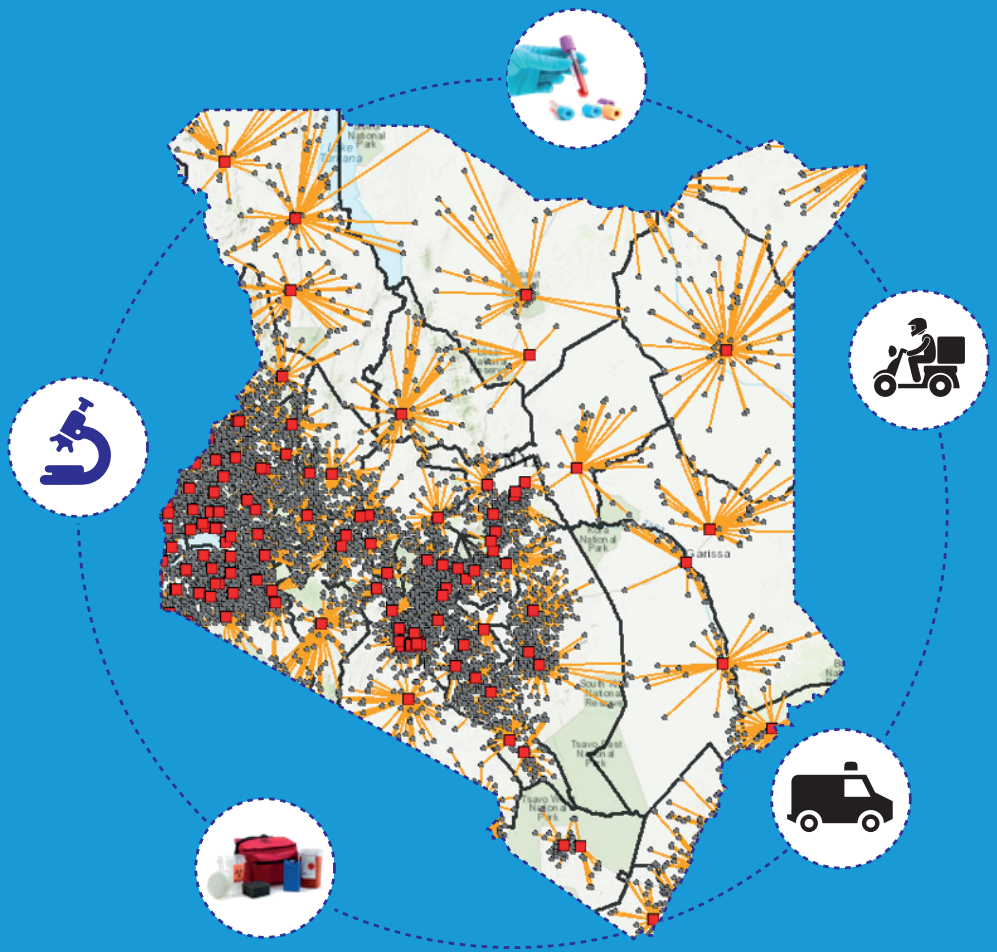
REPUBLIC OF KENYA

MINISTRY OF HEALTH

NATIONAL GUIDELINES FOR INTEGRATED LABORATORY SPECIMEN REFERRAL NETWORKS | 2019



National Guidelines for Integrated Laboratory Specimen Referral Networks | 2019

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FOREWORD

Article 43 of the constitution of Kenya has entrenched the right to health care services for all. Enjoyment of this right by all is anchored firmly in the spirit of universal healthcare coverage (UHC) and all the measures put in place to ensure universal access, uptake and coverage of healthcare services by all the citizens.

The Kenya Health Policy 2011–2030 (1) has set the goal of "attaining the highest possible health standards in a manner responsive to the population needs," which will be achieved through provision of equitable, affordable, and quality health and related services. Similarly this is reiterated in the current health sector report of the Third Medium Term Plan (2018 -2022) (2) of Kenya Vision 2030 (3) and the Kenya Health Sector Strategic Plan (KHSSP) 2012–2017 (4), aims at "accelerating attainment of health impact goals," aims to implement a broad base of health and related services that will impact on the health of persons in Kenya.

These national policy and strategic guidance documents recognize the importance of referral systems in the attainment of these overall health goals in Kenya, and articulate measures to be taken to strengthen these systems. Specimen transfer is a key component of the national referral system which increases citizens' access to the highest level of laboratory services, regardless of the point where they are seeking health care. The aim of the specimen referral guideline is to provide a framework to support shared testing resources to increase uptake and coverage of specialized laboratory test through networking. This will ensure moving specimens for clinical diagnosis, disease monitoring and surveillance to markedly reduce impact of patient catastrophic cost including those associated with seeking testing services

The Kenya Health Policy 2011–2030 has operationalized the two-tier health management system, corresponding with national and county governments. Providing standard guidance documents, capacity building of counties and support quality management systems initiatives to ensure quality healthcare service delivery to all Kenyans is one of the roles of the national ministry responsible for health.

Dr. J.W. Masasabi

Ag. Director General for Health, Ministry of Health

EXECUTIVE SUMMARY

Strengthening integrated specimen referral system through objective assessments designed to continuously improve efficiency, quality and safety of the system is an essential mirror to reflect on progress gained and challenges that can be turned into opportunities for improvement. By identifying gaps to provide opportunities for programmatic interventions is key to rolling out HIV, TB and other priority diseases diagnostic, care and treatment services to the general population in line with the spirit of Universal Health Coverage (UHC) and global health security agenda.

This assessment is aligned to proactively support government initiative of providing UHC to its citizens and contribute significantly towards attainment of Kenya Vision 2030 social pillar to prevent communicable diseases, HIV AIDS, TB and Malaria among other priority diseases of global health concern. GOK MOH Strategy for referral of both patients and clinical samples articulates approaches that are rational, feasible and cost effective with expected outcomes that are geared to safeguard patient safety, quality and markedly reduce catastrophic costs associated with patient transport and upkeep in trying to access services. These costs create inequality to access of healthcare among the vulnerable populations; poverty afflicted, old, pregnant, children under five (5) and people living with disability among others.

The KHSSP 2012-2017 has laid out deliberate system strengthening investment inputs that drives a robust healthcare service delivery. Article 43(1) a. in the Constitution of Kenya 2010; provides an entitlement to people in Kenya to access the highest standards of healthcare available.

To achieve this milestone, the National Public Health Laboratory (NPHL) with stakeholders will provide guidance in both technology and practices; this exercise will ensure standardization of commodities in specimen management chain, use of technology in testing data transmission and monitoring and above all the possibility of utilization of green and renewable energy, deploying drones in airspace to transport specimens, blood among other essential supplies where feasible and above that deploying virtual monitoring and interactive ICT innovative tools designed to fit our challenges.

Mapping specimen referral system to provide geospatial data on facilities and testing referral laboratories to help understand operating terrain in relation to; roads, referral distances, geographical terrains, targets population and whether patterns among other essential data layers that are determinants of successful specimen referral networks. Robust specimen referral and testing systems that is efficient, adoptive and cost effective in operation is critical to a country needs in a quest to realize MOH Mission of provide quality, equitable and cost-effective healthcare to all people in Kenya.

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
CDC	U.S. Centers for Disease Control and Prevention
CHMT	County Health Management Team
CHS	Center for Health Solutions
CQI	Continuous Quality Indicator
CRL	County Referral Laboratory
DBS	Dry Blood Spot
DDSR	Division of Disease Surveillance and Response
DST	Drug Susceptibility Testing
EID	Early Infant Diagnosis of HIV
EQA	External Quality Assessment
FIF	Facility Improvement Fund
FIND	Foundation for Innovative New Diagnostics
GOK	Government of Kenya
HIV	Human Immunodeficiency Virus
IATA	International Air Transport Association
ICT	Information Communication Technology
IDSR	Integrated Disease Surveillance and Response
IHR	International Health Regulations
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
KEPH	Kenya Essential Package for Health
KHSSP	Kenya Health Sector Strategic Plan
KMLTTB	Kenya Medical Laboratory Technicians and Technologist Board
KNASP	Kenya National AIDS Strategic Plan
KPI	Key Performance Indicator
NHSSP II	Second National Health Sector Strategic Plan of Kenya

Lab ICC	Laboratory Interagency Coordinating Committee
LIMS	Laboratory Information Management System
LPA	Line Probe Assay
M&E	Monitoring and Evaluation
MOH	Ministry of Health
NASCOP	National AIDS/STD Control Programme
NPHL	National Public Health Laboratory
NRL	National Reference Laboratory
NTLD-P	National Tuberculosis Leprosy and Lung Disease Program
NTRL	National TB Reference Laboratory
NTRL	National TB Reference Laboratory
POC	Point of Care
PPE	Personal Protective Equipment
PPP	Public-Private Partnership
QA	Quality Assurance
SOP	Standard Operating Procedure
TAT	Turnaround time
TB	Tuberculosis
UAV	Unmanned Aerial Vehicle
UHC	Universal Health Coverage
UN	United Nations
UoM	University of Maryland
VL	Viral Load
WHO	World Health Organization
WHO/AFRO	World Health Organization Regional Office for Africa

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1

INTRODUCTION AND BACKGROUND TO HEALTH SERVICES IN KENYA

The global commitment to achieve disease reduction targets set by the Millennium Development Goals for 2015 that has shifted to Sustainable Development Goals by 2030 has led to increased demands for countries to improve their healthcare systems. Countries with limited resources have had to identify opportunities for optimizing resources to achieve functional health systems that meet national priorities and support global disease control objectives.

The Government of Kenya (GOK) is a signatory to the United Nations (UN) Millennium Declaration and has stated its duty to provide its citizens with the highest attainable standard of healthcare available in line with article 43(1) a. of its Constitution 2010. The goal of the Kenya Health Policy 2011–2030 (1) is "better health in a responsive manner." The strategic objectives of the policy include increasing equitable access to affordable health services and improving the quality and responsiveness of services in the sector, as well as the efficiency and effectiveness of service delivery.

Health services in Kenya are structured in a hierarchal manner, with four levels of care: community, primary care, county, and national services, as shown in Figure 1. The categorization ensures efficiency in the use of existing resources. The Kenya Essential Package for Health (KEPH) in the Second National Health Sector Strategic Plan of Kenya (NHSSP II) 2005-2010 (5) defines the scope of services to be provided at each level of the health system, including on-site laboratory testing capacity.

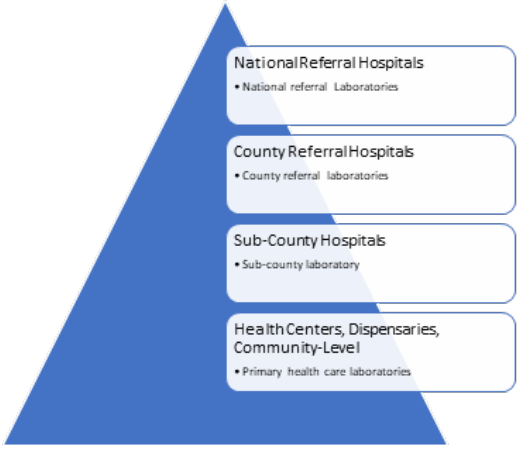


Figure 1: Kenya's tiered health system

1.1 The Laboratory Network

The vision for the laboratory sub-sector is to have an efficient and high-quality health care system that is accessible, equitable, and affordable for all. The mission statement of the laboratory is to provide effective, efficient, accessible, equitable, and affordable services that support the diagnosis and management of patients, public health disease surveillance, and the regulation and monitoring of standards of laboratory practice in Kenya.

The laboratory strengthening efforts of development partners in support of diagnosis and management of HIV and AIDS, tuberculosis (TB), and malaria have provided several laboratories with the capacity to provide more tests than those prescribed under the KEPH schedules (5). The infrastructure, staff capacity, and quality systems built into these laboratories can also be utilized to support the management of other communicable and non-communicable diseases, including diabetes, hypertension and cancer, which are emerging as public health threats in developing countries.

The important role of public health laboratories has been emphasized by the World Health Organization (WHO), which, through the Maputo Declaration (6) in 2008, urged member states to develop well-staffed and properly equipped laboratories and formulate guidelines for national integrated specimen referral networks. Although the emphasis of this resolution was on disease surveillance and response, the benefits apply equally for patient management. Such benefits include supporting the management of communicable and non-communicable diseases which are among the leading causes of illness, disability, and death in African communities.

The laboratory referral network functions go beyond analysis of specimens. They include provision of equipment, supplies, QA, and training so that tests can be performed accurately and reports made available in a timely manner. The data obtained through the networks can be used in patient care and linked to disease surveillance activities and the planning of health services.

1.2 The Need for Specimen Referral Systems

Due to the structure of the tiered health system and because many diagnostics services are only available at higher levels of the system, clients may not be able to receive all the services they require at the health service delivery unit they visit, particularly if they are only able to visit the community level.

The Ministry of Health (MOH) has developed the Kenya Health Sector Referral Strategy (2014-2018) (National Referral Strategy) (7) to address this shortcoming. From this document, it states, "A referral system is defined as a mechanism to enable clients' health needs to be comprehensively managed using resources beyond those available where they access care."

