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Contents

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LIST OF ACRONYMS

CHW	community health worker
EQA	external quality assessment
FST	fluorescent spot testing
G6PD	glucose-6-phosphate dehydrogenase
IQC	internal quality control
LMIS	logistics management Information system
NMCP	national malaria control programme
QA	quality assurance
QC	quality control
RDT	rapid diagnostic test
SOP	standard operating procedure
WHO	World Health Organization

PURPOSE OF THIS DOCUMENT

The purpose of this user guide is to outline a common set of practices to be applied across all settings where malaria rapid diagnostic tests (RDTs) are used in routine clinical case management in order to promote quality and safe testing services. Malaria RDTs play a pivotal role in malaria diagnosis, particularly in health facility and community-based settings where there is no laboratory infrastructure or trained laboratory personnel. Consequently, RDT services are often provided by non-laboratory personnel in pharmacies, drug shops, outpatient departments, clinics and dispensaries and through community-based programmes. While the focus of this guide is on malaria RDTs, it is important to note that the safety and quality practices described in this guide may be applicable to other RDTs (including RDTs for HIV, COVID-19, syphilis, pregnancy and dengue fever) and their performance in different settings.

The guide is aimed at national malaria control programmes (NMCPs) and agencies, or bodies involved in the implementation, management and/or oversight of malaria RDT services, including regulatory bodies, funding and procurement agencies, and RDT providers in both the private and public sectors. This guide is also aimed at people who own or manage health facilities where RDTs are used, who may not be involved in testing patients themselves, but who are responsible for ensuring that testing personnel maintain quality and safety practices. Outlining these safety and quality practices is intended to:

- provide technical and operational guidance to NMCPs wishing to strengthen RDT testing, particularly in non-laboratory settings, or those intending to roll out RDTs to non-laboratory settings;
- outline the critical components of an RDT testing quality management system at all levels that will ensure the quality of results while safeguarding testing personnel and the environment;
- guide regulators, policy-makers and professional bodies on the practices that need to be enforced to ensure quality-assured results and personnel safety;
- guide policy-makers and implementers in resource mobilization to ensure that testing facilities comply with required quality and safety practices.

Following the safety and quality practices laid out in this document will ensure the safety of patients and health workers administering the tests, as well as accurate and reliable test results at all levels in both the private and public sectors. It is also hoped that these principles and practices will be extended to point-of-care testing for other diseases.

KEY POINTS

Good practices for rapid diagnostic testing services should be in place at all points of care across the health sector and these should include the following:

- Proper policies and standard operating procedures should be in place and enforced by regulatory authorities.
- Testing facilities should be accredited, and testing personnel trained and authorized to conduct rapid diagnostic tests (RDTs).
- Testing facilities should have a system for clinical governance and appoint a person who is responsible and accountable for the RDT services.
- RDTs should be stored in suitable environments and stock management systems should be in place.
- Testing should only be conducted in appropriate environments with proper equipment.
- Only quality-assured RDTs should be used, and they should be suitable for the malaria epidemiology of the country.
- Proper safety and waste disposal practices should be followed at all testing sites.
- All adverse incidents with RDTs should be reported, investigated and resolved with cooperation of users, clients, manufacturers and national regulatory authorities.
- Quality assurance – both internal (including regular audits) and external – is a crucial component of an RDT programme and should be carried out regularly. Actions should be taken to rectify any failures in quality checks.

1. INTRODUCTION

In the past, fever was equated with malaria in many malaria-endemic countries. However, recent control efforts have significantly reduced the malaria burden, even in high-transmission areas of Africa. Improved access to and targeting of antimalarial drugs has been a major factor in the fight against malaria globally. Prompt, accurate diagnosis and treatment of malaria is essential for any malaria control programme, with the aim of febrile patients accessing treatment within 24 hours of onset of fever. While malaria diagnosis has historically been based on symptoms alone, parasitological diagnosis is good clinical practice and ensures better targeting of antimalarial treatment. Continued presumptive treatment of malaria may result in drug wastage, antimalarial drug resistance and undertreatment of other febrile illnesses. WHO recommends that all cases of suspected malaria have a parasitological test (microscopy or RDT) to confirm the diagnosis, and that both microscopy and malaria RDT testing be supported by a quality assurance (QA) programme *(1)*. Microscopy, which enables visualization of malaria parasites, species identification and parasite quantification, has remained the gold standard for clinical malaria diagnosis.

WHO also recommends the use of patients' glucose-6-phosphate dehydrogenase (G6PD) status to guide the administration of primaquine for preventing relapse. Primaquine is used for treating relapses of *Plasmodium vivax and P. ovale* malaria, due to its specific activity against malaria hypnozoites. The objective of using primaquine is to provide radical cure to prevent relapse of illness and recrudescence of infectivity *(1)*. However, this medicine induces dose-dependent acute haemolytic anaemia in individuals with G6PD deficiency, a genetically X-linked disorder. G6PD status is, however, rarely known, except in a few countries (e.g. Malaysia and the Philippines) where G6PD testing is part of newborn screening programmes. Quantitative G6PD testing using spectrophotometric assays and cytochemical assays provide precise measurements of G6PD activity. However, these tools require a cold chain, laboratory equipment and skilled laboratory technicians, and are expensive to deploy and maintain *(2)*. As an alternative, for several decades, fluorescent spot testing (FST) has been recommended as a semiquantitative test to screen for G6PD deficiency. Although technically less complex, FST is still reliant on a power source (for a water bath), UV light and refrigeration for reconstituted reagents and controls. More user-friendly point-of-care G6PD tests have been commercialized. Some are lateral flow tests, similar to malaria RDTs, whereas others require hand-held instruments. Expanded use of these tests in *P. vivax*-endemic areas is expected in the coming years, and many of the practices outlined in this document will apply.

In many malaria-endemic areas, the capacity for microscopy has remained a challenge. Most malaria patients live and seek care in resource-limited peripheral health care facilities in countries where ensuring good-quality malaria microscopy at all levels of the health care system has not been feasible *(3,4)*.

Malaria RDTs work by detecting antigens in the blood from a single finger prick. Conducting malaria RDTs and interpreting their results require less training and experience than microscopy, and their diagnostic performance does not depend on the availability of highly trained laboratory technicians. WHO, therefore, recommends the use of malaria RDTs in cases where quality-assured malaria microscopy is not readily available *(1)*.

RDTs can be performed by non-laboratory personnel in pharmacies, drug shops, outpatient departments, clinics and dispensaries, through community-based programmes, and in many other settings where there are no laboratories. The

introduction of RDTs that require no electricity or laboratory facilities and are easily performed in remote rural settings has made it possible to achieve the WHO recommendation for parasitological confirmation before treatment and the use of patients' G6PD status to guide administration of primaquine for preventing relapse.

