities. Mechanisms for skills transfer and internal mentorships (including leadership) to mitigate skills drain when retiring staff finally exit the service are vital. Currently, there are no institutionalized approaches to transitioning either knowledge or skills from individuals nearing or retiring to others left behind. Having a transition guideline (or SOP) would help to reduce skills drain during transitions.

Conversely, 37% of staff from the sampled facilities were between 20-35 years old. This is a critical time in their careers as it is both an entry and prime time to for learning new knowledge and acquiring new skills. Mechanisms for training through continuing education and certification to enhance their professional development and skills while standardizing their knowledge are vital to ensure a competent workforce. In this regard, this study proposes development and roll out of a simple orientation plan for all new and current lab staff. It further recommends strengthened information sharing sessions through a revamped and more robust continuous medical education (CME) guided by current public health needs.

Overall, 59% of all staff were GOK employees while the remainder were non-GOK. Only 17% of staff at research facilities were government employees. There is need for the government to make deliberate efforts and strengthen its presence in the research arena by investing more in workforce which will in turn entitle the government to owning the research outcomes and allow showcase government led initiatives.

PRIORITY COMMUNICABLE DISEASES AND METHODS

Cholera: There are seven counties (Lamu, Isiolo, Nyandarua, Uasin Gishu, Nandi, West Pokot and Elgeyo- Marakwet) that did not report testing for cholera. However, cholera outbreaks can occur anytime anywhere. These tests were done across different facility levels in different counties.

Typhoid fever: This is widely tested by different facilities levels in different counties except Lamu which did not have a single facility conducting typhoid fever tests.

Malaria: Nine in every 10 facilities (and in all counties) tested for malaria mostly by smear microscopy.

Tuberculosis: This was tested across all counties and ZN microscopy used across all the facility levels.

Pneumonia (bacterial): Only 31 out of 47 counties and only in 64 laboratories tested pneumonia.

Measles: Of the sampled facilities, only KEMRI WRP Kondele tested for measles even though the WHO reference laboratory at KEMRI Nairobi that wasn't sampled also conducts measles tests.

Dysentery: only Level 4, 5, 6 and NFL conducted dysentery testing.

Poliomyelitis: None of the sampled facilities reported testing for polio even though the WHO reference laboratory at KEMRI Nairobi that wasn't sampled also conducts polio tests.

Meningococcal meningitis (bacterial): Kwale, Tana River, Lamu, Mandera, Isiolo, West Pokot, Elgeyo Marakwet, Narok, Vihiga, Busia and Baringo were the 11 counties that did not have any facility conducting meningitis testing, neither did any Level 2 facility.

Yellow fever: National virology reference lab, IDRL-CIPDCR KEMRI-Alupe and KEMRI WRP - Kondele tested for yellow fever.

Influenza: Only seven facilities tested for influenza pathogens (2 Level 5 and 5 NFL).

HIV/AIDS: Almost all (97%) facilities offered HIV/AIDS testing services.

With the existing laboratory infrastructure (there are NFL, Level 5 and 6 facilities in all the major regions in Kenya), if well-equipped and the capacity of staff enhanced, they can conduct surveillance and regular testing for these critical pathogens. The MOH can achieve strengthened laboratory infrastructure to respond to these diseases through working in partnership with bilateral partners, internal and external research institutions with interest in each specific pathogens/diseases; collaborating with external governments and or their ministries with special interest in specific pathogens/diseases; strengthening existing community health volunteer mechanisms; and sensitizing susceptible communities to strengthen monitoring and reporting of signs, symptoms and cases of these pathogens/diseases as well continuous building of existing staff capacity through non-resource intensive approaches like supportive supervision, mentorship, continuous medical education and on-the-job training.

Laboratory diagnosis is a critical component of communicable disease surveillance, both for routine confirmation of infections and for the rapid identification of the cause of outbreaks and epidemics. In order for laboratories to provide adequate and responsive support, there is need to accurately and correctly identify the microbial cause of an outbreak which is of potential public health concern. Consequently, prompt and accurate diagnosis of cholera pathogens is vital to cholera outbreak surveillance, which translates to rapid intervention and prevention to minimize disease spread and mortality.

