Implementation Framework for Malaria Rapid Diagnostic Tests



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FOREWORD

Malaria remains a significant public health burden in Kenya, contributing substantially to morbidity, mortality, and socio-economic challenges. In 2023, millions of malaria cases were reported, underscoring the continued need for strengthened interventions to reduce transmission and improve case management. The Government of Kenya, in collaboration with development partners, civil society, and the private sector, continues to implement high-impact interventions, including vector control, intermittent preventive treatment, and prompt diagnosis and treatment in line with national guidelines.

Accurate and timely diagnosis is a cornerstone of effective malaria case management. While microscopy services have traditionally been limited to higher-level health facilities, the adoption of a universal parasitological diagnosis policy in 2024 marked a major shift towards ensuring that all suspected malaria cases are confirmed before treatment, regardless of age or transmission setting. However, current evidence indicates that diagnostic coverage remains suboptimal, necessitating expanded access to diagnostic services across all levels of care.

The scale-up of malaria rapid diagnostic tests (mRDTs) provides a critical opportunity to bridge this gap. By enabling timely, reliable diagnosis at peripheral health facilities and community level, mRDTs support appropriate treatment, reduce misuse of antimalarial medicines, and strengthen surveillance systems. This Implementation Framework for Malaria Rapid Diagnostic Tests outlines the strategic and operational approaches required to guide the nationwide expansion of mRDTs.

This framework is aligned with the Kenya National Malaria Policy (2024), the Kenya Malaria Strategy (2023–2027), and global recommendations from the World Health Organization. Its successful implementation will require coordinated efforts across national and county governments, the private sector, and implementing partners.

The Ministry of Health calls upon all stakeholders to support the implementation of this framework and ensure adherence to test-based malaria management. Together, we can strengthen malaria diagnosis, improve treatment outcomes, and advance towards a malaria-free Kenya.



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PREFACE

Kenya has made notable progress in malaria control through the implementation of evidence-based interventions, including effective case management guided by national policies and guidelines. A key milestone in this effort has been the adoption of a universal parasitological diagnosis policy, which ensures that all suspected malaria cases are confirmed prior to treatment.

Despite these gains, access to diagnostic services has remained uneven, particularly at lower levels of care where microscopy services and trained laboratory personnel may be limited. The scale-up of malaria rapid diagnostic tests (mRDTs) provides a practical and effective approach to expanding access to timely and accurate malaria diagnosis, especially within primary healthcare and community settings.

This **Implementation Framework for Malaria Rapid Diagnostic Tests** has been developed to guide the systematic deployment and use of mRDTs across all levels of the health system. It outlines key operational and technical considerations, including service delivery, supply chain management, quality assurance, training, supervision, and data management. The framework supports the operationalization of the national test-based policy and strengthens the delivery of integrated, people-centered primary healthcare services.

The framework is aligned with the **Kenya Malaria Strategy (2023–2027)** and is informed by national programme data, implementation experience, and global recommendations from the World Health Organization. It emphasizes the importance of coordinated implementation across national and county levels, as well as engagement of both public and private sector providers.

The Ministry of Health, through the Directorate of Primary Health Care Services, reaffirms its commitment to strengthening malaria diagnosis as a core component of quality primary healthcare. We call upon all stakeholders to support the implementation of this framework to ensure equitable access to accurate diagnosis and improved health outcomes for all Kenyans.



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ACKNOWLEDGMENT

The National Malaria Control Programme (NMCP) expresses its sincere appreciation to all individuals and institutions that contributed to the development of the **Implementation Framework for Malaria Rapid Diagnostic Tests**.

We acknowledge the leadership and technical guidance of the **Diagnostic Sub-Committee of the Case Management Committee of Experts (CoE)** and the **Malaria Health Sector Working Group (MHSWG)**, whose deliberations and expert inputs were instrumental in shaping this framework.

The NMCP is grateful for the technical and programmatic contributions of key partners and institutions, including AMREF Health Africa, PMI Impact Malaria, Kenya Medical Research Institute, Kenya Medical Laboratory Technicians and Technologists Board, Association of Kenya Medical Laboratory Scientific Officers, and Kenyatta National Hospital.

