Government of Malawi

MINISTRY OF HEALTH

NATIONAL GUIDELINES FOR LABORATORY DIAGNOSIS OF MALARIA IN MALAWI
March 2020 - 2024

National Malaria Control Programme
Community Health Sciences Unit
Private Bag 65
Lilongwe
MALAWI

Contents

Abbreviations

Amref	African Medical and Research Foundation
CHSU	Community Health Sciences Unit
DHIS 2	District Health Information Software version 2
ECAMM	External Competency Assessment of Malaria Microscopists
EQA	External Quality Assurance
HIV	Human Immunodeficiency Virus
HRP2	Histidine-Rich Protein 2
HSA	Health Surveillance Assistant
HTSS	Health Technical Support Services
IQC	Internal Quality Control
IVD	In-Vitro Diagnostics
MDRT	Malaria Diagnostics Refresher Training
MIS	Malaria Indicator Survey
mRDT	Malaria Rapid Diagnostic Test
NMCP	National Malaria Control Program
NPHRL	National Public Health Reference Laboratories
NPRL	National Parasitology Reference Laboratory
OTSS	Outreach Training and Supportive Supervision
PCR	Polymerase Chain Reaction
PHIM	Public Health Institute of Malawi
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
VHC	Village Health Clinic
WHO	World Health Organization

Glossary

False negative: A positive blood smear that is misread as negative.
False positive: A negative blood smear that is misread as positive.
Feedback: Communication of the results of proficiency testing or external quality assessment to the original laboratory, with identification of errors and recommendations for remedial action.
Internal Quality Control: Daily control and monitoring of each stage of testing by laboratory staff/rapid diagnostic test performers to ensure that all tests are performed accurately and precisely.
Lot testing: Checking the quality of batches or lots of malaria RDTs at or after purchase, and before they are sent to the field for use by clinicians and health workers.
Microscopist: A person who uses a microscope to read blood films to assist or confirm a diagnosis of malaria and then reports the findings. The term used in these guidelines includes personnel at all levels of a malaria program who are involved in such work, from professors involved in teaching and research to laboratory assistants, as per Ministry of Health policy.
National Malaria Control Program: The countrywide program responsible for all activities related to the prevention, control, and elimination of malaria. These include activities integrated with general health services to provide diagnosis and treatment for malaria.
National Parasitology Reference Laboratory: This is part of the National Public Health Reference Laboratory housed at the Community Health Sciences Unit. It works directly with the National Malaria Control Program and academic institutions. It plays an essential role in the preparation of guidelines for standardizing methods, maintaining slide banks, producing locally adapted training materials, providing basic and refresher training, overseeing training activities, assuring the quality of testing, and supporting external quality assurance in collaboration with the National Malaria Control Program.
On-site supportive supervision: A decentralized method of supportive supervision by a team of clinical and laboratory supervisors whose competence has been rigorously assessed. They may function at national, intermediate, peripheral, or even community level. Supervisory visits and on-site evaluations include a comprehensive assessment of the laboratory's organization, equipment, adequacy and storage of supplies, reagent quality, and availability, use of standard operating procedures, reporting of results, safety, and infection control measures. On-site evaluation with a standardized supervisory checklist provides a realistic overview of malaria microscopy diagnostic services at the site. This overview can be used to supervise the program, correct poor performance identified by cross-checking of slides, and provide strategies and corrective actions for immediate problem-solving.
Proficiency testing: A system in which a reference laboratory sends blinded samples to a laboratory for examination, and the laboratory that receives the samples is not informed of the correct results until it has reported its findings back to the reference laboratory.
Quality assurance: The maintenance and monitoring of the accuracy, reliability, and efficiency of laboratory services. Quality assurance addresses all the factors that affect laboratory performance, including test performance (internal and external quality control), the quality of equipment and reagents, workload,

workplace conditions, training and supervision of laboratory staff, and continuous quality improvement. It includes procedures put in place to ensure accurate testing and reporting of results.

Quality control: Assessment of the quality of a test or a reagent. Quality control encompasses external quality control and internal quality control.

Quality improvement: A process in which the components of microscopy and rapid diagnostic test are analyzed in order to identify and permanently correct any deficiencies. .

Quality management system: Management system to direct and control an organization with regard to quality. A system by which a laboratory's performance is checked objectively by an external agency or facility or a reference laboratory.

Rapid diagnostic test: Immunochromatographic tests for detecting parasite-specific antigens in blood samples. Some malaria rapid diagnostic tests detect only one species (*Plasmodium falciparum* or *Plasmodium vivax*), while others detect multiple species (*Plasmodium falciparum* with one or more of the other three species of human malaria parasite i.e. *Plasmodium vivax*, *Plasmodium malariae*, and *Plasmodium ovale*). Rapid diagnostic tests are commercially available in different formats, such as dipsticks, cassettes, or cards.

Severe or complicated malaria: This is a life-threatening condition defined as the detection of *Plasmodium falciparum* in peripheral blood, together with signs of severity and/or evidence of vital organ dysfunction.

Slide positivity rate: The proportion of positive results detected by microscopy among all slides examined over a defined period.

Uncomplicated malaria: Symptomatic infection with malaria parasitemia without signs of severity and/or evidence of vital organ dysfunction. It is characterized by fever. Other common features common include chills, profuse sweating, muscle pains, joint pains, headache, abdominal pain, diarrhea, nausea, vomiting, loss of appetite, irritability, and refusal to feed (in infants). These features may occur singly or in combination and are due to the presence of parasites in the peripheral blood.