A wide range of health workers perform RDTs, including community health workers (CHWs), drug shop attendants, pharmacy technicians, pharmacists, nurses and doctors. CHWs are members of the community who are increasingly being used to access remote populations. These workers have educational levels that range from primary school leavers or below with no qualifications, to tertiary-level graduates with medical diplomas and degrees. The testing environments also vary and can include well equipped, specifically designated RDT testing rooms, multipurpose outpatient consulting rooms, drug-selling points and informal settings such as the patient's house. In cases of community outreach, the testing area is usually a small table and chair carried from place to place *(5,6)*.

Despite the reduced technical capacity required to conduct RDTs compared to microscopy, the massive and diverse groups of operators and diverse settings of use means that a common set of practices must be agreed upon, widely disseminated and enforced in order to ensure the quality and safety of RDT testing services. For example, conducting training and regular supervision, and ensuring that RDTs are performed under the recommended conditions are as essential for RDTs as they are for microscopy. RDT service providers should ensure compliance with all local laws and regulations to ensure patient and health worker safety, as well as accurate diagnosis and treatment of patients.

2. ROLES AND RESPONSIBILITIES FOR SAFE ADMINISTRATION OF RDTs

Ensuring that safety and quality practices are adhered to requires participation of stakeholders from all levels of the health system, including national, subnational and local levels. The roles and responsibilities of some key stakeholders involved in RDT testing are discussed below.

2.1 Ministries of health

NMCPs, which operate under ministries of health, are responsible for the overall oversight and coordination of national RDT services. They coordinate with several stakeholders, review progress of the programmes and implement QA programmes. NMCPs play a pivotal role in developing malaria diagnostic policies. Steering committees and technical working groups are usually created to review and manage certain aspects of the programme along with other stakeholders.

2.2 Regulatory bodies

The role of and level of involvement of regulatory bodies in RDT services will vary depending on the country. Regulatory bodies participate in the development and review of regulations and enforce compliance. They are involved in the QA of the testing services and conduct safety monitoring. They are responsible for registering RDTs based on assessments of the quality and safety specifications set by the ministry of health, ensuring that only registered RDTs are in use, and ensuring proper transportation and storage of RDTs. They determine who can test and which facilities can provide RDT services. They also have a role to play in the post-market surveillance of RDTs.

2.3 RDT providers

RDT providers include public and private sector health facilities and outlets, and community-level testing programmes. They may range from large hospitals to individuals such as CHWs, private providers such as pharmacies or drug stores, and informal itinerant vendors and general stores. CHWs are usually associated with a larger organization or body, such as a health facility, nongovernmental organization or local-level ministry of health, and are managed and monitored by that body. The types of facilities that are permitted to perform RDTs vary depending on a country's policies and regulations. Testing facilities and personnel are required to adhere to the country's policies and regulations. RDT providers have a role to play by adhering to all set national policies, regulations and guidelines.

Safety and quality performance in both private and public sectors is very heterogeneous across different countries, but several studies have highlighted safety and quality deficiencies in developing countries. These deficiencies include recommended procedures not being followed, infrastructural deficiencies in testing areas, poor waste management practices and supply chain issues *(4,7)*. The practical information in this guide is therefore critical in addressing challenges due to infrastructural deficiencies, lack of training, poor quality control (QC) measures, use of poor-quality RDTs, and deficiencies in supervision and enforcement of national policies, regulations and guidelines. NMCPs should ensure participation of both private sector and public sector providers in quality monitoring and improvement activities. RDT providers can use this guide as an audit tool to identify areas in need of improvement.

3. QUALITY ASSURANCE PROGRAMME

Countries should have a functional QA programme with clearly defined goals to monitor and continuously improve the quality of RDT testing. While the central-level ministry of health is usually responsible for implementing an RDT QA system nationwide, every level and all testing personnel have a role to play to ensure the success of the QA programme. The QA programme should have a national coordinating agency or coordinator; this can be part of a larger malaria diagnosis (RDT and microscopy combined) QA programme. The responsibilities of the QA coordinating agency or coordinator vary, but may include:

- coordinating all malaria RDT QA/QC activities;
- developing and reviewing training curricula, standard operating procedures (SOPs), job aids, internal QC sheets and results logbooks;
- preparing and overseeing national QA/QC implementation plans;
- preparing a budget to support the implementation plan;
- compiling and presenting summary reports on the QA/QC programme;
- participating in setting the RDT kit specifications as per WHO recommendations;
- conducting regular internal audits of testing facilities;
- providing oversight of the supervision scheme;
- coordinating relevant post-market surveillance activities.

More information can be found in the *Malaria microscopy quality assurance manual, version 2*, where there is a description of the principles of setting and running a malaria microscopy QA programme; these principles are also applicable to RDTs *(8)*. The QA programme should be supported by a national reference laboratory, core group of RDT master trainers, and intermediate/provincial-level focal people and supervisors. Key activities within the QA programme include having appropriate policies and guidelines, a functional training programme, QC, and regular supportive supervision and assessment.

4. RECOMMENDED QUALITY AND SAFETY PRACTICES

4.1 Regulations and policies

Setting policies and regulations that include minimum performance requirements for the importation and registration of RDTs is vital for both procurement agencies and service providers. Minimum performance requirements should follow the requirements for WHO prequalification *(9)*. Regulations should ensure the delivery of RDT services only in registered/licensed facilities and by trained and competent personnel. Ideally, regulatory bodies should have the required legal instruments and mandate, capacity and enforcement mechanisms to regulate the importation of RDTs, the premises where testing is performed and the personnel performing the tests in both public and private sector health facilities.

NMCPs should support RDT providers to achieve safety and quality by developing and disseminating QA/QC guidance, post-market surveillance guidance, testing algorithms and reporting formats. NMCPs should have the capacity and mechanisms to monitor adherence to national diagnostic guidelines, and provide regular training and technical assistance to RDT providers where necessary.

4.2 Certification and accreditation

Providers should be trained and recognized by relevant authorities as RDT providers, in line with national regulations. Recognition can be in the form of registration/licensing, certification, authorization letters to perform RDT testing or ministry of health policy allowing such task shifting. Testing facilities, including informal facilities, should have permission to perform testing from relevant authorities. Ideally, they should be registered/licensed to sell and/or perform RDTs. Testing facilities should follow practices laid out in EN ISO 22870:2016 *(10)*. In addition, testing facilities should follow local town/state regulations or by-laws relating to business licences, premises licences, safety and waste management laws. This also applies to where RDT testing is performed by lay providers as part of outreach programmes to communities or schools.