The WHO recommends laboratory confirmation (by culture) for the first 10–20 cases of suspected cholera. It also recommends that a few samples be taken during an outbreak to monitor antimicrobial sensitivity and about 20 stool samples tested to confirm the end of the outbreak (all should be culture negative).[6] It is therefore important that all counties have at least one facility with the capacity to test for and respond to cholera should an outbreak occur.

Results show that only two of the sampled facilities conducted tests for measles detection, only seven tested for influenza, only four tested yellow fever and no facility tested poliomyelitis. Without monitoring the incidences and prevalence of such pathogens and/or diseases, it is difficult to provide sufficient data to both inform public health interventions and promote proper policy advocacy. With the existing laboratory infrastructure (there are NFL, Level 5 and 6 facilities in all the major regions in Kenya), if well-equipped and the capacity of staff enhanced, they can conduct surveillance and regular testing for these critical pathogens.

The MOH can achieve strengthened laboratory infrastructure to respond to these diseases through working in partnership with bilateral partners, internal and external research institutions with interest in each specific pathogens/diseases, collaborating with external governments and or their ministries with special interest in specific pathogens/diseases. Strengthening existing community health volunteer mechanisms and sensitizing susceptible communities to strengthen monitoring and reporting of signs, symptoms and cases of these pathogens/diseases as well continuous building of existing staff capacity through non-resource intensive approaches like supportive supervision, mentorship, continuous medical education and on-the-job training will also strengthen the laboratory infrastructure. Working with all stakeholders in the public health laboratories space, the MOH should prioritize strengthening existing laboratory infrastructure especially at regional/county level to be better equipped to respond to diseases that the counties do not have capacity to respond to otherwise.

6 WHO: https://apps.who.int/iris/bitstream/handle/10665/43017/WHO_CDS_CPE_ZFk_2004.4_eng.pdf;jsessionid=43AEB581BD6069DA1EBB1030A-23B9631?sequence=1

PRIORITY TRADE SENSITIVE DISEASES AND METHODS

The eleven laboratories under the Division of Veterinary Services (DVS) mapped for this study tested six priority trade sensitive diseases (foot & mouth, contagious bovine, contagious caprine, Rift Valley fever, Newcastle disease and MERS-CoV). None of the sampled laboratories conducted testing for ovarian rinderpest commonly known as Des Petits Ruminants (PPR) and the African swine fever (ASF).

The respective ministry should set up short-term mechanisms to establish testing for the two diseases in select facilities (or as many as feasible) while in the long term seeking sustainable funding mechanisms to ensure continuous funding for testing and surveillance of all priority trade sensitive diseases and methods.

PRIORITY FOOD SAFETY TESTS (CONTAMINANTS)

The Government Chemists in Nairobi, Kisumu and Mombasa and the Food Safety and Nutrition Laboratory were mapped for the testing of six priority food safety contaminants namely: Aflatoxins, *Clostridium perfringens*, *Staphylococcus aureus*, *Campylobacter* species, *Salmonella* species and *Escherichia coli*.

- Aflatoxin: Food safety and Nutrition laboratory, Government Chemists in Nairobi and Mombasa tested for aflatoxin while the Government Chemist in Kisumu did not.
- *Staphylococcus aureus*, *Salmonella* species and *Escherichia coli*: Only Government Chemist Mombasa tested for *Staphylococcus aureus* and *Salmonella species*.
- *Clostridium perfringens* and *Campylobacter* species: No laboratory tested for *Clostridium perfringens*.

PRIORITY ZOONOTIC DISEASES AND METHODS

Eighteen priority zoonotic diseases were mapped during the assessment.

Twelve zoonotic diseases were tested among various facilities in the country (avian influenza, leishmaniasis, brucellosis, anthrax, leptospirosis, rabies, bovine tuberculosis, salmonellosis, helminths, fungal diseases, schistosomiasis and trypanosomiasis).

None of the laboratories reported testing for five of the zoonotic diseases: plague, West Nile virus, tularemia, rickettsia and toxoplasmosis.