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Dr. Dan Namarika

Secretary for Health

Preamble

Quality assurance is critical in malaria diagnosis for maintaining and monitoring the accuracy, reliability, and efficiency of laboratory services. Quality assurance addresses all of the factors that affect laboratory performance, including test performance (internal and external quality control), the quality of equipment and reagents, workload, workplace conditions, training and supervision of laboratory staff, and continuous quality improvement. It includes procedures put in place to ensure accurate testing and reporting of results

These guidelines are intended for use by laboratory personnel and other health workers involved in:

- Routine laboratory work.
- Pre-service, in-service training and practical attachments.
- Continuous professional development.
- Supervision.

These guidelines shall also be used by health facility managers in determining essential requirements for malaria diagnosis. By combining information for several cadres in one document, it is hoped that these guidelines will increase understanding and communication between cadres in all aspects of the diagnostic process.

The main goal of these guidelines is to improve the quality of laboratory diagnosis of malaria in Malawi. The specific objectives of the guidelines are to:

- Standardize laboratory practices and procedures in malaria diagnosis.
- Promote utilization of laboratory results in making clinical decisions in malaria case management.
- Standardize training approaches for laboratory diagnosis of malaria.
- Provide standardized reference material for trainers and supervisors on laboratory diagnosis of malaria.
- Monitor quality assurance of laboratory testing equipment/products
- Instill trust in the people utilizing the services (both patients and clinicians)

The guidelines shall be reviewed every four years or when there are major changes in the diagnosis of malaria

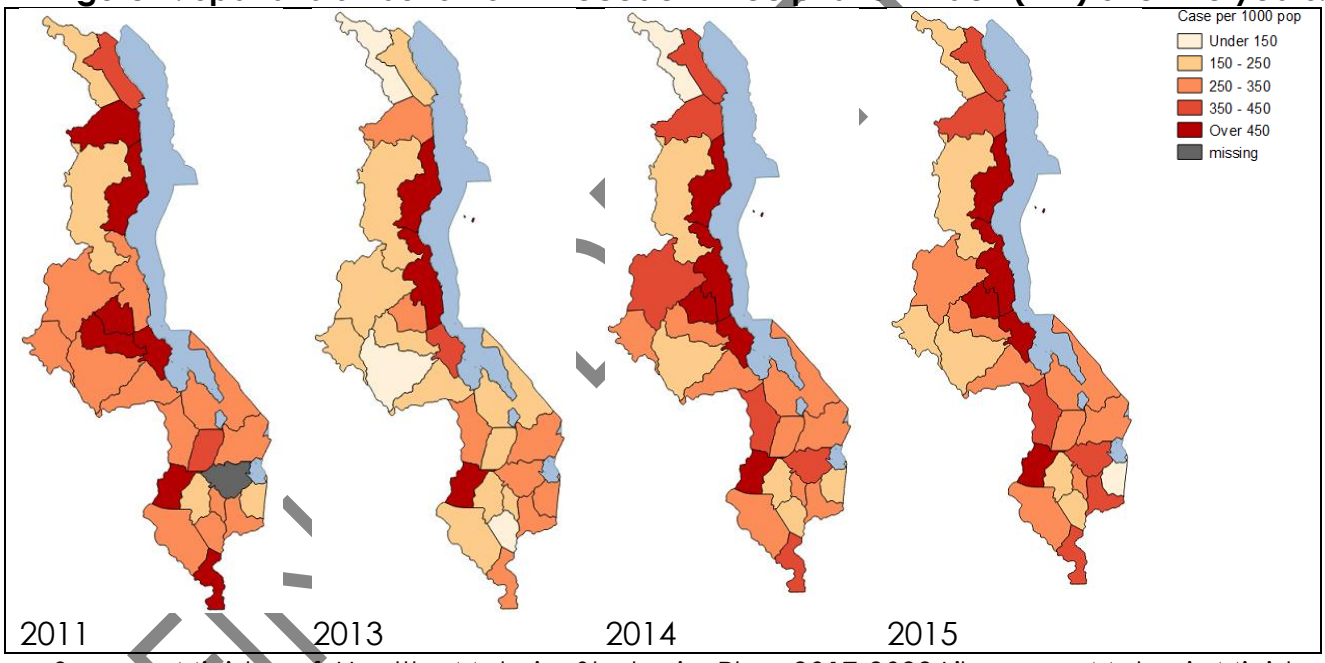
Background

Malaria is hyper-endemic in Malawi. Malaria transmission occurs throughout the year in most areas; it is highest during the rainy season, mainly in the low-lying or lakeshore areas. The entire population of Malawi is at risk of malaria. Pregnant women, people living with HIV and children under the age of five years are at the greatest risk of severe malaria.

Malaria epidemiology

In Malawi, the malaria burden is a result of the interaction of the three determinants of the disease, namely, host (age, sex, and immunity), environment (climate and altitude), and parasite/agent (antigenicity, strain, resistance, and behavior). Malaria transmission is higher in areas with high temperatures and during Malawi's rainy season (December through April), particularly along the lakeshore. The variable altitude of the country creates a wide range in climate, as shown in Figure 1. The highest temperatures occur in the low- areas. Rains are more prolonged in the north. Temperature levels are lower and rainfall levels are higher in higher altitudes.[1]

Figure 1. Spatial distribution of Antecedent Precipitation Index (API) over the years.



Source: Ministry of Health. *Malaria Strategic Plan 2017-2022*.Lilongwe, Malawi: Ministry of Health; 2017.