In all cases, operators of RDTs should:

- ☐ follow national testing guidelines, testing algorithms and reporting formats;
- ☐ be trained to perform RDTs and related tasks;
- ☐ perform only tests and tasks that are allowed at their operational level;
- ☐ keep all training records and business licences/written authorizations up to date.

4.3 Personnel requirements to deliver RDT services

Testing facilities should have adequate[1] personnel with sufficient time and skills to reliably and accurately perform all activities needed for testing, in addition to their other duties. High turnover of personnel in testing facilities can lead to loss of skills and experience, so mechanisms should be in place to ensure that all staff are suitably trained.

Testing personnel should:

- ☐ have the recommended literacy level to be able to read and understand testing instructions and record results legibly; where necessary, manufacturers' instructions should be translated into a language well understood by all testing personnel;
- ☐ have good physical and mental ability and motivation to perform testing;
- ☐ have good visual acuity; vision should be assessed for acuity and colour-blindness, which could affect the ability to read results;
- ☐ be regularly visited by relevant subnational or national authorities as part of quality improvement support;
- ☐ have clearly defined roles and responsibilities.

While facility owners do not necessarily need to have a health professional background, they should demonstrate a commitment to the quality of testing services by complying with applicable regulatory requirements and promoting good laboratory practices. It is the duty of facility owners to facilitate the participation of testing personnel in refresher training and provision of job aids translated into the local language, where necessary, for all testing personnel. Annex 1 provides an example of a malaria RDT personnel assessment checklist.

4.4 Designated responsibilities

The roles and responsibilities of testing personnel, testing facility owners and managers should be clearly defined. Roles and responsibilities of testing personnel and operators of testing facilities include performing the tests, reporting the results, compiling and reporting surveillance data, and adhering to national safety and waste management guidelines.

In the absence of a suitably qualified facility supervisor and/or manager, it is recommended that testing facilities have at least one person designated as a focal person for RDTs, who is responsible for good governance of the RDT services *(11)*. The designated individual should have national and institutional knowledge of RDT regulations and guidelines, in addition to experience performing malaria RDTs. This person can be the focal person for other RDTs, such as those for pregnancy, HIV or syphilis, and should have the appropriate background and knowledge to be responsible for testing oversight and making key decisions about the testing facility. In facilities with medical laboratories, a laboratory technician is the preferred focal person for RDT testing. The focal person is responsible for supportive supervision of RDT testing at facility level, compliance with safety standards, stock management of RDTs at the facility, documenting challenges encountered by testing personnel, and liaising with the national programme on issues to do with the training of testing personnel, QA and post-market surveillance. For facilities manned by a single person, that person should have the above-mentioned competencies. NMCPs can also have subnational or subregional RDT focal persons.

[1] Adequate personnel is measured by the ability of the health facility to ensure the availability of parasitological test results within two hours of patients presenting.

4.5 Selection and procurement of RDTs

The NMCP in each country is responsible for the selection and procurement of appropriate RDTs; WHO provides guidance on this process *(9)*. Consideration must be given to products registered in the country and their alignment with WHO prequalification lists, target species, the prevalence of *pfhrp2/3* deletions in the country, suppliers' production capacity and delivery schedules, shelf life and storage capacities. Regulatory bodies, in collaboration with the NMCP, should have a list of approved/registered RDT kits from which private sector providers and other implementing partners such as nongovernmental organizations can choose.

Procurement agencies are encouraged to avoid frequent changes of RDT brands, as changes may require revisions to job aids and other supporting tools, which can be costly and time-consuming. Nevertheless, it is critical for RDT providers to be sensitive to the fact that protocols of the same brand and between brands can change over time; therefore, measures to regularly review job aids should be in place.

4.6 Supply chain and stock management of RDTs

Strict monitoring of RDT stock is essential from the central warehouse down to individual CHWs and testing facilities. In the public sector, logistics management information systems (LMISs) should be in place at the national level to monitor supply needs, quantification, procurement, transportation, consumption and financial transactions associated with RDT supplies in the country. Warehouses and testing facilities should have inventory or stock management mechanisms, such as the use of stock bin cards (Annex 2), to prevent RDT overstocking, understocking and expiries while in storage. Stock bin cards are used to monitor how many RDTs are in stock at any given time, and to record the number of RDTs ordered, received and consumed. The stock bin cards should record at least the following information:

- ☐ stock in/stock out
- ☐ lot/batch numbers of RDTs
- ☐ expiry dates of the batches of RDTs
- ☐ average monthly consumption
- ☐ minimum stock levels (the stock level at which RDTs should be reordered)
- ☐ maximum stock levels (the total quantity of RDTs to meet the needs of the facility or catchment area).

The NMCP should also have in place a plan for dealing with any overstock that may occur, and for coordinating and monitoring the redistribution of stock between health facilities or subnational levels. All facilities, including warehouses at the national level, should use "first in, first out" (FIFO) and "first expiry, first out" (FEFO) strategies to limit expiration of RDTs.

Testing personnel at lower level facilities and CHWs should check and refill their own RDT kits regularly to avoid over or understocking RDTs. They should avoid storing large quantities of RDTs, but rather obtain supplies in smaller batches more often. The *Guide for malaria commodities logistic management systems* provides more information on LMISs *(12)*, along with the *Supply chain manager's handbook: a practical guide to the management of health commodities (13)*.

4.7 Storage of RDTs

Testing facilities and central warehouses should have adequate and safe storage areas for testing kits and accessories. RDTs should always be stored in line with manufacturer's instructions. Transportation and storage of RDTs should ensure that RDTs are not subjected to temperatures that exceed the manufacturer's recommended temperature ranges. Warehouses stocking RDTs should:

- ☐ have adequate storage area under the manufacturer's recommended environmental conditions (temperature, humidity and moisture);
- ☐ be air-conditioned or located in the coolest part (except freezing or very cold areas) of the building/facility;
- ☐ be protected from moisture: i.e. no leaks in the roof; a sealed floor; an area that is not vulnerable to flooding;
- ☐ have temperature monitoring mechanisms;
- ☐ have restricted access to storage areas of test kits and other accessories;
- ☐ have rodent control mechanisms to protect the supplies from rats and mice.

Among other conditions, RDTs should be stored at least 30 cm away from walls and at least 1 m from the ceiling to avoid exposure to heat radiating from the walls and ceiling. They should be stored as close to the floor as possible (but at least 10 cm above the floor) and away from direct sunlight.

CHWs and health facilities should also have suitable storage conditions for RDTs to avoid exposure to high temperatures. CHWs may be required to store RDTs in their houses or other undesignated places and so should try as much as possible to follow the guidance above when storing their supply of RDTs. Further practical guidance on transporting, storing and handling malaria RDTs is provided in the *Transporting, storing, and handling malaria rapid diagnostic tests* manual *(14, 15)*. An example of a temperature recording form for central warehouses can be found in Annex 3.