PRIORITY ANALYTICAL TESTS

Priority analytical tests were done by the Government Chemists in Nairobi, Kisumu and Mombasa. Apart from food safety and Nutrition lab, none of the three facilities reported carrying out tests for vitamins in foods and amino acids in foods. All the three labs conducted DNA profiling for species identification. The Nairobi Government Chemist is the only one that reported conducting testing for cannabis, pesticide poisoning and antibiotic residue in food.

WORKLOAD AND REFERRALS

Laboratory referral networks are a critical pathway in ensuring detection, testing and surveillance for pathogens and diseases. More and more people and institutions look to laboratory systems for resilience and efficiency in the ever changing public health environment like Ebola outbreaks in Democratic Republic of Congo accompanied by massive movement (of people and goods) by road and air across Africa; change from a central to county government health system, continuous population growth without specific data on which sub-populations are where among others. The role of national health laboratories in public health response is currently extended beyond laboratory testing and they play a crucial role in other public health spaces like emergency response, training and outreach, communications, laboratory-based surveillance, data management and policy advocacy. Laboratory referral systems are at the heart of these functions.

This expanded role calls for proactive and not reactive public health laboratories. In order to proactively achieve the ever-expanding scope, this study suggests the following components:

Communication Within and Between Laboratories

Results from the mapping study show that most Level 2, 3 and 4 referred samples of critical diseases/pathogens to higher up laboratories. The results also show a silo of laboratory activities among the Level 5, 6 and NFLs. However, most of this referral system was one directional (from the lower lab to the higher lab) with the exception of results going the other way. It is vital that communication between labs is two-way at all times (not during sample referrals only) but also during regular surveillance processes. Specialized labs like veterinary, research, food safety and government chemists all play a crucial role in supporting both lower level and national laboratory systems. A strong and functional communication system between and within laboratory tiers is vital. This study proposes establishing and rolling out a robust communication strategy between laboratories. Such a strategy should be developed by select persons from key stakeholders and will ensure that there is timely information of any suspected outbreak and the nature of the outbreak; laboratories communicate results of investigations promptly and accurately and; that laboratories share information regularly as a public health protocol for better response.

Collection, Processing and Interpretation of Results (Specimen Management)

There have been (few) reported cases of samples that either did not reach a referral station, taken to the wrong reference point before or after testing or samples that took long to be processed. Whilst there are protocols and guidelines for sample collection and transfer, many lower level facilities have no mechanisms for enforcing their implementation due to staff shortages, staff capacity, resource constrains, geographical challenges, infrastructural handicaps among others. While most referral systems are working fine, the advent of the county system has also brought to light previously hitherto effective referral networks based on the provincial general hospital systems have now been dismantled and replaced with the county referral hospital system which is mostly effective but in some cases especially Northern Kenya is not as effective. A more robust approach that considers efficiency and effectiveness of sample collection and referral is needed.

Results from the mapping study show that most Level 2, 3 and 4 referred samples of critical diseases/pathogens to higher up laboratories. It is vital that communication between labs is 2-way at all times (not during sample referrals only) but also during regular surveillance processes. A strong and functional communication system between and within laboratory tiers is vital. This study proposes establishing and rolling out a robust communication strategy between laboratories.

Even though there are protocols and guidelines for sample collection and transfer, many lower level facilities have no mechanisms for enforcing their implementation due to staff shortages, staff capacity, resource constrains, geographical challenges, infrastructural handicaps among others.

While most referral systems are functional, the county system still uses the earlier referral pathways based on the old administrative system where that relied on provincial general hospitals are still used even when it is more effective and efficient to use neighboring county infrastructure. A more robust approach that considers efficiency and effectiveness of sample collection and referral is needed.

This study proposes a revision of the current referral network systems to reflect both the new political dispensation but also appreciate other working systems for synergy. **Referral networks should provide adequate laboratory testing coverage for all populations in order to meet public health needs. Where feasible, this study proposes the inclusion of non-public sector laboratories in the referral network.**

The structure of the tiered laboratory network has been established. However, it has only taken into consideration political boundaries and not geographical distribution, population distribution, infrastructure and availability of personnel and skills in order to place laboratories in appropriate areas to assure patient care coverage.