Malaria parasite prevalence in Malawi decreased from 43 percent in the 2010 Malaria Indicator Survey (MIS) to 28 percent in the 2012 MIS, with a subsequent increase to 33 percent in the 2014 MIS. *Plasmodium falciparum* (*P. falciparum*) is the most common (>90 percent) species in Malawi; it is associated with significant morbidity and mortality. Other species found in the country include *Plasmodium malariae* (*P. malariae*) and *Plasmodium ovale* (*P. ovale*), which sometimes occur as mixed infections with *P. falciparum*. *Plasmodium vivax* (*P. vivax*) is very rare (<5 percent).

Diagnostic policy

The World Health Organization strongly advocates a policy of "test, treat, and track" to improve the quality of care and surveillance. Therefore, all suspected malaria cases must be confirmed using parasitological test (microscopy or mRDT). Tests used to confirm presence of malaria

a) mRDT
   - To confirm presence of malaria in uncomplicated cases

b) Microscopy for
   - Suspected uncomplicated malaria cases
   - Confirming treatment failure
   - Confirming severe malaria cases and monitor treatment progress.

c) Elisa
   - Research purposes

d) PCR
   - A reference test to confirm malaria parasite species.
   - Research purposes

e) Quantitative buffy coat

f) Thin film acridine orange (Kawamoto)

General guidelines

- NPRL shall oversee quality issues and shall work with DHSS through laboratory managers
- Document and guidelines shall be reviewed and revised every four years or when there are major changes (WHO)
- Initial or on job training shall be a once off activity
- Refresher training shall be conducted after 2yrs (WHO)
- Kit validation shall be done before a test is allowed
- Only Government approved tests shall be used, which are Giemsa for malaria microscopy and SD Bioline, Care Start or First response for mRDT
- Only trained and certified personnel shall be allowed to practice

Health facilities in Malawi

There are three major levels of health facilities in Malawi that are addressed in these guidelines: village health clinics, health centers, and hospitals (teaching, regional, and district). However, the information in these guidelines also applies to faith-based organizations and private-sector health facilities.

Village health clinics

As part of the Community Integrated Management of Childhood Illness initiative, uncomplicated malaria may be diagnosed and managed at the home level in children under five years. mRDTs shall be used

- **Criteria for diagnosis**: **hot body (by touch), a temperature clinically** or **history of fever** (given by the parent or guardian) and positive mRDT result.

- **Regulation of diagnostic staff**: Malaria Rapid Diagnostic Test will be performed by staff that are trained and certified by the Ministry of Health.
- **Who must be referred?**
  - Any patient with danger signs or evidence of severe disease (like a history of vomiting or convulsion)
  - Any patient in whom treatment failure is suspected

Health centers

In health centers, the basis of diagnosis is mRDT and/or microscopy.

- **Regulation of diagnostic staff**:
  - Microscopy: Malaria microscopy will be performed by staff who are trained and qualified in medical laboratory technology (laboratory technologist, laboratory technicians, and laboratory assistants), participate in a malaria external quality assurance (QA) program. Registration with Medical Council of Malawi is a must.
  - mRDTs shall be performed by staff who are trained and approved by the Ministry of Health.
- **Who must be referred?**
  - Any patient with danger signs of severe disease must be referred to an inpatient facility together with a blood sample (normally a blood film) collected before pre-referral treatment.
  - Patients returning for a follow-up visit among whom treatment failure is suspected must be referred to a facility with microscopy, if not available on-site.

All hospitals (community/rural, district and central/teaching)

In hospitals, the basis of diagnosis is mRDT and/or microscopy.

Regulation of diagnostic staff:

- Malaria microscopy will be performed by staff that are trained and qualified in medical laboratory technology (laboratory technologist, laboratory technicians, and laboratory assistants). Registration with Medical Council of Malawi is a must.
- mRDTs will be performed by staff that are trained and approved by the Ministry of Health.

Structure and function

- The QA system shall be organized in a hierarchical structure with well-defined roles and responsibilities for the national, intermediate (regional/district), and peripheral (district, township, or village) level structures. The QA system is integrated with other programs to simplify administration and maximize use of available resources. The system's structure allows for the flow of information from the central to the peripheral facilities and vice versa. Private-sector and community health programs play a key role and are part of this structure.

