

## **PROTOCOL ON RESPONDING TO PROBLEMS WITH MALARIA RDTs**

This protocol is intended to provide practical steps for solving problems that may arise when using malaria RDTs. It describes the measures to be taken to ensure that the ongoing quality of RDTs is maintained and the test demonstrates consistently reliable results. Where ongoing non-conformity is detected, this document provides possible response pathways on how to resolve the problems at point of use or take further action. This guidance is intended for staff overseeing malaria control programmes and for those responsible for post-market surveillance or quality assurance/ quality control.

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## **Abbreviations**

CDC: Centers for Disease Control and Prevention  
CHW: Community health worker  
FIND: Foundation for Innovative New Diagnostics  
HRP2: Histidine rich protein 2  
IQC: Internal quality control  
IVD: In vitro diagnostics  
MFP: Malaria focal person  
NDC: National diagnostics coordinator  
NMEP: National malaria elimination programme  
NMCP: National malaria control programme  
NRA: National regulatory agency  
NRL: National reference laboratory  
PCW: Positive control well  
pLDH: plasmodium lactate dehydrogenase  
QA: Quality assurance  
QC: Quality control  
RDT: Rapid diagnostic test  
SOP: Standard operating procedure  
VHT: Village health team  
WHO: World Health Organization

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## Definitions

- **Lot (of rapid diagnostic tests):** A lot (or batch) of RDTs is defined as a production run in which particular batches of monoclonal antibodies and nitrocellulose were used. Each lot is usually identified by a number by the manufacturer and usually consists of 40 000–80 000 tests.
- **Lot testing:** Lot testing is the quality control testing of a product lot (batch) after release from the manufacturing site.
- **Panel detection score:** Main measure (score between 0 and 100) of performance used in WHO-FIND product testing of malaria RDTs, corresponding to the percentage of times a malaria RDT gives a positive result on all tests from two different lots tested against samples of parasite panels at a specific parasite density (i.e. four tests at 200 parasites per microliter, two at 2000 parasites per microliter). It is not a direct measure of RDT sensitivity or specificity.
- **Parasite density:** Number of asexual parasites per microliter of blood
- **Quality assurance:** All processes involved in ensuring that results obtained with a tool are as accurate as the tool is designed to be (all diagnostic tools have limitations). Addresses all factors that affect diagnostic performance, including test performance by health staff, internal audits, external quality assessment, microscopy equipment and reagent quality, quality of RDT devices, storage and transport of RDTs, use of test results by clinicians, workload, workplace conditions, training and staff support and community perception.
- **Quality management system:** System to direct and control an organization with regard to quality.
- **Quality monitoring:** All activities involved in ensuring that the diagnostic tests continue to conform to established specifications during storage, distribution and use; part of quality assurance

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## **I. Introduction**

### ***I.1. Background***

The World Health organization (WHO) recommends that malaria case management be based on parasite diagnosis in all suspected cases. The use of antigen-detecting rapid diagnostic tests (RDTs) is a vital part of this strategy, forming the basis for extending access to malaria diagnosis by providing parasite-based diagnosis in areas where good-quality microscopy cannot be maintained, especially peripheral health facilities and community-based fever management programs.

The development of RDTs in the last decade has steadily led to a wide range of products coming on the market. Despite the large number of rapid diagnostic tests (RDTs) on the market, there are ongoing challenges related to test quality, from manufacture to proper storage and use in remote tropical settings. RDT lot-to-lot variation and susceptibility to deterioration upon exposure to high temperatures and humidity in supply chains have been documented. In addition, some reports attribute health workers' poor adherence to RDT results at least in part to lack of confidence in test results. To this end, a robust but streamlined quality assurance and quality control system is a critical component of effective RDT implementation.

### ***I.2. How to ensure the quality of malaria RDTs from procurement until use***

The Malaria RDT Product Testing Programme is an independent, laboratory-based comparative evaluation of malaria RDTs, designed to help malaria control programmes and procurement agencies to select high-quality RDTs from the large number of products available on the market. RDT manufacturers that operate according to international quality standards (ISO 13485:2003) are invited to submit their RDTs for evaluation. All eligible RDTs are tested using highly standardized and characterized samples from a malaria specimen bank. The results include a ranking of RDT products according to their ability to consistently detect parasite samples, as well as data on false positive rates, invalid test rates and heat stability. All major procurement

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agencies now use the product testing results for their selection of RDTs, and market surveys have shown that there has been a shift towards higher quality products since the start of the programme.

WHO–FIND malaria RDT evaluation programme, is part of a continuing programme to improve the quality of RDTs and to support widespread, reliable malaria diagnosis in areas where malaria is prevalent. Product testing provides data on antigen-detecting malaria RDTs and is collaboration among many institutions in malaria-endemic and non-endemic countries, with a global specimen bank and testing performed at the CDC. The results of WHO malaria RDT product testing form the basis for procurement criteria and constitute the laboratory evaluation component of WHO prequalification for malaria RDTs. To date there have been 6 rounds of product testing, the seventh round of product testing began in November 2015, and the results will be published in 2017 ([www.finddx.org](http://www.finddx.org)).

WHO–FIND malaria RDT evaluation programme also support the lot testing at two reference laboratories in the Philippines and Cambodia and new efforts are aimed at scaling up in-country lot testing based on recombinant antigen panels instead of using standardized and characterized samples from a malaria specimen bank. Lot testing is the quality control testing of a product lot (batch) after release from the manufacturing site. Lot testing can be done before and after shipment. FIND is also working on the development of positive control wells (PCWs) to assess the quality of the RDTs at the end user level. PCWs are small tubes containing dried antigens (HRP2 or aldolase), and when reconstituted with water and applied to a good quality RDT, the PCW solution produces a positive reaction on the RDT. PCWs can therefore be used as point-of-care quality control tool by front-line health workers to test stocks of RDTs stored and used at their health facilities, to ensure their validity and accuracy. PCWs may also potentially be used by health facility and laboratory supervisors, as well as transport/storage personnel interested in monitoring RDT quality throughout the supply chain.

## **II. Scope and intended audience**

This protocol is intended to provide practical steps for solving problems that may arise when using malaria RDTs. It describes the measures to be taken to ensure that the ongoing quality of RDTs is maintained and the test demonstrates consistently reliable results. Where ongoing non-conformity is detected, this document provides possible response pathways on how to resolve the

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problems at point of use or take further action. This guidance is intended for staff overseeing malaria control programmes and for those responsible for post-market surveillance or quality assurance/ quality control.

### **III. Guidance for adaptation of this document**

This document gives a brief overview of the quality assurance/control for malaria RDTs and the investigations necessary to address anomalies with the RDTs. Implementing stakeholders are encouraged to adopt these guidelines in relation to their existing systems to fit the country's structures and personnel profiles.

### **IV. Structure for coordination of QA of diagnostics (RDTs)**

#### ***IV.1. General Description***

Quality assurance includes systematic activities carried out to ensure quality of test results. The activities include selection of the tests, test performance by staff, internal quality control (IQC) methods, and correct interpretation and effective use of the results. Quality assurance for RDT implementation at the provider level can be considered under three broad areas – training, supportive supervision and quality control (QC) – all of which are major areas of concern in ensuring in quality RDT implementation. There is a tier system of quality management system that ensure routine quality of the RDTs products and process. The mandate of the national programme (NMCP or its' equivalent) is to coordinate the planning, implementation, monitoring and evaluation of malaria diagnostic services. This should ideally be done by a national diagnostic committee, led by the national laboratory services. The programme should therefore establish such a committee and prepare its terms of reference.