This study proposes a revision of the current referral network systems to reflect both the new political dispensation but also appreciate other working systems for synergy. Referral networks should provide adequate laboratory testing coverage for all populations in order to meet public health needs. Where feasible, this study proposes the inclusion of non-public sector laboratories in the referral network. Channels of regular communication and specimen referral must be defined within and outside the network to assure maximum capacity to perform efficient testing. Working relationships must exist between laboratories at the local, regional, national and international level both for benchmarking but also information sharing.

Finally, referral networks even though incorporated into public health outbreak response systems, should be more responsive through real time data sharing and information dissemination to county and central government.

LABORATORY CAPACITY SCORES

Policy Management

- The overall mean score for all laboratories was 2.28 out of 4.
- The best performing indicator/dimension under policy management was whether the laboratory participated in health management team meetings and strategic planning initiatives (2.9) while the indicators whether a budget was assigned for laboratory activities/services and whether the laboratory complied with the National Laboratory Services Policy Guidelines both scored a 2.1.
- Lamu (1.09) and Taita Taveta (3.47) had the lowest and highest scores respectively.

Equipment Management

- The overall mean score for all laboratories was 1.01 out of 4.
- The best performing indicator/dimension under equipment management was presence of equipment management logs (2.74) while the indicators with the lowest score were routine calibration and availability of service contracts (0.27) respectively.
- Turkana (0.57) and Nairobi (1.64) had the lowest and highest scores respectively.

Commodity/Inventory Management

- The overall mean score for all laboratories was 1.91 out of 3.
- The best performing indicator/dimension under commodity/inventory management was lab reagents/kits being within the manufacturer's expiry dates (2.73) while the indicator with the lowest score was laboratories maintaining a stock of emergency sample collection and transport supplies (1.74) respectively.
- Lamu (1.32) and Nairobi (2.31) had the lowest and highest scores respectively.

Data Management

- The overall mean score for all the labs sampled was 1.63 out 4.
- The best performing indicator/dimension under data management was use of standard data collection tools (3.28) while the indicator with the lowest score was laboratories having a LIS modification protocol (0.36) respectively.
- Nairobi (2.78) had the highest score while Lamu (1.14) had the lowest overall data management score.

Quality Management

- The overall mean score for all the labs in quality management indicators was 1.76 out of 4.
- The best performing indicator/dimension under quality management was laboratories having SOPs (2.97) while the indicator with the lowest score was laboratories having training policies (2.28) respectively.
- Lamu (1.04) and Nairobi (2.67) had the lowest and highest scores respectively.

Safety/Biosafety/Security

- The overall mean score for all the laboratories was 1.31 out of 4.
- The best performing indicator/dimension under safety/biosafety/security was laboratories having safety equipment (2.87) while the indicator with the lowest score was reporting system (0.77) respectively.
- Tana River (0.85) and Nairobi (2.20) had the lowest and highest score respectively.

Zoonotic Testing and Surveillance

- The overall mean score for all the laboratories was 1.19 out of 3.
- The best performing indicator/dimension under zoonotic testing and surveillance was outbreak preparedness (1.37) and the indicator with the lowest score was displayed poster on zoonotic diseases (0.91) respectively.
- Garissa (2.17) and Bomet (0.03) had the highest and lowest scores respectively while Kiambu, Kitui and Homabay did not have data for this section.

- Overall, data management (0.87) and equipment management (1.01) were the laboratory capacity score dimensions that had least rating whilst commodity management (1.91) and policy management (2.28) were the dimensions that were rated highly.

RECOMMENDATIONS FOR LABORATORY CAPACITY SCORES

There is need to establish/revise/implement national laboratory quality standards for policy management, quality management, data management, equipment management, commodity/inventory management, safety/biosafety/security and zoonotic testing and surveillance. The MOH has made great efforts to establish and institutionalize laboratory quality standards. However, some of them may need revision in the face of the changing disease patterns, devolution of health services to county governments as well as population and infrastructural growth.

This report recommends a staged approach in implementing the laboratory quality standards. For instance, basic principal requirements should be expected in the national laboratory standards as a minimum requirement while more advanced and national reference laboratories should be encouraged to aim at meeting internationally accepted standards such as ISO 15189.