We also recognize the important role played by County Health Management Teams, county malaria coordinators, laboratory personnel, and implementing partners in supporting malaria diagnosis and case management across the country.

Finally, we commend all healthcare workers whose continued dedication to delivering quality malaria diagnostic and treatment services remains central to improving health outcomes and advancing Kenya's malaria control and elimination agenda.



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ABBREVIATIONS

ABBREVIATION	MEANING
ACT	Artemisinin Combination therapy
AKMLSO	Association of Kenya Medical Laboratory Scientific Officers
AL	Artemether Lumefantrine
AMREF	African Medical Research Foundation
BCC	Behavior Change Communication
CHMT	County Health Management Team
CMLC	County Medical Laboratory Coordinator
CHEWs	Community Health Extension Workers
CHAs	Community Health Assistants Promoters
CoE	Committee of Experts
DDSR	Division of Disease Surveillance and Response
DHIS2	District Health Information System 2
DHS	Demographic Health Survey
NMCP	Division of National malaria program
DVB&ND	Division of Vector-Borne and Neglected Tropical Diseases
DNPHLS	Division of National Public Health Laboratories
EPR	Epidemic Preparedness and Response
EQA	Eternal Quality Assurance
FEFO	First-to-Expire First-Out
FBO	Faith-Based Organization
FIND	Foundation for Innovative New Diagnostics
GFATM	Global fund to fight AIDS, Tuberculosis, and Malaria
HMIS	Health Management Information System
HRPII	Histidine Rich Protein II
IMCI	Integrated Management of Childhood Illnesses
IQC	Internal Quality Control
KEMRI	Kenya Medical Research Organization
KEMSA	Kenya Medical Supplies Agency
KMIS	Kenya Malaria Indicator
KMLTTB	Kenya Medical Laboratory Technicians and Technologists Board
KMS	Kenya malaria strategy
KMTC	Kenya Medical Training College
KNMP	Kenya National Malaria Policy
KMIS	Kenya Malaria Indicator Survey
LIMS	Laboratory Information Management Systems
iLMIS	Integrated Logistics Management Information Systems
LMU	Logistics Management Unit
MEDS	Mission for Essential Drugs and Supplies
M&E	Monitoring and Evaluation
mRDTs	Malaria Rapid Diagnostic Tests
NMARL	National Malaria Reference Laboratory
MOH	Ministry of Health
NPHI	National Public Health Institute
OPD	Outpatient Department
pLDH	Parasite Lactate dehydrogenase
PMI	Presidents Malaria Initiative
PMS	Post Market Surveillance
PPB	Pharmacy and Poisons Board

PPDA	Public Procurement and Disposal Act
QA	Quality Assurance
QC	Quality Control
QOC	Quality of care
RDTs	Rapid Diagnostic Tests
SOP	Standard Operating Procedure
SCHMT	Sub County Health Management Team
SDGs	Sustainable Development Goals
SMEOR	Surveillance Monitoring and Evaluation and Operational Research
STG	Standard Treatment Guidelines
TTR	Test and Treat Register
TOT	Training of Trainers
WRP	Walter Reed Project
WHO	World Health Organization

DEFINITION OF TERMS

Biosafety

The containment conditions under which infectious agents can be safely manipulated

Case Management

A collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote patient safety, quality of care, and cost-effective outcomes

Endemicity

Relating to a disease or pathogen that is found in or confined to a particular location, region, or people

First-line Treatment

The *treatment* regimen or regimens that are generally accepted by the medical establishment for initial *treatment* of a given type and stage of the disease. It is also called primary *treatment* or *therapy*. *First-line therapy* intends to cure the disease if possible.

Forecasting demand

Collection of information regarding the buying behavior of consumers from experts or through conducting surveys.

In Vitro Diagnostics

(IVDs) are medical *devices* and accessories used to perform tests on samples, (e.g., blood, urine, and tissue that has been taken from the human body) to: Help detect infection. Diagnose a medical condition. Prevent disease.

Presumptive treatment

Defined as a one-time treatment for a presumed infection in a person, or a group of people, at high risk of infection.