WHO published a criteria for selecting malaria RDTs:

1. The choice of RDT is based on the prevalence of malaria species in the country.
2. The type of antigen targeted depends on the species to be detected for detection of *P. falciparum*, tests that detect HRP2 are generally preferred, as they are more sensitive than those that detect pLDH; for detection of non-falciparum species, tests targeting pLDH specific to non-falciparum species or common to all species, or aldolase, are recommended ([WHO. 2011. Good practices for selecting and procuring rapid diagnostic tests for malaria. Geneva.](#)).

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3. Use of the results of the WHO product testing programme for malaria RDTs. An interactive guide, which allows users to identify RDTs by specific thresholds for various parameters of diagnostic performance, is available on [FIND website](#).
4. Procurement should be guided by the needs of the national malaria control programme, taking into account previous experience of use and training requirements of health personnel, especially if a new type of RDT is to be procured. If more than one RDT is to be procured, selection of tests with a similar format, ancillary items and testing procedures is recommended to reduce training requirements and errors in performance.
5. The supplier's production capacity and lead times
6. The stated storage conditions, and shelf-life
7. Ability to commit to delivery schedules as well as registration and budget requirements ([WHO. 2013. Universal access to malaria diagnostic testing – An operational manual. Geneva](#)).
8. The procurement contract should contain mandatory lot testing

At national level there should be lot testing at point of importation (pre- and/or post-shipment) that is coordinated by the NMCP or designated person (national diagnostic coordinator (NDC) or National QA/QC focal person).

Before RDTs are shipped into the country, pre –shipment lot testing should be done. This is performed once the RDT product and supplier have been selected and the first batch of the RDT has been produced. A sample of RDT lot will be sent for testing and the result will be shared before shipment of the RDT into the country. Pre-shipment testing is coordinated by NMCP/NMEP designated person, who confirms results and instructs the shipping. Once the RDTs arrive in the country, post shipment testing is performed. A sample of RDT lot is sent for RDT lot testing and the result is awaited before distributing the RDT to the country.

The NCD (or NMCP) ensures that only quality assured products are received, verified and released to the market. The NCD also coordinates the tracking of stock (batches and lots) sent to specific areas of the health care system. The National level ensures that there are standards for storage and transportation that are adhered to and monitored along the supply chain, broad standards for training competence of health care providers and systems to manage medical waste.



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At regional level/ district there should be a malaria focal person to coordinate the process of distribution and documenting the use do diagnostic tools (RDTs, Transport and Storage guidelines, SOPs and checklists). At the regional level there should be a capacity for field coordination, and routine information monitoring to pick up divergent reports. The team at the region may include supplies, detailers, supervisors and quality assurance focal person.

At the health facility/ Village point of care, the provider gives information on the performance of the RDTs to the QAFF. In return, the focal person ensures that the health worker is competent, has the job aids and SOPs on how to perform the test correctly.

***IV.2. Transport and storage conditions***

RDT kits and reagents for diagnosis of malaria have specific requirements for storage, transportation and handling, which are specified in the manufacturers' instructions. These conditions must be created and maintained to preserve the quality of the products throughout transportation and storage. The NCD must ensure that the procuring and logistics company/organization is supported with good warehousing facilities. It is good practice to inspect and document the appropriateness of the warehouses prior to importation of RDTs based on a simple checklist. (A sample of warehouse checklist in Annexes).

***IV.3. Support supervision***

Quality assurance of diagnostic processes can be maintained through supervision. Supervision of health workers providing malaria diagnostic services is a process of working with individual and groups to make sure tasks are performed as required. Support supervision is a form of continuing professional development and services for the following purposes: a) measuring gaps or deficiencies and help find solutions, b) providing on-the-job training and mentoring c) Providing updated information and feedback and d) Stimulating information exchange and networking within the service providers. This is the basic process through which RDT problem will be received and verified to trigger a response for the appropriate persons. At the end of the supervision visit, a report should be shared with the supervisee, health facility management, the supervisory team members to complete the process.

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#### ***IV.4. Roles and responsibilities of personnel***

1. **RDT user**: The person that performs the diagnostic testing at the point-of-care is the RDT user. The RDT user is responsible to reporting any observed/suspected malfunctioning of the test kit to his/her direct supervisor.
2. **Direct Supervisor**: In the health care system, the direct supervisor is the designated health worker to whom the RDT user reports during his/her day-to-day work. At the community level, this may be the In-Charge of the health facilities in the area or the Malaria Focal person at the district level.
3. **QA/QC focal point (FP)**: The QAFP is responsible for monitoring the performance of the RDTs (and microscopy) at the point of use. He/she collects and collates reports on nonconformity of the RDTs test received either directly from the RDT user or the direct supervisors of the RDT users. *Note: This level of responsibility might not exist in all countries.*
4. **Malaria focal person (MFP)**: The MFP is based at the regional/District level and responsible for supervision of malaria diagnosis and case management activities in the district. The MFP in addition monitors the performance of village health teams (VHTs) or community health workers (CHWs). MFP works under the district director of health services.
5. **National Diagnostics Coordinator (NDC)**: This is the person responsible for malaria diagnosis at national/state level within the national malaria control programme and coordinates all malaria diagnostic services. He/she heads a national committee on malaria diagnosis through a mechanism that link national malaria control programme, the national institutions and regulators such as a reference laboratory, NDA and key stakeholders, and to facilitate information sharing and overseeing of the activities of the different partners. In some setting, this person may be the national QA/QC person if the coordination responsibility is not assigned.

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#### ***IV.5. Roles and responsibilities of institutions & bodies***

1. **National Reference Laboratory (NRL)**: The NRL has the mandate of establishing standards and validation diagnostic performance of the tools (RDTs and Microscopy) through coordinated schemes (EQAS). It is also a point of reference for In-Country Lot testing using recombinant panels. In some setting, the NRL for malaria is under the leadership of Central Public Health Laboratories (CPHL) where it exists. The NRL is supervised by the CPHL, and the designated body in-charge of laboratory services.
2. **National Regulatory Agency (NRA)**: The regulatory authorities have the responsibility to regulate the use of In vitro diagnostics (IVDs) and registration in the country. In case of non-conformity, the NRA will be responsible for the recall of defective diagnostics.
3. **National Malaria Control Programme (NMCP)**: The NMCP is responsible for policy formulation, supervision, capacity building, quality assurance, setting standards, providing guidelines and post market surveillance and partner coordination among others. The NMCP/ministry of health is also responsible for planning, reviews, monitoring and evaluation function as well as resource mobilization and human resource recruitment. In regards to quality assurance, the NMCP is to oversee the implementation of quality assurance systems as mentioned in this document at national level. At regional level and district level, the malaria focal and quality assurance officers will support these functions.

#### ***IV.6. Reporting of problem RDTs and immediate troubleshooting***

Reacting to nonconformity is a key component of a good quality management system, and all procedures should be documented. Health workers are trained to be attentive to significant deviations from expected results in their facilities. If this occurs, the health worker should report the incident to his direct supervisor and request an unscheduled supervisory visit to assess all possible sources of the problem ([WHO. 2013. Universal access to malaria diagnostic testing – An operational manual. Geneva](#)).