The National Referral Strategy recognizes specimen movement from one laboratory to another for investigative purposes or quality assurance (QA), and back movement of results/reports as an indirect referral mechanism. The National Referral Strategy has also defined an investment plan to equip the laboratories to provide the stated minimum packages.

Effective referral networks provide linkages across the different levels of the health system—from the community to the national level, which ensure that the client can receive the full scope of health care available irrespective of where the client physically accesses care. The system aims at maximizing the patient/customers visit and offering a standard, multi-disease laboratory package throughout the health system, thus improving both access and equity.

This strategic approach ensures the laboratory services execute the mandate as stipulated in the National Referral Strategy. The strategy also recognizes faith-based and private institutions as well as international institutions as part of the referral system. The implementation of the strategic plan will provide laboratories with the structure and essential requirements needed for effective specimen referral systems.

2

GOALS OF THE NATIONAL SPECIMEN REFERRAL GUIDELINES

Specimen referral systems have been developed, operational and effective in Kenya's public health facilities; for example, for the referral of TB and HIV specimens. These systems, however, are fragmented/uncoordinated, not systematically integrated, not monitored and evaluated by a standardized framework, and in many cases inefficient. Experiences from countries in the region have shown that establishment of laboratory referral networks using standard guidelines, enhances the effectiveness and efficiencies of the overall diagnostics network.

This document is designed to guide the implementation of the laboratory element of the National Referral Strategy, with the application to integrated, multi-disease diagnostics networks. These guidelines should help the country achieve the goals of a specimen referral system, which, in turn, should support and strengthen the diagnostics network, which should provide the health system with the information and analysis it needs for patient management, as well as surveillance for priority diseases and outbreak response.

2.1 Goals of a Specimen Referral Network

These guidelines support the development and strengthening of specimen referral networks in order to achieve five main goals:

- Improving the quality of specimens delivered to the testing laboratory
- Contributing to increased access to diagnostics where services do not exist by referring the specimen
- Ensuring safety and security of all individuals and the environment that are involved with specimen referrals
- Meeting timeliness requirements of the specimen reaching the testing laboratory and the paper result reaching the facility's records
- Enhancing cost efficiency.

2.2 Benefits of a Well-Functioning Specimen Referral Network

If these guidelines are implemented and the goals of a specimen referral network aforementioned are met, the benefits include the following:

- Improving the quality of tests offered throughout the diagnostics network, which should lead to improved diagnostics services and increased confidence in the services, thus potentially increasing access and utilization of services
- Reduction of the direct costs to patients/clients of accessing and delivering health services, as they will be managed at the appropriate level of care
- Increasing cost efficiency as the specimen referral networks are rationalized/ optimized and integrated
- Improving laboratory-based surveillance and response systems

2.3 Target Users of the Guidelines

The guidelines target a range of stakeholders who are involved in supporting the specimen referral system. These target users include the following:

- Laboratory personnel to guide in specimen referral processes
- Laboratory and disease-program management to aid in planning, budgeting, and quality management
- Clinicians as key consumers of laboratory information for collaboration and creating demand for laboratory services
- Policy makers and administrators of health facilities and counties for planning and coordination, and to ensure funding and other support is provided to maintain and sustain an effective referral system
- Development partners to guide them in their support of the referral systems
- Training institutions to help in the development and review of training curricula.

2.4 Laboratory Handbook as a Companion Guide

The guidelines will be accompanied by a Laboratory Handbook, which will detail standard operating procedures (SOPs) for collection, packaging, storage, transit, turnaround times, and results' return for each specimen-type and laboratory test offered across Kenya, as well as directory for all of the national reference laboratories (NRLs) for each disease, including the Integrated Disease Surveillance and Response (IDSR) referral sites and list of laboratory-based surveillance systems.

This handbook is intended to be created by the laboratory and be available to any users of the laboratory to ensure quality and biosafety/biosecurity.

3

STRUCTURE AND ORGANIZATION OF THE SPECIMEN REFERRAL NETWORK

a. **Policy statement:** Laboratory specimen referrals networks shall be integrated to support detection, monitoring and surveillance of priority diseases of Public Health concern in line with the spirit of UHC in Kenya.

b. **Policy statement:** Laboratory specimen referrals networks shall support national and global health security, in line with the International Health Regulations (IHR).

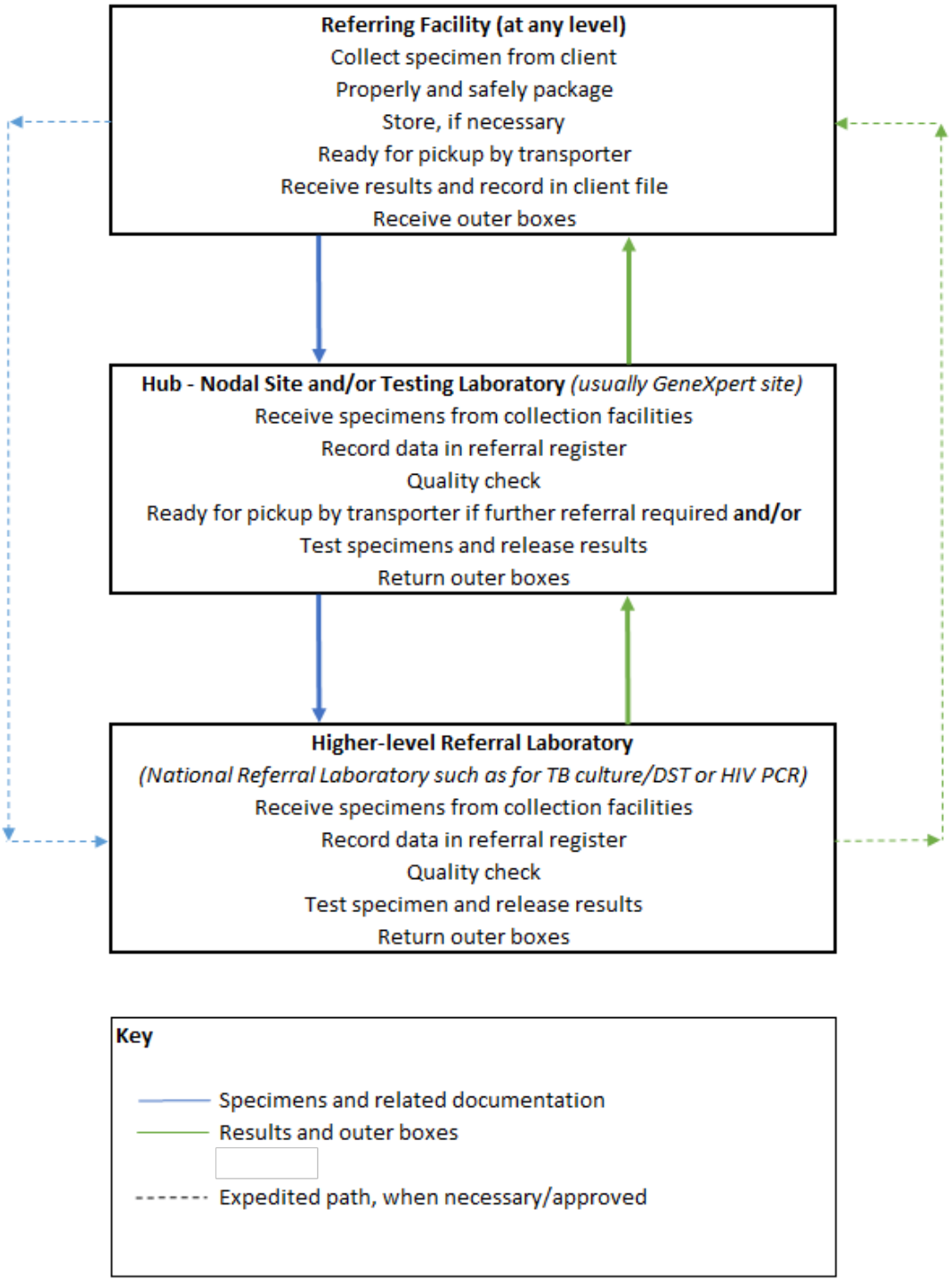
c. **Policy statement:** Healthcare facilities without certain testing capacity shall refer specimens to higher-level facilities where such services are available.

The organizational structure of laboratory specimen referral networks will follow the national health delivery structure based on the KEPH, which is supported by the *Human Resources for Health Norms and Standards Guidelines for the Health Sector (8)*.

This approach enables the laboratory referral system to be entrenched into the national health delivery model and the MOH's health funding structure, thus ensuring sustainability of the networks.

The broad structure and organization of specimen referrals is shown in Figure 2 and is as follows:

Figure 2: Specimen referral and results' process flow



- The facilities in the integrated specimen referral network are included in the referral networks as provided by the National Referral Strategy, including: public, private and faith-based
  - » The referring facility which collects and refers the specimen is called the satellite site
  - » The facility to which the specimen is sent for analysis or further referral is the receiving facility, also called the nodal or testing site
- Laboratories at lower levels lacking testing capacity will send specimens to the next level, where the required analysis will be provided
- Laboratories may bypass the next level in the hierarchy and send the specimen directly to the higher level, where testing will occur
- A laboratory may use several referral laboratories for different tests; for example, a health center laboratory may send blood specimens to the county referral laboratory (CRL) for CD4 testing and sputum samples to the National TB Reference Laboratory (NTRL) for TB culture
- Horizontal referral networks, where a laboratory sends a specimen to another laboratory at the same KEPH level, should also be effectively in place at each tier of the healthcare system. Such horizontal networks should provide alternate testing sites in case of machine breakdown or reagent stock-out, and function effectively as inter-laboratory QA schemes.
- The minimum laboratory activities shall be defined for each level of care in accordance with the National Referral Strategy

3.1 Landscape Analysis of Specimen Referral Networks

3.1.1 HIV services

In 2003, WHO and UNAIDS launched the "3 by 5" Global Initiative, targeting treatment for 3 million HIV patients by 2005. The Kenya National AIDS Strategic Plan (KNASP) (9) developed in 2005 provided a framework for antiretroviral therapy (ART) scale-up based on this initiative. Laboratories did not have the capacity to manage the CD4 testing requirements in support of ART that followed the huge patient inflow at public hospitals.

A strategic approach was devised where 12 high-volume laboratories were identified, equipped with standardized equipment and reagents, and enrolled in common quality assurance (QA) schemes, including external quality assessment (EQA). Standardized protocols and trainings were also adopted for specimen collection, initial processing, packaging, and transportation.

Then, specimens for CD4 tests were collected in four ART pilot sites in Coast Province (2003–2005) and shipped to the nearest processing laboratory using cars, motorcycles, and staff hand-carrying specimens, depending on proximity. Lessons learned were documented, including how clients were cushioned against catastrophic costs of accessing the services since the specimens were referred instead of the client being required to travel to the testing facility.

The approaches were then expanded to Nyanza in 2005–2006 and to all provinces from 2007. The approach improved service uptake and access, which was essential in the ART scale-up strategy. Other tests were added to the network over time, including HIV viral load (VL) and early infant diagnosis (EID), hematology, biochemistry and opportunistic infection detection.

The National Public health laboratory provides oversight and direction for all specimen and testing services across disease of public importance. including specimen referrals, quality assurance, analysis and return of result both electronically and manually. Currently, individual partners support specimen referrals at the sub-county, county and national level. A summary of the current systems employed is as follows:

- The specimens are collected from clients, appropriately packaged/stored and transported with relevant documentation to the nearest testing laboratory.(as detailed in laboratory specimen referral hand book)
    - » Transport happens by a variety of mechanisms, including human carriers (laboratory or facility staff), partner-managed and owned vehicles, and professional courier services
    - » Point-of-care (POC) analyzers are also available throughout the country to further reduce TAT.

- Results for all tests can be accessed electronically, which has greatly improved the TAT, although a paper copy is still sent back to the requesting facility to include in the client's file
- Remote login implementation is being scaled up to help improve patient demographic data capture before the specimen reaches the laboratory, to enhance planning, reduce sample rejections due to incomplete/inaccurate documentation and to save time once the specimen reaches the testing facility

3.1.2 Tuberculosis (TB) services

Clinicians have long relied on traditional methods for diagnosis and treatment monitoring of TB. However, technology evolution has seen WHO shift its guidance for TB diagnostics from smear microscopy using ZN smear technique to more efficacious methods, including more efficient and sensitive FM microscopy and the near-POC device GeneXpert, which was introduced in Kenya in 2012, drastically improving TB diagnostic sensitivity and rifampicin-resistance efficiency in a record two-hours testing turnaround time (TAT).

In addition to the GeneXpert and microscopes available for diagnosis, there are two reference laboratories in Kenya that can perform TB culture and drug susceptibility testing (DST), these are the National TB Reference Laboratory (NTRL) in Nairobi and the Kenya Medical Research Institute (KEMRI)-Kisian Laboratory in Kisumu. Initially solid culture media was used, which had a long TAT of 3-5 months for results but later liquid culture media was introduced, which shortened TAT to two months.

Further, the molecular testing technique Line Probe Assay (LPA) for TB and other mycobacterium species was later introduced in 2000 with a TAT of 3-5 days. Currently NTRL has capacity to do first-line and second-line phenotypic and genotypic DST.