Parasitological diagnosis of malaria

The two methods used routinely for malaria diagnosis are light microscopy and RDTs.

Prevalence

It is a statistical concept referring to the number of cases of a disease that are present in a particular population at a given time, whereas ***incidence*** refers to the number of new cases that develop in a given period

Quality Assurance

The maintenance of a desired level of quality in a service or product, especially through attention to every stage of the process of delivery or production.

Supportive supervision

A facilitative approach to supervision that promotes mentorship, joint problem-solving, and communication between supervisors and supervisees.

Technical specification

A document that describes technical requirements to be fulfilled by the product, process, or service to comply with the functional specification (ISO 13880).

CHAPTER 1: INTRODUCTION

1.1. Background

Globally, malaria continues to be a leading cause of morbidity and mortality in many countries worldwide. In 2023, the number of malaria cases was estimated at 26.3 million, with an incidence of 60.4 cases per 1000 population at risk. This is an increase of 11 million cases from the previous year and a rise in incidence from 58.6 cases per 1000 population at risk in 2022. The WHO African Region continues to carry the heaviest burden of the disease accounting for an estimated 94% of malaria cases worldwide in 2023 (WHO, 2024). The disease remains a significant public health concern in Kenya with three-quarters of the population at risk of infection, particularly older children ages 10–14 years have the highest prevalence, at 11 percent. More importantly, the burden of malaria varies across the country. Kenya has experienced a decline in malaria prevalence among children aged 6 months to 14 years in the lake endemic zone, from 27% in 2015 to 19.2% in 2020, and a slight decrease in the coast endemic zone from 8% in 2015 to 5% in 2020 (KMIS 2015; KMIS 2020).

Kenya adopted the World Health Organization (WHO) recommendation for parasitological confirmation of suspected malaria cases before treatment in 2010. However, due to the inadequacy in coverage of malaria microscopy services, mRDTs use is recommended to provide a parasite-based diagnosis of malaria in situations where microscopy services are not available. The utilization of mRDTs has had an enormous impact on malaria diagnosis, particularly in malaria epidemic-prone and resource-limited regions of Kenya. These tests have transformed case management of malaria enabling timely, accurate, and cost-effective diagnosis of uncomplicated malaria at all levels of the healthcare system.

This implementation framework describes a systematic approach to guide the operation process regarding mRDT in Kenya. The use of the framework will ensure that the various components of mRDT implementations are addressed. The processes shall include training and assessment. Procurement of mRDTS and other commodities, testing and biosafety, quality assurance, advocacy communication and social mobilization (ACSM), monitoring and evaluation. This is in tandem with objective two of the Kenya Malaria Strategy (KMS) 2023-2027.

1.2. Purpose of the mRDT implementation plan

The purpose of the Malaria Rapid Diagnosis Implementation Plan is to:

1) Provide guidance for well-planned and effective parasite-based diagnosis of uncomplicated malaria using quality assured mRDTs
2) Ensure universal access to accurate malaria diagnosis through the use of mRDTs at all levels of healthcare before administering antimalarial treatment
3) Support the implementation of Kenya policy for treatment of malaria based on parasitological diagnosis

1.3. Target audience

The Malaria Rapid Diagnostic Test (mRDT) Implementation Plan has been developed for use by the National Malaria Programme and all levels of the healthcare system utilizing mRDTs to diagnose malaria rapidly. It also serves as a guide for partners interested in funding malaria interventions, as well as public and private sector organizations engaged in implementing parasitological diagnosis and supporting malaria control and elimination efforts through the use of mRDTs.

1.4. Objectives

1.4.1. General Objective

- To implement effective use of malaria RDTs for accurate and timely diagnosis of malaria.