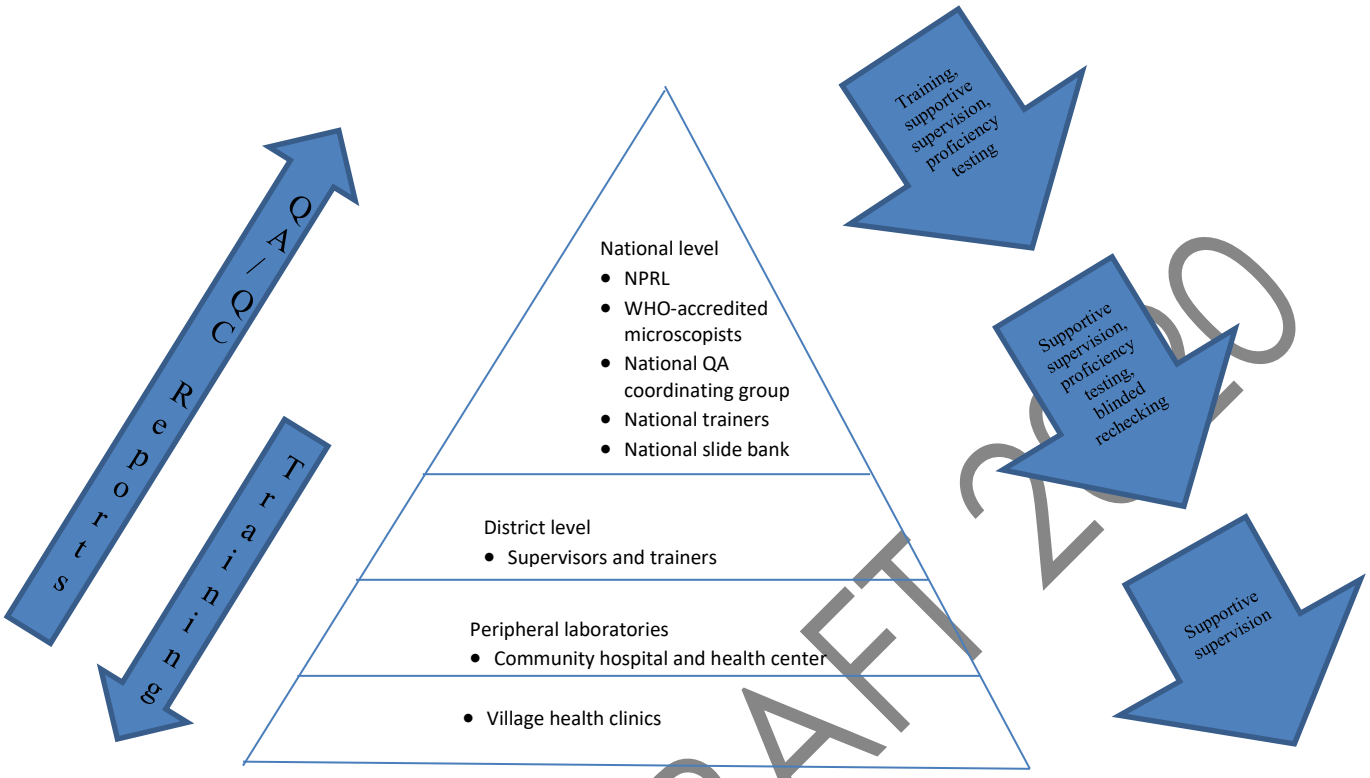


Figure 2. Structure and function of quality assurance system.

- **Quality assurance system and responsibilities**

National level - Reference laboratory

- These are National quality assurance coordinators
- Develop and review guidelines, training tools, job aids, and standard operating procedures (SOPs) and lead in development of testing algorithms.
- Strengthen the supply chain for reagents and equipment, and ensures maintenance of microscopes and other equipment
- Evaluate and validate test kits and reagents
- Act as a communication link between the National Malaria Control Program and laboratory services, as well as among all levels of the laboratory network.
- Coordinate the QA activities of multiple partners.

- Maintain slide bank and ensure availability of all malaria species
- Develop and review QA policies on malaria diagnosis.
- Prepare and oversee QA implementation plans.
- Monitor compliance in universal and safety precautions
- Monitor and evaluate QA program implementation.
- Train laboratory personnel on malaria diagnosis.
- Coordinate the selection of participants for WHO accreditation courses
- Cross-check malaria slide results.
- Conduct on-site supervisory visits on malaria diagnosis.
- Coordinate the proficiency-testing program.
- Set up reference slide banks and validate slides.
- Assist in surveys where examination of malaria is required.
- Plan, budget and mobilize resources for implementation and monitoring of QA nationwide

District level

– Laboratories at the district level shall ensure the quality of malaria diagnosis at all microscopy sites in their districts. This entails the following:

- Perform malaria microscopy and mRDTs
- Maintain proper reports and records of results
- Troubleshoot problems related to testing
- Plan and conduct refresher training, mentorship, and supervision
- Store slides for rechecking
- Ensure that equipment is maintained
- Conduct IQC procedures
- Ensure proper inventory management of test kits and reagents
- Prepare all reagents according to SOPs
- Implement safety standards and precautions
- Report and refer slides for other species
- Give feedback

Rural hospital laboratories and health center level

- Laboratory personnel are responsible for the supervision and QA activities at this level and below to maintain the quality of malaria diagnostic services. This entails implementation of the following:
    - Perform microscopy and mRDTs
    - Maintain reports and record results
    - Troubleshoot problems related to malaria diagnostic testing
    - Store slides for slide rechecking according to guidelines
    - Ensure that equipment is maintained
    - Perform IQC
    - Ensure proper inventory management of kits and reagents
    - Prepare all reagents according to SOPs
    - Implement safety standards and precautions
    - Report and refer slides for other species

Community level (village health clinics)

- Perform mRDTs and provide feedback to the client.
- Participate in training and EQA activities.
- Maintain proper reports and record results
- Report problems related to malaria diagnostic testing to the health center.
- Perform IQC procedures
- Ensure proper inventory management of test kits and reagents
- Implement safety standards and precautions

Faith-based organizations and private-sector health facilities

Faith-based organizations and private-sector health facilities shall also follow the same QA system standards as outlined in this document as recommended by the Ministry of Health. They shall follow the level equivalent to them

Procurement

Procurement of laboratory supplies shall be through the Central Medical Stores Trust. Supplies are procured after a thorough quantification process. If the procurement is by a partner, the partner's conditions shall apply.