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- RDT user observes a problem while performing RDT test. He/she takes action and tries to solve the problem as recommended in the training and troubleshooting guide if it is available (e.g. check RDT procedure and correct any errors, etc.). If the problem persists, the RDT user records the problem on a small tally sheet, keeps all suspicious RDTs, and calls his/her direct supervisor e.g. MFP and/or QA focal person at facility level, as described in the troubleshooting guide.
- Verifications visit to RDT user: When the direct supervisor receives the problem report/or call from RDT users, he/she organizes a site visit to the source of report, bringing with him/her training tools, job aids, the troubleshooting guide, the supervision checklist and PCWs if available. During the visit, the supervisor listens and seeks to understand difficulties encountered by the RDT user (health worker) on the use of RDT, then he/she performs a routine supervision of the user's competence using the supervision checklist (attached form V.4.1), verifies the RDT stocks (expiry dates and adequate storage) and does additional testing with more RDTs (using PCWs if available). Reasons for the problem should be identified and solved by discussion/refresher training if possible. In case the problem cannot be solved and there is a suspicion of quality problems of the RDTs, the supervisor completes the reporting form and informs the national diagnostics or QA/QC coordinator.
- Review of the supervisor's report  
Review the documentation and info provided, check for gaps, collect more info either through sending supervisor back again, and/or call the RDT user and/or make another visit together with the supervisor. If possible, identify reasons for problem and try to solve it. If not possible, next step.
- Investigation visit to RDT user: The national diagnostics or QA/QC coordinator informs the NRL, the NMCP, the NRA (if relevant) and arranges for another visit to the RDT user by a team composed of representatives of each body. During the investigation visit, the visiting person(s)/team assess (es) personnel, management systems and communication channels. They also check expiry dates, stock inventory, workplace safety, physical environment, drugs, diagnostic and supplies storage, RDT preparation, job aid, performance and RDT result interpretation, the current RDT batches at the facility based on the given SOP

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(PCW, dried down blood samples, whole blood samples, (see SOP V.3.1). During the visit, he/she should document the problems on a pre-designed form (reporting form V.5.1); use the trouble shooting guide (reporting form V.5.2) to identify anomalies and verify that they are repetitive occurrences; and conduct a performance evaluation of the health provider. This will document the procedure of performing the RDT, the process of QC available at the site, and directly observe how the health worker handles patients, and interprets and acts on the result (see checklist V.4.1). At the end of the visit, he/she should issue an investigation visit report that documents the assessments done and all findings, along with the tally sheet(s), completed reporting form and completed supervision checklist. He/she must provide immediate feedback to RDT user, and retrieve a random representative sample of RDTs to send to the National Reference laboratory (NRL) for cross-checking.

#### ***IV.7. Field verification of problems related to nonconformity***

- Planning a support supervision visit in response to reported RDTs non conformity must include all the stakeholders. The steps may include the following: a) arrange for a prior meeting with other quality assurance team members to review the information/report received b) review the performance record of the health worker, c) define the scope and method of use to carry out the supervision, d) inform all the relevant authorities about the planned visit and e) prepare the tools to facilitate the activity: review visit checklist, RDTs performance queries, data collection forms, prepare an external quality assessment panel (a set of known RDTs and PCWs if available), a copy of the trouble shooting guide, structure checklist, handouts or brochures to provide current updates (process, procedures, guidelines, job-aids) other quality assurance (QA) supplies, for improving staff competence.
- Use of positive control wells (PCWs). Diagnosis coordinator should prepare a sample of PCWs to be taken to the field by supervisors during their regular supportive supervision to test RDTs stored and in use at facility. If RDT quality failures are observed, possible reasons should be investigated by using a troubleshooting guide and by discussing possible manipulation errors with the RDT care provider. If RDT quality failures persist and are suspected to be due to test quality, RDTs should be withdrawn for laboratory testing.

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- Comparison of stored microscopy slides and RDTs in some peripheral health facility ([Nigeria NMEP QA manual](#)). RDTs and slides can be made in parallel on a number of patients, and the slides read by expert microscopists. All other factors that could affect the quality of slide made during the QC process should be considered in getting optimum result. While interpreting the result, differences of the two methods regarding the diagnostic target (malaria parasites by microscopy, versus the malaria antigens by RDTs) and the sensitivity of the two methods should be taken into account, e.g. some RDTs may achieve higher sensitivities than microscopy and/or detect antigens in circulation after a recently resolved infection and/or in the case of parasite sequestration.

#### **IV.8. Assessment of quality of retrieved RDTs**

- Take/mail samples to national reference laboratory (NRL) for cross-checking.
- Based on the outcome of the verification visit plan/ act on the deficiencies encountered (temporarily replacement of the stock) and train the providers for cases of performance incompetence.
- Provide formal feedback to the RDT-user and the regulatory bodies on the process at the NRL. The information should include the corrective actions planned as well.
- The national diagnostics or QA/QC coordinator arranges to cross-check the RDTs at the NRL against the reference panels (recombinant antigens). In case the local capacity does not exist, the responsible parties arrange to ship the RDTs to the WHO-FIND reference laboratories. The procedures for shipping and receiving results from the WHO-FIND labs are shown in attached SOP (V.3.1).

At the NRL, there are two possible results and actions expected.

1. If the result is a PASS; the testing laboratory informs the National diagnostics or QA/QC coordinator of the results. She/he informs NMCP, NRA (if relevant) as well as the supervisor and the RDT user to continue using the RDT. He/she also investigates what went wrong in the field including visiting the site and cross checking the rest of the samples with PCWs, and addresses possible reasons for the problem.
2. In case of a FAIL result from NRL; the QA/QC focal person is notified and arranges to ship samples to WHO-FIND laboratory for CONFIRMATORY testing. At the WHO-FIND laboratory, the RDTs are cross checked against reference panels and/or reference characterised samples from malaria patients.

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- At the WHO-FIND reference laboratory, there are also two possible results and actions expected.
  1. In case of a PASS result from the WHO –FIND reference laboratories, the QA/QC coordinator leads investigation in identifying what went wrong in the NRL. He/she informs NMCP, NRA (if relevant) as well as the supervisor and the RDT user to continue using the RDT. He/she also investigates what went wrong in the field including visiting the site and cross checking the rest of the samples with PCWs, and address possible reasons for the problem.
  2. In Case of a FAIL result at the WHO-FIND laboratory, this confirms non-conformity of the RDTs. The laboratory informs the national QA/QC focal person and the NRL, plus all concerned stakeholders. The National QA/QC officer (NMCP/NMEP) together with the National Regulatory Agency (NRA) and stakeholders hold a meeting to discuss the possible reasons for the non-conformity. In this meeting, the team decides the next steps in regard to the remaining RDTs at the point of testing and any remaining in the ware houses. They also determine the corrective measured needed to ensure safety of the patients.

The possible next ACTIONS include: a) Further investigation to identify the reason and extent of the problem to determine all the affected tests, e.g. reviewing the storage and transport conditions, on-site and random sampling of RDTs from other testing sites b) If the review shows that the problem is localized to a specific site or set of RDTs ( e.g. due to wrong storage/transportations of a specific lease), the NMCP/NRA take corrective action to replace the defective RDTs, recall the affected RDTs and address the cause of the defect if possible ( address the storage challenges) c) if problem is related to defective RDT lot, the NMCP/NRA release Non-Conformity alert.