1.4.2. Specific Objectives

- Build the capacity of healthcare workers on the use of malaria Rapid Diagnostic Tests (mRDTs), biosafety procedures, and quality assurance through targeted training and post-training assessments
- To ensure timely procurement and distribution of mRDTs and associated malaria diagnostic commodities to all targeted health facilities
- To improve malaria diagnostic coverage and ensure safe testing practices by implementing biosafety standards and expanding access to mRDTs across [insert region or health facilities
- To strengthen quality assurance systems for malaria diagnostics by establishing regular supervision, proficiency testing, and feedback mechanisms across all participating facilities
- To track implementation progress and assess the impact of malaria diagnostic interventions through a robust monitoring and evaluation system with regular data collection and reporting

1.5. Roles and responsibilities of stakeholders

These are individuals, groups, or organizations with a vested interest or stake in the decision-making processes and activities related to the Implementation Framework for Malaria Rapid Diagnostic Tests (mRDTs). Stakeholders include the National Malaria Control Programme, the Case Management Diagnostic Sub-Committee, the National Malaria Reference Laboratory, County and Sub-County Malaria Reference Laboratories, health facilities, Community Health Assistants, Health Development and Implementing Partners, the Kenya Medical Supplies Authority (KEMSA), and relevant regulatory bodies.

National Malaria Control Programme (NMCP)

The NMCP is responsible for:

- Development and review of national malaria framework for mRDT implementation plan
- Mobilizing resources for mRDT implementation plan
- Development and distribution of reporting tools for mRDT implementation plan
- Dissemination of reports
- Provision of oversight and mentorship for mRDT implementation plan
- Coordination of partners and organizations involved in mRDT implementation plan
- Ensuring mRDT security
- Guidance in strengthening mRDT malaria quality assurance
- Capacity-building at national and county levels

Case management diagnostic sub-committee

The diagnostic sub-committee guides and advises on all matters of malaria diagnosis. Management focal person and links with the overall case management technical working group. The roles and responsibilities include:

- Develop and review policies and guidelines related to mRDT
- Guide implementation of mRDT at all levels of healthcare
- Coordinate the activities of various partners and stakeholders involved in the implementation and use of mRDTs).
- Regularly review progress and monitor mRDT activities including quality assurance processes
- Ensure security for mRDT to prevent any risks that could compromise their quality, effectiveness, or reliability.

National Malaria Reference Laboratory (NMARL)

The National Malaria Reference Laboratory gets guidance and direction on malaria diagnostic matters from the malaria diagnostic subcommittee.

The roles and responsibilities include:

- Participate in the development of mRDT technical specification
- Coordinate the implementation of mRDT EQA activities
- Participate in evaluation of mRDT kits
- Participate in post-market surveillance of mRDT kits

County Reference Laboratory

The county reference laboratory is part of the overall county laboratory services and functions under the guidance of the county health management team. The CHMT should include the county malaria quality assurance officer (CMQA) to support the implementation of the mRDTs framework at all levels of healthcare. The responsibility of the laboratory is to:

- Disseminate country mRDT diagnostic guidelines and policies

- Adopt specifications for mRDT in accordance with the manufacturer instructions
- Use consumption data to accurately forecast and quantify mRDT commodity needs, ensuring consistent supply and preventing stockouts or overstocking.
- Develop and implement guidelines for the maintenance of biosafety during mRDT testing
- Collaborate with the National Malaria Reference Laboratory (NMARL) to support the effective implementation of quality assurance (QA) activities for mRDTs.
- Coordinate mRDT IQC, EQA activities at the county level
- Report on the performance of mRDT to the NMCP
- Capacity build healthcare workers on the use mRDT, interpretation of results and biosafety
- Conduct competency assessment of trained community health service providers

Sub County Laboratory

The sub-county medical laboratory is part of the overall sub-county laboratory services and functions under the guidance of the sub-county health management team. The SCHMT should include the sub-County Malaria Quality Assurance Officer (CMQA) to support the implementation of the mRDTs framework at sub-county.