Only items that are WHO and/or donor prequalified shall be recommended for procurement

Quality assurance

Quality Assurance (QA) is the maintenance and monitoring of the accuracy, reliability, and efficiency of laboratory services. QA addresses all of the factors that affect lab performance, including test performance (internal and external QC) and safety, the quality of equipment and reagents, workload, workplace conditions, training and supervision of lab staff, and continuous quality improvement. It includes procedures put in place to ensure accurate testing and reporting of results.

Quality assurance is divided into Internal and external quality assurance in order to achieve the goal

Internal quality assurance helps to ensure that assessments ad IQA activities are valid, authentic, sufficient, fair and reliable. IQA measures the quality, delivery, processes, procedures and learner achievements. Quality controls (QC's) shall be made available and used

External quality assurance is a scheme designed to regularly assess the accuracy of diagnostic tools or method. The following methods activities shall take place in order to ensure quality assurance is in place

Document review

- The guidelines and all documents shall be reviewed and revised every four (4) years or when there are major changes
- There shall be standard operating procedures (SOP's) for every procedure which may be customized to facility requirements
- Each testing site shall have bench and /or job aids at the place of work

Training

Malaria Diagnostics Refresher Training (MDRT)

The MDRT and competency assessment evaluates essential knowledge and competencies in all aspects of malaria microscopy.

Objectives

- To assess the competency of malaria microscopists
- To provide refresher training in all aspects of malaria microscopy based on standardized instruction and revision

The refresher training in malaria diagnostics for microscopists is a 5-day assessment course. The course outline is as follows:

- Pre-workshop theory and practical slide reading test (19 slides).
- Presentations/revision on all aspects of malaria microscopic diagnosis and reporting.
- Examination of 55 slides in 3 days (10 minutes per slide).
- Review of test slides throughout the course.
- Preparation of thick and thin blood film.

Trainers

- WHO-certified Level 1 or Level 2 microscopist for the past three years. All WHO-certified Level 1 or 2 microscopists should recertify every three years to maintain microscopy competency.
- At least a graduate qualification in medical or laboratory science or allied health science.
- Highly developed communication and presentation skills.
- Extensive knowledge and experience in all aspects of malaria microscopy, including QA.
- Comprehensive knowledge of malaria parasite life cycles and malaria epidemiology.

External accreditation of microscopists

The effectiveness of malaria microscopy depends on maintaining a high level of staff competence and performance, ensuring good-quality reagents and equipment at all levels and regular external assessment. It is important that microscopists participate in external competency assessments organized by WHO.

Purpose and target cadres:

- Strengthen knowledge and competencies in all aspects of malaria microscopy.
- The accredited microscopists will provide technical support to microscopists in health facilities.
- Coordination of External Competency Assessment of Malaria Microscopists (ECAMM):
- The NPRL will collaborate with Amref Health Africa/WHO to sustain malaria microscopy activities and accreditation of microscopists.
- The NPRL is responsible for storing and updating the database of ECAMM participants.

Malaria rapid diagnostic test trainings

Trainings and orientations are going to be offered to staff that has been assigned to the mRDT testing services. A refresher training shall be offered to those already conducting testing. Refresher training is to be conducted every two years, o when there are changes to the guidelines

Trainers

- Must have the required knowledge in malaria/fever case management.
- Are also often used as QA supervisors; as such, they must have the necessary training in quality management systems, good laboratory practice, and supervision of mRDT sites.
- Must have highly developed communication and presentation skills.
- Must have extensive knowledge and experience in all aspects of malaria diagnosis, including QA.
- Must have comprehensive knowledge of malaria parasite life cycles and malaria epidemiology.
- Must be capable of facilitating interactive lectures.
- Must be capable of facilitating competency assessments through observation and scoring.
- Must have training basics.
- Must have adult learning principles.
- Must have communication skills
- Must have experience in facilitating trainings.
- Trainers undergo a trainer of trainers' orientation
- The training can be decentralized to the district level but it is important to ensure that the training curriculum is standardized according to national malaria policy, including the duration of training.
- A database of all trained personnel must be kept at the national level. This will help future programming in relation to training need. The district must inform NPRL about any training so as to update the database.
- In addition to the theoretical and practical aspects of mRDT, the training curriculum (TOT) include topics like:

Supervision

Outreach training and supportive supervision (OTSS) is a decentralized method of supportive supervision. It includes a comprehensive assessment of the laboratory's organization, equipment, adequacy and storage of supplies, reagent quality, availability and use of SOPs, reporting of results, safety and infection control measures

OTSS involves mentoring, whereby an experienced, competent supervisor guides personnel in improving their skills. Its objectives are to:

- Establish a trusting, respectful relationship between the supervisor and personnel that is conducive for learning.
- Promote synergy between laboratory and clinical outputs.
- Collect objective evidence of the status of testing and microscopy in order to take corrective action for continual improvement.
- Provide regular (ideally quarterly) support to laboratory and clinical staff in facilities to promote teamwork, advocacy, monitoring, and evaluation.

They are essential to the operation of all QA programs, as they enable the supervisor to:

- Cross-check slides taken routinely.
- Correct errors in procedures on site.
- Relate working conditions to the performance of staff, which is assessed by independent cross-checking of slides.
- Assess the IQC and logistical procedures for maintaining equipment and supplies.
- Ensure the availability of updated SOPs, bench aids, and other reference materials.
- Identify any stockout of supplies or reagents.
- Discuss problems encountered by microscopists and laboratory managers, and suggest solutions.
- Decide on training and retraining needs of health workers.
- Build communication with staff in routine laboratories.
- Ensure retraining, if indicated.