#### ***IV.9. Non-conformity alert***

- I. The QA/QC focal person fills in the WHO complaint form and informs all relevant stakeholders. The information is then shared with the:
  - a. WHO accredited laboratory for central quality assurance (currently the WHO-FIND reference laboratories): Use address on Lot Testing request form/SOP)
  - b. WHO Prequalification of Diagnostics Programme (address on forms and website)
  - c. Procurer of this RDT lot (information is with RDT user and the NMCP)

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d. Other in-country importers and distributors of the RDT lot in question

The NRA, NMCP and the National QC/QA focal person will plan a communication strategy to inform the affected RDT users and stakeholders. These institutions spearhead the recall of the defective RDT lot if distributed in the public health facilities or/and private sector:

- Proper documentation of all the source and numbers of recall RDTs are kept and a copy kept on file after the destruction of the defective RDTs.
- The NMCP/NDA end out messages quarantining the remaining stocks of the affected batches and lots, and recall all the stock at the RDT users stores and clinics.
- They also closely monitor all stocks available to look out for other non-conformity of RDTs or their accessories
- The Procurer of the products communicates with the manufacturer to obtain replacement of RDT lot based on the agreements.
- Once the replacement has been received, the same distribution/supply chain is used to re-distribute the RDTs to the user based on the records used to retrieve the RDTs.

II. Other institutional actions

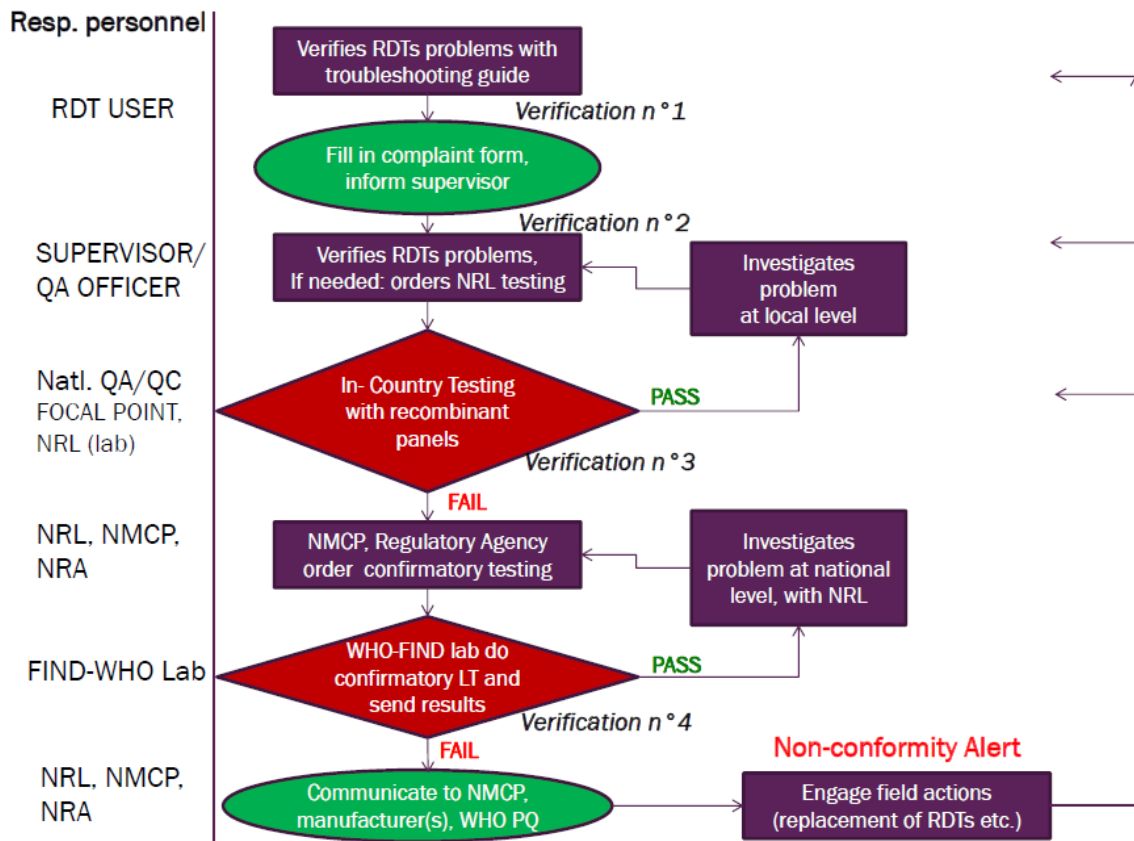
- a. WHO-FIND RDT Evaluation Programme: Information of non-conformity is kept on file and the report shared on the Programme's website  
([http://www.wpro.who.int/malaria/sites/rdt/workplan/who\\_find\\_partnership.html](http://www.wpro.who.int/malaria/sites/rdt/workplan/who_find_partnership.html))
- b. WHO Prequalification Programme: If the RDT product is prequalified and /or is in the pipeline, the PQ programme will engage actions with the RDT manufactures to identify the source of the problem and suggest the corrective actions. The PQ will also follow-up on the manufacturer's actions for systematic re-call of this RDT lot from anywhere in the world including the lot replacement arrangements



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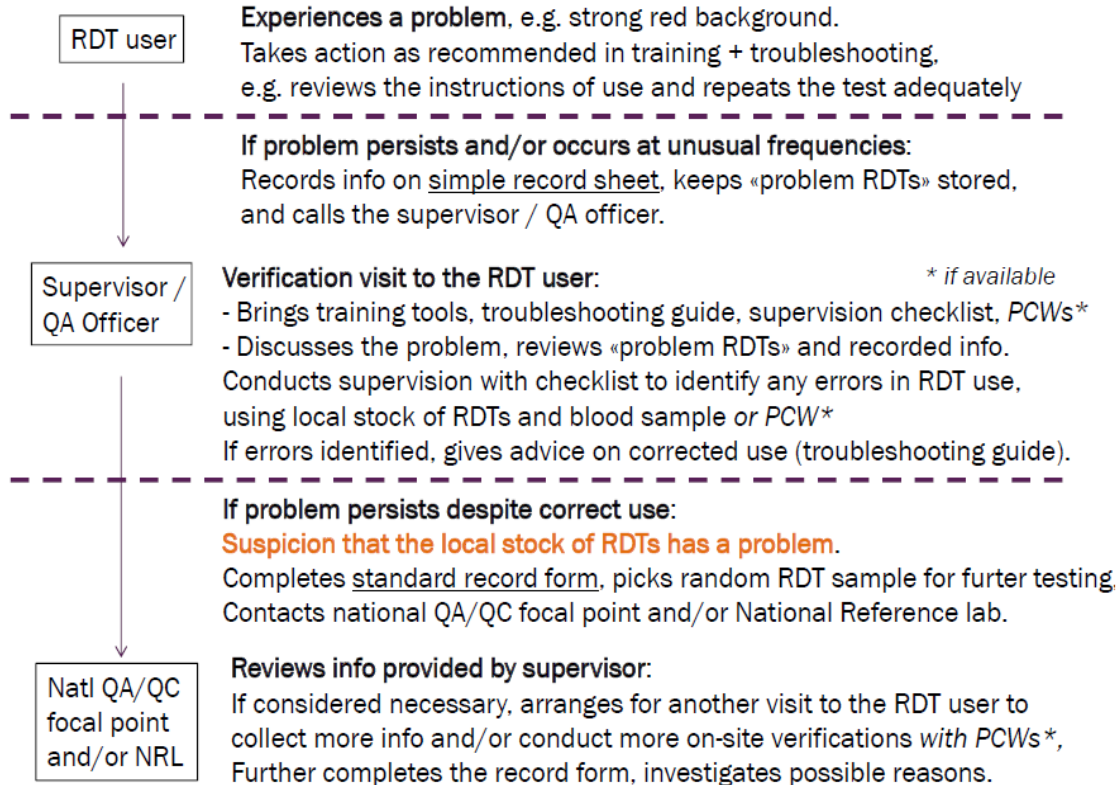
**V. Annexes**