The roles and responsibilities of this laboratory include:

- Disseminate country mRDT diagnostic guidelines and policies
- Coordinate mRDT testing at sub-county
- Report on the performance of RDT to the county referral laboratory
- Participate in capacity building of healthcare workers on the use mRDT, interpretation of results and biosafety level.
- Adopt SOPs for mRDT.
- Trains health care providers on mRDT and biosafety at the community level
- Coordinate community health service provider involved in mRDT activities
- Supervise CHPs and CHAs community health service provider on utilization of mRDT
- Participate in the selection of community health service providers

Link Facility for Community Health Unit

- Ensure availability of mRDTs to the Community Health Units link
- Maintain a stock record book to monitor monthly mRDT consumption, enabling accurate forecasting and timely ordering of supplies to ensure uninterrupted availability at the health facility.
- Adopt SOPs and job aids for mRDTs
- Oversight and supervision to community health service provider involved in mRDT activities
- Assess competency level of trained community health service provider in conjunction with Sub-county Laboratory
- Ensure safe disposal of used mRDTs by the service provider at the community
- Reporting and recording all relevant accidents, biohazardous exposures, and other work-related illnesses to the appointed biosafety officer at the community health link facility

Community Health Officer

The Community Health Officer is responsible for:

- Ensuring all community health service providers are trained on the use mRDTs
- Providing regular reports on the usage of mRDTs
- Ensuring effective use of bio-safety equipment
- Documentation of all Bio-safety procedures and activities
- Determining challenges in usage mRDT by community health service provider
- Managing community health service provider kits
- Compiling and forwarding community health service provider reports to Health records and information officers
- Updating MOH 516 (chalkboard)

Health Development and Implementing Partners

Provide financial and technical support for malaria diagnostics.

Kenya Medical Supplies Authority (KEMSA)

Procure, warehouse, and distribute mRDTs on behalf of the government (ACT 244, 2013)

Regulatory bodies

They include: KMLTTB and PPB.

KMLTTP regulate individual practitioners and training institutions, ensuring competency and ethical practice. The PPB focuses on the certification of mRDTs, ensuring their safety and quality.

CHAPTER 2: TRAINING AND ASSESSMENT

2.1 Training

Malaria Rapid Diagnostic Tests (mRDTs) provide timely diagnosis of malaria, enabling prompt treatment and thereby reducing the risk of complications and malaria-related mortality. Proper training of personnel performing malaria testing is essential to ensure the accuracy and reliability of diagnostic results, which are critical for effective case management and malaria control.

The purpose of this training is to ensure that health service providers can deliver accurate and reliable malaria diagnostic test results. Therefore, it is essential to train health workers to perform quality mRDT testing as part of achieving Objective 3.2 of the Kenya Malaria Strategy (KMS) 2023–2027.

The training should be conducted by appropriate trainers using the approved country's curriculum and supervised to ensure quality. Trainers should be medical laboratory personnel who must have undergone regular training of trainers in clinical skills (TOT) and quality assurance for parasitological diagnosis of malaria as provided by NMCP to ensure they have good facilitation skills and up-to-date technical knowledge. Health service providers will undergo refresher training and mentorship from time to time to update on mRDT testing.

Assessments

Health service providers who have undergone training in malaria RDT will be assessed from time to time to determine their competency using NMCP support supervision checklist

CHAPTER 3: PROCUREMENT OF mRDTS & OTHER COMMODITIES

Procurement of mRDTs require concerted efforts from relevant diagnostic committees to undertake all the necessary steps which include, Planning and Coordination, forecasting and quantifications, Selection of Appropriate mRDTs, Warehousing and distribution of mRDTs. Procurement of mRDTs should be done in accordance to Public Procurement and Disposal Act 2015 (PPDA) for public procurement and partner regulations where a partner procures the commodities

3.1 Planning and coordination

The National Malaria Control Program (NMCP) has the overall mandate of coordinating effective malaria case management across all levels of Healthcare in Kenya. The program will ensure the availability of resources and other logistics necessary for successful implementation.

3.2 Forecasting and Quantification of mRDTs

The annual quantification and forecasting of mRDTs will be estimated at national level by NMCP. This should be harmonized with the current practice and KHIS data. Additional survey data such as malaria and fever prevalence will be necessary to achieve approximate quantities for mRDTs. The quantification methodology shall be reviewed and updated yearly

3.3 Selection of Appropriate mRDTs

There are over 200 types of mRDTs which target Plasmodium specific proteins. This includes Histidine Rich Proteins (HRP2), Plasmodium lactate Dehydrogenase (PLDH), and aldolase. The mRDT procured should be WHO-prequalified based on Kenya local Plasmodium species distribution. The NMCP is responsible for recommending mRDTs that perform well and reproducible results for the intended use.