The specimen referral network falls under the purview of the National Tuberculosis Leprosy and Lung Disease Program (NTLD-P). Other key points of the specimen referral system include the following:

- Sputum specimens are collected from clients, triple packaged and transported with relevant documentation to the nearest GeneXpert laboratory, usually at sub-county level

» Lower-level transport mechanisms include human carriers (laboratory or facility staff), partner-managed and owned vehicles, and professional courier services

- Specimens that need to be sent for culture and DST are referred to one of the two national-level referral laboratories based on the county in which the specimen was submitted. These specimens are transported by a professional courier company.
- Results access from NTRL has transitioned from hardcopy to electronic which has greatly improved the TAT, although a paper copy is still sent back to the requesting facility to include in the client's file
- To improve sample tracking and status of samples within the laboratory, a national dashboard is in place
- Remote login implementation is being scaled up to help improve patient demographic data capture before the specimen reaches the laboratory, to enhance planning, reduce sample rejections due to incomplete/inaccurate documentation and to save time once the specimen reaches the testing facility
- NPHL has developed a national EQA Scheme for panel testing to target GeneXpert, TB smear microscopy, Malaria microscopy, rapid HIV testing, cd4 testing, HIV early infant diagnosis, HIV viral load, haematology, Clinical chemistry Bacteriology among others in the country

3.1.3 Surveillance and response to epidemic-prone diseases

A laboratory network is partially in place for surveillance and management of epidemic-prone diseases, coordinated by the Division of Disease Surveillance and Response (DDSR) and WHO Regional Office for Africa (WHO/AFRO), and the U.S. Centers for Disease Control and Prevention's (CDC's) Guide for National Public Health Laboratory Networking to Strengthen Integrated Disease Surveillance and Response (10).

Technical Guidelines for Integrated Disease Surveillance and Response in Kenya 2012 (11) outline priority diseases, conditions and events under surveillance, which include the following (not exhaustive):

- Poliomyelitis
- Cholera

- HIV
- TB
- Measles
- Plague
- Human influenza caused by a new sub-type
- Rift Valley Fever
- Dengue Fever
- Anthrax
- Chikungunya
- Typhoid Fever
- Schistosomiasis
- Leishmaniasis
- Malaria

Specimens from suspected cases are transported to designated analytical laboratories by staff from the county surveillance officers. The testing laboratories include the NTRL, the National Microbiology Reference Laboratory, the Amref Laboratory, the KEMRI Viral Laboratories and the National Influenza Centre Laboratory.

The Technical Guidelines for IDSR in Kenya 2012 has a full list of referral laboratories for confirming priority diseases, conditions and events. These laboratories play a role in collection of blood specimens (e.g. for measles antibodies), providing transport media for stool samples, and guidance for collection, packaging, storage and transport of the specimens. A summary of the role of laboratories is shown below in Table 1.

Table 1: Laboratory systems by health system level

Level	Collect	Confirm	Report
Community or Health Facilities	• Use standardized case definitions to determine initiation of collection process • Assist First Contact Laboratory in specimen collection within approved guidelines • Document specimens with patients' complete clinical history and description • Transport specimens to First Contact Laboratory and Referral Laboratory within approved guidelines	• Use standardized case definitions to initiate confirmation process as part of an outbreak investigation • Handle specimens within approved guidelines	• Record collection of specimens • Report same
District, County	• Communicate collection policies and procedures to providers • Request additional specimen collection by laboratory or providers, as needed • Store specimens within approved conditions pending transport or additional studies • Direct additional collection as needed based on outbreak investigation	• Perform laboratory studies for presumptive diagnosis as appropriate: microscopy, staining, microscopy, RDT • Store representative slides from the outbreak as needed • Observe changes in trends during routine analysis of laboratory results	• Record laboratory results • Provide results to clinical staff and patients • Report results to relevant health authorities • Report observed changes in trends during routine analysis of laboratory results • Use summary information in response to outbreaks

Referral Laboratories (*some laboratories may function as First Contact and as Referral Laboratories*)	• Set collection policies and procedures with national epidemiology office and national reference laboratories • Distribute specimen collection kits for special surveillance activities • Request additional specimen collection by laboratory or providers, as needed • Store specimens within approved conditions pending transport or additional studies	• Set confirmation policies and procedures with national epidemiology office and national reference laboratories • Perform laboratories studies for confirmation as appropriate: culture, isolation, serogroup identification, antimicrobial susceptibility, serology • Store representative isolates from the outbreak as needed • Observe changes in trends during routine analysis of laboratory results	• Report results to requesting health facility • Report results and summary data to national surveillance office • Report laboratory results from screening sentinel populations at target sites
International Reference Laboratories	• Request additional specimen collection by laboratory or providers as needed • Direct additional collection as needed based on outbreak investigation	Perform additional laboratory studies as appropriate	• Report laboratory results to appropriate epidemiology offices • Use summary information in response to outbreaks

Source: Technical Guidelines for IDSR in Kenya 2012

3.1.4 Non-communicable diseases

The status of referral networks in managing non-communicable diseases is not optimal, with the following capacities and gaps:

- Laboratories which are unable to process histology and forensic specimens send them to the National Public Health Laboratory (NPHL) Services
- Referral of microbiology specimens to the National Microbiology Reference Laboratory has also been operationalized
- There is no formal system for referral of laboratory specimens for other diseases. Most referrals have involved patient movement with the sample, however, there is need to strengthen referral by integration of specimens of other diseases into the referral network in the spirit of UHC.

4

ROLES, RESPONSIBILITIES, COMMUNICATION AND COORDINATION OF THE SPECIMEN REFERRAL NETWORK

a. **Policy statement:** The NPHL, through the head, will serve as the ultimate coordinator of Kenya's specimen referral

b. **Policy statement:** At the national level and each county, there will be a specimen referral technical sub-committee that will coordinate all specimen referral activities in their respective regions

Healthcare service delivery is a devolved function in the Fourth Schedule of Kenya Constitution 2010, under which the Counties provide leadership and coordination of referral services through the county health management team (CHMT). However, the national level MOH will provide the necessary policy guidelines, capacity and implementation framework to support the specimen referral network across the country. For the referral system to function effectively and efficiently, the roles and responsibilities of each stakeholder, and coordination of all collectively, must be clearly defined.

4.1 National-Level Roles and Responsibilities

4.1.1 NPHL

- Developing/reviewing or issuing policies and guidelines within MOH in liaison with Counties and development partners to enhance service delivery in line with the letter and spirit of UHC
- Developing the framework and tools for monitoring and evaluating the performance of referral networks
- Collating and analyzing reports from counties that are submitted to national level
- Building the capacity across Counties (either directly or through its reference laboratories)
- Advocacy for resource mobilization and funding for the overall specimen referral network
- Facilitate coordination of national development partner activities in support of specimen referral networks

4.1.2 National-level referral laboratories

- Planning for laboratory referral networks in support of priority diseases such as HIV and TB, surveillance systems, and as part of laboratory service delivery strategy
- Advocacy for budgetary provisions to support national specimen referral networks and putting in place systems to ensure allocated finances are utilized for the intended purpose
- Contributing to policy formulation and implementation with respect to the specimen referral network
- Forecasting and quantification of national supplies' requirements for specimen referral
- Providing scheduled supervision and support to county referral facilities to strengthen and improve specimen referral networks
- Receiving/sending feedback from lower level referral sites on the efficiency and effectiveness of the sample referral chain for continual performance improvement
- Maintaining and regularly updating a national directory of referral laboratories and relevant collection, packaging, storage and transport SOPs for each, particularly those for highly specialized tests, which will be included in the Laboratory Handbook

4.2 Sub-National-Level Roles and Responsibilities

4.2.1 Referring facilities:

- Developing and regularly updating a list of tests (test menu) done on-site and for referral with specimen requirements, costs, turnaround times, and distributing the same to clinicians. A standard tool for test menu as shown in the Laboratory Handbook should be used for this purpose
- Distributing the Laboratory Handbook to relevant laboratory and clinical staff in the facility and familiarizing with the details and specimen requirements
- Requesting and effectively managing supplies for specimen collection, packaging, storage and transit, and documentation tools
- Ensuring proper specimen collection, initial processing, storage and packaging for safe transportation. A designated dispatch area should be created in the laboratory with a sample management SOP and dispatch checklist.

- Ensuring proper documentation of all processes to provide data that can be used to monitor quality as well as the efficiency and effectiveness of the network using the agreed list of indicators (discussed later in section 7.1)
- Providing reports of network functions to relevant authorities in a timely manner
- Utilizing specimen referral data for continuous quality improvement
- Designating a person for coordinating the management of specimen referral services at the facility
- Where applicable, ensuring necessary payments for referral tests are made, including the cost of specimen transfer, and transfer of the appropriate funds made to the nodal site

4.2.2 County nodal sites

- Performing all the roles of the referring facilities and, in addition, supporting the laboratories of the referring facilities
- Preparing the laboratory tests menu, with specimen requirements, costs, and turnaround times, and distributing the same to clinicians and the referring facilities in the network
- Receiving referred specimens and performing the required tests, assuring quality of analysis and reporting results
- Maintaining a separate register for referral tests to be used for tracking the activity. With respect to program-supported tests, each satellite should have its own separate register at the nodal site to allow for satellite-specific data analysis. Standard information should be captured in the register, including date, number of specimens received, whether acceptable or rejected and reason for rejection, if applicable, name and designation of person delivering the specimens, and mode of transport used.
- Providing reports of network functions to relevant authorities in a timely manner
- Regular data analysis should be done and communicated to the satellite facility to provide information that will guide supportive supervision of satellite sites on pre-analytical processes, where necessary
- Where applicable, confirming payments for tests provided under the Facility Improvement Fund (FIF)

4.3 Development Partners' Roles and Responsibilities

Development partners help provide the resources required to establish specimen referral systems where there are none, as well as support and maintain functional laboratory referral networks. These partners will commit to supporting the roles and responsibilities of the appropriate sub-national and national government officials.

4.4 Communication within Referral Networks

Laboratory tests provided through referral networks form part of the services offered by the laboratory. There should be effective communication within referral networks and therefore all facilities within the network should have effective means of communication with each other and with their respective health services management. Beyond results, nodal sites should provide information to satellite facilities in their region on the following:

- Rejected specimens and corrective measures to prevent recurrences
- Testing service interruptions or delays (breakdowns of service) and resumption
- Alteration in testing schedules for specific tests, changes of analytical method, or changes to reference values
- New tests added to menu, including indications for performing the test, specimen requirements, and the testing schedule if batch analysis is applied

4.5 Coordination of the Laboratory Referral Network

A coordination mechanism is required to provide oversight for the specimen referral systems and monitor their performance. Levels of coordination include national, county, and health facility levels, as detailed below.

4.5.1 National-level

A technical sub-committee should be set up under the Laboratory Interagency Coordinating Committee (Lab ICC) to coordinate the management of specimen referral networks and make recommendations to the Lab ICC. The sub-committee will carry out the following functions:

- The specimen referral sub-committee to convene a meeting on quarterly basis to review progress and provide technical advisory to MOH and partners on specimen referral system
- Provide and regularly review and update the national laboratory test menu and referral mapping directory
- Promote the use of the Laboratory Handbook in all facilities
- Promote best practices in specimen referral operations to support the diagnostics network
- Work collaboratively with referral laboratories to ensure optimal use of referral systems
- Promote community and non-public (private) participation in referral networks' growth and maintenance
- Develop indicators, including Continuous Quality Indicators (CQIs), to be used for monitoring and evaluation (M&E) of networks' progress and to inform measures to improve specimen referral networks and enhance their sustainability

4.5.2 County-level

A sub-committee of the County Lab ICC should be formed to coordinate the referral networks in each of the counties. If the County Lab ICC does not exist then representatives from organizations supporting any and all specimen referral activities should be convened. The sub-committee will advise and make recommendations to the County Lab ICC or CHMT on matters related to laboratory specimen referral networks. The following functions will be carried out at the county level:

- Implement specimen referral guidelines within county health system
- Share best practices for the various activities in the referral chain
- Ensure collaboration between partners and service providers at the county level
- Undertake specimen referral system performance M&E at the county level, including collecting data/reports from the referring facilities, analyzing it (for referrals that are handled at the county) and reporting to the national level, where required
- Coordinate the flow of referral information from community units and facilities to the health management in the county

- Ensure the availability of policy guidelines, the Laboratory Handbook, standard referral tools, such as referral forms, registers and other relevant forms at the facility level
- Ensure availability of financial, human, and other resources to support the specimen referral system
- Implement continuous technical support supervision and capacity building of county facilities in the management of specimen referral systems.

5

SPECIMEN AND RESULTS' MANAGEMENT GUIDED BY QUALITY, ETHICS AND SAFETY

a. **Policy statement:** All staff and personnel involved in specimen referrals (and paper-copy results' return) shall be properly trained and supervised using approved materials and relevant curricula to assure quality and safety of the specimen referral systems

b. **Policy statement:** The Laboratory Handbook shall be provided to and used by all facilities and staff at all levels to detail safe, ethical and quality processes for specimen referrals and results return

c. **Policy statement:** All specimens being referred shall be packaged using standardized triple packaging materials and processes, and transported according to appropriate regulations, approved by the safety regulatory committee at national level

Two of the aforementioned goals of a specimen referral network are maintaining quality of the specimen/result and biosafety of those involved throughout the referral process. These dual goals are closely related and are met through proper management of specimens (and results).