**V.1. Flow chart summary**



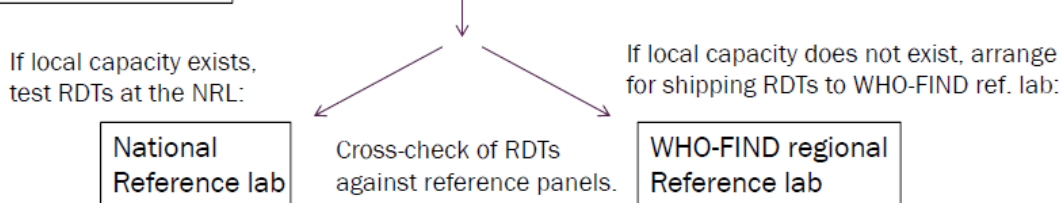
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**V.2. Process of reporting and communicating RDT problems from the field**



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Natl QA/QC focal point and/or NRL **Informs NMCP and NRA about suspicion of non conformity (send copy of standard record form) and arranges for cross-checking of RDTs:**



**1. In case of PASS result:** inform the Natl QA/QC focal point and/or NRL (**PASS report**).

Natl QA/QC focal point and/or NRL **Leads investigation to identify what went wrong in the field (e.g. on-site visit, cross-check of samples/PCWs used in the field tests).**

**2. In case of FAIL result:** ship RDTs to another laboratory for confirmatory testing



**1. In case of PASS result:** informs the Natl QA/QC focal point and/or NRL (**PASS report**).

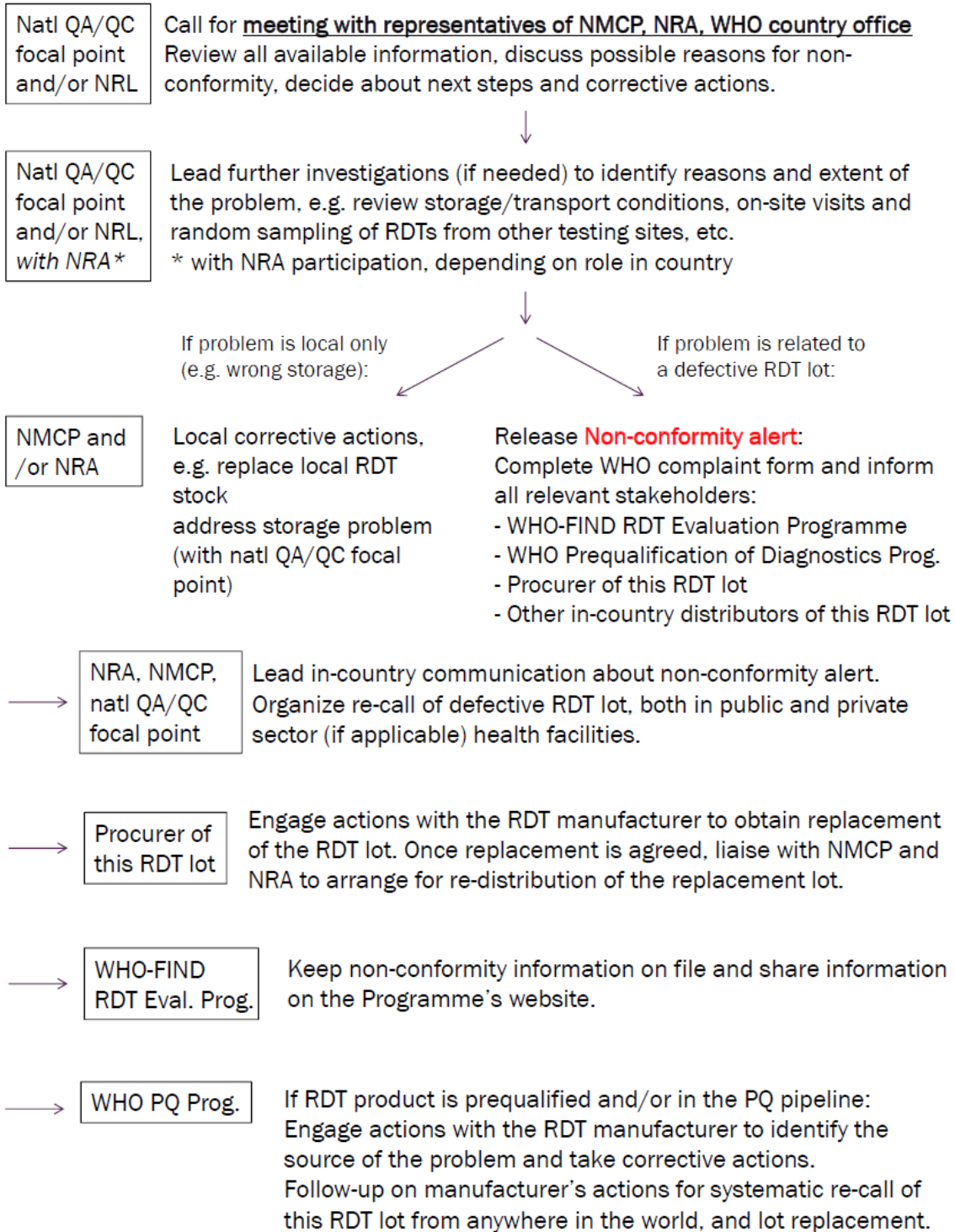
WHO-FIND regional Reference lab **Leads investigation to identify if something went wrong in the first Reference lab (e.g. cross-check of samples used in the first testing).**

Natl QA/QC focal point and/or NRL **Leads investigation to identify what went wrong in the field (e.g. on-site visit, cross-check of samples/PCWs used in the field tests).**

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**2. In case of FAIL result: Confirmation of non-conformity of RDTs.**

Inform the natl QA/QC focal point and/or NRL (**FAIL report**).



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### **V.3. Standard operating procedure (SOP)**

#### **V.3.1. SOP LT 01.0: Process for lot testing of malaria RDTs in the context of the “RDTs in the public and private sector.**

**PURPOSE:** This standard operating procedure (SOP) describes the process and communication pathway for lot testing of malaria RDTs before distribution to both public and private sector outlets monitored by (country NMCP). More specifically, this SOP describes all the steps required for timely lot testing before RDTs are shipped to the country (pre-shipment lot testing), and/or before RDTs are distributed in-country (post-shipment lot testing), and highlights which project partner and staff is responsible for each.

**SCOPE:** This procedure is to be used in the context of Ministry of Health in (countries) and is complemented by the procedures of chapter 2 of the “Methods Manual for laboratory quality control testing of malaria rapid diagnostic tests”, which describe the WHO-FIND lot testing procedures in detail (see <http://www.who.int/malaria/publications/rdt-lab-quality-manual/en/>).

**PROCEDURE:** Note: NMCP Manager or Deputy be copied on all correspondence related to malaria RDT lot testing for (country)

#### **A. Pre-shipment lot testing**

Definition: Pre-shipment lot testing is performed once the malaria RDT (RDT) product and supplier has been selected and the first batch of RDTs has been produced. A sample of the RDT lot will be sent for RDT lot testing and the result is awaited before arranging for shipment of RDTs to the project country.