It is recommended to procure WHO prequalified mRDTS and in country specification. The choice of mRDT should be based on the prevalence of malaria and the type of species antigen targeted in the country. The Kenya Malaria Indicator Survey (KMIS) conducted in 2020 revealed that 76 percent of children ages six months to 14 years who tested positive for malaria had a Plasmodium falciparum infection, four percent had *Plasmodium malariae*, one percent had *Plasmodium ovale*, and 19 percent had a mix of Plasmodium falciparum and *Plasmodium malariae* infection (DNMP and ICF, 2021). Counties in northern Kenya (Isiolo, Mandera, Turkana, Marsabit, and Wajir) have reported, through routine surveillance, Plasmodium vivax cases. In Turkana County, 2.1 percent of household members of patients with Plasmodium falciparum infections were infected with *Plasmodium vivax* (O'Meara et al., 2023). mRDTs that detect only P. falciparum are preferred as a general rule, for the detection of *P. falciparum* in all transmission settings, the panel detection score against *P. falciparum* samples should be at least 75% at 200 parasites/µL. (WHO, 2018).

3.3.1 Regulation of mRDTs.

Malaria RDTs should be registered by an authorized regulator body mandated by the Ministry of

Health.

3.3.2 Technical specification of mRDTs

The specifications for the procurement of malaria rapid diagnostic tests (mRDTs) are provided in the malaria commodities catalogue. The specification will be as follows

Section	Specification Details
a) General	• Unit pack size – kit of 25 tests or kit of 10 tests. Single use *Plasmodium falciparum* HRP2 antigen reactive Rapid Diagnostic Test kits packaged with buffer, safety needle, and alcohol swab.
b) Regulatory Requirement	• **International:** Must be WHO Prequalified. • **National:** Valid registration with Pharmacy and Poisons Board (PPB) – listed under *in vitro* diagnostics.
c) Technical	• **Specificity:** Minimum 95% • **Sensitivity:** Minimum 95% • **Antigen detection:** HRP2 or HRP2/PLDH • **Shelf life:** Minimum or ≥24 months on in-country delivery and 75% at manufacture • **Panel Detection Score:** Minimum 75% at 200 parasites/µl • **Invalid rate:** <5% • **False positivity rate:** <10%
d) Physical Requirements	• Test Format: Cassette • Each box of test kits must contain the following items: o 25 cassettes or 10 cassettes, each marked "GOK NOT FOR SALE" or "USAID NOT FOR SALE," foil-wrapped/packed together with buffer o Sample collection pipette o Blood lancet o Alcohol swab o Instruction sheet o Desiccant Shrink wrap
e) Adhere to Specification for RDT Cassette and Accessories	
Item	Specifications
1. Blood Collection Transfer Devices	• Inverted cup or loop with permanent volume mark • Ability to collect/deposit accurate required volume of blood • User friendly
2. Testing Device / Cassette	• Clearly labeled at sample and buffer wells
3. Pricker / Safety Needle	• Adequate to match the number of rapid test kits • Pricker with stopper for safety • Retractable needle • User friendly

3.4 Warehousing and distribution of mRDTs

Warehousing and distribution include aspects of inventory management, which is the process of ordering, receiving, storing, and issuing of mRDTs. Warehousing is undertaken at the central warehouses; while distribution and good storage practices including quality assurance processes focus on movement of commodities from the central warehouses to the health facilities and ensuring commodities are transported in the correct manner to maintain product quality.

Ordering: This requires consumption data, stock on hand, to inform quantity for re-order and it is important to emphasize on credible and reliable data from the health facilities while uploading data into Kenya Health Information System.

Transportation: Quality parameters such as temperature, humidity, cold chain, and light sensitivity should be maintained during distribution.

Receiving: Receipt of mRDTs entails ascertaining that the right commodity, in the right quantities, of the right quality is delivered to the right health facility. It is recommended that the distributor should send a dispatch note to the county pharmacist immediately the commodities are dispatched from the warehouse for distribution to the health facilities.