4.8 Infrastructure and equipment at the testing site

Testing should be conducted in places with suitable environmental conditions and with all required accessories and equipment.

Specifically, the testing room/space should:

- ☐ have adequate room to enable the tester to work safely and efficiently without unnecessary distractions, ensuring ease of specimen collection, waste disposal and test performance;
- ☐ have mechanisms for controlling the temperature to the manufacturer's recommended operating temperature range; this will be more difficult for CHWs, but care should be taken to find the most suitable space in which to conduct the test;
- ☐ have sufficient lighting (natural or electric) to ensure good specimen collection, test performance and interpretation of test results;
- ☐ have functional clocks or timers to monitor incubation time;

- ☐ have work surfaces that are clean and level, preferably a bench or table made of a material that can be disinfected with bleach and that has no gaps, cracks or surface damage, with a chair or stool for the tester;
- ☐ have provisions for safe disposal of sharps, clinical and non-clinical waste;
- ☐ have easy access to appropriate instructions for use and/or job aids for the RDTs used in the testing setting.

The testing facility/site should ensure confidentiality of patient information, including patient identification, test results and records. To ensure patient confidentiality the testing facility/space should:

- ☐ have a designated place to maintain patient privacy, so that other clients cannot see test results or hear communication between provider and client;
- ☐ have a secure storage system and location to prevent unauthorized access to patient records.

To ensure patient confidentiality, testing personnel should:

- ☐ avoid sharing patient information with any other person besides the client and requesting clinician; this includes issuing results only to the patient (or parent/guardian of a child);
- ☐ safely dispose of labelled cassettes used for testing patients such that the public has no access to read results from the used cassettes.

4.9 Waste management and infection control

Proper waste management and infection control practices are necessary to safeguard testing personnel, patients and the environment. SOPs for the management of waste from malaria diagnostic tests can be found in Annex 6 of *Universal access to malaria diagnostic testing (16)*.

Testing facilities and personnel should, therefore, adhere to safety and waste management practices and ensure that proper waste management is adhered to at the testing site. Adequate supplies must be brought to the testing site to allow for this, and waste should be disposed of appropriately after the test.

The testing facility/site should:

- ☐ have a hand basin and continuous supply of water and soap or soap dispensers (or antiseptic hand-washing solutions) for the washing of hands;
- ☐ have paper towels and/or hand dryers for the drying of hands;
- ☐ have adequate supplies of personal protective equipment (PPE) such as disposable masks and gloves;
- ☐ have sharps boxes to dispose of sharps including lancets and needles;
- ☐ have biohazard trash bags and bins to dispose of infectious non-sharps waste such as used gloves, used cassettes, cotton wool and alcohol swabs;
- ☐ have 10% hypochlorite, 70% alcohol or equivalent surface disinfectant to regularly disinfect the testing surfaces;

- ☐ have a procedure to prevent injury with contaminated sharps, deal with such incidents, and ensure post-exposure evaluation and follow-up for testing personnel in the event of an "exposure" incident;

- ☐ have an effective biohazard waste disposal process, while CHWs should have a method of disposing of biohazard waste safely at a suitable testing facility or disposal site.

All testing personnel should:

- ☐ have the required safety and waste management training;

- ☐ have all their required vaccines, which may include hepatitis B and COVID-19 vaccines;

- ☐ practice basic laboratory safety measures, e.g. not eating, drinking, storing food or applying make-up where testing supplies or specimens are collected or where testing is performed;

- ☐ disinfect work surfaces at the beginning and end of each testing session.

More information on post-exposure prophylaxis after exposure to potentially HIV-contaminated sharps is contained in the WHO guideline on *Post-exposure prophylaxis to prevent HIV infection (17)*. For more information on the management of biohazard waste, refer to the WHO guideline on the *Management of solid health-care waste at primary health-care centres (18)*.

4.10 Reporting and record-keeping

Recording, compiling and reporting all testing data is critical for the overall analysis of trends, stratification and planning of resource allocation *(19)*. The testing facility or personnel should therefore record, compile and report all surveillance data to the relevant authorities as per national guidelines.

The testing facility or personnel should:

- ☐ record all RDT results in a results book/sheet or electronic system;

- ☐ compile weekly and monthly surveillance data and report them in a timely manner to the relevant authorities as may be required;

- ☐ keep legible, readily identifiable and retrievable records, as required by national surveillance guidelines, and make them available to the relevant authorities when requested.

NMCPs are responsible for:

- ☐ implementing and updating health information management systems and data reporting forms for RDT use;

- ☐ distributing reporting forms;

- ☐ designing templates for data entry and analysis;

- ☐ training staff to analyse data;

- ☐ analysing incoming data to calculate malaria indicators;
- ☐ providing feedback to subnational levels, providers and communities on the timeliness and completeness of reporting.

4.11 Post-market surveillance

A strong post-market surveillance system is required to protect individual and public health through combined efforts of multiple stakeholders, including users and clients/patients, manufacturers and their economic operators, and national regulatory authorities (Table 1). More information can be found in the WHO handbook *Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics* and *Troubleshooting for supervisors overseeing users of malaria RDTs (20, 21)*.

TABLE 1. Stakeholders' roles in post-market surveillance and market surveillance of medical devices, including in vitro diagnostics *(20)*

Stakeholder	Activity	Details
I Users and clients/patients (see **Part I** of this document)	Observe/detect issues	Users, and their clients/patients should be vigilant for issues with medical devices.
	Document feedback	Users should document the product codes/serial numbers/lot numbers and expiry dates of affected medical devices at the very least.
	Provide feedback	Users are encouraged to provide feedback to the manufacturer as soon as they become aware, and to inform their NRA at the same time, as applicable.
	Follow manufacturer's instructions	Users will be informed of important information on the use of the medical device via an FSN and should act as instructed in the FSN.
II Manufacturers and their economic operators (see **Part II** of this document)	Implement a system for post-market surveillance	An effective post-market surveillance system should include both active and passive collection of post-market information. Collecting and evaluating feedback are critical.
	Classify feedback and escalate if required	Manufacturers must establish a documented procedure for a feedback system and be able to quickly classify feedback.
	Establish if reporting to NRA is required	The manufacturer needs to establish if reporting to the NRA is required. Initial, follow-up and final investigation reports should contain all details of any investigation conducted.
	If required, undertake root cause analysis	The manufacturer should perform root cause analysis to establish the root cause for the issue, allowing adequate action to be initiated. Corrections and corrective/preventive actions may also be required to protect public safety.
	If required, make a correction	
	If required, implement corrective and/or preventive actions	