Implementation structure

Management of the OTSS program shall be provided by the NPRL at CHSU and closely coordinated with the NMCP and partners.

OTSS shall be implemented on a quarterly basis

Method

- Collecting information:
  - Observing the health-facility environment.
  - Listening to health workers.
  - Reviewing records.
  - Using a checklist.
  - Talking with patients, parents and community members.
  - Reviewing recommendations from past visits.
- Problem-solving and feedback:
  - Giving feedback, accompanied with objective evidence, to the health staff concerned.
  - Describing the problem and its impact.
  - Discussing the causes of the problem with health staff.
  - Implementing solutions and monitoring regularly.

- On-the-job training:
  - Explaining the skill or activity to be learned.
  - Demonstrating the skill or activity using an anatomical model or role-playing.
  - Participants practicing the demonstrated skill or activity.
  - Reviewing the practice session and giving constructive feedback.
  - Practicing the skill or activity with clients under a trainer's guidance.
  - Evaluating the participant's ability to perform the skill according to the standardized procedure, if possible as outlined in the competency-based checklist.
- Recording the results of supervision:
  - Completing a supervisory checklist.
  - Recording the date of the visit, main observations, training given and agreed-on follow-up actions.
- Sharing results of the supervision with facility management
  - Seeking audience with facility management in the presence of the staff concerned.
  - Providing a summary of findings and agreed upon follow-up actions.
  - Identifying and sharing with facility management areas in which their assistance is needed.
- What to do after a supervision visit:
  - Act on issues you agreed to work on.
  - Discuss equipment supply and delivery problems with higher levels.
  - Review monthly reports.
  - Establish regular communication.
  - Follow up to see if recommendations are being implemented.
- Conduct follow-up visits:
  - Ensure problems identified at a previous visit do not persist.
  - Reinforce with the health worker that issues found during the last visit are still important.
  - Support the health worker to fix any pending problem.
  - Check if on-site training rendered previously has been effective.
  - Ensure that the performance of the health worker is being monitored and improved.

Corrective action

- Summary reports shall be produced and shared with all stakeholders.
- The NMCP and NPRL shall be responsible for addressing the gaps identified during OTSS.

- OTSS supervisors shall develop an action plan that highlights the gaps identified, which will be shared with facility management. This will help the facility to generate actions that could address the gaps.

Competency assessment

Is assessment of the staff to verify that they do the right things. The assessor follows the whole process or procedure
It shall be done for all the staff every year
It may be conducted as part of staff appraisals
Corrective actions shall be taken for staff that does not perform

Quality controls

Quality controls are samples whose results are known to the tester. They are used to ensure that reagents are working to the required standards. If the result differs from the expected value, test results are not going to be released until the problem is investigated and rectified. Test positive and negative control:

- Preferably once per day with each run, at the beginning of the day, but no less than once a week

In addition, when;

- New shipment of test kits or reagents arrives or is prepared
- Beginning of a new lot number
- Environmental conditions exceed range needed for stability of kits

Proficiency testing

Proficiency testing is the evaluation of participating laboratories' or individuals' performance against pre-established criteria or against criteria established by inter laboratory comparisons.
Quarterly, the NPRL will prepare samples and dispatch them to all facilities for examination. The various facilities or individuals will send back the results to the reference laboratory within 3 weeks of receiving the proficiency testing samples. Results will be assessed and individual reports will be sent within a month. Poor performing facilities will be identified; a proper root cause analysis will be done; and corrective action will be taken.
Objectives:

- Assess the performance of participating testing facilities or individuals in providing accurate and reliable results.
- Monitor the performance of participating testing facilities over a period of time.
- Identify problems or areas for improvement in malaria testing with the aim of carrying out preventative and corrective action on identified or potential nonconformities.

- Compare the performance of malaria testing laboratories and individuals to identify laboratories of excellence that can assist other laboratories.
- Provide assurance to customers that the laboratories can provide accurate and reliable results.
- Provide training and educational materials to laboratories.

Implementation structure

The NPRL will be responsible for the preparation and distribution of samples and the provision of feedback to testers. Once the slides are received, the peripheral lab will examine them and send to the national level as shown in Figure 4 below.

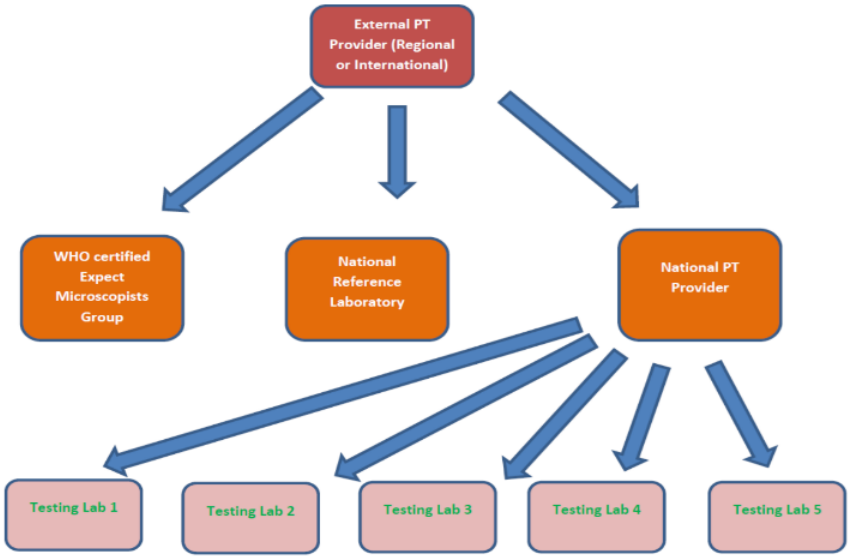


Figure 2. Proficiency testing structure

Method

Operating a proficiency testing scheme

- In proficiency testing schemes, test laboratories examine a set of prepared samples received from an international, national, regional or district laboratory, in order to gauge the ability of technicians' competency. Participation in a malaria proficiency testing scheme is compulsory for laboratories planning to upgrade their quality standard to achieve accreditation for malaria testing or any other accreditation scheme. Figure 5 provides the workflow for how the proficiency testing scheme should operate.
- The NPRL shall be responsible in selecting samples and enrolling laboratories on PT.
- Laboratories conducting malaria testing will be enrolled into the program
- PT shall be conducted quarterly and/or biannually.
- Size of panel/composition:

- A panel of five samples shall be evaluated by MRDT testers
- A panel of ten slides shall be evaluated by laboratories that conduct malaria microscopy as shown in Table 3. While the total number of slides is greater than many proficiency testing panels, this composition specifically addresses the potential for lack of or irregularity of frequency.

Figure 3. Proficiency testing scheme workflow.

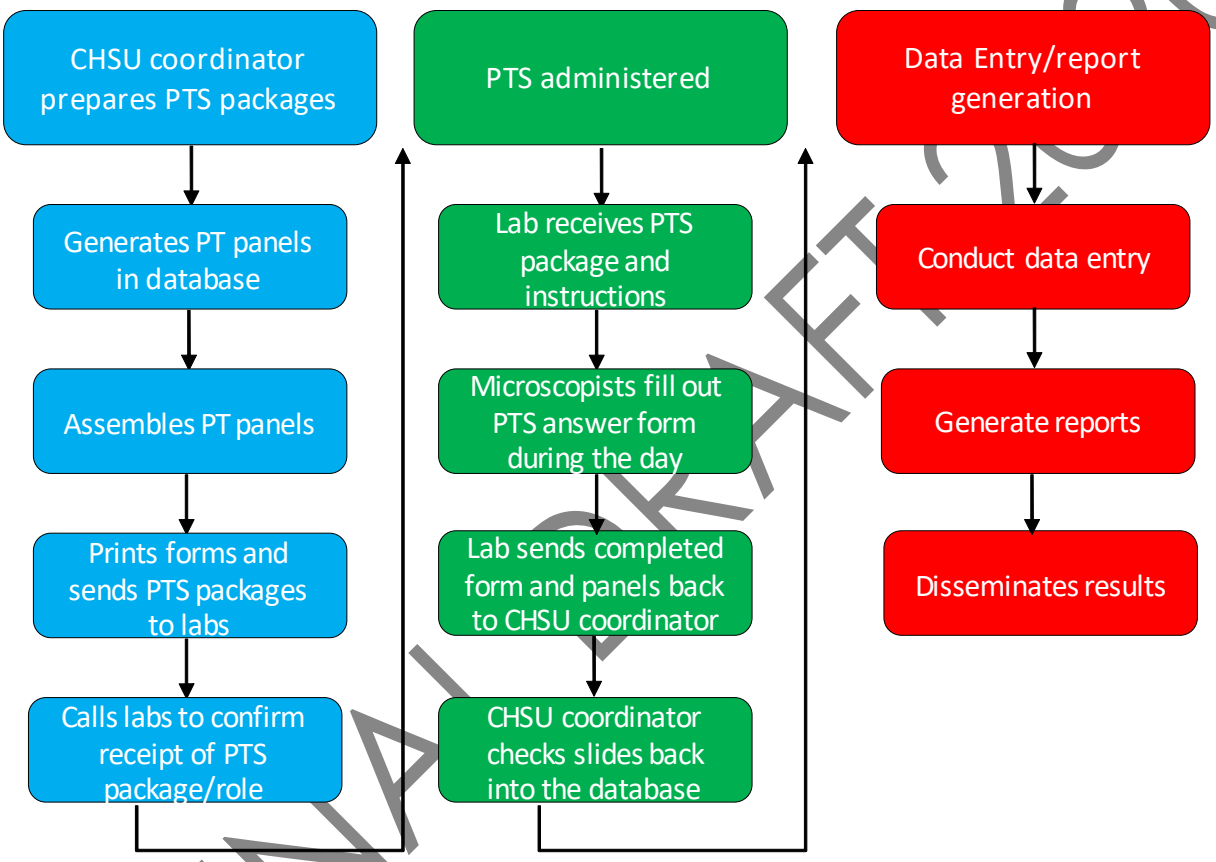


Table1. Proficiency testing panel composition for malaria microscopy

Description	No. of Slides
Negatives	2
Pm	1
Po	1
Pf/Po	1
Pf/Pm	1
Pf high density (>100,000 p/ul)	1
Pf moderate density (>5,000 p/ul - <10,000 p/ul)	1
Pf low density (<200 p/ul)	2
Subtotal	**10**

- Most programs provide too few samples too irregularly for error detection (as addressed above).
- Similar to a traditional proficiency testing scheme, this program addresses competency at the facility and individual level. Incompetency will be addressed during refresher trainings or even through a national competency assessment once such a program has been established.

Corrective action

Results from the PT assessment will determine the next course of action, such as on-site mentorship or refresher training.