Storage: Necessary documentation should be maintained: bin cards to be updated every time transactions occur, temperature log chart, expiry tracker, relevant job aids to assist in storage; Store mRDTs at Manufacturer's recommended conditions.

Use: Good diagnostic practices should be observed; malaria rapid diagnostic tests (mRDTs) are recommended for use where microscopy is not available i.e., mainly at community level, dispensaries (level 2) and health centers (level 3). Stock should be rotated to ensure that mRDTs that are expiring first are given priority when issuing, thus following the principle of 'first expiry first out' (FEFO)

All expired, obsolete, or damaged mRDTs should be documented; removed from stock cards (inventory); separated and kept away in a secured location; and disposed with the most appropriate method following the laid down PPB guideline and in due consideration of the legal procedure as laid out in the PPADA.

Commodity data capture and reporting: Documentation of mRDTs should go hand in hand with their use; and aligned to the way they are intended to be documented at health facilities.

CHAPTER 4: TESTING AND BIOSAFETY

Testing and biosafety practices ensure accurate results and protect health workers and patients from infection and environmental hazards.

4.1 Personnel involved in testing

KMLTTB Cap 253A provides for the regulation of personnel performing medical laboratory tests. To achieve effective malaria case management across all levels of care, other Healthcare providers may be allowed to perform mRDT after adequate training and continuous supervision by a registered medical laboratory practitioner. The shift shall require high standards of quality-assured testing,

Roles of Medical Laboratory Personnel in Malaria rapid diagnostic testing

- Train and mentor health care workers including CHPs on the proper use and interpretation of mRDTs
- Train health care workers including CHPs on biosafety and infection prevention control (IPC) practices including waste and sharp management, during testing
- Evaluate compliance to biosafety measures in health facilities and the community
- Coordinate documentation of all biosafety procedures, incidents and training activities
- Investigate incidents occurrences and coordinate corrective actions.
- Provide reports on the usage of mRDTs and biosafety apparatus
- Coordinate distribution of CHPs biosafety kits and mRDTs test kits
- Coordinate quality assurance of mRDTs
- Ensure proper disposal of waste generated during malaria testing in the facility and community
- Reviewing of mRDT test cassettes for quality assurance
- Conduct proficiency testing for mRDT

Roles of CHPs in Malaria rapid diagnostic testing

- Receive training and adhere to the biosafety standard operating procedure applicable to their activities.
- Reporting and recording all relevant accidents, biohazardous exposures, and work-related illnesses to the appointed biosafety officer at the link facility and the supervising CHAA.
- Taking appropriate safety measures to protect themselves, co-workers, clients, community members, animals, wildlife, and the environment.
- Using personal protective equipment as prescribed at all times when conducting the relevant procedures.
- Conduct quality testing using malaria rapid diagnostic tests in accordance with the existing protocols.

4.2 Biosafety during testing

Diagnosis of malaria using mRDTs generates health care waste including used alcohol swabs, cotton wool, gloves, lancets, cassettes, and empty buffer ampoules. Unsafe disposal of hazardous health care waste may increase risks of needle stick injuries and transmission of infectious agents such as hepatitis B, hepatitis C, and HIV.

This section provides guidelines on the implementation of adequate procedures to minimize the overall risks associated with malaria testing procedures at all levels. The main focus shall be the prevention of work occupation-related accidents and prevention and control of infections to healthcare providers, the community, and the environment

Biosafety at the community level

Biosafety Guidelines for Malaria Rapid Diagnostic Testing shall be used at Community Level to ensure CHPs, community, and environment are protected.

Role of facility Health Management Team:

The facility Health Management team shall be responsible for biosafety activities in the communities under their support and supervision.

CHAPTER 5: QUALITY ASSURANCE

The purpose of quality assurance for mRDTs is to ensure reliable, relevant, timely results that are interpreted correctly, thereby increasing efficiency, effectiveness, enhancing user satisfaction, improving patient care, and decreasing the costs due to misdiagnosis.

5.1. Malaria RDTs Quality assurance structure

Quality assurance of mRDTs involves coordination and implementation of quality assurance (QA) activities for mRDT testing. This include lot testing, pre-shipment evaluation of mRDTs, in-country post-shipment evaluation and post market surveillance of mRDTs.