This section explains management of general specimens and results within the referral system, although it does not go into great detail on specific specimen-types or tests.

The Laboratory Handbook will provide all the necessary SOPs for sample collection, storage, packaging and transportation, receipt at the testing facility and results' return – all with the underlying goals of safety, quality and patient confidentiality.

The procedures will be detailed and will be specific for the specimen-type and test requested. The Laboratory Handbook will also provide contact details (both physical locations, address, phone and emails) and focal persons for referral laboratories.

Updated copies of the Laboratory Handbook will be obtained from **nphl.go.ke** and hard copies will be officially printed and launched as a companion to these guidelines.

5.1 Biosafety and Biosecurity

The process of specimen referrals involves handling and movement of specimens, which poses a risk to the specimen handlers and the environment. A key element of biosafety and biosecurity practices is to ensure that all environments and people who come into contact with specimens are protected from potentially hazardous microorganisms. In addition, these practices ensure that laboratory microorganisms are not used as bio-weapons.

Biosafety measures in referral networks will include application of universal safety precautions, waste segregation, and disposal protocols. Each laboratory should have a safety officer who ensures the following:

- Staff are trained and proficient in the practices and techniques of handling such materials
- Biosafety and biosecurity guidelines, laboratory safety handbooks, material safety data sheets, incident reporting procedures and documentation, and SOPs relevant to safety are developed, based on the WHO's Laboratory Biosafety Manual (12) and made available to staff
- Procedures and policies are in place covering occupational exposure and first aid, and the required materials for these are available
- Laboratories and transporters at all levels have SOPs and spill kits for dealing with biological, chemical, and radiological spills. The spill kit should be kept in an easily accessible place. (See Annex 1 for recommended contents of a spill kit.)

5.2 Ethics

As specimens, related documents and results move throughout the referral pathway, it is important that client confidentiality is maintained:

- Where possible, full client names should be replaced by unique identification numbers/ codes
- Regardless of whether client names or IDs are used, all client information should be kept private and records kept secure, including during transit
- Couriers/transporters should not have access to client names unless they are involved with data entry – and if so, there should be training on ethics and confidentiality

5.3 Specimen Collection, Handling, Packaging, Storage and Documentation

It is important that good-quality specimens are collected, packaged, stored and documented and prepared for analysis. Rejection of poor-quality referred specimens leads to significant delays in obtaining laboratory results, with health care workers delay in patient care. Further, laboratory specimens contain potential infectious agents and pose a risk to health care workers and transporters. Appropriate biosafety measures MUST be used in handling all biological materials.

5.3.1 Specimen collection

In addition to the policies in this area, the following conditions should be followed during laboratory specimen collection (all in accordance with the Laboratory Handbook):

- Laboratory specimens should be collected and handled according to the type of specimen collected and the test required
- Plastic vials should be used for specimens whenever possible to prevent breakage during transportation
- Use of standardized, appropriate collection supplies should be provided and used
- Use of appropriate safety measures including PPE and administrative controls are in place and enforced
- Specimens MUST be transported to the referral laboratory for examination within test-specific time requirements
- Specimens should be stored and maintained at the correct temperature (test-specific) and monitored under suitable environmental conditions

5.3.2 Packaging and documentation

Triple packaging, according to the International Air Transport Association (IATA) Dangerous Goods Regulations (13), shall be used for shipping all potentially bio-hazardous specimens (see Annex 2 for instructions). Appropriate packaging materials and bio-hazard labels should be provided and the following items to be adhered to:

- If glass collection tubes (the primary receptacle) are used, they should be well padded
- Cool boxes should be provided to maintain required temperatures during specimen transfer

- The documentation requirements of the referring laboratory should be defined and applied including filling out registers, specimen referral forms, requisitions forms, etc.
- All specimens should be packed according to their SOPs (test-specific) with due attention to temperature requirements
- Temperature data loggers should be used, where possible, to enable monitoring of shipment temperature conditions to assure quality and integrity of specimens at the pre-analytical phase

5.4 Specimen Reception at the Laboratory

Reception at the testing laboratory involves handoff from the person who transported the specimens, inspection for any non-conformities for the specimens, documents and packaging, and documentation of the receipt. Specific responsibilities of the laboratory include:

- Arrange for the most timely and efficient arrival
- Acknowledge receipt with the transporter
- Maintain documentation for shipment receipt
- Inspection of delivery box for signs of damage or leakage – record any non-conformities even if the specimens are not rejected (this will allow for data collection on the biosafety-related indicators)
- Disinfect outside and inside of delivery box
- Record specimens in logbooks or electronic system on the day of receipt at the laboratory, not on day of processing
- Maintain a specimen rejection log including the reason for rejection (this will allow for data collection on the quality-related indicators)
    - » All laboratories, from the laboratory of origin, nodal sites, and testing laboratories shall keep records of samples rejected
    - » Full rejection criteria per test can be found in the Laboratory Handbook

5.5 Results' Return

The Laboratory Handbook will also provide a detailed instruction on how results and reports are handled by health care workers from both facility level and testing laboratories. The testing laboratory should maintain documentation for results' release. The process of sending results must be clearly established for each test and reference laboratory used.

Although the use of an electronic communication system for returning results and reports should be prioritized, the hard copies of results will always be returned and should be collected when specimens are delivered to the testing laboratory using the same transport mode and mechanisms.

6 OTHER CONSIDERATIONS FOR AN EFFECTIVE AND EFFICIENT NETWORK

a. **Policy statement:** Specimen referral system shall be financed within both National and County budgetary planning including attracting co-financing from development partners and private-public partnerships (PPP)

To operationalize the requirements of elements described in these guidelines, customized county level operational planning will be required. To ensure effective and efficient operations, counties will need to consider system design, transportation and logistics, supplies, human resources and financial resources, as well establishing mechanisms to ensure adequate monitoring performance of the system. Further guidance, to be provided in the form of a county-level operational planning guide to complement the national guidelines, may be used at the county level to inform specimen referral implementation.

6.1 System Design

Design of the specimen referral systems must work within the diagnostics network, i.e. the testing algorithms, physical location and capacity of the collection points and physical location and capacity of the diagnostic testing sites. It is important that each county maps out using geocodes health facilities/collection points, nodal sites (or establishes these locations if they do not already exist) and referral laboratories.

This mapping can be done in several ways – using paper maps and pins, Google maps or specialized mapping software, depending on what is available and the capacity for use in the counties. Once the facilities are all mapped using geocodes, their referral linkages can be added and then the network can be examined under various scenarios to match diagnostic supply and demand, or to optimize access and/or cost efficiency. An example from the NTLD-P of this process of mapping facilities, referral linkages and designing an optimized network can be found in Annex 3. Other system design considerations include:

- Optimization can be done on the diagnostic network (i.e. placement of equipment) or on the referral route network (i.e. given the existing placement of the equipment and collection points, which routes are most efficient).

- As already mentioned in section 3.0, "jumping a level" such that the specimen travels from the referring facility to the testing laboratory without stopping at a hub, as well as avoiding strict adherence to administrative boundaries, can allow for more efficient routing.
- System design needs to be considered any time there are changes in the overall diagnostic network, for example the addition of new equipment, the addition of new tests, significant changes in volumes of testing at certain sites, changes in the transportation routes, etc.

6.2 Transportation and Logistics

Transportation and logistics are an important piece of the overall referral network. The transport mechanism, type of transportation used and logistics details such as routing and frequencies of collection/delivery are technical decisions that require the knowledge and skills of an expert in this area.

The transport mechanism should be well-defined and ensure that specimens are safe, good-quality, cost-efficient and sustainable. Various types of transport mechanisms include:

» MOH/GOK vehicles

» Partner-supported vehicles

» Contracted courier services

The mode of transport (vehicle-type) for any of those listed above can range from four-wheeled motor vehicles to motorcycles to boats, planes, and unmanned aerial vehicles (UAVs) or drones. When selecting the mode of transport, consideration should be given to distances between facilities and the terrain, to maintain specimen integrity. Whichever system is used, the transporters (drivers/riders) should also be trained on biosafety and quality measures, including how to deal with spillages during transportation (a spill kit with the recommended contents, as described in Annex 1, should be provided to transporters), as well as documentation requirements for the referral chain. Incidents during specimen transportation which may affect quality of the specimen or safety of personnel should be documented and action taken by the quality officer and/or bio-safety officer.

Where third party vendors are used to provide courier services, there is a benefit to sharing current contracts including pricing, terms and conditions, then analyzing this information and finally negotiating contracts centrally. This practice allows for aggregating demand and benefitting from volume-based pricing. Individual projects can still pay for their own use but there will be an opportunity to standardize the way that the pricing is determined, as well as the terms and conditions of the contract.

Scheduling and frequencies of transport should be carefully considered. Shipment days may be specified in each facility for tests that can be batched. In such cases, the shipment day(s) shall be documented and communicated to the clinical teams. The batched specimens should be stored at the appropriate temperature and conditions that maintain specimen integrity. However, tests supported through programmes (e.g., DBS, TB samples) and those with short turnaround times should not be batched unless specified.

In the name of integration, specimens being referred to the same nodal site should be transported together to minimize transport costs.

6.3 Supplies

Commodities required for specimen collection, packaging and transfer should be budgeted for and procured either centrally or from the county resources. Major laboratory reagent procurements are done by the Kenya Medical Supplies Agency (KEMSA) upon received request from NPHL while procurement for consumables is done directly by NPHL. However, NPHL is advocating for the counties to budget for the consumables and packaging materials. In the meantime, many partners support the procurement of packaging supplies directly.

6.4 Human Resources

The human resources required for effective referral networks encompass more than just the laboratory professional. A nodal site may require health records information officers and messengers to function efficiently. The need for these additional cadres has been captured in the National Referral Strategy.

6.5 Finance

Many laboratory tests are provided for under the County resources and, as such, sustainability of the test provision for satellite sites requires a cost-recovery approach. Revenue collection structures are in place in all health facilities. Formal systems are needed for the transfer of funds between public health facilities. UHC is a paradigm shift to the way healthcare service delivery approaches are being implemented with respect to patient catastrophic costs. For sustainability of the specimen referral system, the following should be adopted:

- The annual and quarterly laboratory budgets should include budgetary provisions for specimen referral systems
- The cost of each test provided should be determined, including those supported through programmes. A standard tool for test costing should be developed and applied across the referral chain through an elaborate forecasting and quantification exercise.
- A cost-recovery plan should be developed for referred tests if these are not supported fully. The referring facility should retain the cost of commodities used for specimen collection, handling, packaging and transfer if these are procured through County resources.
- Where the specimen referral system is currently funded by a development partner, costs supported should be transparent and shared with the County and plans for contributions from the County over time should be made
- Formal agreements on payments should be made when specimens are referred to nodal laboratories. The agreements should indicate the amounts, mode, and schedules of revenue remittance to the testing laboratory. Such agreements should also be done if specimens are referred to faith-based organization or private laboratories.

7 MONITORING AND EVALUATION

M&E involves the routine collection and tracking of key data over time on performance of the specimen referral network to determine whether or not it is meeting the five aforementioned goals:

- Improving the **quality of specimens** delivered to the testing laboratory
- Contributing to increased **access to diagnostics** where services do not exist by referring the specimen
- Ensuring **safety and security** of all individuals and the environment that are involved with specimen referrals
- Meeting **timeliness requirements** of the specimen reaching the testing laboratory and the paper result reaching the facility's records
- Enhancing **cost efficiency**

It is also a process that helps to ensure the planned activities are being implemented effectively, identify network problems early so that they can be quickly corrected and also allows for comparison in performance among fragmented systems that are already in place.

The M&E framework requires identification of the key performance indicators (KPIs) and routine collection, compilation, analysis, and utilization of data. The documentation and monitoring systems used should, however, not overburden the service providers. Mechanisms should be established to ensure the quality of the data collected and protect the confidentiality of the client as data moves up and down the networks. A system of maintaining records and information at all levels is mandatory for this function. Although there are specific KPIs that are relevant to specimen referrals and, as such, a specific M&E framework, as an integral part of the diagnostics network and overall health care system, the specimen referral M&E framework must be embedded in the overall laboratory and health M&E systems.

7.1 Indicators

A set of indicators (process, outcome and impact) will be tracked to assess effectiveness and efficiency of the specimen referral systems and overall network. A summary of the indicators can be found in Table 2 below and are shown in additional detail in Annex 4.