Further, whilst many quality assurance activities associated should be implemented by local laboratories, strategic and policy support and oversight should continue to be provided at the national level-NPHLS.

In this regard, this report recommends that the MOH should:

- Establish and revise all national quality standards as well as their implementation guidelines to reflect changes in national health policies and priorities, pathogen/disease patterns, laboratory infrastructure & capacities and global standards among others.
- Establish and implement strategies to measure progress for the national quality standards on policy management, quality management, data management, equipment management, commodity/inventory management, safety/biosafety/security and zoonotic testing and surveillance.
- Establish and implement data management processes and systems that allow for both timely and accurate capture, collation and reporting on laboratory data. Where feasible, ensure that data is reported through a single/central repository for ease of consolidation, learning and decision making at facility, county and country levels.
- Ensure that laboratory facilities and infrastructure are adequate and properly maintained for all testing being performed. Where lacking like polio, measles or yellow fever, institute mechanisms that support establishment of their testing.
- Establish long-term roadmap for ensuring adequate and sustainable staff numbers and capacity of properly trained personnel for conducting laboratory operations including carrying out laboratory quality assurance initiatives.
- Develop long term funding mechanisms through partnerships and collaborations with stakeholders/institutions to ensure resources for internal quality control and for external quality assessments are available in a sustainable manner.
- Develop a framework for monitoring and evaluating laboratory performance system strengthening/quality assurance processes.
- Establish/strengthen the functionality of an advisory team for laboratories with representatives drawn from all key stakeholders. Such a structured approach will ensure a standardized oversight to all laboratory quality assurance initiatives. Such an advisory committee's role may include:
    - Continuously setting or revising minimum standards (according to WHO/CDC/ CLSI guideline)
    - Continuously providing guidance on equipment, maintenance, supplies and a functional referral system
    - Continuously setting/revising minimum personnel requirements, skills and training
    - Setting up and standardizing methods for national quality assurance performance systems
    - Establish a system of laboratory quality champions either through more targeted sensitization or a trainer of trainers (TOT) model that would create a critical mass of lab quality point persons for internal and sustainable quality assurance support.

In conclusion, the functions of public health laboratory systems in Kenya can be made more robust and responsive if national laboratory strategic planning and implementation efforts recognize the need and continue to strengthen human resource

and infrastructure development, quality management, supply chain management, specimen referral, and results-reporting and laboratory information systems, in an integrated, coordinated and collaborative laboratory network led by NPHLs and key stakeholders.

APPENDIX

Table A1: Minimum Recommendations for Capabilities and Capacities of Laboratories

LABORATORY LEVEL	STAFFING RECOMMENDATION	TESTING SERVICES RECOMMENDATION
2	2	HB, ABO grouping, Gram stain, Blood glucose, BS for malaria, Stool microscopy, PT test, Syphilis, HIV rapid test
3	2	All Level 2 tests above plus total and differential WBC count, ZN stain, KoH, sickle cell screening test
4	24	All of the Level 3 test plus; Full hemogram, Bleeding time, Prothrombin time, ESR, Compatibility testing, Coombs test, Indian ink, Blood, Stool and urine cultures, sensitivity testing, LFT, Urea & Electrolytes, ASOT, Hepatitis testing, RF, CD4/CD8, PSA, RFTs
5	38	All of Level 4 tests plus Reticulocytes, HB electrophoresis, LE, Transfusion medicine, H Pylori, Culture and sensitivity testing for urine, stool, blood, pus swab and aspirates. P24 antigen, Histology/cytology tests for cervical smears, aspirates, biopsies, bone marrows and mortuary services

Table A2: Laboratory Equipment by Types and Numbers

LABORATORY EQUIPMENT BY:	
NAME/TYPE	NUMBERS
1. Microscope	2149
2. Glucometer	1547
3. Refrigerator	1405
4. Centrifuge	1372
5. HB Meter	1288
6. Mechanical Pipettes	568
7. Analytical Weighing Balance	457
8. Chemistry Analyzer	512
9. Hematology Analyzer	476
10. Incubator	381
11. Water Bath	329
12. Bio-safety Cabinets	313
13. Shakers	275
14. Molecular Equipment	269
15. CD4 Analyzer	273
16. Rotator	233
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