Lot Testing

Lot testing involves evaluation of the diagnostic performance of mRDTs from different manufacturing lots against quality control parasite panels at defined density, to ensure that they perform to the required standard.

Pre-Shipment evaluation of mRDTs

MRDTs are subject to inter-lot variation. WHO, good manufacturing practice (GMP), good laboratory practice (GLP) and good clinical practice (GCP) all require that a sample from each production lot be tested centrally before delivery to ensure that it meets appropriate diagnostic performance standards. When procuring mRDTs, the National malaria program in conjunction with the regulators and KEMSA shall ensure pre-shipment evaluation of mRDTs by the manufacturer in accredited WHO laboratory. This shall be specified in the tendering documents specifically for pre-shipment inspection.

In-country post-shipment evaluation

Lot testing shall be carried out to ascertain that the goods shipped by the manufacturer correspond to those in the tender documents and that no damage has occurred during shipment specified or transport to KEMSA depots before distribution to the last mile. Vendors will be notified to recall shipments not meeting NMCP specifications and requirements in collaboration with NMARL.

Post Market Surveillance of mRDTs

Post-market surveillance (PMS) is the practice of monitoring the safety and performance of products such as mRDTs and accessories, after releasing them in the market as part of quality assurance. The PMS shall be performed by NMCP in collaboration with NMARL and regulatory bodies. This will cover public, private, and community levels. A robust tool to support this work shall be utilized. NMCP shall develop PMS protocols and end-user training to ensure accurate data capture and information transmission.

Post-market surveillance shall include but not limited to the following:

- Confirmation of product registration by all necessary regulatory boards
- Follow up and confirmation of any complaints regarding the mRDT device

5.2 Quality Assurance/Quality control at the user level

Internal quality control

Users of malaria rapid diagnostic tests shall be required to implement internal quality control measures to ensure the reliability and accuracy of test results. All mRDTs shall adhere to standard operating procedures, follow manufacturers' instructions and testing protocols, and must use known positive and negative blood samples for quality control and interpret results correctly. Positive and negative controls shall be recorded as patient samples

External quality assessment

During support supervision, the CHA shall at defined intervals be observed on adherence to testing procedures including waste management. A comprehensive checklist exists to assess the competency level of individual CHPs. Corrective action and measures shall be initiated promptly. Poor performing CHPs shall be retrained and mentored to improve performance and assure the quality of results

Supportive supervision

Routinely scheduled support supervision shall be conducted by qualified and registered medical laboratory personnel every quarter to ensure tests are carried out according to SOPs and the results produced are accurate. A support supervision checklist shall be used during the supervision.

CHAPTER 6: MONITORING & EVALUATION

The purpose of Monitoring and Evaluation of the mRDT implementation framework is to provide the basic performance indicators. The performance parameters to be measured will be based on targeted activities as per the objectives guided by set indicators that lead to periodic evaluation:

Indicators	Source	Frequency of Measuring	Responsibility
Process Indicators			
Number of health service providers trained	Training reports	Quarterly	NMCP, Partners
Number of laboratory personnel trained in mRDT QA & QC	Training reports	Bi-annually	NMCP, CMLC, Partners
Number of health service providers refreshed in mRDT training	Training reports	Bi-annually	NMCP, KNPHI, CMLC, Partners
Number of post-marketing surveillance activities conducted	Post-marketing surveillance reports	Bi-annually	NMCP, KNPHI, KMLTTB
Number of supportive supervisions conducted	Supervision reports	Bi-annually	NMCP, KNPHI, KMLTTB
Number of CHPs conforming to malaria testing standards	Assessment reports	Quarterly	NMCP, KNPHI, Partners

i. Proportion of health facilities without stock-outs of mRDTS, Health facility reports, Quarterly, Health facilities, CDH, NMCP

ii. Proportion of patients with suspected malaria who received an mRDT tests

Indicators	Source	Frequency of Measuring	Responsibility
Outcome Indicators			
Type of mRDT in use	Records	Bi-annually	NMCP, CMCL,

APPENDIX

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