1. NMCP has to ensure that the procurement contract with the manufacturer includes a clause that the manufacturer makes the necessary arrangements for pre-shipment lot testing of RDTs once the first RDTs of each procured lot are released from the production line. Any criteria for acceptance or rejection of an RDT lot should also be part of the procurement contract (please refer to sections C and D of this SOP).
2. After a procurement contract for RDTs is signed and an order is placed, the manufacturer is responsible for retrieving the Lot Testing Request Form from the FIND website at: <http://www.finddx.org/quality-assurance/malaria-rdt-qa/>. He/she should complete the form, making sure that the NMCP procurement contact point is the recipient of the lot testing report. The manufacturer then sends the completed form to the FIND Lot Testing coordinator ([christian.nsanjabana@finddx.org](mailto:christian.nsanjabana@finddx.org)). The FIND Lot Testing Coordinator

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designates which WHO-FIND lot testing laboratory will carry out this lot testing, confirms this to the manufacturer, and transmits the full shipping instructions.

3. The RDT manufacturer ships the required number of RDTs according to specific instructions for transport to the testing laboratory, with a copy of the lot testing request form.
4. The required number of RDTs for pre-shipment lot testing is: 100 RDTs in case of *P. falciparum*-only tests, 150 RDTs in case of combination tests, e.g. Pf-Pan, or Pf-Pv, or Pf-Pv-Pan tests per lot. The required number is also specified on the lot testing request form, and should be checked each time, in case of any changes in numbers.
5. The RDT manufacturer sends the shipping documents to the FIND lot testing coordinator, with copy to the PSI procurement contact point.
6. Upon receipt of the RDTs, the testing laboratory sends the delivery confirmation to the PSI procurement contact point (if he/she has been correctly designated as the recipient of the lot testing results in the request form, as noted above) and the RDT manufacturer.
7. The testing laboratory performs an Initial QC Testing upon arrival. The remainder of RDTs is stored at controlled temperature according to manufacturer's instructions.
8. If the RDTs PASS the initial QC assessment, the testing laboratory staff emails a signed lot testing report within 5 working days of receipt to the RDT manufacturer and the NMCP/ NDC procurement contact point, with copy to the Lot Testing coordinator and the FIND project manager.
9. The testing laboratory later proceeds with a long term testing of the RDTs 6 months before their expiry, and sends the lot testing report to the same recipients as noted above.
10. If the RDTs do NOT pass (deferred) the Initial QC assessment, the following action is taken:
  - a. The testing laboratory will send an internal QC report to the Lot Testing coordinator and the FIND project manager, *noting that results are DEFERRED*.
  - b. The testing laboratory will dispatch the RDTs to another (confirmatory) WHO-FIND lot testing laboratory for further testing and confirmation of results.
  - c. The confirmatory laboratory will send an internal *PASS* or *FAIL* Report to the initial testing laboratory.

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- d. The initial QC laboratory will prepare the final *PASS* or *FAIL* report, which will be sent to the RDT manufacturer and to the PSI procurement contact point, with copy to the Lot Testing coordinator and the FIND project manager.
- e. If the RDTs have FAILED the lot testing, it is the responsibility of the PSI procurement contact point to handle the subsequent steps with the RDT manufacturer, according to the relevant clauses of the procurement contract.

### **B. Post-shipment lot testing**

Definition: Post-shipment lot testing is performed once the RDT lot(s) have arrived in the project country. A sample of the RDT lot(s) is sent for RDT lot testing laboratory and the result is awaited before distributing the RDTs to the Health facilities and private provider outlets.

Note: Post-shipment lot testing follows the same procedure as pre-shipment lot testing, with the following differences:

- Arrangements for sample collection and shipping RDTs are National Malaria Reference Laboratory is done by NDC/NRA, instead of the RDT manufacturer, as RDTs are sent within the country
- Only designated personnel (in NMCP/NRA) and the FIND staff (lot testing coordinator and project manager) are the recipients of the lot testing reports, i.e. the manufacturer is not informed of this lot testing, unless NMCP decides to inform the manufacturer of the results.
- Long term testing (at 6 months before expiry) is not performed, as this is already done as part of the pre-shipment lot testing. The required number of RDTs is therefore lower.

Post-shipment lot testing will be done on all imported RDTs.

1. Immediately upon arrival in the country, the NDC/NRA or procurement contact point arranges for sampling of the required number of RDTs for post-shipment lot testing, by adhering to the recommendations for sampling stated in the shipping instructions available on the WHO website at: [http://www.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/lot\\_testing\\_shipping\\_instructions.pdf?ua=1](http://www.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/lot_testing_shipping_instructions.pdf?ua=1)
2. The required number of RDTs for post-shipment lot testing is: 70 RDTs in case of *P. falciparum*-only tests, 100 RDTs in case of combination tests, e.g. Pf-Pan, or Pf-Pv, or Pf-Pv-Pan tests.

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3. In parallel, the NDC/NRA contact person retrieves the Lot Testing Request Form from the FIND or WHO websites at: <http://www.finddx.org/quality-assurance/malaria-rdt-qa/> or <http://www.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/evaluation-lot-testing/en/>. He/she then completes the form, ensuring that the relevant contact point people (NRA, NMCP WHO) are noted as the recipients of the lot testing results. He/she then sends it to the national malaria reference lab. Coordinator. NRL will carry out the lot testing, and will inform the PSI procurement contact point of full shipping instructions.
4. The NDC/NRA contact point sends the required number of RDTs according to specific instructions (see [http://www.finddiagnostics.org/programs/malaria-afs/malaria/rdt\\_quality\\_control/lot\\_testing/forms.html](http://www.finddiagnostics.org/programs/malaria-afs/malaria/rdt_quality_control/lot_testing/forms.html)) for transport to the testing laboratory, with a copy of the lot testing request form.
5. Upon receipt of the RDTs, the NRL testing laboratory confirms reception to the NCD or contact point.
6. The NRL testing laboratory performs an Initial QC Testing upon arrival. If the RDTs PASS the initial QC assessment, the testing laboratory staff emails a signed lot testing report within 5 working days of receipt to the NMCP /NRA contact point, with copy to the Lot Testing coordinator and FIND (if part of specific project).
7. If the RDTs do NOT pass the Initial QC assessment (deferred), the same actions as described above under A. 10 are taken, except that only NMCP/NRA contact point and the FIND staff (lot testing coordinator and project manager) are the recipients of the final lot testing report.

**C. General notes on the lot testing programme**

1. The PASS/FAIL decision of the WHO-FIND Programme is based only on detection of parasite samples at a threshold of 200 parasites per microliter of blood (p/ul), to determine if a product has a sensitivity considered sufficient for safe use in the field. RDTs must therefore detect those parasite-positive panels at 200 p/ul in order to pass the quality control evaluation.
2. The meaning of the PASS, DEFERRED and FAIL results of the lot testing is:



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**PASS:** This means that the RDT sample detected antigens at a threshold **sufficient for use in the field**. The RDT lot passed the quality control assessment.

**DEFERRED:** This means that the RDT lot failed the initial quality control assessment and has been sent to another institution for confirmation. A final report will be issued upon receipt of confirmatory results. It is recommended that the lot be **retained** until a final report is received.

**FAIL:** This means that the RDT lot failed the initial quality control assessment and also failed confirmatory testing at another lot-testing centre. It is recommended that this lot **should not be used in the field** since it lacks sufficient sensitivity, and that the manufacturer be contacted and advised of the results.