Table 2: Summary of indicators

#	Indicator	Type of indicator	Monitored where/by whom	Monitoring frequency
1.	Number of specimens referred for testing	Output	Referring facility	Monthly
2.	Percentage of referring facilities whose specimen referral logbook (or equivalent) has been filled completely	Process	Referring facility/ by supportive supervisory visits	Quarterly
3.	Proportion of specimens picked up by transporter for referral within required time	Outcome	Referring facility	Monthly
4.	Proportion of referred specimens whose result was received within the specified target time	Outcome	Referring facility	Monthly
5.	Number of shipments transported to the hub or referral laboratory	Output	Transport service provider	Monthly
6.	Proportion of shipments that were lost or damaged in transit	Output	Transport service provider	Monthly
7.	Proportion of shipments/specimens delivered or received at the referral laboratory within the required time	Outcome	Transport service provider and referral laboratory	Monthly
8.	Number of referred specimens received for testing	Output	Referral laboratory	Monthly
9.	Percentage of referring facilities that fill the specimen referral form (or equivalent) for each shipment made	Outcome	Referral laboratory	Quarterly
10.	Proportion of specimens that were rejected (disaggregated by reason for rejection)	Outcome	Referral laboratory	Monthly
11.	Proportion of test results released within the specified TAT	Outcome	Referral laboratory	Monthly
12.	Proportion of referring facilities participating in the specimen referral system	Input	At county or national level by CHMT or MOH/NPHL	Quarterly

13.	Percentage of facilities (referring and referral laboratories) that submit complete routine data summary forms	Process	At sub-county or county level by S/CHMT or MOH/CHD	Quarterly
14.	Percentage of Counties that submit complete routine data summary forms	Process	At national level by MOH/NPHL	Quarterly
15.	Proportion of facilities (referring and referral laboratories) sensitized on National Specimen Referral Guidelines	Process	At sub-county or county level by S/CHMT or MOH/CHD	Annually
16.	Proportion of transport service providers trained on National Specimen Referral Guidelines requirements	Process	At county or national level by CHMT or MOH/NPHL	Annually

7.2 Data Collection Tools

The indicators listed in Table 2 shall be collected through various data collection tools at different locations throughout the system. These tools include:

- Logbooks for each test that are kept at the referring facility
- Sample manifest or referral form that travels with the specimens and tracks every time the specimens change hands, also called the "chain of custody"
- Test requisition form (can be integrated with the sample manifest as one form) that travels with the specimens
- Logbook for rejected specimens or incidents kept at the referral laboratory
- Transporter logbook that tracks vehicle kilometres, fuel and movements and possibly specimens/packages
- Electronic laboratory information management system (LIMS)
- Supportive supervision audit tool with questions related to the specimen referral network

There are many data collection tools available, but they are not necessarily all standardized. In Annex 5, these guidelines offer standardized versions of all the data collection tools necessary for M&E.

It may not be immediately possible to collect all indicators listed in Table 2 but it will be important for each county to assess which indicators are feasible based on existing data collection tools. Any other necessary tools for data collection and reporting shall be developed, adopted and communicated to all laboratories in the referral network.

7.3 Reporting, Analysis, Feedback and Improvement

Beyond the recording of data in the data collection tools, this data then needs to be routinely compiled and sent (reported) to be analyzed at specific frequencies (*see Annex 6 for reporting forms*).

The general flow of data will be from the primary data source (facility/laboratory logbooks, transporter logbooks, supportive supervisory tools) to the CHMT and then the aggregated county data will be reported to the NPHL. For the national reference laboratories, they will report directly to the M&E team at NPHL.

Based on what the indicators reveal about the performance of the referral network, feedback should be shared with the facility/team who compiled and shared the data, and together a plan for improvement and advocacy for support should be made, if necessary. Key activities and considerations include:

- A reporting framework should be adopted across the referral chain for activities related to clinical management of patients, surveillance activities, and referral network management
- Frequency of reporting from facilities to the regional and national levels should be established
- Results from the audits and supportive supervision should be analyzed and shared with all facilities in the referral chain in sub-committee of the County Laboratory ICC (*mentioned in section 4.5.2*)

- The laboratory staff and managers should be trained on the referral system M&E framework, including indicators and the methods of documentation, data retrieval, analysis for decision making and improvement planning
- Operational research should be encouraged and supported, using the indicators to provide the evidence base to guide improvement of the specimen referral networks
- A paper-based laboratory information system should be used to facilitate compilation of summary reports; however, national referral laboratories should have computers with e-mail services

7.3.1 Communication with regional disease surveillance teams

Timely sharing of information on referral systems is also necessary for disease surveillance. Regular reports should be provided on laboratory diagnosis of priority diseases as required. The format and tools for reporting should be provided to the laboratory.

7.3.2 County and national reference laboratories

- The NRLs should assess and built capacity to the CRLs, which in turn, would assess the Primary Care Laboratories in their region
- CRLs should be in charge of supervision of primary care laboratories in their catchment
- There should be regular feedback on the effectiveness of the supportive visits and follow-up of agreed improvements.

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15. FIND, Optimizing TB diagnostic networks to improve patient access to quality TB diagnosis and treatment. Kenya – Final Report. 1 December 2018.

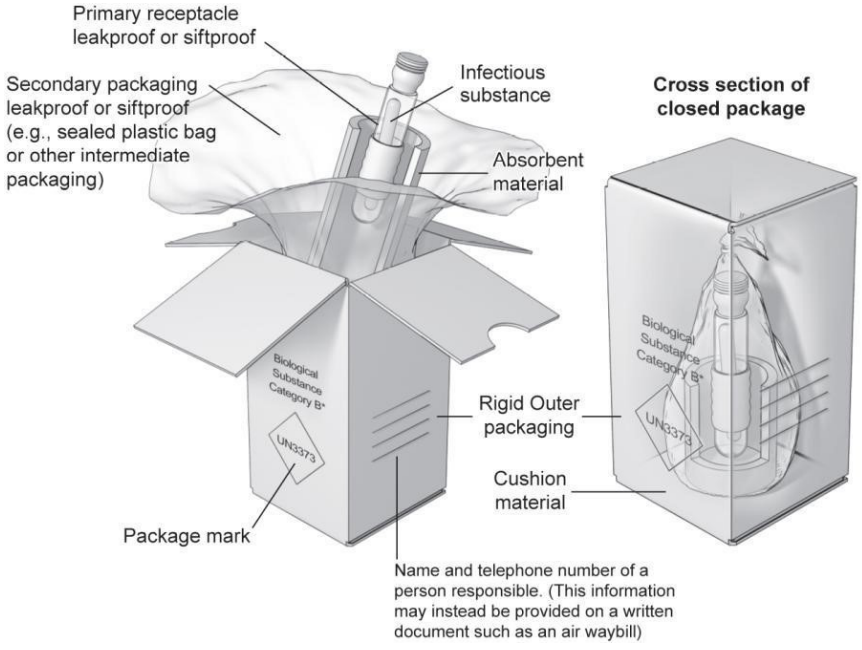
ANNEX 1: Contents of a Biological Spill Kit

The contents of the biological spill kit should include, but not be limited to:

1. Biological spill response and clean-up SOP
2. Personal Protective Equipment (PPE)
    a. Gloves, various sizes
    b. Disposable gown
    c. Disposable shoe covers (booties)
    d. Protective goggles
    e. Respirator N95
3. Biological spill warning sign
4. Disinfectant
    a. Concentrated hypochlorite
    b. Bottle for hypochlorite, with instructions for preparation on the label
5. Material for cleaning
    a. Absorbent material (paper towel or gauze)
    b. Autoclavable biohazard waste bags
    c. Tweezers
    d. Rigid container for disposal of sharps

ANNEX 2: Instructions for Triple Packaging of Specimens

Triple Packaging Requirements



Source: WHO Laboratory Biosafety Manual, 2004 (12)

Primary container: The primary packaging that contains the specimen must be watertight. Example: Vacutainer with adhesive tape around the screw cap. Use screw-cap conical test tubes or cryo-vials. Do not use Eppendorf tubes, with tape or parafilm around the cap.

Secondary container: The secondary packaging may contain several primary containers and must also be watertight. Examples of watertight secondary containers include Ziploc plastic bags, a conical 50ml test tube and screw-cap containers. Absorbent material must be placed between the primary and secondary container. The quantity should be sufficient to absorb all liquid in the shipment. Examples include paper towels, cotton balls, filter paper, etc.

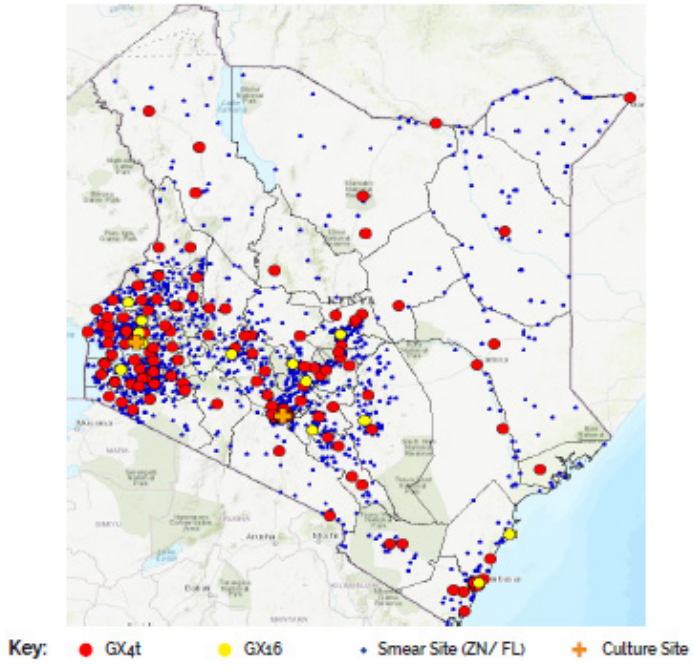
If dry ice is needed to keep samples frozen, it should be put between the secondary and tertiary packaging. Styrofoam and cardboard both allow dry ice vapor to escape, so dry ice must be placed only OUTSIDE the secondary packaging. Packaging dry ice inside impermeable, screw-cap containers may cause the shipment to explode.

Outer shipping container: The tertiary packaging (outside) must protect the inside packaging to prevent breakage or perforation under normal transport conditions. Corrugated cardboard is the usual choice. Styrofoam boxes, plastic bags, or paper envelopes are unacceptable outer containers for shipping biological materials.

ANNEX 3: Example of Mapping and Optimizing TB Diagnostics and Specimen Referral Networks

As part of its national strategic planning process, the NTLD-P went through an exercise to map its diagnostics facilities and optimize the network design and sample referral linkages to increase patient access to services and improve network efficiency with support from partners FIND/LLamasoft. Although these analyses largely focused on TB diagnostic testing, there are also county-level integrated network and specimen referral system designs under development. Figure 3 illustrates national mapping of TB diagnostic sites, which is included in the National Strategic Plan for Tuberculosis, Leprosy and Lung Health, 2019-2023 (14).

Figure 3: Map showing distribution of diagnostic sites in Kenya

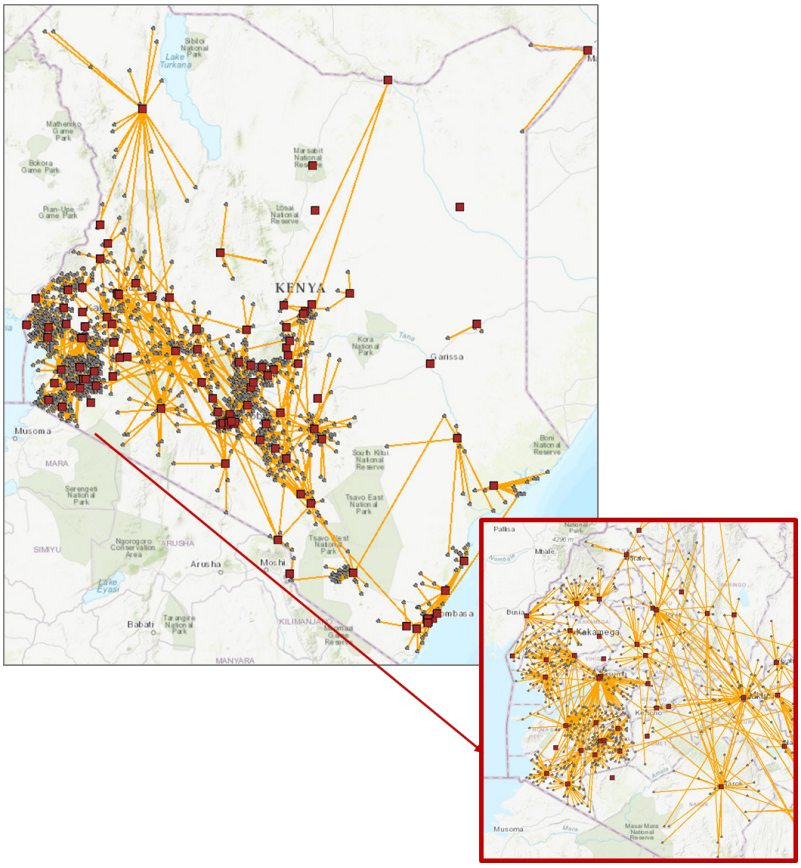


Source: National Strategic Plan for Tuberculosis, Leprosy and Lung Health, 2019-2023

The current sample referral linkages to GeneXpert sites are shown in Figure 4, excerpted from FIND's Optimizing TB diagnostic networks to improve patient access to quality TB diagnosis and treatment. Kenya – Final Report, 1 December 2018 (15).

Although the data are incomplete, they show that health facilities often refer to multiple testing sites, and that referrals are mostly within county boundaries, although not always to the closest site. Coverage of sample referral networks varies widely across the country.