Inter laboratory comparison

A standard criterion, based on the WHO competency criteria for national assessment, is used to conduct inter-laboratory comparisons. Laboratories are scored against the established criteria for parasite detection, species identification, and parasite quantitation. Each slide (n=10) is examined for all three skill components and component scores are averaged as a total percentage correct.

Table 4 outlines the current recommended competency standards for malaria microscopy at the national level detailed in the WHO Malaria Microscopy Quality Assurance Manual.

Competence level	Parasite detection (%)	Species identification (%)	Parasite count within 25% of true count
A	90-100	90-100	50-100
B	80-89	80-89	40-49
C	70-79	70-79	30-39
D	0-69	0-69	0-29

Table 2. Competence levels in a national competency assessment.

In addition to the individual health facility report, additional reports have been developed for the district and national levels as a way to conduct inter-laboratory comparisons, as well as to identify laboratories in need of refresher training and/or supervision.

Malaria microscopy slide bank

There shall be a slide bank so that the NPRL can assess and improve the competency and performance of malaria microscopists. The slide bank contains well-characterized, high-quality national reference malaria slide sets. The slide bank shall be used for continuous training and assessment of malaria microscopists in clinical settings and of microscopists who may manage and supervise national QA programs.

The objectives of the slide bank are to:

- Provide sets of known, replicate slides for training or assessment in malaria microscopy and QA.
- Serve as a permanent reference collection of the malaria species present in the country.

On request, provide sets of reference slides from outside the country.

Data control

The laboratories/testing facilities shall produce trustworthy, timely, and relevant data. In turn, QA/QC programs shall take measures to ensure that the quality of data being generated in the testing centers can be guaranteed.

Data collection

- Data collection system
  - At the facility (health center to district hospital levels), data shall be collected from the register using forms. The reporting form shall be used to submit data on a monthly basis to the district Health Management Information System.
  - The data collected shall directly be entered into DHIS 2, and the NMCP receives the data by logging into the system.
- List of key parameters
  - At the laboratory, the following are key parameters:
    - Suspected cases tested with microscopy.

        - Suspected cases tested with mRDTs.
        - Positive cases tested with mRDTs.
        - Positive cases tested with microcopy.
    - At the outpatient unit, data shall be collected on the following:
        - Confirmed malaria cases.
        - Presumed malaria cases (clinically diagnosed without test).
        - Total outpatient cases.
    - At the inpatient unit, data shall be collected on:
        - Confirmed malaria cases (microscopy).
        - Presumed malaria cases (clinically diagnosed without test).
        - Total inpatient cases
- In order to ensure that high-quality data is collected, the following QA/QC measures must be put in place:
    - Only MOH approved registers and forms shall be used
    - Orientation of all health care workers who are directly involved in data collection.
    - Daily summaries shall be made at the bottom of each page of the malaria laboratory register.
    - On monthly basis, the monthly data shall be consolidated for the facility and health facility staff shall meet to discuss the data to ensure that all data collected is in line with set standards.
    - Data review meetings organized by the NMCP shall be conducted every quarter. The meeting's aim shall be to discuss best practices, performances, and challenges experienced by health care workers.
    - Routine data audit shall be conducted on quarterly basis.
    - In addition, quarterly supervision shall be conducted at health facilities in order to provide support and mentorship where necessary.
- Available standard log books in use are:
    - Malaria laboratory register.
    - Malaria health facility monthly reporting form.
    - Outpatient department register.

Data storage

Data that shall be collected shall be stored at the Health Management Information System unit of the Ministry of Health. The Ministry of Health shall be the custodian of all the data collected. All registers and forms shall be archived at the facility when they are taken out of use or are filled up.

Post market surveillance

Shall be done when reagents or test kits are already in use

Reagents or test kits shall be selected randomly and tested against the set standards

Storage and transport of materials

Reagents shall be transported and stored according to manufacturer's recommendations

Cartons shall be stacked at least 10 cm off the floor, 30 cm away from the walls and other stacks, and no more than 2.5m high

The commodities shall be stored to facilitate FEFO and stock management procedures. (FEFO= First-to-Expire, First-Out)

Conduct regular physical inventory. It is ideal to do it at the end of each month

Lot testing

This is an exercise to make sure that the test being used meet the required standards

Different tests shall be collected on arrival according to their lots and be tested against the available standards

This shall happen before test kits or reagents are distributed or dispatched

Only reagents that pass a validation shall be distributed and used

Method, supplies and reagent selection

There shall be a validation to choose test kits or reagents amongst the many that are available on the market

Annex 1. Malaria laboratory register

	PATIENT DETAILS						MALARIA RAPID DIAGNOSTIC TEST (RDT)					MALARIA MICROSCOPY			LABORATORY TECHNICIAN		
DATE	TIME IN	LAB #	FIRST AND LAST NAME	AGE	SEX (M/F)	ADDRESS	TEST LINE (CP) (pos/neg)	RDT RESULT (pos/neg/ invalid)	mRDT BRAND	EXP. DATE	LOT #	BLOOD FILM TEST RESULT (Pos/Neg)	SPECIES (Pf, Pv, Po, Pm)	DENSITY (/µl)	TIME OUT	COMMENT	INITIAL

PAGE SUMMARY

	U5	O5		U5	O5		U5	O5
Total no. microscopy Tested:			Total no. positive microscopy:			Total no. Pf:		
Total no. Pf:			Total no. Positive mRDTs:			Total no. Invalid mRDTs:		

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DPDx - Laboratory Identification of Parasites of Public Health Concern:www.cdc.gov/parasites/.