3. The lot testing reports additionally provide comments on other observations, such as false positive results noted on parasite negative samples, and/or a series of other observations, such as red background, poor clearing etc. that are listed in the 'Guide ' available at:

[http://www.finddx.org/wp-content/uploads/2016/02/malaria\\_rdt\\_guide\\_for\\_observations\\_30jul13.pdf](http://www.finddx.org/wp-content/uploads/2016/02/malaria_rdt_guide_for_observations_30jul13.pdf)

Photos of the testing results are also provided with the report when the testing workload allows it. The procurer is free to use this additional information for making procurement decisions.

4. The lot testing reports and photos of the testing results cannot be released to any third party without the agreement of the requesting party. In all cases it is the requesting party that can make the report available, and not the lot testing programme.
5. The programme is not responsible for final decisions to accept or reject an RDT lot by a procurement agent or malaria programme. This decision is to be taken by the procurer.
6. The FIND project manager and/or lot testing coordinator can be contacted to provide any additional useful background information on lot testing results and observations to assist in the decision-taking.

#### **D. Notes for the interpretation of lot testing reports**

There are three main criteria to be taken into account for deciding to accept or reject an RDT lot.

1. The main criterion is obviously the PASS or FAIL result of the lot testing report.
2. A second criterion is the **number** of invalid tests and false positive results.

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3. A third criterion is the **number** of RDTs with anomalies noted in the comments section, according to the guide of RDT observations available on the FIND website (see C.3. above).

The critical observations impacting RDT quality in the field are the following:

- Invalid tests (i.e. no control line), including tests that have no control line because of a failure to flow
  - Any red background or blood streaking that is so strong that it obscures the test line(s), including a strong red background with ghost test lines
4. A fourth criterion is any issue with the accessories, as noted in the RDT observations guide, with critical observations being the following:
- Buffer bottles with no buffer or insufficient volume, either because of leakage or because of evaporation
  - Discoloured buffer
  - Missing essential test accessories
  - Damaged sachet of desiccant, or desiccant indicating humidity

For items number 2 and 3, it is critical to take into account that the RDT lot testing is carried out using a very limited number of RDTs. The number of problematic RDTs observed in RDT lot testing can therefore not be converted into a percentage of problem occurrences, and it cannot be concluded that this same problem would occur with the same percentage, or probability, within the entire lot.

However, if the critical problems listed under items number 2 and 3 occur in e.g. more than 10 RDTs, it could indicate that there is indeed a possible issue in the manufacturing quality of this RDT lot, and results should be discussed with the manufacturer.

In general, the FIND project manager and/or lot testing coordinator can be contacted before discussing with the RDT manufacturer to provide more background information and discuss experience of similar observations.

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#### V.4. Checklists

##### V.4.1. Malaria RDT user supervision checklist

RDT USER SUPERVISION CHECKLIST				
Date(ddmmyyyy)	_____		_____	
District	_____		_____	
Outlet Name	ID	_____	Outlet	_____
Supervisor Name	ID	_____	Supervisor	_____
<b>General Information</b>	1	Name of the provider interviewed _____		
	2	Job title of the provider _____		
	3	Has the provider received any IMCI training through the project? Yes / No		
	4	Are there other staff(s) who have received IMCI training through the project? Yes / No		
<b>Use the section below to assess the competence of the provider with regards to case management of Malaria, Diarrhoea and Pneumonia.</b>				
Are the assessments done on a real patient? Insert the correct answer; Yes/No				
<b>Integrated case management - Competency assessment</b>			<b>Case 1 (Malaria)</b>	<b>Case 2 (Diarrhoea)</b>
<b>Case Management</b>	1	Ask patients identification (name AND age AND sex AND first vs. re-visit)		
	2	<b>Assesses for general danger signs (all 6)</b>	Yes/No	Yes/No
	3	Asks and look for main symptoms		
	4	<b>Classify patient's illness correctly</b>	Yes/No	Yes/No
	5	<b>Gives correct treatment as per iCCM manual (full course and observe patient take 1st dose)</b>	Yes/No	Yes/No
			<b>Case 3 (Pneumonia)</b>	

6	(i)Makes correct referral decision (ii)Referral facilitated (gives referral slip, first dose as appropriate)			
7	<b>Counsels (correct messages, including correct drug AND dose AND duration and when to return for follow-up)</b>	Yes/No	Yes/No	Yes/No
8	Confirms understanding (probe for questions AND request mother/patient to repeat instructions)			
	-			
1	<b>Records Review - Correct relation between classification/diagnosis and treatment for last month</b>	Yes/No	Yes/No	Yes/No
<b>Case management competence score</b>	<i>Case management competence score will be automatically generated taking into account the key steps highlighted in bold</i> <b>Target: 80% and above</b>	<b>100%</b>		
<b>Use the section below to assess the competence of the provider in demonstrating the key steps in performing an RDT.</b>				
<b>Rapid Malaria Test -Competency assessment</b>				<b>Case 1 (Malaria)</b>
<b>RDT Procedure</b>	1	Assembles new test packet, swab, buffer, pipette, lancet and gloves		
	2	<b>Puts a new pair of gloves</b>	Yes/No	
	3	(i)Checks expiry date on package (ii)checks desiccant sachet is still dry (iii) Write patient's name or ID on cassette (iv)Places cassette on a level surface		
	4	<b>Cleans finger with antiseptic/ alcohol</b>	Yes/No	
	5	Allows finger to dry before pricking it		
	6	<b>Use a sterile lancet for finger pricking</b>	Yes/No	
	7	Puncture the side of the ball of the finger		
	8	<b>Dispose of lancet in sharps bin immediately after pricking finger</b>	Yes/No	
	9	Collect blood with the enclosed pipette making sure to fill close to the first cross line		
	10	<b>Using a pipette, blots blood onto the pad in the correct well</b>	Yes/No	

	11	Disposes of pipette in sharps container immediately	
	12	<b>Dispense correct number of drops of clearing buffer into the correct well</b>	Yes/No
	13	<b>Wait correct time before reading negative results</b> (positive results may be read before the specified time if control line has appeared. Results should not be read after the maximum specified time minutes)	
	14	<b>Read the results test correctly</b>	Yes/No
	15	Record results in the register	
	16	<b>Dispose gloves, wrappers, alcohol swab and dessicant safely</b>	Yes/No
<b>RDT procedure competence score</b>	<i>RDT procedure competence score will be automatically generated taking into account the key steps highlighted in bold</i> <b>Target: 80% and above</b>		<b>100%</b>
<b>Overall quality of care competence Classification</b>	<i>Overall quality of care competence score will be automatically generated taking into account the case management and RDT procedure competency scores</i> <b>Above 80% (at least one competence assessment every quarter)</b> <b>50% - 80% ( At least 2 competence assessment every quarter)</b> <b>Below 50% (One competence assessment every month until reach 3 in the quarter)</b>		<b>100%</b>
<b>Use the sections below to assess the work environment (workplace, equipment, supplies and consumables, documentation and reporting) at the outlet.</b>			
<b>Workplace assessment</b>	1	Adequate water supply(Sufficient for outlet operations)	Yes/No
	2	Adequate lighting(Sufficient for reading test) and	Yes/No
	3	Space for conducting RDT(Confidentiality)	Yes/No
	4	Presence of job Aids	Yes/No
	<b>Workplace assessment score (automatically generated as %)</b>		
<b>Equipment, supplies and consumables assessment</b>	<i>Based on the assessment WEEK, check if the following stocks are present;</i>		
	1	Alcohol, Lancets, Gloves	Yes/No
	2	Timers, Lead/grease pencils, marker pens	Yes/No
	3	Biohazard waste bags	Yes/No
	4	Cotton wool, Disinfectants, Soap	Yes/No
	5	Sharps container	Yes/No
	6	RDTs and ACTs	Yes/No