Figure 4: 2017 TB sample referral flows – partial snapshot (and zoomed in on Homa Bay)

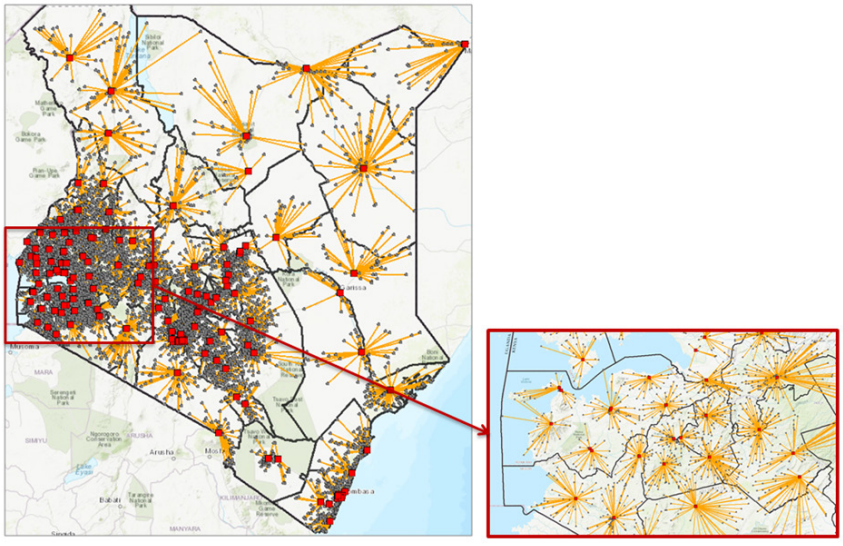


Source: FIND. Optimizing TB diagnostic networks to improve patient access to quality TB diagnosis and treatment. Kenya – Final Report, 1 December 2018.

After the diagnostics network and referral linkages were mapped, scenarios were explored using modelling software to design a more optimal network. Optimization scenarios for current and predicted future testing volumes were considered that enabled better use of instrument capacity and reduced the overall transport distance by referring samples to the closest testing site with available capacity.

However, in the north, despite rationalizing the referral of samples from health facilities to the nearest GeneXpert facility, transport distances remained long. In such cases, NTLD-P may consider placement of additional instruments to improve TAT of results. An illustrative optimized sample transport network design is shown in Figure 5. More in-depth operational planning of county-level integrated referral networks is being explored using the established models.

Figure 5: Designing demand-driven TB sample referral networks *(and zoomed in on Homa Bay)*



Source: FIND. Optimizing TB diagnostic networks to improve patient access to quality TB diagnosis and treatment. Kenya – Final Report, 1 December 2018.

ANNEX 4: Detail on M&E Indicators for Specimen Referrals

Indicators to be monitored at the referring facility

Indicator 1	Number of specimens referred for testing
Indicator 2	Percentage of referring facilities whose specimen referral logbook (or equivalent) has been filled completely
Indicator 3	Proportion of specimens picked up by transporter for referral within the required time
Indicator 4	Proportion of referred specimens whose result was received within specified target time

Detailed description of indicators, targets, indicator calculations and remarks

Indicator 1: Number of specimens referred for testing	
Purpose	Assess the utilization and uptake of referral services, identify gaps, and assist with planning
Target	Expected to increase initially
Numerator	Number of specimens referred
Denominator	Not Applicable
Frequency and location	Monitored monthly at each referring facility
Data Sources	Referring facility specimen referral logbook (or equivalent), specimen referral form or transporter logs
Disaggregation	By referral laboratory
Remarks	Although the number is expected to increase initially overall up to a certain point, there may be temporary decreases as the system is implemented if there is a transition from one system to another or while confidence in the reliability of the new system is established

Indicator 2: Percentage of referring facilities whose specimen referral logbook (or equivalent) has been filled completely	
Purpose	Assess the training and practice of staff at referring health facilities for data collection SOPs
Target	At least 95%
Numerator	Number of referring facilities whose specimen referral logbook (or equivalent) has been filled completely
Denominator	Total number of referring facilities
Frequency and location	Monitored quarterly through direct observation during supportive supervision at each referring facility
Data Sources	Referring facility specimen referral logbook (or equivalent)
Disaggregation	By referral laboratory
Remarks	None

Indicator 3: Proportion of specimens picked up by transporter for referral within the required time	
Purpose	Assess the performance of the system with respect to the timeliness of specimen pick-up by the transport service provider
Target	At least 95%
Numerator	Number of referred specimens which were picked up by the transportation service within the specified time after specimen collection
Denominator	Number of specimens picked up by the transportation service
Frequency and location	Monitored monthly at each referring facility
Data sources	Referring facility specimen referral logbook (or equivalent), specimen referral form or transporter logs
Disaggregation	By individual transport service provider (i.e. rider or driver)
Remarks	• Target should be determined for each collection schedule (e.g., on demand, daily, twice weekly). For example, <24 hr for daily pick-up or <7 days for weekly pick-up • During a quarterly or semi-annual supervisory visit, the average time between collection of the specimen and pick-up by the transport service may be calculated as an additional performance indicator

Indicator 4: Proportion of referred specimens whose result was received within the specified target time	
Purpose	Assess whether the referral system is meeting the target of improving the timeliness of diagnostic test results
Target	At least 95%
Numerator	Number of referred specimens for which a test result was received within the specified time
Denominator	Total number of specimens referred (same as Indicator 1)
Frequency and location	Monitored monthly at each referring facility
Data sources	Referring facility specimen referral logbook (or equivalent)
Disaggregation	By referral laboratory
Remarks	• Target time should be determined for each test required (e.g., Xpert MTB/RIF or culture) and the collection schedule used (e.g., on demand, daily, twice weekly, etc.) • For this calculation, an entry that the specimen was rejected should be counted as a result and a target time for rejected sample notification determined • The indicator should be calculated for specimens for which the target turnaround time for the requested test has passed, for example with TB: » For microscopy and molecular tests and rejected samples, this indicator may be calculated using information from the prior month rather than the current month » Because of the long turnaround time for culture and DST, this indicator may be calculated using data for specimens that were referred 60 to 90 days earlier • During a quarterly or semi-annual supervisory visit, the average time between collection of the specimen and receipt of the result by the referring site may be calculated as an additional performance indicator

Indicators to be monitored by the transport service provider as part of their service agreement

Indicator 5	Number of shipments transported to the hub or referral laboratory
Indicator 6	Proportion of shipments that were lost or damaged in transit
Indicator 7	Proportion of shipments delivered at referral laboratory within required time

Detailed description of indicators, targets, indicator calculations and remarks

Indicator 5: Number of shipments transported to the hub or referral laboratory	
Purpose	Assess the utilization and uptake of referral services, identify gaps, and assist with planning
Target	Expected to increase initially and as new collection sites are added
Numerator	Number of shipments transported to the hub or referral laboratory
Denominator	Not applicable
Frequency and location	Monitored monthly by the transport service
Data sources	Transporter logs, specimen referral form
Disaggregation	By hub and by referral laboratory
Remarks	• Monitoring the indicator should be included in the transport service's service agreement • Although the number is expected to increase initially overall up to a certain point, there may be temporary decreases as the system is implemented if there is a transition from one system to another or while confidence in the reliability of the new system is established

Indicator 6: Proportion of shipments that were lost or damaged in transit	
Purpose	Assess the reliability of transport
Target	5% or less
Numerator	Number of shipments that were lost or damaged in transit
Denominator	Total number of shipments
Frequency and location	Monitored monthly by the transport service
Data sources	Transporter logs, incident form at referral laboratory
Disaggregation	• Shipments that were lost • Shipments that were damaged • If applicable, by route or individual courier
Remarks	• Monitoring the indicator should be included in the transport service's service agreement • The county or sub-county quality officer may also compare the number of specimens received by the referral laboratory (indicator 8) with the number of specimens sent from the referring facilities (sum of indicator 1 for all referring facilities) as an additional quality check

Indicator 7: Proportion of shipments delivered at referral laboratory within the required time	
Purpose	Assess the reliability of transport
Target	At least 95%
Numerator	Number of shipments that delivered at the referral laboratory within the required time
Denominator	Total number of shipments that were delivered at the referral laboratory
Frequency and location	Monitored monthly by the transport service
Data sources	Transporter logs, specimen referral form
Disaggregation	• By referring facility • By transporter
Remarks	This is essentially the same indicator 7 that is tracked at the referral laboratory but this indicator is self-reported by the transport provider

Indicators to be monitored at the referral laboratory

Indicator 8	Proportion of specimens received at the referral laboratory within the required time
Indicator 9	Number of referred specimens received at the referral laboratory for testing
Indicator 10	Percentage of referring facilities that fill the specimen referral form (or equivalent) for each shipment made
Indicator 11	Proportion of specimens that were rejected
Indicator 12	Proportion of test results released within the specified TAT

Detailed description of indicators, targets, indicator calculations and remarks

Indicator 8: Proportion of specimens received at the referral laboratory within the required time	
Purpose	Assess the performance of the referring facility and transport service provider with respect to the timeliness of specimen transport
Target	At least 95%
Numerator	Number of specimens that were delivered within the required time
Denominator	Total number of specimens received during the reporting period
Frequency and location	Monitored monthly by the referral laboratory
Data sources	Referral laboratory specimen reception logbook (or equivalent) and test requisition form with date of specimen collection from patient or Laboratory Information Management System (LIMS)
Disaggregation	• By referral laboratory • If applicable, by route or individual courier
Remarks	• Target required time will depend on the mode of transportation and distance and may also vary by referring facility, referral laboratory, and transport route • Collection at the referral laboratory allows for confirming of transporter's reported timeliness performance • Average time between pick-up of a shipment to delivery to the receiving laboratory may be calculated as an additional performance indicator

Indicator 9: Number of referred specimens received at the referral laboratory for testing	
Purpose	Assess the utilization and uptake of referral services, identify gaps, and assist with planning
Target	Expected to increase initially and as new collection sites are added
Numerator	Number of referred specimens that were received at the referral laboratory
Denominator	Not applicable
Frequency and location	Monitored monthly at each referral laboratory
Data sources	Referral laboratory specimen reception logbook (or equivalent) or LIMS
Disaggregation	By referring facility
Remarks	• Although the number is expected to increase initially overall up to a certain point, there may be temporary decreases as the system is implemented if there is a transition from one system to another or while confidence in the reliability of the new system is established. • During a quarterly or semi-annual supervisory visit, the number of specimens received by the referral laboratory could be compared to the number of specimens sent to the referral laboratory (i.e., sum of indicator 1 for all referring facilities) as an additional indicator to assess potential issues with the transportation process

Indicator 10: Percentage of referring facilities that fill the specimen referral form (*or equivalent*) for each shipment made	
Purpose	Assess the training and practice of staff at referring health facilities for data collection SOPs
Target	At least 95%
Numerator	Number of referring facilities whose specimen referral form(s) (or equivalent) has been filled and accompanies the shipment
Denominator	Total number of referring facilities
Frequency and location	Monitored quarterly by the referral laboratory
Data Sources	Specimen referral form(s) (or equivalent)
Disaggregation	By referral laboratory
Remarks	None

Indicator 11: Proportion of specimens that were rejected	
Purpose	Assess the performance of the system with respect to safety, quality, and documentation
Target	5% or less
Numerator	Number of specimens that were rejected
Denominator	Number of specimens received
Frequency and location	Monitored monthly at each referral laboratory
Data sources	Referral laboratory specimen reception logbook (or equivalent), rejection forms or LIMS
Disaggregation	• By reasons for rejection, including: » Inadequate specimen volume or quality » Specimen leaked » Specimen contaminated or of insufficient quality » Specimen label is missing or illegible » Specimen not packaged according to SOP » Incomplete or illegible test requisition form » Transport time exceeded maximum allowed time » Cold chain not maintained (if applicable) • If possible, by referring facility or individual transport provider
Remarks	It is very important to disaggregate this indicator to identify where within the referral process there are problems.

Indicator 12: Proportion of test results released within the specified TAT	
Purpose	Assess the timeliness of reporting results
Target	At least 95%
Numerator	Number of test results that were released within the specified turnaround time after generation of the test result
Denominator	Number of test results that were generated for referred specimens and returned to the referring sites
Frequency and location	Monitored monthly at each referral laboratory
Data sources	LIMS
Disaggregation	By test type
Remarks	• Target turnaround will depend on type of test requested/performed • During a quarterly or semi-annual supervisory visit, the average time between generation of a test result and pick-up by the transportation service or electronic transmission may be calculated as an additional performance indicator • The number of test results that were generated for referred specimens and returned to the referring sites may be monitored by as an additional output measure to assess the extent to which the system is improving access to diagnostic testing

Indicators to be monitored at the sub-county, county or national level by the relevant health body

Indicator 13	Proportion of referring facilities participating in the specimen referral system
Indicator 14	Percentage of facilities (referring and referral laboratories) that submit complete routine data summary forms
Indicator 15	Percentage of Counties that submit complete routine data summary forms
Indicator 16	Proportion of facilities (referring and referral laboratories) sensitized on National Specimen Referral Guidelines
Indicator 17	Proportion of transport service providers trained on National Specimen Referral Guidelines requirements

Detailed description of indicators, targets, indicator calculations and remarks

Indicator 13: Proportion of referring facilities participating in the specimen referral system	
Purpose	Assess the utilization and uptake of referral services, identify gaps, and assist with planning
Target	Initially expected to increase and eventually include all specimen collection sites in a catchment area
Numerator	Number of referring sites participating in the specimen referral system
Denominator	Total number of sites eligible to participate in the specimen referral system
Frequency and location	Monitored quarterly by county (CHMT) or national level (MOH/NPHL)
Data source	Schedule/routing chart for transportation or survey or mapping
Disaggregation	By county
Remarks	The indicator may also be monitored by catchment area of testing laboratory

Indicator 14: Percentage of facilities (referring and referral laboratories) that submit complete routine data summary forms	
Purpose	Assess the training and practice of staff at referring facilities and referral laboratories for reporting SOPs
Target	At least 95%
Numerator	Number of facilities that submit/report complete routine data summary forms
Denominator	Total number of facilities
Frequency and location	Monitored quarterly by sub-county or county level by S/CHMT or MOH/CHD
Data Sources	Data summary/reporting forms (*see Annex 6*)
Disaggregation	By county/sub-county
Remarks	None

Indicator 15: Percentage of Counties that submit complete routine data summary forms	
Purpose	Assess the training and practice of CHMT staff for reporting SOPs
Target	At least 95%
Numerator	Number of counties that submit/report complete routine data summary forms
Denominator	Total number of counties
Frequency and location	Monitored quarterly at national level by MOH/NPHL
Data Sources	Data summary/reporting forms (*see Annex 6*)
Disaggregation	None
Remarks	None

Indicator 16: Proportion of facilities *(referring and referral laboratories)* sensitized on National Specimen Referral Guidelines	
Purpose	Highlight training of staff at referring facilities and referral laboratories on National Specimen Referral Guidelines
Target	At least 95%
Numerator	Number of facilities that have had at least one representative trained/ sensitized on the National Specimen Referral Guidelines
Denominator	Total number of facilities
Frequency and location	Monitored annually at sub-county or county level by S/CHMT or MOH/CHD
Data Sources	Training records
Disaggregation	By county/sub-county/referral laboratories
Remarks	None

Indicator 17: Proportion of transport service providers trained on National Specimen Referral Guidelines requirements	
Purpose	Highlight training of staff at transport service providers on National Specimen Referral Guidelines
Target	At least 95%
Numerator	Number of transport service providers that have had at least one representative trained/sensitized on the National Specimen Referral Guidelines
Denominator	Total number of transport service providers
Frequency and location	Monitored annually at county or national level by CHMT or MOH/NPHL
Data Sources	Training records
Disaggregation	By county/sub-county
Remarks	None

ANNEX 5: Data Collection Tools

A. Test Requisition Forms

These forms are filled at the referring facility (specimen collection point) and travel to the referral laboratory with the specimen. Examples from this and the next two pages are from HIV VL and EID, and TB, respectively.

They are a data source for Indicator 7. Note that these HIV VL and EID forms are also manifests or referral forms and so replace the need for the tools found in sub-section B of this Annex.

Version- March 2015

Ministry of Health
Viral Load Lab Requisition Form

Date Samples Dispatched..... County:..... Sub-County:.....
Facility Name..... Contact name..... Facility Telephone.....
Facility MFL code..... Health Care Provider mobile number:..... Facility email address.....

Sample collection Material Requisition (please indicate the quantity required)
1. DBS blood collection (50/pack) ☐ 2. DBS blood collection (20/pack) ☐ 3. Plasma Preparation Tubes (50/pack) ☐

Comments:

Serial No.	CCC No	Sex	D.O.B	Date of collection	Sample type *(select from code below)*	Date started on ART	Current ART Regimen (select from code below)	Date Initiated on current regimen	Indicate if 1st Line (1) or 2nd Line (2)	Justification code	
										code (1)	code (2)
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											

Code for Sample Type: **1**= Frozen plasma **2**= Venous blood (EDTA) **3**= DBS capillary (infants) **4**= DBS venous

Codes for Justification: **1**= Routine VL **2**= Confirmation of treatment failure (repeat VL at 3M) **3**= Clinical failure **4**= Immunological failure **5**= Single Drug Substitution **6**= Pregnant Mothers **7**= Lactating Mothers **8**= Baseline VL

ART Regimen Codes	1=AZT/ 3TC/NVP	2=AZT/ 3TC/EFV	3=TDF/ 3TC/NVP	4=TDF/ 3TC/EFV	5=AZT/ 3TC/LPVr	6=AZT/ 3TC/ABC	7=TDF/ 3TC/LPVr	8=AZT/ 3TC/ATVr	9=TDF/3TC/ ATVr	10= ABC/ 3TC/ATVr	11= ABC/ 3TC/NVP	12= ABC/ 3TC/EFV	13= ABC/ 3TC/LPVr	14= Other (please specify)

AMPATH REFERENCE LAB	COAST PGH LAB	CDC HIV/R LAB	KEMRI ALUPE LAB	KEMRI HIV P3 LAB	NHRL LAB	WALTER REED LAB
Nandi Road, off Nairobi-Uganda Road, Eldoret Tel: 0733-787-710 email:eid-ampath@googlegroups.com	Molecular Section, Hospital Road, Mombasa Tel: 0722-207-868 email:eid-coast@googlegroups.com	Kisian Road,Kisumu-Busia Road, Kisumu Tel: 0719-867-752 email:eid-kisian@googlegroups.com	CIPDCR, Busia-Malaba Road, Busia Tel: 0726-156-679 email:eid-alupe@googlegroups.com	Mbagathi Road, Nairobi Tel: 0725-793260 0725-796842 email:eid-nairobi@googlegroups.com	KNH Complex, Nairobi email:nhrl@nphls.or.ke	HIV Lab Hospital Road, Kericho Tel: 0716-430261 email:eid-wrp@googlegroups.com

MINISTRY OF HEALTH
NATIONAL AIDS AND STD CONTROL PROGRAM (NASCOP)
EARLY INFANT DIAGNOSIS (DNA-PCR) LABORATORY REQUISITION FORM

(Version: 1 FEB, 2014)

SUBMISSION FORM Date Samples were dispatched ----------

G4S Courier A/C: C00339

Facility Name: ----------
Facility Code: ----------
Province:----------
County----------
District Code----------
District----------
Tel (Mobile): ----------
Tel (Facility): ----------
Facility contact person: ----------

Address (Samples will be rejected if address is incomplete)
Receiving address (Nearest G4S courier collection office to your facility) ----------
- Email (If available) ----------

Sample Collection Material Requisition (Indicate Quantity)
DBS Filter Paper: ----------
Ziploc Bags: ----------
Desiccants: ----------
Lab Requisition Forms----------
Glycine Envelops: ----------
Drying Racks: ----------
Lancets: ----------
Other (Specify):----------

Comments/Requests/Issues

DBS SAMPLES LOG

DBS Sample		Infant Information						Mother PMTCT Information		Confirm if 2nd PCR sample	
No.	Date of sample collection (dd/mm/yy)	Infant ID	Date of Birth (dd/mm/yy)	SEX (M/F)	Entry Point (code)	Infant Prophylaxis (code)	Infant Feeding (code)	HIV Status (NEG/POS)	PMTCT REGIMEN (code)	Repeat (code)	Confirmatory PCR @ 9 months (Y/N)
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											

MOLECULAR CENTRAL TESTING LABS CONTACTS

BUSIA	COAST	ELDORET	KERICHO	KISUMU	NAIROBI	NAIROBI
KEMRI Alupe lab	CPGH Molecular Lab	AMPATH Lab	WRP CRC Lab	CDC HIV/R Lab	KEMRI HIV-P3 Lab	NHRL Lab
KEMRI Alupe, Busia- Malaba Rd, Busia.	Hospital Rd, Mombasa.	Nandi Hill Rd, Nairobi- Uganda Rd, Eldoret	Hospital Rd, Kericho	Kisian, Kisumu- Busia Rd, Kisumu	Centre for Virus Research, KEMRI HQ, Mbagathi Rd, Nairobi	KNH Grounds, NPHLS Complex, Off Ngong Rd, Nairobi
Tel: 0726-156679	Tel: 0722-207868	Tel: 0733-87710	Tel: 0716-430261 Landline:052-30388	Tel:0757-2053017/8	Tel 1: 0725-793260; Tel 2:0725-796842 Landline:020-2722541 Ext2256	Tel: 020-2011660
Email: eid-alupe@googlegroups.com					Email: eid-nairobi@googlegroups.com	Email: nhrl@nphls.or.ke nhrlresults@gmail.com

KEY CODES

Entry Points: 1= OPD, 2= Paediatric Ward, 3= MCH/PMTCT, 4= CCC, 5= Maternity, 6= Other (Specify)

Infant Prophylaxis: 1= sdNVP Only, 2= sdNVP+AZT+3TC, 3= NVP for 6 Wks (*Mother on HAART or not BF*), 4= NVP during BF period, 5= None,6= Other (specify)

Infant Feeding : 0-6 Months: EBF= Exclusive Breastfeeding, ERF= Exclusive Replacement Feeding, MF= Mixed

Infant Feeding : >6 Months: BF= Breastfeeding, NBF= Not Breast Feeding

Mother PMTCT Regimen: 1= sdNVP only: 2= Interrupted HAART (*HAART until end of BF*): 3= AZT(*From 14wks or later*) + sdNVP+3TC+AZT in labour then AZT+3TC for 7 days; 4=HAART; 5=None, 6=Other (Specify)

Repeat testing: 1= Repeat for rejection; 2= Repeat for positive confirmation;

REPUBLIC OF KENYA

MINISTRY OF HEALTH

NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM/NATIONAL TUBERCULOSIS REFERENCE LABORATORYAFB/XPERT/LPA /CULTURE AND DST LABORATORY REQUEST FORM

**********ALL FIELDS ARE MANDATORY**********

Patient Name (3 Names): .....

Age: ..... Sex: ..... Patient's Mobile No. .....

Physical Address ..... Guardian/Alternative Mobile No. .....

TB / MDRTB Register No: ..... IP/OP No: .....

Ward/Department: ..... Facility: ..... sub County: ..... County: .....

Clinician Mobile No: ..... Email: ..... Signature: .....

SCTLC Mobile No: ..... Email: ..... MFL Code: .....

Date sample was collected: ..... Time: .....

Sample Type: .....

HIV Status: ☐ Positive ☐ Negative ☐ Not Done ☐ Declined

Type of TB: ☐ PTB ☐ EPTB ☐ Specify type of EPTB .....

Type of Patient: ☐ New ☐ Relapse ☐ Failure of First Line ☐ Treatment after loss to follow up ☐ Failure of Retreatment ☐ Treatment after loss to follow up

Test requested: ☐ AFB Smear ☐ First Line LPA ☐ Culture & First Line DST ☐ GeneXpert ☐ Second Line LPA ☐ Culture & Second Line DST

Reasons for Examination

Drug sensitive TB: ☐ New ☐ Follow up at 2 months ☐ 4 Months ☐ 6 months Others specify .....

Drug resistant: ☐ Baseline ☐ Follow up Specify Month of follow up .....

Indications for GeneXpert: (Tick√) (See the various indications and tick corresponding box)

Low Risk for DR TB

- ☐ People Living with HIV with TB symptoms
- ☐ Children <15 years with TB symptoms
- ☐ All Presumptive TB cases with a negative smear microscopy result

High Risk for DR TB

- ☐ Previously treated TB patients:
- ☐ Drug Resistant TB patient contacts
- ☐ TB patients with a positive smear result at month 2 or month 5 of TB treatment
- ☐ Patients who develop TB symptoms while on IPT or has had previous IPT exposure
- ☐ Healthcare workers with TB symptoms
- ☐ Prisoners with TB symptoms
- ☐ Refugees with symptoms of TB

LAB REPORT

Date..... Time Sample received ..... Method used: ☐ ZN ☐ FM ☐ Xpert

Lab serial no.	Specimen type	Visual Appearance	Results						
			Neg	Actual no.	+	++	+++	Xpert results**	Date & Time dispatched

**select one of the following

TS MTB detected Rif resistance not detected
RR MTB detected & Rif resistance detected
TI MTB detected Rif resistance indeterminate
N MTB not detected
I Invalid/No results/Error

Examined by (Name and Signature)..... Laboratory Name Date...../...../.....

Reviewed by (Name and Signature)..... Laboratory Name Date...../...../.....

MOH/DPPH/NPHLS/NTRL/F/138 Version 1:0 Effective Date: (DD/MM/YYYY)

B. Specimen Referral Form

This form travels with the specimen and requisition form to document chain-of-custody. It is a data source for Indicators 1, 3, 5, 7 and 9.

As seen below, an additional VIII section asks the referral laboratory to report any damages of the shipment/package upon receipt (*including when a shipment/package is damaged but specimens can still be tested*). This question in particular is a data source for Indicator 6.

Original

Serial No. 608

REPUBLIC OF KENYA

MINISTRY OF HEALTH

Specimen Ref No.....

SAMPLE AND SPECIMEN REFERRAL FORM

Note: incompletely filled forms will not be processed

I. Patient and Specimen details

IP/OP No:.....

Patient's Name..... Age(yrs/months) ..... Sex M☐ F☐

Physical address.....Postal address.....

Sample / specimen and description..... Source.....

Collection date *(dd/mm/yyyy)* ___/___/_____ Time *(24hrs)* .....

Date of preservation..... Method of preservation.....

II. Referring Lab (name and address) .....

Reasons for Referral.....

III. Details of Person Referring sample

Name..... Designation..... Mobile No. .....

email..... Signature.....

IV. Investigations Requested .....

V. Lab referred to (name and address) .....

VI. Details of the Person Receiving sample

Name..... Designation..... Mobile No. .....

Email..... Signature.....

VII. Condition of Sample:

Accepted ☐ Rejected ☐ (specify reason) _____

VIII. Condition of Shipment Upon arrival _____

C. Specimen Referral Logbook or Specimen/Results Tracker

This logbook sits in the referring facility or hub to keep track of when specimens left the facility and when results were returned. There are three examples for TB, HIV and an integrated document, respectively. These are a data source for Indicators 1-4.

MINISTRY OF HEALTH
NATIONAL TUBERCULOSIS REFERENCE LABORATORY
P.O.BOX 20781-00202, NAIROBI.
KENYATTA NATIONAL HOSPITAL GROUNDS off NGONG ROAD

SAMPLE REFERRAL LOG

Date	Lab No.	Tests					Test Sent by	Results received by	Date received	comments
		Smear	Molecular	MGIT	LJ	DST				

Reviewed by:……..Signature:……Date:……

HEALTH FACILITY SAMPLE AND RESULTS TRACKING LOG

S/No	Patient Name	PSC No.	Age	Sex	Viral load 1 (Initial)					Viral load 2 (3 months after initial)					Comments
					Date & Time sample collected	Time of dispatch H/facility	Date Results received	TAT (Days)	Vload 1 Results (cp/ml) & Log10	Date & Time sample collected	Time of dispatch H/facility	Date Results received & received by	TAT (Days)	Vload 1 Results (cp/ml) & Log10	

Reviewed by.....

Signature.....

Date .....

SAMPLE AND RESULTS TRACKING LOG

County Name
Facility Name

Facility code
Contact (Mobile and Email)

Test requesting facility						Sample procesing facility (HUB where applicable)			Molecular testing labs			Facility	
S/NO	Patient Name	Patient CCC unique no	Type of test (specify)	Date of Collection	Date of dispatch	Date of receipt	Date of processing	Date of dispatch to testing lab	Date when sample received	Date samples tested	Date Results dispatched	Date Results received at facility	TAT from Collection to Result dispatch
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													

Requesting Facility	Name	Signature	Date
Sample processing laboratory	Name	Signature	Date
G4 S driver	Name	Signature	Date
Testing Laboratory	Name	Signature	Date

D. Specimen Reception Logbook

This logbook sits at the referral laboratory to track all specimens received. It is a data source for Indicators 7, 8 and 10.

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NATIONAL TUBERCULOSIS REFERENCE LABORATORY
P.O.BOX 20750-00202, NAIROBI.
KENYATTA NATIONAL HOSPITAL GROUNDS off NGONG ROAD

SPECIMEN RECEPTION LOG

DATE	NUMBER RECEIVED	NUMBER REJECTED	REASON FOR REJECTION	MDR F/UP	RECEIVER INITIALS	PROCESSED SAMPLES		
						DATE	NUMBER PROCESSED	INITIALS OF PROCESSING OFFICER

Reviewed by……..Date……..

E. Rejection Form

This form is filled at the referral laboratory if a specimen is rejected. It is a data source for Indicator 10.

MINISTRY OF HEALTH
NATIONAL AIDS AND STD CONTROL PROGRAM
(NASCOP)

Date/Time: _____

Report Submitted by: _____

Supervisory Review & Date:

_____

Test(s) Requested: _____

Lab Section: _____

Submitting Location: _____

Phlebotomist (if known) _____

☐ **Specimen Rejected- Briefly describe why (Use back if necessary):** _____

_____

Indicate Category of Event:

☐ **Improper collection technique**(Circle one)
Clotted Hemolyzed Short-draw Lipemic

☐ **Incorrect container/tube received**

☐ **Patient ID error/No specimen label**

☐ **Requisition & specimen do not match**

☐ **Delayed delivery of specimens**

☐ **Flow cytometry specimen > 48 hours**

☐ **Testing/ results delay**

☐ **Specimen processing delayed**

☐ **No requisition form specimen**

☐ **Improperly packaged specimens/ shipment (leaking specimen/breakage/high temperature)**

☐ **Other (Explain)**

Indicate whether rejected samples were : DESTROYED or SENT BACK TO THE SITE (circle one)

PersonNotified at Submitting Location: _____ **Date/Time:** _____

Resolution of Incident: _____

_____

_____

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ANNEX 6: Data Reporting Forms

Specimen Referral Data Summary Collection Form

The purpose of this summary form is to report key performance indicators for specimen referral and reporting of results. Only fill the section that is related to your operations:

- **Referring Facility** is one that collects specimens from patients and sends to another laboratory for processing and testing – referring facilities reports to their respective sub-county or county health management teams (CHMTs)
- **Referral Laboratory** is one that receives any specimen for testing or further referral to higher-level referral laboratories – county referral laboratories report this information to their respective CHMTs whereas national reference laboratories report to the National Public Health Laboratory (NPHL)
- **Courier or transport service provider** is the one that physically picks up specimens or results and transports them to their intended destination – these transporter providers report to their respective CHMTs
- **Sub-county or CHMTs** collect information from the facilities/service providers within its catchment area and report this information to the county or NPHL
- **Question to add to the Integrated Supportive Supervision Tool.**

Name of facility	
Location of facility (C*ity/town, Sub-county, County, etc.***)**	
Referring facility, referral and/or hub lab, or transport provider?	
Reporting period: (*dd/mm/yy*)	
Reporting frequency: (*monthly, quarterly, bi-annually*)	

Referring Facility

Key Performance Indicator	Result
a. Number of specimens referred for testing during the month	
b. Number of shipments (multiple specimens are likely to be in one package/shipment) dispatched for testing during the month (optional)	
c. Specified transport time for specimens to be picked up by transport service after collection (in days or hours), especially if different from national guidelines	
d. Number of specimens picked up by the transporter for referral within the required time listed in indicator c	
e. Proportion of specimens picked up by transporter for referral within the required time (indicator e divided by indicator f)	
f. Specified time by which the results should be received by the referring facility (in days or hours), especially if different from national guidelines	
g. Number of referred specimens for which a result was received within the specified turnaround time listed in indicator f	
h. Proportion of referred specimens for which a result was received within the specified turnaround time (indicator g divided by indicator	

Referral Laboratory

Key Performance Indicator	Result
a. Total number of referred specimens received at the referral laboratory for testing	
b. Total number of shipments received at the referral laboratory (optional, if known)	
c. Specified time for specimens to be received by the referral laboratory (in days or hours), especially if different from national guidelines	
d. Total number of referred specimens received at the referral laboratory within the required time listed in indicator c	
e. Proportion of specimens received at the referral laboratory within the required time (indicator d divided by indicator a)	
f. Total number of referring facilities that refer specimens to this laboratory for testing during this month	

g. Number of referring facilities that fill the specimen referral form (or equivalent) for each shipment made (this form travels with the shipment and is different from the test requisition forms – this form shows each time the specimens change hands from referring facility to transporter to referral lab)	
h. Percentage of referring facilities that fill the specimen referral form (or equivalent) for each shipment made (indicator d divided by indicator c)	
i. Number of specimens that were rejected because of factors related to inadequate or improper transport (i.e. rejection caused by hemolysis, improper temperatures during transit, etc.)	
j. Proportion of specimens that were rejected because of factors related to inadequate or improper transport (indicator f divided by indicator a)	
k. Number of specimens that were rejected because of factors related to inadequate or improper packaging	
l. Proportion of specimens that were rejected because of factors related to inadequate or improper packaging (indicator h divided by indicator a)	
m. Number of specimens that were rejected because of factors related to inadequate or improper documentation	
n. Proportion of specimens that were rejected because of factors related to inadequate or improper documentation (indicator j divided by indicator a)	
o. Total number of referred specimens that were rejected for any reason	
p. Proportion of referred specimens that were rejected for any reason (indicator l divided by indicator a)	
q. Total tests results released	
r. Total test results released within the laboratory's specified turnaround time (TAT)	
s. Proportion of test results released within the specified TAT (indicator o divided by indicator n)	

Courier / Transport Service Provider

Key Performance Indicator	Result
a. Number of specimens transported during the month (if known)	
b. Number of shipments transported during the month	
c. Specified transport time for specimens to be delivered by transport service after pick up (in days or hours), should be listed in service agreement	
d. Number of shipments that are delivered within the specified transport time	
e. Proportion of shipments that are delivered within the specified transport time (indicator d divided by indicator b)	
f. Number of shipments that were lost or damaged	
g. Proportion of shipments that were lost or damaged (indicator f divided by indicator b)	

Sub-county or CHMT

Key Performance Indicator	Result
a. Number of referring facilities in this (sub-)county participating in the specimen referral system	
b. Total number of health facilities in this (sub-)county	
c. Proportion of referring facilities participating in the specimen referral system (indicator a divided by indicator b)	
d. Number of facilities in this (sub-)county (referring and referral laboratories) that submit complete routine data forms	
e. Proportion of facilities in this (sub-)county (referring and referral laboratories) that submit complete routine data forms (indicator d divided by indicator a)	
f. Number of facilities in this (sub-)county (referring and referral laboratories) that have been sensitized on the National Specimen Referral Guidelines	
g. Proportion of facilities in this (sub-)county (referring and referral laboratories) that have been sensitized on the National Specimen Referral Guidelines (indicator f divided by indicator a)	

h. Number of transport service providers in this (sub-)county trained on the National Specimen Referral Guidelines requirements	
i. Total number of transport service providers in this (sub-)county	
j. Proportion of transport service providers in this (sub-)county trained on the National Specimen Referral Guidelines requirements (indicator h divided by indicator i)	
k. Total number of specimens referred for testing this month in this (sub-) county (add up all indicator a's under the Referring Facility sections submitted)	
l. Number of referring facilities in this (sub-)county that have filled their specimen referral logbook (or equivalent) completely (add up all 'yes' answers to indicator c's under the Questions added to the Integrated Supportive Supervision Tool submitted)	
m. Total number of specimens picked up by the transporter for referral within the required time in this (sub-)county during this month (add up all indicator d's under the Referring Facility sections submitted)	
n. Proportion of specimens picked up by transporter for referral within the required time in this (sub-)county during this month (indicator m divided by indicator k)	
o. Number of referred specimens for which a result was received within the specified turnaround time in this (sub-)county during this month (add up all indicator g's under the Referring Facility sections submitted)	
p. Proportion of referred specimens for which a result was received within the specified turnaround time in this (sub-)county during this month (indicator o divided by indicator k)	
q. Total number of shipments transported in this (sub-)county during this month (add up all indicator b's under the Transport Service Provider sections submitted)	
r. Total number of shipments lost or damaged in transit in this (sub-)county during this month (add up all indicator f's under the Transport Service Provider sections submitted)	
s. Proportion of shipments lost or damaged in transit in this (sub-)county during this month (indicator r divided by indicator q)	

t. Total number of shipments delivered at the referral laboratory within the required time in this (sub-)county during this month (add up all indicator d's under the Transport Service Provider sections submitted)	
u. Proportion of shipments delivered at the referral laboratory within the required time in this (sub-)county during this month (indicator t divided by indicator q)	
v. Total number of specimens received at the referral laboratories for testing this month in this (sub-)county (add up all indicator a's under the Referral Laboratory sections submitted)	
w. Total number of specimens received at the referral laboratory within the required time in this (sub-)county during this month (add up all indicator d's under the Referral Laboratory sections submitted)	
x. Proportion of specimens received at the referral laboratory within the required time in this (sub-)county during this month (indicator w divided by indicator v)	
y. Total number of referring facilities that fill the specimen referral form in this (sub-)county during this month (add up all indicator g's under the Referral Laboratory sections submitted)	
z. Proportion of referring facilities that fill the specimen referral form in this (sub-)county during this month (indicator y divided by indicator a)	
aa. Total number of specimens that were rejected (disaggregated by reason for rejection) in this (sub-)county during this month (add up all indicator o's under the Referral Laboratory sections submitted)	
ab. Proportion of specimens that were rejected (disaggregated by reason for rejection) in this (sub-)county during this month (indicator aa divided by indicator v)	
ac. Total number of results released in this (sub-)county during this month (add up all indicator q's under the Referral Laboratory sections submitted)	
ad. Total number of results released within the specified TAT in this (sub-) county during this month (add up all indicator r's under the Referral Laboratory sections submitted)	
ae. Proportion of specimens that were rejected (disaggregated by reason for rejection) in this (sub-)county during this month (indicator dd divided by indicator cc)	

Question to add to the Integrated Supportive Supervision Tool

Questions	Answer
a. Does this facility refer specimens to an offsite destination for testing?	
b. If yes to question a, does this facility have a specimen referral logbook (or equivalent) that remains at the facility and records each specimen that was referred and the results returned?	
c. If yes to question b, is the specimen referral logbook (or equivalent) filled out completely?	

Notes

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The Global Fund To Fight AIDS, Tuberculosis and Malaria
USAID FROM THE AMERICAN PEOPLE
TB ARC II Accelerated Response and Care
PEPFAR
chs Centre for Health Solutions - Kenya
amref health africa