Stakeholder	Activity	Details
III NRA (see **Part III** of this document)	Ensure user feedback is forwarded to manufacturers	If NRAs receive feedback directly from users, they should forward user feedback to the manufacturer, with a copy to the local economic operator. The NRA may also conduct a risk assessment.
	Conduct risk assessment, as appropriate	
	Collect reports, review manufacturer investigation and other actions	NRAs should collect investigation reports (initial, follow-up, final), and review for evidence of documented procedures, timeliness and scientific rigour.
	Conduct or coordinate testing using a risk-based approach	NRAs may coordinate testing using a risk-based approach.
	Collect other market information	NRAs should strive to collect other forms of market intelligence.
	Take regulatory action, if needed, and ensure its implementation	NRAs may need to undertake their own regulatory action, if the manufacturer does not take adequate actions or not in a timely manner. The NRA may also undertake actions when they consider that the observed issues have wider implications.
	Share information with other NRAs and/or WHO, if applicable	NRAs should share information with other NRAs.

Testing personnel play a role in identifying product defects and/or associated adverse incidents and making reports to responsible authorities, including their supervisors and RDT focal persons. These should be transferred to the NMCP, which in turn will involve the regulatory authority. The regulatory authority has a role to compile all complaints, verify complaints coming from health facilities, carry out investigations and make appropriate reports to WHO and/or the manufacturer. Annex 5 provides an example of a malaria RDT supervisor reporting form for RDT kit problems and RDT anomalies.

Participation in the WHO malaria RDT lot testing programme, operated by the Research Institute for Tropical Medicine (RITM), Philippines, should be undertaken to screen RDTs for major defects prior to deployment and post-shipment to ensure that transport conditions have not negatively affected product performance, and/or to assess the accuracy of tests when there are concerns about a product defect post-deployment.

Information on how to participate in WHO lot testing pre- and post-purchase can be found at https://www.who.int/teams/global-malaria-programme/case-management/diagnosis/rapid-diagnostic-tests/lot-testing

4.12 Quality control

Testing facilities and personnel should perform QC as stipulated in their national malaria diagnosis QC guidelines. QC is a set of activities or techniques to ensure that all quality requirements are being met. It is loosely divided into internal quality control (IQC) and external quality assessment (EQA). Testing facilities and/or testing personnel should perform IQC activities to ensure reliable and accurate test results, and the NMCP or associated entity should conduct EQA of all RDT testing facilities to monitor and continuously improve the quality of RDT testing.

IQC comprises activities done at the point of testing. The objective is to ensure that reliable and accurate test results are always produced by monitoring the pre-analytical, analytical and post-analytical phases of RDT testing. The purpose of IQC is to immediately detect and correct errors that might arise due to test system failure, adverse environmental conditions and/or operator performance. It also aids in monitoring the accuracy and precision of tests over time and rectifying any system deficiencies *(22)*. Facility managers, RDT focal persons and managers of RDT testing programmes should ensure that facilities and testing personnel perform IQC.

Below is a list of some of the IQC activities that are important for ensuring accurate and reliable RDT results.

Pre-analytical

- ☐ Ensure correct and consistent identification of patient and blood samples for testing.
- ☐ Ensure that the test device pouch is not expired and/or damaged before testing.
- ☐ Open the device package immediately before testing.
- ☐ Check the colour of the desiccant pouch each time a test device is opened to see whether it conforms to the manufacturer's recommendations.
- ☐ Keep and refer to product instructions/kit inserts during testing.

Analytical

- ☐ Perform the RDT procedure as per the manufacturer's instructions, e.g. using the correct volume of sample and buffer.
- ☐ Read the test results within the timeframe stipulated by the manufacturer.
- ☐ Take into consideration the presence or absence of the control band/line. The test is considered invalid if the control band does not appear, and, in such cases, the test should be repeated with a new test device. The control line only confirms that the test has run and does not provide information on the accuracy of the test result.
- ☐ Leftover buffers from one kit should not be used when performing tests using a different kit.
- ☐ A few manufacturers provide control materials with RDTs (either in the kit or sold separately). These may be helpful to identify when performance has been compromised. WHO has also provided guidance to manufacturers on how to produce appropriate control materials for antigen-detection RDTs, but it is unknown whether these will become available in the future *(23)*.

Post-analytical

- ☐ Promptly report and send results to requesting clinicians.

The testing facility/personnel should record and keep all IQC data in RDT QC registers/sheets to be inspected by supervisors during on-site visits.

EQA enables comparison of the performance of RDT providers in an area or country. All testing facilities should participate in an EQA programme that involves regular on-site supportive supervision. Supervisors should use standardized supervisory checklists that provide an overview of malaria diagnostic services at the site. The supportive supervision should be conducted by well trained and certified supervisors. The aim of the on-site supportive supervision is to identify and correct deficiencies in supply, storage, testing procedures, equipment and training status of personnel, and to review testing personnel practical skills, workload, safety, waste management, performance of IQC, reporting and record-keeping. Data gathered should be used to compare performance among different test sites; provide early warning for systematic problems associated with RDT kits or operations; indicate areas in need of improvement; identify training needs; and assure customers, including patients and health authorities, that testing facilities are producing reliable results *(20)*.

The testing facility/personnel should participate and cooperate with supervisors during EQA visits. Annex 6 shows a checklist of activities related to quality management of RDT provision and how frequently each activity needs to be completed.

4.13 Training

Regular standardized training and refresher training are essential to maintain the competency of testing personnel. To ensure the quality of the training programme, trainers should be certified as competent before conducting trainings; training should be conducted according to standardized training curricula; and there should be regular training of trainers and competency assessment for all trainers. Given the broad range of testers, trainers and supervisors must be selected from a range of backgrounds in order to facilitate the long-term sustainability of training, refresher training and supervision that will be required to meet the needs across the health sector. Trainers or supervisors may include pharmacists, allied health professionals, drug vendor shop managers, etc. The training programme should target all testing personnel and cover both public and private sector sites where RDTs are in use. Trainers are often used as QA supervisors and, as a result, should have the necessary training in quality management systems, good laboratory practice and supervision of RDT testing sites.

A training programme with sufficient practical sessions on performing malaria RDTs is recommended. However, in certain countries and environments, this may be challenging, as training is cascaded from trained people to non-trained personnel as on-the-job training at facility level. Where training is cascaded, measures should be put in place to ensure that the quality of the training is maintained. The training programme should also include continuing education/refresher training for testing personnel. Training can be delivered through instructional videos, workshops, computer-based programmes, and other methods. Records of training should be kept at all levels

An example of a timetable for a training session for RDTs can be found in Table 8 of *Universal access to malaria diagnostics (16)*. More information on training health workers in using RDTs, troubleshooting and on useful job aids can be found in the WHO/FIND malaria instructions and training materials *(21,24,25)*.

5. CONCLUSION

Since the global scale-up of RDTs, they have played an increasingly important role in malaria case management and have been a vital tool for improving clinical effectiveness. While the expertise required is significantly less than that for microscopy, there are still critical practices that should be adhered to in order to ensure the best performance and safety for both the patient and test operator. Advances in malaria control and eventual elimination will require coordinated efforts across both public and private health sectors and, therefore, will require engagement, cooperation and allocation of responsibilities to train, supervise and monitor RDT testing services by new stakeholder groups. Only through a common set of practices can standards be kept high across the entire testing spectrum. The practices laid out in this document facilitate a safe and effective system for providers at all levels of the health system to introduce, monitor and improve the performance of RDTs.

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7. ANNEXES

Annex 1: Malaria RDT personnel assessment checklist (adapted from the Botswana national malaria diagnosis QA/QC guidelines, 2022)

Annex 2: Malaria commodity stock bin card

Annex 3: Central warehouse malaria RDT temperature monitoring form

Annex 4: Malaria RDT facility assessment checklist (adapted from Botswana national malaria diagnosis QA/QC guidelines, 2022)

Annex 5: Malaria RDT supervisor reporting form for RDT kit problems and RDT anomalies (adapted from the FIND Protocol on responding to problems with malaria RDTs)

Annex 6: Activities required for quality management of RDT testing

ANNEX 1: . MALARIA RDT PERSONNEL ASSESSMENT CHECKLIST (ADAPTED FROM THE BOTSWANA NATIONAL MALARIA DIAGNOSIS QA/QC GUIDELINES, 2022)

GENERAL INFORMATION

Name of facility:	
Name of health district:	
Name of testing personnel:	
Profession of testing personnel:	
Name of assessor(s) and affiliation:	
Date of assessment:	
RDT in use (product name and code)	

1. Information on testing personnel			
1.1 Do testing personnel have the recommended literacy level to read and understand testing instructions?	☐ Yes	☐ No	☐ Cannot determine
1.2 Do testing personnel have good physical and mental ability?	☐ Yes	☐ No	☐ Cannot determine
1.3 Do testing personnel have good visual acuity?	☐ Yes	☐ No	☐ Cannot determine
1.4 Do testing personnel have the required vaccinations?	☐ Yes	☐ No	☐ Cannot determine
1.5 Are testing personnel trained in malaria rapid diagnostic testing?	☐ Yes	☐ No	☐ Cannot determine
1.6 Do testing personnel have clearly defined roles and responsibilities?	☐ Yes	☐ No	☐ Cannot determine
1.7 Do testing personnel report confidence in the results of malaria RDTs?	☐ Yes	☐ No	☐ Cannot determine
1.8 How many years have the testing personnel been performing malaria RDTs?	☐ Yes	☐ No	☐ Cannot determine
1.9 How many tests do the testing personnel perform per month on average?	☐ Yes	☐ No	☐ Cannot determine

2. Demonstration/observation of malaria RDT procedure					
Was this test done on a real patient? **Circle the correct answer: 1= Yes 2= No.**					**Comments**
For each step below, circle 1 if the health worker performed the step correctly; circle 2 if the health worker performed the step incorrectly; circle 3 if the health worker skipped the step; circle 4 if not evaluated					
2.1 Assemble all the required accessories (kits, 70% alcohol swab, dry cotton swab, buffer, pipette, sharps container, lancet & gloves).	1	2	3	4	
2.2 Use clean testing basin/surface for the pipette and dry cotton swab.	1	2	3	4	
2.3 Put on a new pair of gloves.	1	2	3	4	
2.4 Check expiry date on test kits and buffer.	1	2	3	4	
2.5 Open the device package immediately before use.	1	2	3	4	
2.6 Check the colour of the desiccant pouch.	1	2	3	4	
2.7 Write patient's name/ID on test kit.	1	2	3	4	
2.8 Place testing cassette on a level surface.	1	2	3	4	
2.9 Clean finger with antiseptic/alcohol.	1	2	3	4	
2.10 Allow finger to dry before pricking it.	1	2	3	4	
2.11 Use a sterile lancet for finger prick.	1	2	3	4	
2.12 Puncture off centre on the fingertip.	1	2	3	4	
2.13 Dispose lancet in sharps bin immediately after pricking finger.	1	2	3	4	
2.14 Avoid air bubbles during sample collection.	1	2	3	4	

2. Demonstration/observation of malaria RDT procedure					
Was this test done on a real patient? Circle the correct answer: 1= Yes 2= No.					**Comments**
For each step below, circle 1 if the health worker performed the step correctly; circle 2 if the health worker performed the step incorrectly; circle 3 if the health worker skipped the step; circle 4 if not evaluated					
2.15 Collect enough blood with the collection device for testing.	1	2	3	4	
2.16 Correctly dispense blood with device.	1	2	3	4	
2.17 Put correct volume of blood on testing device.	1	2	3	4	
2.18 Dispose of blood collection device in a biohazard bag immediately.	1	2	3	4	
2.19 Dispense buffer with the bottle in an upright position.	1	2	3	4	
2.20 Dispense the correct number of drops of buffer.	1	2	3	4	
2.21 Incubate the test for the right amount of time.	1	2	3	4	
2.22 Read test results correctly.	1	2	3	4	
2.23 Interpret the results correctly.	1	2	3	4	
2.24 Record the results in a register.	1	2	3	4	
2.25 Dispose of gloves, wrappers, alcohol swabs and desiccant safely.	1	2	3	4	

3. CHALLENGES
3.1 What challenges does the health care worker face in the process of doing his/her duties?

ANNEX 2: MALARIA COMMODITY STOCK BIN CARD

Commodity name: _____ **Commodity code:** _____ **Supplier:** _____

Average monthly: consumption: _____

Maximum stock: _____ **Minimum stock:** _____

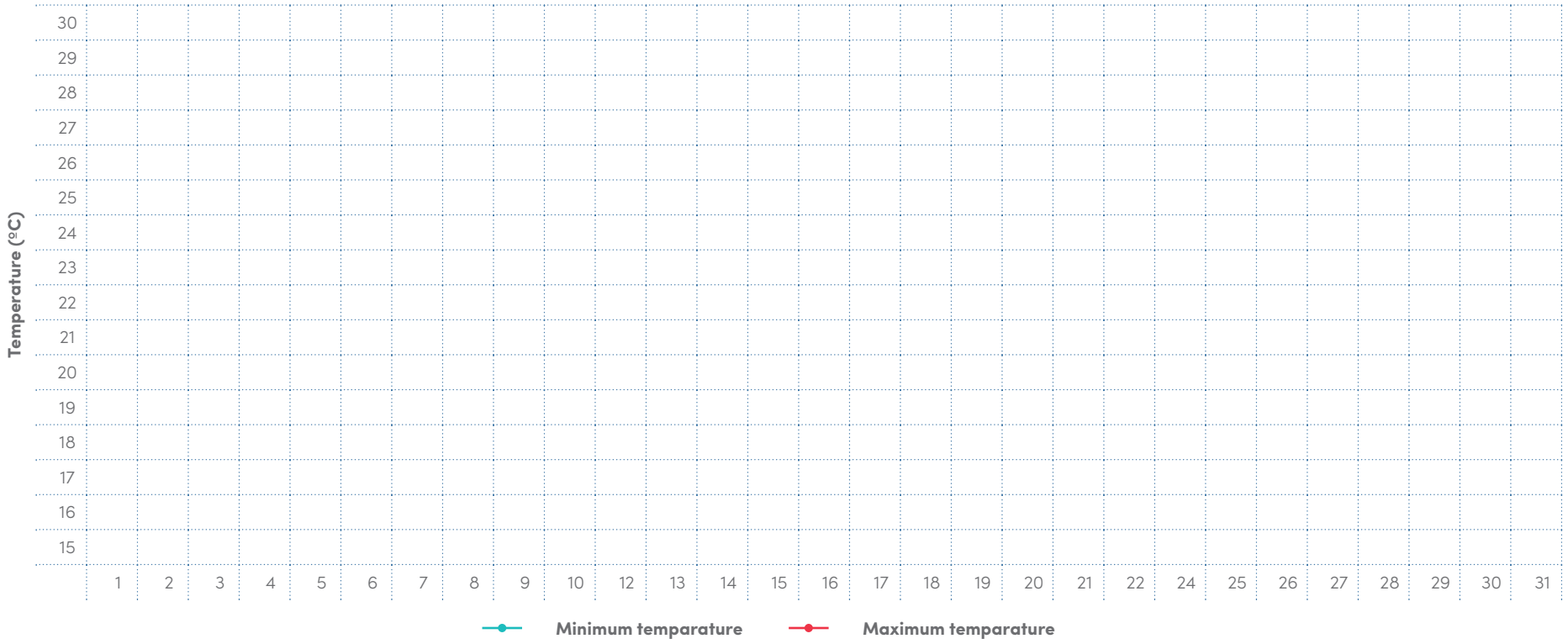
Date	Receipt				Issued			Balance	Name
	From	Lot Number	Expiry Date	Quantity	Issued To	Lot Number	Quantity		

ANNEX 3. CENTRAL WAREHOUSE MALARIA RDT TEMPERATURE MONITORING FORM

Month _____ **Year** _____ **Temperature range** _____

Date	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Minimum																															
Maximum																															
Time																															
Initials																															

Temperature monitoring chart



ANNEX 4. MALARIA RDT FACILITY ASSESSMENT CHECKLIST (ADAPTED FROM BOTSWANA NATIONAL MALARIA DIAGNOSIS QA/QC GUIDELINES, 2022)

GENERAL INFORMATION

Name of facility:	
Name of health district:	
Name of assessor(s) and affiliation:	
Date of assessment:	

				Comment
Regulations and policies	Is the facility licensed to perform RDTs?	☐ Yes	☐ No	
	Is the facility using the recommended testing algorithm?	☐ Yes	☐ No	
	Is the facility using the recommended reporting formats?	☐ Yes	☐ No	
	Is the facility performing only tests and tasks allowed at their operation level?	☐ Yes	☐ No	
	Is the facility adequately[1] staffed?	☐ Yes	☐ No	
Designated responsibilities	Are roles of facility owners and managers clearly defined?	☐ Yes	☐ No	
	Is an appropriate and qualified person in place for overseeing the RDT testing service?	☐ Yes	☐ No	
Selection and procurement of RDTs	Is the facility using recommended RDTs?	☐ Yes	☐ No	
	Are SOPs/job aids that correspond to the RDT in use available where testing is performed?	☐ Yes	☐ No	

[1] Adequate personnel is measured by the ability of the health facility to ensure the availability of parasitological test results within two hours of patients presenting.

				Comment
Supply chain management of RDTs	Is the RDT brand and type in use approved for use in the country? (refer to list of registered products in country and WHO prequalification list)	☐ Yes	☐ No	
	Is there a stock monitoring system in place to ensure that RDT stockouts, overstocking and expiries do not occur?	☐ Yes	☐ No	
	Are personnel following the "first expiry, first out" method when managing stock?	☐ Yes	☐ No	
	Are all RDTs within their expiry date?	☐ Yes	☐ No	
	Have there been any stockouts in the past six months?	☐ Yes	☐ No	
	Is there a procedure for re-ordering kits and accessories?	☐ Yes	☐ No	
Storage of RDTs	Is space adequate for the storage of kits and accessories?	☐ Yes	☐ No	
	Are kits stored within the manufacturer's recommended temperature ranges?	☐ Yes	☐ No	
	Are RDTs protected from moisture during storage?	☐ Yes	☐ No	
	Is there restricted access to RDT storage areas?	☐ Yes	☐ No	
	Are there rodent control mechanisms to protect RDT kits?	☐ Yes	☐ No	
Infrastructure and equipment	Is the RDT testing carried out in a private area/room that offers privacy to the patient?	☐ Yes	☐ No	
	Is there testing temperature monitoring?	☐ Yes	☐ No	
	Is lighting sufficiently available in all testing rooms/spaces?	☐ Yes	☐ No	
	Are functional timers/clocks available for use where testing is performed?	☐ Yes	☐ No	
	Is there adequate testing space?	☐ Yes	☐ No	
	Is the testing room/space clean?	☐ Yes	☐ No	
	Are work surfaces level?	☐ Yes	☐ No	
	Are work surfaces made of a material that can be disinfected?	☐ Yes	☐ No	

				Comment
Waste management	Is there a hand basin and continuous supply of water and soap for the washing of hands?	☐ Yes	☐ No	
	Are there paper towels and/or hand dryers for the drying of hands?	☐ Yes	☐ No	
	Is there adequate supply of face masks?	☐ Yes	☐ No	
	Is there adequate supply of gloves?	☐ Yes	☐ No	
	Are sharps containers available?	☐ Yes	☐ No	
	Are biohazard trash bags and bins available?	☐ Yes	☐ No	
	Is there bench surface disinfectant such as 10% hypochlorite and 70% alcohol available?	☐ Yes	☐ No	
	Is there a procedure to prevent and deal with injuries from contaminated sharps?	☐ Yes	☐ No	
	Is there an effective biohazard waste disposal process?	☐ Yes	☐ No	
Reporting and record keeping	Are all test results interpreted and recorded according to protocols?	☐ Yes	☐ No	
	Does the facility compile weekly and monthly surveillance reports as required by relevant authorities?	☐ Yes	☐ No	
	Does the facility keep legible, readily identifiable and retrievable records as required by national surveillance guidelines?	☐ Yes	☐ No	
	Are records kept in a safe and secure place?	☐ Yes	☐ No	
Post-market surveillance	Are there any product defects and/or associated adverse incidents observed with the RDT?	☐ Yes	☐ No	
	If yes, was the product defect and/or adverse incident reported to the relevant authorities?	☐ Yes	☐ No	
Quality control	When was the last on-site assessment for malaria RDTs done? (DD/MM/YYYY)	… … /… … /… …		
	Does the testing facility record and keep all QC data?	☐ Yes	☐ No	
	Does the facility perform required IQC activities?	☐ Yes	☐ No	

ANNEX 5. MALARIA RDT SUPERVISOR REPORTING FORM FOR RDT KIT PROBLEMS AND RDT ANOMALIES (ADAPTED FROM THE FIND PROTOCOL ON RESPONDING TO PROBLEMS WITH MALARIA RDTS)[1]

FACILITY DETAILS

Name of laboratory/facility/provider:		
Physical address of the laboratory/facility:		
Municipality/city/town:	Region/province:	
Telephone:	Fax	E-mail:
Name of head of facility:		
Name(s) of testing personnel and profession:		

DETAILS

Name of product/malaria RDT:	Catalogue number:	
Manufacturer:	Name of supplier/detailer:	
Type of RDT pack involved:	☐ Hospital pack ☐ Pharmacy pack	
Telephone:	Fax	E-mail:
Lot number/batch number:	Expiry date:	
Date purchased/received:	Date opened:	

1 Adapted from https://www.finddx.org/wp-content/uploads/2020/02/protocol-on-responding-to-problems-with-malaria-rdts-24JUN16.pdf

DESCRIPTION OF ANOMALY (Tick appropriate and complete where relevant)

A. Problems with RDT packaging

- ☐ Damaged RDT packaging
- ☐ Wrong labelling
- ☐ Missing labelling
- ☐ Other (Specify) _____

B. Insufficient number or missing test device/buffer/accessory

	Expected number	Observed number
☐ Test device		
☐ Lancet		
☐ Blood transfer device		
☐ Alcohol swab		
☐ Buffer bottle/ampoule		
☐ Instructions for use		
☐ Other (Specify) _____		

C. Problem with buffer

- ☐ Unusual buffer colour: specify colour _____
- ☐ Particulate matter in buffer
- ☐ Other (Specify) _____

For individually packed ampoules/vials (Pharmacy packs)

- ☐ Leaked/evaporated buffer in ampoule
- ☐ Empty buffer ampoule
- ☐ Too much buffer in ampoule
- ☐ Inconsistent volumes in ampoules
- ☐ Buffer ampoule does not puncture

For boxes with a single buffer bottle for all tests (Hospital packs)

- ☐ Insufficient buffer volume in bottle to perform all tests

D. Problem with alcohol swab

- ☐ No alcohol on swab (swab dry)
- ☐ Too little alcohol on swab (swab partially dried out)
- ☐ Other (Specify) _____

E. Problems with blood collection device

- ☐ Failure or much difficulty to collect blood
- ☐ Failure to deposit/release blood on sample pad
- ☐ Failure or much difficulty to transfer required volume of blood
- ☐ Other (Specify) _____

F. Problems with desiccant

- ☐ No desiccant
- ☐ Desiccant colour indicates exposure to humidity (if colour indicator included)
- ☐ Desiccant sachet damaged
- ☐ Other (Specify) _____

G. Problems with test device – Structural

☐ Damaged RDT test device ☐ Strip misplaced in cassette ☐ No sample pad in sample window

☐ Other (Specify) _____

H. Problems with test device – Result interpretation

☐ Failure to flow ☐ No control line ☐ Incomplete clearing

☐ Red background ☐ Faint test lines ☐ Irregular migration

☐ Ghost test lines ☐ Patchy broken test lines ☐ Diffuse test lines

☐ Other (Specify) _____

Event/problem description narrative (Explain what went wrong with the product and the observed or likely/probable consequences. Attach photos if available).

FREQUENCY OF PROBLEM/ANOMALY

% Number of test devices/buffer ampoules/accessories/tests or test kit boxes involved:

(Number of test devices/buffer ampoules/accessories missing or with problems ÷ total number in box) or (Number of tests with interpretation problems ÷ number of tests performed per time period)

Number of occurrences:	Dates of occurrences:

Date problem first reported:

INVESTIGATIONS CARRIED OUT

Are tests from different kit boxes involved?	☐ Yes	☐ No
Has more than one operator experienced the problem with the product?	☐ Yes	☐ No
Are storage conditions at outlet level favourable?	☐ Yes	☐ No
Is the provider following the recommended RDT procedure?	☐ Yes	☐ No
As part of the investigation, did the supervisor perform the testing?	☐ Yes	☐ No

If yes: How many tests did he/she perform:

How many had similar problems:

Preliminary action taken:

Name of person preparing report:	Affiliation:
Date:	Signature:

ANNEX 6. ACTIVITIES REQUIRED FOR QUALITY MANAGEMENT OF RDT TESTING[1]

Quality management activity	Frequency that activity needs to be performed				
	Daily	Weekly	Monthly	Quarterly	Yearly
At the testing site					
Check that infectious waste bags that are three quarters full are disposed of	X				
Check that sharps containers that are three quarters full are disposed of	X				
Directly observe health workers performing RDTs				X	
Ensure that any adverse incidents are reported and properly managed			X		
At the RDT storage area					
Check the expiry dates of RDTs			X		
Check the temperature regulation of the RDT storage area	X				
Check stock inventory to calculate the number of RDTs and microscopy supplies that have been used			X		
At the management level					
Check whether a monthly health information management report has been completed[2]			X		
Perform an internal audit of facility					X
Check whether guidelines need to be updated					X
Plan training for health workers performing RDTs or make sure all health workers' training is up-to-date					X

[1] Adaptation of Table 7 in Universal access to malaria diagnostic testing: an operational manual. Geneva: World Health Organization; 2011 (https://apps.who.int/iris/handle/10665/44657, accessed 1 August 2022).

[2] This may vary based on each country's requirements for reporting; some countries might have real-time electronic reporting systems in place.

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