	<b>Equipment, supplies and consumables assessment score (automatically generated as %)</b>		
<b>Work environment score</b>	<i>Work environment score will be automatically generated taking into account the workplace assessment and 'equipment, supplies and consumables' assessment</i> <b>Target: 80% and above</b>		<b>100%</b>
<b>Documentation and reporting</b>	<i>Based on the month preceding the assessment, identify if the following are present;</i>		
	1	Logbook/register/record book is present at the outlet	Yes/No
	2	The patients details are recorded and organised in legible manner, including Date of test is recorded	Yes/No
	4	Results of the tests are recorded/if not test action taken is recorded	Yes/No
	5	Reports for the weeks preceding the assessment have been submitted	Yes/No
	<b>Documentation and reporting assessment score (%)</b>		
<b>Overall supervision visit assessment score</b>	<i>Overall supervision visit assessment score will be automatically generated taking into account the 4 key aspects of the supervision visit.</i> <b>Target: 80% and above</b>		<b>100%</b>
<b>Comments/follow-up:</b>			
I confirm that the information above is accurate, based on engagement with the provider during the supervision visit - Yes/No			
Supervisor electronic signature _____			

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**V.4.2. Checklist for RDT transport, storing and handling**

<b>Transport Storing and Handling RDTs- Checklist</b>				
1	<b>RECEIVING RAPID DIAGNOSTIC TEST</b>	Rating	Short comments	"Flags"
1.1	<b>Planning for the receiving RDTs in-Country Stores</b>			
1.2	Are documents available to show volume of RDTs expected			
1.3	Are staff responsibilities defined to receive and inspect in-coming RDTs?			
1.4	Are there written procedures to follow in handling RDTs/ capture details?			
1.5	Are RDTs inspected on arrival and is inspection outcome recorded?			
1.6	Is there sufficient storage space, appropriate equipment to handle supplies?			
1.7	Is there a schedule for stock movement (in and out as per plan: calendar/ dates etc.)?			
2	<b>*****RDT STORAGE ***</b>			
2.1	Is the storage temperature controlled and recorded? How often?			
2.2	Are RDTs protected from direct heat, pests, water, and penetration?			
2.3	Are they stored using 'first to expire, first out (FEFO),			
2.4	Can RDT be easily inspected (dates and details visible)?			
	Stack Boxes and Cartons			
	Keep products in original cartons, 30cm from walls, 1meter from ceiling			
	Keep stack to maximum 2.5m high to avoid crushing bottom boxes			
	Use Pallets to stack cartons, Arrange cartons to identify labels, expire dates			
2.5	Are there fire safety equipment available, visible and functional			
2.6	Is storage access limited to Authorised personnel?			
3	<b>*** SETTING STORAGE TEMPERATURES ***</b>			
3.1	Is storage less than 4-25 degrees C?			
3.2	Are RDTs kept in an Air-conditioned room?			
	<b>Where Air-Conditioning is not possible</b>			
	Protect RDTs from direct Sun light, ensure natural ventilation, use ceiling fans			
3.3	Is the temperature monitoring performed (thermometers and recording seen) ?			
4	<b>*** MANAGING INVENTORY***</b>			
4.1	Are stock cards (or electronic systems) used to monitor quantity & expiry of RDTs?			

4.2	Are there schedules for physical inventory?			
	Are all negative QA results repeated and confirmed with a new panel?			
	If a lot fails, do you check the panels with stock RDTs?			
	Are enough RDTs available for initial and long-term QC (pick out $\geq 3$ different RDT lots)?			
5	<b>*** DISPATCHING &amp; TRANSPORT OF RDTs ***</b>			
5.1	Is there a policy on dispatching RDTs ( Push or pull systems)			
5.2	Is the 6 months minimum shelf-life to expiry date of RDTs ensured at dispatch?			
5.3	What cars of Trucks are used to transport RDTs to point of use?			
6	<b>*** WASTE MANAGEMENT ***</b>			
6.1	Do you have a waste management plan?			
6.2	Do have separate areas to keep expired kits?			
	<i>For Rating, Write 1 - if the Ware house has component to satisfaction, 2- available but less satisfactory, 3 - component missing, 4 if component missed. Note any difficulties or problems observed</i>			





<input type="checkbox"/> Instructions for use		
<input type="checkbox"/> Other (Specify) _____		
<b>C. Problem with Buffer</b>		
<input type="checkbox"/> Unusual buffer colour: specify colour _____ <input type="checkbox"/> Particulate matter in buffer <input type="checkbox"/> Other (Specify) _____		
<b>For individually packed ampoules/vials (Pharmacy Packs)</b>		
<input type="checkbox"/> Leaked/Evaporated buffer in ampoule <input type="checkbox"/> Empty buffer ampoule <input type="checkbox"/> Too much buffer in ampoule <input type="checkbox"/> Inconsistent volumes in ampoules <input type="checkbox"/> Buffer ampoule does not puncture		
<b>For boxes with a single buffer bottle for all tests (Hospital Packs)</b>		
<input type="checkbox"/> Insufficient buffer volume in bottle to perform all tests		
<b>D. Problem with alcohol swab</b>		
<input type="checkbox"/> No alcohol on swab (swab dry) <input type="checkbox"/> Too little alcohol on swab (swab partially dried out) <input type="checkbox"/> Other (Specify) _____		
<b>E. Problems with blood collection device</b>		
<input type="checkbox"/> Failure or much difficulty to collect blood <input type="checkbox"/> Failure or much difficulty to transfer required volume of blood <input type="checkbox"/> Failure to deposit/release blood on sample pad <input type="checkbox"/> Other (Specify) _____		
<b>F. Problems with desiccant</b>		
<input type="checkbox"/> No desiccant <input type="checkbox"/> Desiccant sachet damaged <input type="checkbox"/> Desiccant colour indicates exposure to humidity (if colour indicator included) <input type="checkbox"/> Other		
<b>G. Problems with test devices - Structural</b>		
<input type="checkbox"/> Damaged RDT test devices <input type="checkbox"/> Strip misplaced in cassette <input type="checkbox"/> No sample pad in sample window <input type="checkbox"/> Other (Specify) _____		
<b>I. Problems with test devices – Result interpretation</b>		
<input type="checkbox"/> Failure to Flow <input type="checkbox"/> No control line <input type="checkbox"/> Incomplete clearing <input type="checkbox"/> Red background <input type="checkbox"/> Faint test lines <input type="checkbox"/> Irregular migration <input type="checkbox"/> Ghost test Lines <input type="checkbox"/> Patchy broken test lines <input type="checkbox"/> Diffuse test Lines <input type="checkbox"/> Other (Specify) _____		
<b>Event/problem description narrative (explain what went wrong with the product and the observed or likely/probable consequences (Attach photos if available)).</b>  <div style="border: 1px solid black; height: 100px; width: 100%;"></div>		

**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 occurrences:	Dates of occurrences:
Date problem first reported:	

**INVESTIGATIONS CARRIED OUT**

Are tests from different kit boxes involved? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Has more than one operator experienced the problem with the product? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Are storage conditions at outlet level favourable? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Is the provider following the recommended RDT procedure? <input type="checkbox"/> Yes <input type="checkbox"/> No	
As part of the investigations, did the supervisor perform the testing? <input type="checkbox"/> Yes <input type="checkbox"/> 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:

